This Agreement (‘the Agreement’) is between the following parties:

on the one part,

the European Union (‘the EU’), represented by the European Commission (‘the Commission’), represented for the purposes of signature of this Agreement by the Head of Unit, DIRECTORATE-GENERAL RESEARCH & INNOVATION, Health, Administration and finance, Mila BAS SANCHEZ,

and

on the other part,

1. ‘the coordinator’:

MEDIZINISCHE UNIVERSITAET WIEN (MUW), established in SPITALGASSE 23, WIEN 1090, Austria, VAT number: ATU57469858, represented for the purposes of signing the Agreement by Iris WEINBUB

and the following other beneficiaries, if they sign their ‘Accession Form’ (see Annex 3 and Article 56):

2. UNIVERSITAETSKLINIKUM HAMBURG-EPPENDORF (UKE), established in Martinistrasse 52, HAMBURG 20246, Germany, VAT number: DE218618948,

3. BUDAPESTI CORVINUS EGYETEM (CUB), established in FOVAM TER 8, BUDAPEST 1093, Hungary, VAT number: HU15329743,

4. UNIVERSITEIT MAASTRICHT (UM), established in Minderbroedersberg 4-6, MAASTRICHT 6200 MD, Netherlands,

5. ERASMUS UNIVERSITEIT ROTTERDAM (EUR), established in BURGEMEESTER OUDLAAN 50, ROTTERDAM 3062 PA, Netherlands, VAT number: NL804735298B02,

6. SERVICIO CANARIO DE LA SALUD (SESCS), established in PÉREZ DE ROZAS, 5, 4 PLANTA, SANTA CRUZ DE TENERIFE 38006, Spain, VAT number: ESQ85550111,

7. ASOCIACION CIENTIFICA PSICOST (Psicost), established in CALLE ENERGIA SOLAR BLOQUE G 1, SEVILLA 41014, Spain, VAT number: ESG11729571,

8. LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE (LSE), established in Houghton Street 1, LONDON WC2A 2AE, United Kingdom, VAT number: GB629588094,
9. UNIVERSITY OF BRISTOL (UnivBris), established in TYNDALL AVENUE SENATE HOUSE, BRISTOL BS8 1TH, United Kingdom, VAT number: GB991261800,

10. EURICE EUROPEAN RESEARCH AND PROJECT OFFICE GMBH (EURICE), established in STUHLSATZENHAUSWEG 69, SAARBRUCKEN 66123, Germany, VAT number: DE210372698,

Unless otherwise specified, references to ‘beneficiary’ or ‘beneficiaries’ include the coordinator.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action
Annex 2 Estimated budget for the action
    2a Additional information on the estimated budget
Annex 3 Accession Forms
Annex 4 Model for the financial statements
Annex 5 Model for the certificate on the financial statements (CFS)
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This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2  ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the action entitled ‘ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluations’ — ‘PECUNIA’ (‘action’), as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be 36 months as of 1 January 2018 (‘starting date of the action’).

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The ‘estimated budget’ for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and budget category (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 55) — by transfers of amounts between beneficiaries, budget categories and/or forms of costs set out in Annex 2, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

CHAPTER 3  GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The ‘maximum grant amount’ is EUR 2,999,943.75 (two million nine hundred and ninety nine thousand nine hundred and forty three EURO and seventy five eurocents).

5.2 Form of grant, reimbursement rates and forms of costs
The grant reimburses **100% of the action's eligible costs** (see Article 6) (‘reimbursement of eligible costs grant’) (see Annex 2).

The estimated eligible costs of the action are EUR **2,999,943.75** (two million nine hundred and ninety nine thousand nine hundred and forty three EURO and seventy five eurocents).

Eligible costs (see Article 6) must be declared under the following forms (‘forms of costs’):

(a) for **direct personnel costs**:
   - as actually incurred costs (‘actual costs’) or
   - on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (‘unit costs’).

   Personnel costs for SME owners or beneficiaries that are natural persons not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2a (unit costs);

(b) for **direct costs for subcontracting**: as actually incurred costs (actual costs);

(c) for **direct costs of providing financial support to third parties**: not applicable;

(d) for **other direct costs**:
   - for costs of internally invoiced goods and services: on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices (‘unit costs’);
   - for all other costs: as actually incurred costs (actual costs);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E (‘flat-rate costs’);

(f) **specific cost category(ies)**: not applicable.

5.3 **Final grant amount — Calculation**

The ‘final grant amount’ depends on the actual extent to which the action is implemented in accordance with the Agreement’s terms and conditions.

This amount is calculated by the Commission — when the payment of the balance is made (see Article 21.4) — in the following steps:

- **Step 1** – Application of the reimbursement rates to the eligible costs
- **Step 2** – Limit to the maximum grant amount
- **Step 3** – Reduction due to the no-profit rule
- **Step 4** – Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

**5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs**
The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries (see Article 20) and approved by the Commission (see Article 21).

### 5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

### 5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

‘Profit’ means the surplus of the amount obtained following Steps 1 and 2 plus the action’s total receipts, over the action’s total eligible costs.

The ‘action’s total eligible costs’ are the consolidated total eligible costs approved by the Commission.

The ‘action’s total receipts’ are the consolidated total receipts generated during its duration (see Article 3).

The following are considered receipts:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action’s results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

### 5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the Commission will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.
The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the Commission rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the ‘revised final grant amount’ for the beneficiary concerned by the findings.

This amount is calculated by the Commission on the basis of the findings, as follows:

- in case of rejection of costs: by applying the reimbursement rate to the revised eligible costs approved by the Commission for the beneficiary concerned;
- in case of reduction of the grant: by calculating the concerned beneficiary’s share in the grant amount reduced in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations (see Article 43.2).

In case of rejection of costs and reduction of the grant, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

‘Eligible costs’ are costs that meet the following criteria:

(a) for actual costs:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary’s accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary’s usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

(b) for unit costs:
(i) they must be calculated as follows:

{amounts per unit set out in Annex 2a or calculated by the beneficiary in accordance with its usual
cost accounting practices (see Article 6.2, Point A and Article 6.2.D.5)
multiplied by
the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by
  records and documentation (see Article 18);

(c) for flat-rate costs:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs) to which the flat-rate is applied must comply with the
  conditions for eligibility set out in this Article.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions
set out below for each of the following budget categories:

A. direct personnel costs;
B. direct costs of subcontracting;
C. not applicable;
D. other direct costs;
E. indirect costs;
F. not applicable.

‘Direct costs’ are costs that are directly linked to the action implementation and can therefore be
attributed to it directly. They must not include any indirect costs (see Point E below).

‘Indirect costs’ are costs that are not directly linked to the action implementation and therefore cannot
be attributed directly to it.

A. Direct personnel costs

Types of eligible personnel costs

A.1 Personnel costs are eligible, if they are related to personnel working for the beneficiary under
an employment contract (or equivalent appointing act) and assigned to the action (‘costs for
employees (or equivalent)’). They must be limited to salaries (including during parental leave),
social security contributions, taxes and other costs included in the remuneration, if they arise
from national law or the employment contract (or equivalent appointing act).
Beneficiaries that are non-profit legal entities\(^1\) may also declare as personnel costs additional remuneration for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary’s usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

‘Additional remuneration’ means any part of the remuneration which exceeds what the person would be paid for time worked in projects funded by national schemes.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

\[
\left\{ \frac{\text{EUR 8 000}}{\text{the number of annual productive hours (see below)}} \right\} \times \text{the number of hours that the person has worked on the action during the year}.
\]

A.2 The costs for natural persons working under a direct contract with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);

(b) the result of the work carried out belongs to the beneficiary (unless exceptionally agreed otherwise), and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The costs of personnel seconded by a third party against payment are eligible personnel costs, if the conditions in Article 11.1 are met.

\(^1\) For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: ‘non-profit legal entity’ means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.
A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises (‘SME owners’) who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

A.5 **Costs of ‘beneficiaries that are natural persons’** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.

**Calculation**

Personnel costs must be calculated by the beneficiaries as follows:

\[
\{ \text{hourly rate} \times \text{the number of actual hours worked on the action} \},
\]

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1).

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant is:

\[
\{ \text{number of annual productive hours for the year (see below)} - \text{total number of hours declared by the beneficiary for that person in that year for other EU or Euratom grants} \}.
\]

The ‘**hourly rate**’ is one of the following:

(a) for personnel costs declared as **actual costs** (i.e. budget categories A.1, A.2, A.3): the hourly rate is calculated *per full financial year*, as follows:

\[
\{ \text{actual annual personnel costs (excluding additional remuneration) for the person} \div \text{number of annual productive hours} \}.
\]

using the personnel costs and the number of productive hours for each full financial year covered by the reporting period concerned. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the ‘**number of annual productive hours**’, the beneficiaries may choose one of the following:

(i) ‘**fixed number of hours**’: 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);
(ii) ‘individual annual productive hours’: the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

\[
\text{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law) } \\
\text{plus } \\
overtime worked \\
\text{minus } \\
absences (such as sick leave and special leave)}.
\]

‘Annual workable hours’ means the period during which the personnel must be working, at the employer’s disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) ‘standard annual productive hours’: the ‘standard number of annual hours’ generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the ‘standard annual workable hours’.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on parental leave by a person assigned to the action may be deducted from the number of annual productive hours.

As an alternative, beneficiaries may calculate the hourly rate per month, as follows:

\[
\frac{\text{actual monthly personnel cost (excluding additional remuneration) for the person}}{\text{number of annual productive hours / 12}}
\]

using the personnel costs for each month and (one twelfth of) the annual productive hours calculated according to either option (i) or (iii) above, i.e.:

- fixed number of hours or
- standard annual productive hours.

Time spent on parental leave may not be deducted when calculating the hourly rate per month. However, beneficiaries may declare personnel costs incurred in periods of parental leave in proportion to the time the person worked on the action in that financial year.

If parts of a basic remuneration are generated over a period longer than a month, the beneficiaries may include only the share which is generated in the month (irrespective of the amount actually paid for that month).
Each beneficiary must use only one option (per full financial year or per month) for each full financial year;

(b) for personnel costs declared on the basis of unit costs (i.e. budget categories A.1, A.2, A.4, A.5): the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2a (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary’s usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

   - the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

   - the hourly rate is calculated using the actual personnel costs recorded in the beneficiary’s accounts, excluding any ineligible cost or costs included in other budget categories.

   The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information;

and

   - the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13.1.1 are met.

C. Direct costs of providing financial support to third parties

Not applicable

D. Other direct costs

D.1 Travel costs and related subsistence allowances (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary’s usual practices on travel.

D.2 The depreciation costs of equipment, infrastructure or other assets (new or second-hand) as recorded in the beneficiary’s accounts are eligible, if they were purchased in accordance with Article 10.1.1 and written off in accordance with international accounting standards and the beneficiary’s usual accounting practices.

The costs of renting or leasing equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.
The costs of equipment, infrastructure or other assets contributed in-kind against payment are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11.1 are met.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.

D.3 Costs of other goods and services (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10.1.1 or
(b) contributed in kind against payment and in accordance with Article 11.1.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

D.4 Capitalised and operating costs of ‘large research infrastructure’² directly used for the action are eligible, if:

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure³);

(b) the beneficiary’s methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission (‘ex-ante assessment’);

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the conditions as further detailed in the annotations to the H2020 grant agreements.

D.5 Costs of internally invoiced goods and services directly used for the action are eligible, if:

(a) they are declared on the basis of a unit cost calculated in accordance with the beneficiary’s usual cost accounting practices;

² ‘Large research infrastructure’ means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

³ For the definition, see Article 2(6) of the H2020 Framework Programme Regulation No 1291/2013: ‘Research infrastructure’ are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be ‘single-sited’, ‘virtual’ or ‘distributed’.

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(b) the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

(c) the unit cost is calculated using the actual costs for the good or service recorded in the beneficiary’s accounts, excluding any ineligible cost or costs included in other budget categories.

The actual costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating the costs, reasonable and correspond to objective and verifiable information;

(d) the unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

‘Internally invoiced goods and services’ means goods or services which are provided by the beneficiary directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

**E. Indirect costs**

**Indirect costs** are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting and

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary’s premises;

(c) not applicable;

(d) not applicable.

Beneficiaries receiving an operating grant\(^4\) financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.

**F. Specific cost category(ies)**

Not applicable

**6.3 Conditions for costs of linked third parties to be eligible**

Not applicable

**6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible**

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary), if the costs incurred by the third party fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.1.

6.5 Ineligible costs

‘Ineligible costs’ are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary’s bank for transfers from the Commission;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Commission for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action
The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14);
- call upon international partners to implement action tasks described in Annex 1 (see Article 14a).

In these cases, the beneficiaries retain sole responsibility towards the Commission and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

Not applicable

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.
10.1.2 Beneficiaries that are ‘contracting authorities’ within the meaning of Directive 2004/18/EC\(^5\) (or 2014/24/EU\(^6\)) or ‘contracting entities’ within the meaning of Directive 2004/17/EC\(^7\) (or 2014/25/EU\(^8\)) must comply with the applicable national law on public procurement.

### 10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

### ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

#### 11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties’ costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The third parties and their contributions must be set out in Annex 1. The Commission may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

#### 11.2 Consequences of non-compliance

---


If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

**ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE**

**12.1 Rules for the use of in-kind contributions free of charge**

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The Commission may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

**12.2 Consequences of non-compliance**

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

**ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS**

**13.1 Rules for subcontracting action tasks**

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Commission may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:
- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are ‘contracting authorities’ within the meaning of Directive 2004/18/EC (or 2014/24/EU) or ‘contracting entities’ within the meaning of Directive 2004/17/EC (or 2014/25/EU) must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

Not applicable

ARTICLE 14a — IMPLEMENTATION OF ACTION TASKS BY INTERNATIONAL PARTNERS

Not applicable

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

Not applicable

15.2 Financial support in the form of prizes

Not applicable

15.3 Consequences of non-compliance

Not applicable

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE
16.1 Rules for providing trans-national access to research infrastructure
Not applicable

16.2 Rules for providing virtual access to research infrastructure
Not applicable

16.3 Consequences of non-compliance
Not applicable

SECTION 2  RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 General obligation to provide information upon request
The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 41.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement
Each beneficiary must keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the Commission and the other beneficiaries — of any of the following:

(a) events which are likely to affect significantly or delay the implementation of the action or the EU’s financial interests, in particular:

   (i) changes in its legal, financial, technical, organisational or ownership situation

(b) circumstances affecting:

   (i) the decision to award the grant or

   (ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance
If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.
ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of five years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Commission may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for actual costs: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for unit costs: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, for unit costs calculated in accordance with the beneficiary's usual cost accounting practices, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2.

The beneficiaries may submit to the Commission, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions (‘certificate on the methodology’). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for flat-rate costs: adequate records and other supporting documentation to prove the eligibility
of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, for personnel costs (declared as actual costs or on the basis of unit costs), the beneficiaries must keep time records for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the Commission may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for persons working exclusively on the action, there is no need to keep time records, if the beneficiary signs a declaration confirming that the persons concerned have worked exclusively on the action.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the ‘deliverables’ identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the Commission may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The coordinator must submit to the Commission (see Article 52) the technical and financial reports set out in this Article. These reports include requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following ‘reporting periods’:

- RP1: from month 1 to month 18
- RP2: from month 19 to month 36

20.3 Periodic reports — Requests for interim payments
The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The periodic report must include the following:

(a) a ‘periodic technical report’ containing:

   (i) an explanation of the work carried out by the beneficiaries;

   (ii) an overview of the progress towards the objectives of the action, including milestones and deliverables identified in Annex 1.

   This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

   The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated ‘plan for the exploitation and dissemination of the results’.

   The report must indicate the communication activities;

   (iii) a summary for publication by the Commission;

   (iv) the answers to the ‘questionnaire’, covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a ‘periodic financial report’ containing:

   (i) an ‘individual financial statement’ (see Annex 4) from each beneficiary, for the reporting period concerned.

   The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

   The beneficiaries must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Commission.

   If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

   The individual financial statements of the last reporting period must also detail the receipts of the action (see Article 5.3.3).

   Each beneficiary must certify that:

   - the information provided is full, reliable and true;
   - the costs declared are eligible (see Article 6);
   - the costs can be substantiated by adequate records and supporting documentation
(see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an explanation of the use of resources and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary, for the reporting period concerned;

(iii) not applicable;

(iv) a ‘periodic summary financial statement’, created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the request for interim payment.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The final report must include the following:

(a) a ‘final technical report’ with a summary for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a ‘final financial report’ containing:

(i) a ‘final summary financial statement’, created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the request for payment of the balance and

(ii) a ‘certificate on the financial statements’ (drawn up in accordance with Annex 5) for each beneficiary, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2).

20.5 Information on cumulative expenditure incurred

Not applicable

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries with accounting established in a currency other than the euro must convert the costs
recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission’s website, calculated over the corresponding reporting period.

Beneficiaries with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

### 20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

### 20.8 Consequences of non-compliance

If the reports submitted do not comply with this Article, the Commission may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder, the Commission may terminate the Agreement (see Article 50) or apply any of the other measures described in Chapter 6.

**ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS**

### 21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;

- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and

- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

### 21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR **2,399,955.00** (two million three hundred and ninety nine thousand nine hundred and fifty five EURO).

The Commission will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR **149,997.19** (one hundred and forty nine thousand nine hundred and ninety seven...
EURO and nineteen eurocents), corresponding to 5% of the maximum grant amount (see Article 5.1), is retained by the Commission from the pre-financing payment and transferred into the ‘Guarantee Fund’.

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Commission will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The amount due as interim payment is calculated by the Commission in the following steps:

   Step 1 – Application of the reimbursement rates
   Step 2 – Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries (see Article 20) and approved by the Commission (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

\[
\{ 90\% \text{ of the maximum grant amount (see Article 5.1)} \\
\text{minus} \\
\{ \text{pre-financing and previous interim payments} \} \}
\]

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the Commission will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.
The **amount due as the balance** is calculated by the Commission by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

\[
\text{final grant amount (see Article 5.3)} - \text{pre-financing and interim payments (if any made)}.
\]

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;
- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:
  - is positive, it will be paid to the coordinator
  - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the Commission or an executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

**21.5 Notification of amounts due**

When making payments, the Commission will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

**21.6 Currency for payments**

The Commission will make all payments in euro.

**21.7 Payments to the coordinator — Distribution to the beneficiaries**

Payments will be made to the coordinator.

Payments to the coordinator will discharge the Commission from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and
(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

- Name of bank: ERSTE BANK DER OESTERREICHISCHEN SPARKASSEN AG
- Full name of the account holder: MEDIZINISCHE UNIVERSITAT WIEN
- IBAN code: AT362011140410070700

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the Commission bears the cost of transfers charged by its bank;
- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the Commission are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the Commission does not pay within the payment deadlines (see above), the beneficiaries are entitled to late-payment interest at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros (‘reference rate’), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the Official Journal of the European Union.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).
Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission

22.1.1 Right to carry out checks

The Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Commission may be assisted by external persons or bodies.

The Commission may also request additional information in accordance with Article 17. The Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For on-the-spot reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.
Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a ‘review report’ will be drawn up.

The Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations (‘contradictory review procedure’).

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Commission may request beneficiaries to provide such information to it directly.

For on-the-spot audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a ‘draft audit report’ will be drawn up.

The Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations (‘contradictory audit procedure’). This period may be extended by the Commission in justified cases.

The ‘final audit report’ will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Commission may also access the beneficiaries’ statutory records for the periodical assessment of unit costs or flat-rate amounts.

22.2 Investigations by the European Anti-Fraud Office (OLAF)
Under Regulations No 883/2013\textsuperscript{16} and No 2185/96\textsuperscript{17} (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012\textsuperscript{18}, the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

Not applicable

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions (‘extension of findings from this grant to other grants’).

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants


\textsuperscript{17} Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

The Commission may extend findings from other grants to this grant (‘extension of findings from other grants to this grant’), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern eligibility of costs: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit revised financial statements for all grants affected;

(c) the correction rate for extrapolation established by the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

   (i) considers that the submission of revised financial statements is not possible or practicable or

   (ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated alternative correction method. This period may be extended by the Commission in justified cases.

The Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved;

- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the findings concern substantial errors, irregularities or fraud or serious breach of obligations: the formal notification will include:
(a) an invitation to submit observations on the list of grants affected by the findings and
(b) the flat-rate the Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The Commission may then start a reduction procedure in accordance with Article 43, on the basis of:
- the proposed alternative flat-rate, if accepted
or
- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the EU programme.

Evaluations may be started during implementation of the action and up to five years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Commission may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY
23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities19. This does not change the obligations set out in Subsections 2 and 3 of this Section.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Commission may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

24.1 Agreement on background

The beneficiaries must identify and agree (in writing) on the background for the action (‘agreement on background’).

‘Background’ means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

24.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing (‘request for access’).

‘Access rights’ means rights to use results or background under the terms and conditions laid down in this Agreement.

19 Commission Recommendation C(2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.
Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

**25.2 Access rights for other beneficiaries, for implementing their own tasks under the action**

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

**25.3 Access rights for other beneficiaries, for exploiting their own results**

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

‘Fair and reasonable conditions’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

**25.4 Access rights for affiliated entities**

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities established in an EU Member State or ‘associated country’, if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

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20 For the definition see Article 2.1(2) Rules for Participation Regulation No 1290/2013: ‘affiliated entity’ means any legal entity that is:

- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

‘Control’ may take any of the following forms:

(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;

(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

However the following relationships between legal entities shall not in themselves be deemed to constitute controlling relationships:

(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

Not applicable

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

‘Results’ means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership (‘joint ownership agreement’), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive

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21 For the definition, see Article 2.1(3) of the Rules for Participation Regulation No 1290/2013: ‘associated country’ means a third country which is party to an international agreement with the Union, as identified in Article 7 of Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.
licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and
(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 EU ownership, to protect results

26.4.1 The EU may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the Commission and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Commission decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may take place before the end of this period or, if the Commission takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 The EU may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:
(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the Commission at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the Commission decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 Obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 EU ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, the EU may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the Commission requests or agrees otherwise or unless it is impossible — include the following:

“The project leading to this application has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 779292”.

27.4 Consequences of non-compliance
If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 Obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure ‘exploitation’ of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);
(b) developing, creating or marketing a product or process;
(c) creating and providing a service, or
(d) using them in standardisation activities.

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

If results are incorporated in a standard, the beneficiary concerned must — unless the Commission requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

“Results incorporated in this standard received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 779292”.

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — ‘disseminate’ its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in
Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the Commission before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms “European Union (EU)” and “Horizon 2020”;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

Regarding the digital research data generated in the action (‘data’), the beneficiaries must:
(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible;

(ii) other data, including associated metadata, as specified and within the deadlines laid down in the 'data management plan' (see Annex 1);

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex 1, would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the Commission requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

“This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 779292”.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Commission.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding Commission responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the Commission is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).
Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice (or less if agreed in writing) to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing) for specifically-identified third parties, any other beneficiary may object within 30 days of receiving notification (or less if agreed in writing), if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licenses

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the access rights under Article 31 and

(b) not applicable.

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 Commission right to object to transfers or licensing

Not applicable

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS
31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

The beneficiaries must give access to their results — on a royalty-free basis — to EU institutions, bodies, offices or agencies, for developing, implementing or monitoring EU policies or programmes.

Such access rights are limited to non-commercial and non-competitive use.

This does not change the right to use any material, document or information received from the beneficiaries for communication and publicising activities (see Article 38.2).

31.6 Access rights for third parties

Not applicable

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).
Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers\(^\text{23}\), in particular regarding:

- working conditions;
- transparent recruitment processes based on merit, and
- career development.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Commission may apply any of the measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the Commission may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

The beneficiaries must respect the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity.

This implies notably compliance with the following essential principles:

- honesty;
- reliability;
- objectivity;
- impartiality;
- open communication;
- duty of care;
- fairness and
- responsibility for future science generations.

This means that beneficiaries must ensure that persons carrying out research tasks:

- present their research goals and intentions in an honest and transparent manner;
- design their research carefully and conduct it in a reliable fashion, taking its impact on society into account;

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24 The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.

- use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned;

- exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;

- ensure objectivity, accuracy and impartiality when disseminating the results;

- allow — in addition to the open access obligations under Article 29.3 as much as possible and taking into account the legitimate interest of the beneficiaries — access to research data, in order to enable research to be reproduced;

- make the necessary references to their work and that of other researchers;

- refrain from practicing any form of plagiarism, data falsification or fabrication;

- avoid double funding, conflicts of interest and misrepresentation of credentials or other research misconduct.

### 34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the ‘ethics requirements’ set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the Commission (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

### 34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or

- the coordinator has obtained explicit approval (in writing) from the Commission (see Article 52).

### 34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).
Such breaches may also lead to any of the other measures described in Chapter 6.

**ARTICLE 35 — CONFLICT OF INTERESTS**

**35.1 Obligation to avoid a conflict of interests**

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (‘conflict of interests’).

They must formally notify to the Commission without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Commission may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

**35.2 Consequences of non-compliance**

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

**ARTICLE 36 — CONFIDENTIALITY**

**36.1 General obligation to maintain confidentiality**

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (‘confidential information’).

If a beneficiary requests, the Commission may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The Commission may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:
(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and
(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for Participation Regulation No 1290/2013\(^{25}\), the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;
(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;
(c) the recipient proves that the information was developed without the use of confidential information;
(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or
(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Results with a security recommendation

Not applicable

37.2 Classified information

Not applicable

37.3 Activities involving dual-use goods or dangerous materials and substances

Not applicable

37.4 Consequences of non-compliance

Not applicable

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the Commission (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the Commission requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

For communication activities: “This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 779292”.

For infrastructure, equipment and major results: “This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 779292”.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Commission.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding Commission responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the Commission is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the Commission

38.2.1 Right to use beneficiaries’ materials, documents or information

The Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any
other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the Commission’s use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the Commission not to use it (see Article 52).

The right to use a beneficiary’s materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the Commission or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) translation;

(e) giving **access in response to individual requests** under Regulation No 1049/2001\(^{27}\), without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the Commission.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the Commission will insert the following information:

“© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the European Union (EU) under conditions.”

### 38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the Commission

Any personal data under the Agreement will be processed by the Commission under Regulation No 45/2001 and according to the ‘notifications of the processing operations’ to the Data Protection Officer (DPO) of the Commission (publicly accessible in the DPO register).

Such data will be processed by the ‘data controller’ of the Commission for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the Commission.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the Commission may apply any of the measures described in Chapter 6.

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE COMMISSION

The beneficiaries may not assign any of their claims for payment against the Commission to any

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third party, except if approved by the Commission on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the Commission has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the Commission.

CHAPTER 5 DIVISION OF BENEFICIARIES’ ROLES AND RESPONSIBILITIES
— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES —
RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

ARTICLE 41 — DIVISION OF BENEFICIARIES’ ROLES AND RESPONSIBILITIES
— RELATIONSHIP WITH COMPLEMENTARY BENEFICIARIES —
RELATIONSHIP WITH PARTNERS OF A JOINT ACTION

41.1 Roles and responsibility towards the Commission

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the technical implementation of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Commission expressly relieves them of this obligation.

The financial responsibility of each beneficiary is governed by Article 44.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each beneficiary must:

(i) keep information stored in the Participant Portal Beneficiary Register (via the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the technical reports (see Article 20);

- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);
- any other documents or information required by the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Commission.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the Commission (in particular, providing the Commission with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the Commission and verify their completeness and correctness before passing them on to the Commission;

(iv) submit the deliverables and reports to the Commission (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the Commission of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the Commission.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including linked third parties).

### 41.3 Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must have internal arrangements regarding their operation and co-ordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written ‘**consortium agreement**’ between the beneficiaries, which may cover:

- internal organisation of the consortium;
- management of access to the electronic exchange system;
- distribution of EU funding;
- additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);
- settlement of internal disputes;
- liability, indemnification and confidentiality arrangements between the beneficiaries.

The consortium agreement must not contain any provision contrary to the Agreement.

### 41.4 Relationship with complementary beneficiaries — Collaboration agreement

Not applicable
41.5 Relationship with partners of a joint action — Coordination agreement

Not applicable

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — SANCTIONS

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

The Commission will — after termination of the participation of a beneficiary, at the time of an interim payment, at the payment of the balance or afterwards — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

The rejection may also be based on the extension of findings from other grants to this grant (see Article 22.5.2).

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the rejection of costs does not lead to a recovery (see Article 44), the Commission will formally notify the coordinator or beneficiary concerned of the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the Commission of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the Commission will follow the contradictory procedure with pre-information letter set out in Article 44.

42.3 Effects

If the Commission rejects costs at the time of an interim payment or the payment of the balance, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Commission rejects costs after termination of the participation of a beneficiary, it will deduct them from the costs declared by the beneficiary in the termination report and include the rejection in the calculation after termination (see Article 50.2 and 50.3).

If the Commission — after an interim payment but before the payment of the balance — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible
costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the Commission rejects costs after the payment of the balance, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

**ARTICLE 43 — REDUCTION OF THE GRANT**

**43.1 Conditions**

The Commission may — after termination of the participation of a beneficiary, at the payment of the balance or afterwards — reduce the grant amount (see Article 5.1), if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:

   (i) substantial errors, irregularities or fraud or

   (ii) breach of serious obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings from other grants to this grant; see Article 22.5.2).

**43.2 Amount to be reduced — Calculation — Procedure**

The amount of the reduction will be proportionate to the seriousness of the errors, irregularities or fraud or breach of obligations.

Before reduction of the grant, the Commission will formally notify a ‘pre-information letter’ to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification

If the Commission does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify confirmation of the reduction (if applicable, together with the notification of amounts due; see Article 21).

**43.3 Effects**

If the Commission reduces the grant after termination of the participation of a beneficiary, it will calculate the reduced grant amount for that beneficiary and then determine the amount due to that beneficiary (see Article 50.2 and 50.3).
If the Commission reduces the grant at the payment of the balance, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the Commission reduces the grant after the payment of the balance, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the Commission will recover the difference (see Article 44).

**ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS**

**44.1 Amount to be recovered — Calculation — Procedure**

The Commission will — after termination of the participation of a beneficiary, at the payment of the balance or afterwards — claim back any amount that was paid, but is not due under the Agreement.

Each beneficiary’s financial responsibility in case of recovery is limited to its own debt, except for the amount retained for the Guarantee Fund (see Article 21.4).

**44.1.1 Recovery after termination of a beneficiary’s participation**

If recovery takes place after termination of a beneficiary’s participation (including the coordinator), the Commission will claim back the undue amount from the beneficiary concerned, by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Commission will recover the amount:

(a) by ‘offsetting’ it — without the beneficiary’s consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU’s financial interests, the Commission may offset before the payment date specified in the debit note;

(b) not applicable;

(c) by taking legal action (see Article 57) or by adopting an enforceable decision under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial regulation No 966/2012.

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by late-payment interest at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.
Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the Commission will formally notify a *pre-information letter* to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;
- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;
- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Commission decides to pursue recovery despite the observations it has received, it will confirm recovery (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, if the difference is positive or
- formally notify to the coordinator a debit note for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, if the difference is negative. This note will also specify the terms and the date for payment.

If the coordinator does not repay the Commission by the date in the debit note and has not submitted the report on the distribution of payments: the Commission will recover the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the Commission by the date in the debit note, but has submitted the report on the distribution of payments: the Commission will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

\[
\left\{ \left\{ \text{beneficiary’s costs declared in the final summary financial statement and approved by the Commission multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned} \right\} \div \text{the EU contribution for the action calculated according to Article 5.3.1} \right\} \times \text{the final grant amount (see Article 5.3)},
\]

minus

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(b) formally notify to each beneficiary identified according to point (a) a debit note specifying the terms and date for payment. The amount of the debit note is calculated as follows:

\[
\text{amount calculated according to point (a) for the beneficiary concerned} \\
\text{divided by} \\
\text{the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)} \\
\text{multiplied by} \\
\text{the amount set out in the debit note formally notified to the coordinator}.
\]

If payment is not made by the date specified in the debit note, the Commission will recover the amount:

(a) by ‘offsetting’ it — without the beneficiary’s consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU’s financial interests, the Commission may offset before the payment date specified in the debit note;

(b) by drawing on the Guarantee Fund. The Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by taking legal action (see Article 57) or by adopting an enforceable decision under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by late-payment interest at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the Commission.

The beneficiary’s share of the final grant amount is calculated as follows:
\{(beneficiary’s costs declared in the final summary financial statement and approved by the Commission multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned) \}

divided by

the EU contribution for the action calculated according to Article 5.3.1 \}

multiplied by

the final grant amount (see Article 5.3) \}.

If the coordinator has not distributed amounts received (see Article 21.7), the Commission will also recover these amounts.

The Commission will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Commission decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Commission will **recover** the amount:

(a) by ‘**offsetting**’ it — without the beneficiary’s consent — against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU’s financial interests, the Commission may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund**. The Commission will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) not applicable;

(ii) by **taking legal action** (see Article 57) or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.
ARTICLE 45 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the Commission may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 966/2012 (i.e. exclusion from future procurement contracts, grants, prizes and expert contracts and/or financial penalties).

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the Commission

The Commission cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The Commission cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the Commission for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The Commission may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The Commission will formally notify the coordinator of the suspension and the reasons why.

The suspension will take effect the day notification is sent by the Commission (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be lifted — and the remaining period will resume.
If the suspension exceeds two months, the coordinator may request the Commission if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the Commission may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The Commission may — at any moment — suspend payments, in whole or in part and interim payments or the payment of the balance for one or more beneficiaries, if:

(a) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles) or

(b) a beneficiary (or a natural person who has the power to represent or take decision on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings from other grants to this grant; see Article 22.5.2).

If payments are suspended for one or more beneficiaries, the Commission will make partial payment(s) for the part(s) not suspended. If suspension concerns the payment of the balance, — once suspension is lifted — the payment or the recovery of the amount(s) concerned will be considered the payment of the balance that closes the action.

48.2 Procedure

Before suspending payments, the Commission will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Commission does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify confirmation of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will take effect the day the confirmation notification is sent by the Commission.

If the conditions for resuming payments are met, the suspension will be lifted. The Commission will formally notify the coordinator or beneficiary concerned.
During the suspension, the periodic report(s) for all reporting periods except the last one (see Article 20.3), must not contain any individual financial statements from the beneficiary concerned. The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

**ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION**

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular force majeure (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the Commission the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will take effect the day this notification is received by the Commission.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the Commission and request an amendment of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the Commission

49.2.1 Conditions

The Commission may suspend implementation of the action or any part of it, if:

(a) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure
(including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(b) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings from other grants to this grant; see Article 22.5.2), or

(c) the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the Commission will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to suspend the implementation and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the Commission does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify confirmation of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will take effect five days after confirmation notification is received (or on a later date specified in the notification).

It will be lifted if the conditions for resuming implementation of the action are met.

The coordinator or beneficiary concerned will be formally notified of the lifting and the Agreement will be amended to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the Commission (see Article 46).

Suspension of the action implementation does not affect the Commission’s right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement, by the beneficiaries

50.1.1 Conditions and procedure
The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Commission (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Commission considers the reasons do not justify termination, the Agreement will be considered to have been ‘terminated improperly’.

The termination will take effect on the day specified in the notification.

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and
(ii) the final report (see Article 20.4).

If the Commission does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Commission will calculate the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries’ obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.2 Termination of the participation of one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Commission (see Article 52) and inform the beneficiary concerned.

If the coordinator’s participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Commission considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

### 50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a ‘termination report’ from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Articles 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Commission, (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Commission, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The Commission will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — **calculate** the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The **amount which is due** is calculated in the following steps:

**Step 1** — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary in the termination report and approved by the Commission.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.
Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the Commission will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received **exceed the amounts due**:  

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The Commission will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the Commission will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the Commission will formally notify a debit note to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Commission the amount due and the Commission will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator according to the procedure above, unless:
  
  - termination takes effect after an interim payment and
  
  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

In this case, the Commission will formally notify a debit note to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Commission the amount due. The Commission will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the Commission does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Commission does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that

- the beneficiary concerned must not repay any amount to the coordinator.
Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary’s obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

50.3 Termination of the Agreement or the participation of one or more beneficiaries, by the Commission

50.3.1 Conditions

The Commission may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

   (i) resumption is impossible, or

   (ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) not applicable;

(j) not applicable;

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed:
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(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under the Agreement or during the award procedure (including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles);

(m) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings from other grants to this grant; see Article 22.5.2).

(n) not applicable.

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Commission will formally notify the coordinator or beneficiary concerned:

- informing it of its intention to terminate and the reasons why and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (i.ii) above — to inform the Commission of the measures to ensure compliance with the obligations under the Agreement.

If the Commission does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator or beneficiary concerned confirmation of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will take effect:

- for terminations under Points (b), (c), (e), (g), (h), (j), (l.ii) and (n) above: on the day specified in the notification of the confirmation (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after the notification of the confirmation is received.

50.3.3 Effects

(a) for termination of the Agreement:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.
If the Commission does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Commission will calculate the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the Commission’s right to reduce the grant (see Article 43) or to impose administrative sanctions (Article 45).

The beneficiaries may not claim damages due to termination by the Commission (see Article 46).

After termination, the beneficiaries’ obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

(b) for termination of the participation of one or more beneficiaries:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a termination report from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the Commission, (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the Commission, the Agreement is amended to introduce the necessary changes (see Article 55).

The Commission will — on the basis of the periodic reports, the termination report and the report on the distribution of payments — calculate the amount which is due to the beneficiary and if the (pre-financing and interim) payments received by the beneficiary exceed this amount.

The amount which is due is calculated in the following steps:
Step 1 — Application of the reimbursement rate to the eligible costs

The grant amount for the beneficiary is calculated by applying the reimbursement rate(s) to the total eligible costs declared by the beneficiary in the termination report and approved by the Commission.

Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Step 2 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

In case of a reduction (see Article 43), the Commission will calculate the reduced grant amount for the beneficiary by deducting the amount of the reduction (calculated in proportion to the seriousness of the errors, irregularities or fraud or breach of obligations, in accordance with Article 43.2) from the grant amount for the beneficiary.

If the payments received exceed the amounts due:

- if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The Commission will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the Commission will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- in all other cases (in particular if termination takes effect after the period set out in Article 3), the Commission will formally notify a debit note to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Commission the amount due and the Commission will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

- if the beneficiary concerned is the former coordinator, it must repay the new coordinator according to the procedure above, unless:
  - termination takes effect after an interim payment and
  - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

In this case, the Commission will formally notify a debit note to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the Commission the amount due. The Commission will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

If the payments received do not exceed the amounts due: amounts owed to the beneficiary concerned will be included in the next interim or final payment.
If the Commission does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the Commission does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary’s obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38, 40, 42, 43 and 44) continue to apply.

SECTION 4  FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

‘Force majeure’ means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties’ control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7  FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES
52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, ‘formal notifications’, etc.) must:

- be made in writing and
- bear the number of the Agreement.

All communication must be made through the Participant Portal **electronic** exchange system and using the forms and templates provided there.

If — after the payment of the balance — the Commission finds that a formal notification was not accessed, a second formal notification will be made by registered post with proof of delivery (‘formal notification on paper’). Deadlines will be calculated from the moment of the second notification.

Communications in the electronic exchange system must be made by persons authorised according to the Participant Portal Terms & Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a ‘legal entity appointed representative (LEAR)’. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Participant Portal Terms & Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Commission websites.

52.2 Date of communication

**Communications** are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

**Formal notifications** through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications on paper sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:


The Commission will formally notify the coordinator and beneficiaries in advance any changes to this URL.
Formal notifications on paper (only after the payment of the balance) addressed to the Commission must be sent to the official mailing address indicated on the Commission’s website.

Formal notifications on paper (only after the payment of the balance) addressed to the beneficiaries must be sent to their legal address as specified in the Participant Portal Beneficiary Register.

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

53.2 Privileges and immunities

Not applicable

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71, periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;

- the appropriate supporting documents;

- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The Commission may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Commission has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

**ARTICLE 56 — ACCESSION TO THE AGREEMENT**

**56.1 Accession of the beneficiaries mentioned in the Preamble**

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52) within 30 days after its entry into force (see Article 58).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Commission’s right to terminate the Agreement (see Article 50).

**56.2 Addition of new beneficiaries**

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

**ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES**

**57.1 Applicable law**

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.
57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Commission or the coordinator, depending on which is later.

SIGNATURES

For the coordinator

Iris WEINBUB with ECAS id rweinibl signed in the Participant Portal on 15/11/2017 at 09:57:57 (transaction id Sigld-78380-gls3oAsUgclIdsPHybwwj5JScgVXawIUozqSY0Snzxizis0a CWzRkFb6ikCyjQIOZ2wv4V0fia0sPM7ksAO- PHsULMVsicxGmsk0JguV09y- 60g500109SzQoVaRDqz78Pz2mpOS3l4v3rlN510h). Timestamp by third party at Wed Nov 15 09:58:15 CET 2017

For the Commission

Signed by Mila BAS SANCHEZ with ECAS id bassami as an authorised representative on 27-11-2017 16:36:42 (transaction id Sigld-224242- kxnxLSAS6i6jJdcdWvOx4uemkkij1V67enhueqr3FiogfgPCJgs O5sdmG1HUXhB0iCUH4Jce5cDrETJlz0t0EAq- PHsULMVsicxGmaw0JguV09y- aeJ5ls6k057z9pEv8JW9ysQIo00MrzPWCe6O2PHhOQ Jm) Mon Nov 27 16:36:48 CET 2017
ANNEX 1 (part A)

Research and Innovation action

NUMBER — 779292 — PECUNIA
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# 1.1. The project summary

<table>
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<tr>
<th>Project Number</th>
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<th>Project Acronym</th>
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## General information

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**Abstract**

ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluations (PECUNIA) addresses the call SC1-PM-20-2017 Methods research for improved health economic evaluation. The consortium brings together 10 partners from 6 countries with complementary methodological expertise. It represents differing health care systems with varying feasibility and acceptability of economic evaluations in evidence-informed decision making. Some countries have established national unit cost programmes (DE, NL, UK), some early stage initiatives (AT, ES, HU). Availability of health utility value sets for outcome evaluations and requirements in terms of the primary analytical perspective of economic evaluations (health & social care vs. societal) also differ.

Over 36 months, PECUNIA will develop standardised, harmonised and validated multi-sectoral, multi-national and multi-person methods, tools and information for 1) self-reported resource use measurement, 2) reference unit cost valuation, 3) cross-national health utility assessment, and 4) broader wellbeing measurement. To achieve the widest impact possible and exploit its disruptive innovation potential for end users, decision makers, payers and the industry, the work will be executed in close collaboration with 5) external scientific advisors and broad outreach to all relevant stakeholders. Considering feasibility and relevant societal challenges in the European health systems, selected mental health disease areas (depression, schizophrenia, PTSD) will be used as illustrative examples for cost assessment. PECUNIA will lead to better understanding of the variations in costs and outcomes within and across countries, improve the quality, comparability and transferability of economic evaluations in Europe, and support the feasibility of broader economic and societal impacts measurement and valuation in multi-sectoral economic evaluations also for HTA.
## 1.2. List of Beneficiaries

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## 1.3. Workplan Tables - Detailed implementation

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**Total** 399.60
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### 1.3.3. WT3 Work package descriptions

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#### Objectives

Standardised methods on the measurement and valuation of services in the health and social care sector that are applicable across countries are currently lacking. WP1 will focus on the development of such methods and tools allowing for low-threshold extension and update in the future. Depression, schizophrenia and PTSD will be used as illustrative disease areas.

- **O1.1**: Develop internationally standardised methods and tools to make resource use identification, definition, measurement and valuation of health and social care services for economic evaluations comparable across and within countries.
- **O1.2**: Provide a library of common resource use components per country allowing for harmonised future multi-national cost analyses/economic evaluations and regular, sustainable updates.
- **O1.3**: Provide harmonised country-specific unit costs for health and social care services across selected EU countries allowing for regular, sustainable updates.

#### Description of work and role of partners

**WP1 - Health and social care** [Months: 1-36]

**UKE, MUW, UM, Psicost, LSE, UnivBris**

**Task 1.1: Identification of services and resources**

The aim of this task is to develop harmonised health and social care service descriptions across selected EU countries (AT, DE, HU, NL, UK, ES) and illustrative mental health disease areas (depression, schizophrenia, PTSD) to produce an EU glossary of terms. To obtain an overview of nationally available services, relevant previous health system research projects (e.g. MHEEN, REFINEMENT, ROAMER, EU Joint Action on Mental Health and Wellbeing) will be screened and reviews of national clinical guidelines and reimbursement lists will be conducted by respective partners in the selected countries. This will be complemented by an analysis of health economic review articles in mental health. Furthermore, national experts including clinicians, patient groups, national psychiatric associations, ministries (of health and social affairs) and health economists experienced with health services research cost measurement in mental health will be consulted. After generating comprehensive national lists of services, these will be discussed with national experts in order to find a consensus on the completeness of the list and appropriateness for economic evaluation purposes. In a final step, nominal group discussions involving all partners and experts for international mental health care research will be used to develop a harmonised classification system for services to which the national services can be mapped for purposes of economic evaluations. The deliverable of the task (D1.1) is a comprehensive, internationally comparable list of the selected countries’ services and descriptions of service characteristics including relevant resources and activities and the type of professionals completing them for the selected mental disorders. This list is due in month 18 and provides the foundation for T1.2 and T1.3.

**Partners involved**: UKE*, MUW

**Duration**: month 1 – 18

**Task 1.2: Definition of measurable and internationally transferable units of service use (granularities)**

This task builds upon and complements the results of T1.1. It aims at the definition of measurable and internationally transferable units of service use (granularities) based on the harmonised list of services (D1.2). The deliverables of this task are a hierarchical taxonomy of units (e.g. minutes, consultations, treatment episodes) allocated to the identified services (so called ‘service atoms’ D1.2) and contribution to the development of the relevant sections for health and social care of an internationally standardised instrument for multi-sectoral service and resource use measurement (D1.3). To come up with D1.2, we will conduct a systematic review of existing generic and mental-health specific instruments for health and social care service use. Potential sources of information are literature databases (e.g. Medline, Embase, PsycInfo, www.DIRUM.org) as well as national and international associations, agencies and experts in the field of mental health economics. From the identified instruments single service items and their related measurement units will be extracted. Extracted items will be categorised according to the harmonised classification system developed in T1.1. A hierarchical taxonomy of units for the service items (D1.2) will be created by ordering item/unit pairs according to
their granularity and will be added to the classification system developed in T1.1. Missing units for services identified in T1.1 will be developed and consented by the participating partners.

Partners involved: UKE*, MUW, Psicost
Duration: month 1 – 18

Task 1.3 Measurement of services and resources
D1.2 serves as the basis for the development of D1.3 as it consists of a variety of different approaches to measure use of identical services. The exact design of D1.3 depends on the results of T1.2 since one important criterion for selecting item/unit pairs for D1.2 is the availability of unit costs. Identified RUM instruments in T1.3 will consist of a variety of different approaches to measure use of identical services and serve as the basis for the development of D1.3, a standardised pilot RUM instrument for measurement of services/activities and resources for the health and social care sector. This pilot RUM instrument will be finalised through focus group discussions involving the partners and the SAB and contribute to the integrated, multi-sectoral, multi-lingual RUM instrument (D7.5) which will undergo further tests and piloting.

Partners involved: UKE*, MUW, UM, UnivBris
Duration: month 1 – 24

Task 1.4: Valuation of services and resources
This task aims at developing an internationally standardised valuation template based on alternative costing methods (e.g. activity-based, bottom-up, top-down) for core services identified in T1.1. To this end, a review of current unit cost programmes, costing manuals, guidelines and relevant methodological publications will be conducted. The feasibility of the alternative costing methods will be explored in the selected partner countries listed above, following an assessment of relevant data from statistical offices, insurance funds and reports based on partner input. Multiple costing templates will be pilot tested in the relevant countries including the calculation of country-specific unit cost ranges for resource use components and development of standardised service costs using fuzzy logic techniques (D1.4). The templates will be applied to derive an electronic compendium including information on available unit costs, relevant resource use data and derived service unit costs for core services allowing for low-threshold, sustainable updating and prospective extension (D1.5). This will provide the necessary methodology and data base for more harmonised costing of selected services for mental disorders delivered in the health and social care sectors across European health care systems. Further within-country and between-country transferability and applicability of the developed tools will be determined in WP6.

Partners involved: MUW*, UKE, LSE
Duration: month 1 – 36

* Task Leaders are marked with an asterisk.
List of deliverables

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<tr>
<th>Deliverable Number</th>
<th>Deliverable Title</th>
<th>Lead beneficiary</th>
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Description of deliverables

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Internationally comparable list of services: health and social care
D1.2 : List of units for services: health and social care [18]
List of units for services: health and social care
D1.3 : Pilot instrument for service and resource use measurement: health and social care [24]
Pilot instrument for service and resource use measurement: health and social care
D1.4 : Standardised costing template for selected costing approaches: health and social care [24]
Standardised costing template for selected costing approaches: health and social care
D1.5 : Electronic compendium of harmonised unit costs and service costs: health and social care [36]
Electronic compendium of harmonised unit costs and service costs: health and social care

Schedule of relevant Milestones

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Work package number 9 | WP2 | Lead beneficiary 10 | 4 - UM

Work package title | Criminal justice and education
Start month | 1 | End month | 36

Objectives

Mental disorders are known for their wide impact on the capabilities and social behavior of those diagnosed, the significant others, as well as on the society as a whole. Intervention in mental health care generates costs and benefits that spill over to sectors outside the health care sector, such as the educational sector and the criminal justice system. Little work has been done looking at the identification, measurement, and valuation of these costs within economic evaluation. Therefore, we will:

O2.1: Develop internationally standardised methods and tools to make resource use identification, measurement, and valuation of education and criminal justice for economic evaluations comparable across and within countries
O2.2: Provide a library of common resource use components per country allowing for harmonised future multinational cost analyses/economic evaluations and regular, sustainable updates
O2.3: Provide harmonised country-specific unit costs for education and criminal justice across selected EU countries allowing for regular, sustainable updates

Description of work and role of partners

WP2 - Criminal justice and education [Months: 1-36]
UM, MUW, UKE, Psicost, LSE, UnivBris

Task 2.1: Identification of relevant services in criminal justice and education
The aim of this task is to develop harmonised education and criminal justice descriptions across selected EU countries (AT, DE, HU, NL, UK, ES) and illustrative disease areas (depression, schizophrenia, PTSD) to produce an EU glossary of terms. To obtain an overview of education and criminal justice we will use mixed methods, i.e. expert interviews, screening of relevant national and European projects, and a systematic review aiming at economic studies in the field of depression, schizophrenia, PTSD. The initial identification will be based on the desk research (screening of project and systematic review). In order to validate the scheme’s (inter)national applicability in the mental health domain experts interviews will be conducted with (inter)national experts including clinicians, patient groups, national psychiatric associations, ministries, and mental health economists. This latter is done in order to find a consensus on the completeness of the list and appropriateness for economic evaluation purposes. In a final step, nominal group discussions involving all partners and experts for international mental health care research will be used to develop a harmonised classification system for services to which the national services can be mapped for purposes of economic evaluations.

The deliverable of the task (D2.1) is a comprehensive, internationally comparable list of the selected countries’ services and descriptions of service characteristics in the sector of criminal justice and education including relevant resources and activities and the type of professionals completing them for the selected mental disorders. This list is due in month 18 and provides the foundation for T2.2 and T2.3.

Partners involved: UM*, UKE
Duration: month 1 – 18

Task 2.2: Definition of measurable services and resources in criminal justice and education (granularities)
This task builds upon and complements the results of T2.1. It aims at the definition of measurable and internationally transferable units of service use (granularities) based on the harmonised list of services (D2.1). The deliverables of this task are a hierarchical taxonomy of units (e.g. minutes, consultations, episodes) allocated to the identified services (so called ‘service atoms’ D2.2) and contribution to the development of the relevant sections for criminal justice and education of an internationally standardised, pilot instrument for multi-sectoral service use measurement (D2.3).

To come up with D2.2, we will conduct a systematic review of existing generic and mental-health specific instruments for education and criminal justice use. Potential sources of information are literature databases (e.g. Medline, Embase, Econlit, PsycInfo, www.DIRUM.org) as well as national and international associations, agencies and experts in the field of mental health economics. Appraisal of the psychometric properties of the RUMs will be done by criteria used in the DIRUM database and by COSMIN elements. From the identified RUMs single service items and their related measurement units will be extracted. Extracted items will be categorised according to the harmonised classification system developed in T2.1. A hierarchical taxonomy of units for the service items (D2.2) will be created by ordering item/unit pairs according to their granularity and will be added to the classification system developed in T2.1. Missing units for services identified in T2.1 will be developed and consented by the participating partners.
Partners involved: UM*, Psicost, UnivBris
Duration: month 1 – 18

Task 2.3 Measurement of services and resources in criminal justice and education
D2.2 serves as the basis for the development of D2.3 standardised pilot instrument for measurement of services and resources in the criminal justice and education sectors, which will be developed with stakeholder involvement including the partners and the SAB using focus group technique. This will result in a final development version of the RUM in criminal justice and education which will then contribute to the integrated, multi-sectoral, multi-lingual RUM instrument (D7.5) which will undergo further tests and piloting.
Partners involved: UM*, MUW, UnivBris
Duration: month 1 – 24

Task 2.4: Valuation of services and resources
This task aims at developing internationally standardised valuation templates based on alternative costing methods (e.g. activity-based, bottom-up, top-down) for the services identified in T2.1. To this end, a review of current unit cost programmes, costing manuals, guidelines and relevant methodological publications will be conducted. The feasibility of the alternative costing methods will be explored in the selected partner countries listed above, following an assessment of relevant data from statistical offices, insurance funds and reports based on partner input. Multiple costing templates will be pilot tested in the relevant countries including the calculation of country-specific unit cost ranges for resource use components and development of standardised service costs using fuzzy logic techniques (D2.4). The template will be applied to derive an electronic compendium including information on available unit costs, relevant resource use data and derived service unit costs for core services allowing for low-threshold, sustainable updating and prospective extension (D2.5). This will provide the necessary methodology and data base for more harmonised costing of selected services for mental disorders delivered in the education and criminal justice sectors across European health care systems. Further within-country and between-country transferability and applicability of the developed tools will be determined in WP6.
Partners involved: UM*, MUW, LSE
Duration: month 1 – 36

* Task Leaders are marked with an asterisk.

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List of units for services: criminal justice and education

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Pilot instrument for service and resource use measurement: criminal justice and education

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D2.5: Electronic compendium of harmonised unit costs and service costs: criminal justice and education [36]
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**Objectives**

Productivity losses refer to costs associated with production loss and replacement costs due to illness, disability and death of productive persons, in both paid and unpaid work. To be able to identify health-related productivity changes it is important to understand where and when they can emerge. In general, the several ways are: (i) lower production levels and hence welfare decrease; (ii) higher cost of production levels (e.g., hiring additional labor); or (iii) some combination of both (e.g., when a replacement is not as productive as the worker replaced). In this WP, the relevant factors driving productivity costs are identified. Therefore, we will:

O3.1: Develop internationally standardised methods and tools to include, identify, measure and value productivity losses in economic evaluations comparable across and within countries

O3.2: Identify relevant factors driving productivity costs for paid and unpaid production

O3.3: Identify sources for sound measurement of the relevant components of productivity loss

O3.4: Provide valuation methods and values for productivity loss allowing for harmonised future multinational cost analyses/economic evaluations and regular, sustainable updates

**Description of work and role of partners**

**WP3 - Employment and productivity [Months: 1-36]**

**EUR, MUW, UKE, UM, Psicost, LSE, UnivBris**

Task 3.1: Approaching the expert consortium

The first task of this WP will be to approach and prepare the expert group. This group will consist of experts in the field of Health Technology Assessment and productivity costs of paid and unpaid work. The group of experts will be a balanced reflection of stakeholders including methodological specialists as well as international experts on implementation of HTA from the EUnetHTA group. EUnetHTA is established to create an effective and sustainable network for HTA across Europe – they work together to help developing reliable, timely, transparent and transferable information to contribute to HTAs in European countries (http://www.eunethta.eu).

Partners involved: EUR*

Duration: month 1 – 4

Task 3.2: Measuring instruments of productivity loss of paid and unpaid work

A sound estimation of productivity costs requires valid measurement of the number of days/hours of absenteeism or reduced productivity at work followed by a validated valuation. Firstly, a systematic review will be conducted to provide an overview of measuring instruments and sources to measure productivity loss in paid and unpaid work. This systematic review will be conducted according a standardised method to select relevant databases and develop a search strategy for detecting studies, as well as to perform the search and to extract relevant data from retrieved records. The systematic review is conducted according a 5-steps approach for preparing a systematic review for Economic Evaluations. The first step is to compose a multi-disciplinary project team (covered in task 3.1.), framing the study, prioritising the topics, and to write the protocol. All further steps will be coordinated with the expert consortium. In the second step, studies need to be identified; this includes (1) selecting relevant databases, (2) developing an adequate search strategy, (3) performing the searches, and (4) selecting the relevant studies. The third step consists of data extraction, risk assessment and transferability of the results. During the fourth step, the results are reported while in the final step the results are discussed and interpreted in collaboration with the expert consortium. This task results in a template to digitally search for selecting the preferred source(s) for measuring productivity loss based on relevant selecting criteria, like feasibility, validity, country specific accessibility. The deliverable of the task (D3.1) is a systematic review of generic and mental health specific instruments for measuring production loss of paid and unpaid work. This review will consist of a variety of approaches to measure productivity loss of paid work (absence, presenteeism, compensation mechanisms and multiplier effects) and unpaid work. This overview forms the basis of a standardised pilot RUM instrument for measurement of productivity loss of paid and unpaid work (D3.3) using the same development methods outlined in T1.3, T2.3 and T4.3.

Partners involved: EUR*, MUW, UKE, UM, Psicost, UnivBris

Duration: month 1 – 24

Task 3.3: Valuation methods of productivity loss of paid and unpaid work
Task 3.3 aims to develop an internationally standardised valuation template based on alternative costing methodologies (e.g. human capital approach, friction cost method) for valuation of relevant drivers of productivity costs. Subsequently, we will carry out a systematic review on the valuation methods for productivity losses on paid and unpaid work. The systematic review on valuation methods is also conducted according to the validated five-step approach for preparing a systematic review for economic evaluations. The feasibility of the alternative costing methodologies will be pilot tested including the calculation of country-specific productivity cost per working day/hour to value productivity loss of paid and unpaid work. The template will be applied to derive an electronic compendium including information on the productivity cost per working day/hour, the length of the friction period (provides an upper limit to productivity costs per worker in case of long-term absenteeism when applying the friction cost method), methodology allowing for sustainable updating and prospective extension. The first deliverable of the task (D3.2) is a systematic review of valuation methods of productivity loss of paid and unpaid work. The feasibility of the alternative costing methods will be explored in the selected partner countries listed above, following an assessment of relevant data from statistical offices and reports based on partner input. Costing templates will be pilot tested in the relevant countries including the calculation of country-specific unit cost ranges (D3.4). This task will provide the necessary methodology and database including practical data and tools to apply the method for more harmonised costing of productivity loss across European studies in health care. Further, within-country and between-country transferability and applicability of the developed tools will be determined in WP6.

Partners involved: EUR*, MUW, LSE
Duration: month 1 – 24

Task 3.4: Electronic compendium for measuring and valuation of productivity loss of paid and unpaid work
This task will provide an electronic template including practical data and tools to apply for measuring and valuing productivity loss allowing for harmonised future multinational cost analyses/economic evaluations and regular, sustainable updates (D3.5).

Partners involved: EUR*, MUW, UM
Duration: month 1 – 36

* Task Leaders are marked with an asterisk.

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<td>Websites, patents filling, etc.</td>
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## Description of deliverables

D3.1 : Systematic review of generic and mental health specific instruments for measuring production loss of paid and unpaid work [18]

Systematic review of generic and mental health specific instruments for measuring production loss of paid and unpaid work

D3.2 : Systematic review of valuation methods for generic and mental health specific instruments for measuring production loss of paid and unpaid work [18]

Systematic review of valuation methods for generic and mental health specific instruments for measuring production loss of paid and unpaid work

D3.3 : Pilot measuring instrument: production loss of paid and unpaid work [24]

Pilot measuring instrument: production loss of paid and unpaid work

D3.4 : Standardised costing template for selected costing approaches: production loss of paid and unpaid work [24]

Standardised costing template for selected costing approaches: production loss of paid and unpaid work

D3.5 : Electronic compendium of harmonised measuring and values for productivity costs [36]

Electronic compendium of harmonised measuring and values for productivity costs
## Schedule of relevant Milestones

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Objectives

Especially in mental health, patient, family and informal care costs can be a major cost component in economic evaluations conducted from a societal perspective. However, existing methods for measurement and valuation are diverse, resulting in cross-study differences driven by methodological inconsistencies. Against this background, the objectives of WP4 are threefold:

O4.1: Develop internationally standardised methods and tools to make resource use measurement and monetary valuation of informal caregiving activities and family/relatives/friends and other caregivers’ costs as well as patients’ costs for economic evaluations comparable across and within countries and map out the existing datasets on informal care available in the selected country settings.

O4.2: Provide a library of common resource use components per country allowing for harmonised future multinational cost analyses/economic evaluations and regular, sustainable updates.

O4.3: Provide harmonised country-specific unit costs for informal caregiving activities and patient and family costs across selected EU countries allowing for regular, sustainable updates.

Description of work and role of partners

WP4 - Patient, family and informal care [Months: 1-36]

CUB, MUW, UKE, UM, Psicost, LSE, UnivBris

Task 4.1: Identification and mapping of services and resources

The aim of this task is to develop harmonised informal care service and family costs and descriptions across selected EU countries (AT, DE, HU, NL, UK, ES) and illustrative disease areas (depression, schizophrenia, PTSD). Both direct (time spent on caregiving, out-of-pocket expenses) and indirect (forgone working hours, limited productivity in terms of presenteeism and absenteeism) impacts of informal care and all relevant types of family costs (home remodelling, environmental modifications, out-of-pocket expenses, patient time, and travel expenses) will be considered. Cultural and contextual differences between countries might have significant impact on informal care: carers think of themselves as carer or not, service is declared as informal care or usual daily activity in case of joint production. To identify all relevant types of informal care tasks (such as domestic help, nursing tasks, personal care, household tasks, health care/medicine monitoring and social and emotional support) and all relevant type of family costs a literature review and a qualitative analysis of national costing and health economic guidelines will be conducted. This will be complemented by an interview based survey among patients, family members and non-kinship carers in selected diseases. After generating comprehensive national lists of services, nominal group discussions involving health economists, patients, carers and clinical experts will be conducted in order to find a consensus on the completeness of the list and appropriateness for economic evaluation purposes. The deliverable of the task (D4.1) is a comprehensive, internationally comparable list of the selected countries’ services and descriptions of service characteristics including relevant resources and activities for the selected mental disorders. In addition, relevant official survey/datasets on informal care activities (e.g. the British Household Panel Survey in the UK) would be identified and also mapped out in the selected countries in a systematic manner. This would feed into the design of the relevant resource use questionnaires, which have not been covered by the datasets in each country. The diversity of financing mechanisms of caregiving activities would be explored in terms of whether the time spent on informal care would be reimbursed and paid to carers by social care/long-term care budgets and joint production issues. This list is due in month 15 and provides the foundation for tasks 4.2 and 4.3.

Partners involved: CUB*, UKE, LSE

Duration: month 1 – 18

Task 4.2: Definition of measurable and transferable units of patient and family specific resource input

This task builds upon and complements the results of T4.1. It aims at the definition of measurable and internationally transferable units of service use (granularities) based on the generalisable list of services (D4.1). The deliverables of this task are a hierarchical taxonomy of units (e.g. hours, missed working hours, treatment episodes of carer, patient time) allocated to the identified services (so called ‘service atoms’, D4.2).

To come up with D4.2, we will conduct a systematic review of existing generic and mental-health specific RUM instruments for patient and family sector and informal care. Potential sources of information are previous systematic literature reviews, literature databases (e.g. Medline, Embase, PsycInfo, www.DIRUM.org) as well as national and
international associations, agencies and experts in the field of mental health economics. From the identified instruments single service items and their related measurement units will be extracted. Extracted items will be categorised according to the harmonised classification system developed in T4.1. A hierarchical taxonomy of units for the service items (D4.2) will be created by ordering item/unit pairs according to their granularity and will be added to the classification system developed in T4.1. Missing units for services identified in T4.1 will be developed and consented by the participating partners.

Partners involved: CUB*, LSE, Psicost

Duration: month 1 – 18

Task 4.3: Measurement of patient and family specific services and resources

The deliverable of this task is a contribution to the development of the relevant sections of an internationally standardised, pilot instrument for multi-sectoral service use measurement for patient, family and informal care (D4.3). The exact design of D4.3 depends on the results of T4.2 since one important criterion for selecting item/unit pairs for D4.2 is the availability of unit costs. Identified RUM instruments in T4.2 will consist of a variety of different approaches to measure use of identical services and serve as the basis for the development of D4.3, a standardised RUM instrument for measurement of services/activities and resources for patients and family. The RUM instrument will be finalised through focus group discussions involving adult volunteers (patients, family members, carers), health economists and health care professionals in all PECUNIA development countries following prior translatability assessment (D1.4) and within consortium forward translations. The final pilot version of D4.3 will be consented between the participating partners and stakeholders, and further tested for within-country and between-country transferability and applicability in WP6.

Partners involved: CUB*, MUW, UM, LSE, UnivBris

Duration: month 1 – 24

Task 4.4: Valuation of patient and family specific services and resources

This task aims at developing an internationally standardised monetary valuation template based on alternative costing methods (e.g. willingness-to-pay, opportunity costs, proxy good, and wellbeing) for the services identified in T4.1. The task also aims to measure differences in monetary value of different types of informal care tasks (such as domestic help, nursing tasks, personal care, health care/medicine monitoring, and social and emotional support). A systematic review of economic evaluation including family costs and informal care will be conducted. Based on literature review, an interview based survey will be developed to measure societal value of different type of informal care tasks and family costs among a representative sample of general population in the selected countries. The resulting costing template(s) will be pilot tested in the relevant countries including the calculation of country-specific unit costs or ranges for resource use components and development of standardised service costs (D4.4). The template will be applied to derive an electronic compendium including information on available unit costs, relevant resource use data and derived service unit costs allowing for low-threshold, sustainable updating and prospective extension (D4.5). This will provide the necessary methodology and data base for more harmonised costing of informal care services and family costs for mental disorders delivered in the health and social care sectors across European health care systems. Further within-country and between-country transferability and applicability of the developed tools will be determined in WP6.

Partners involved: CUB*, MUW, LSE

Duration: month 1 – 36

* Task Leaders are marked with an asterisk.

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### List of deliverables

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### Description of deliverables

D4.1 : Internationally comparable list of services: patient, family and informal care [18]
Internationally comparable list of services: patient, family and informal care

D4.2 : List of units for services: patient, family and informal care [18]
List of units for services: patient, family and informal care

D4.3 : Pilot instrument for service and resource use measurement: patient, family and informal care [24]
Pilot instrument for service and resource use measurement: patient, family and informal care

D4.4 : Standardised costing template for selected costing approaches: patient, family and informal care [24]
Standardised costing template for selected costing approaches: patient, family and informal care

D4.5 : Electronic compendium of harmonised unit costs and service costs: patient, family and informal care [36]
Electronic compendium of harmonised unit costs and service costs: patient, family and informal care
## Schedule of relevant Milestones

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### Objectives

WP5 will focus on the harmonised assessment of outcomes in multi-national, multi-sectoral and (where relevant) multi-person economic evaluations. It will carry out two parallel activities, one addressing cross-country variations in utility measurement, the other one harmonising methods for broader wellbeing measurement. No limitations to disease areas will be used. Therefore, we will:

**O5.1:** Develop methods and estimates for applied cross-national utility value sets allowing for increased comparability and transferability of outcomes in economic evaluations using the EQ-5D as an illustrative example

**O5.2:** Collate and synthesise information and develop sustainable guidance for outcome assessment including broader wellbeing measurement in multi-national, multi-sectoral and multi-person economic evaluations

### Description of work and role of partners

**WP5 - Outcomes** [Months: 1-36]

**MUW, EUR**

**Task 5.1:** To develop a pan-European value set for the EQ-5D-5L, EQ-5D-3L and EQ-5D-Y (Youth)

In the absence of a national value set, investigators tend to use a value set from a neighboring country as a proxy of national-specific value set. The validity of the use of such proxies can be increased if the values sets from different countries sets were combined. Therefore, the aim is to develop a ‘pan-European value set’ on the basis of exiting value sets. For this, the EQ-5D will be used as an illustrative example.

Value sets can be developed on the basis of a Visual Analogues Scale (VAS) or Time Trade-Off (TTO) method. TTO is more often used in HTA. At this moment, March 2017, there are ten official 3L European national TTO value sets (Belgium, Denmark, Finland, France, Germany, Netherlands, Poland, Slovenia, Spain, UK) and three European national 5L value sets (Netherlands, Spain, UK) published. The number of 5L values will be doubled soon, as Germany, France, Poland and several other European countries are conducting such studies. Through the EuroQol Group, we have access to these data and we will cooperate with the original authors, to get maximal information and acceptance.

D5.1 Report on the pan-European value set for the EQ-5D-5L, EQ-5D-3L, and EQ-5D-Y (Youth)  
Partners involved: EUR*, MUW  
Duration: month 1 – 18

**Task 5.2:** To develop supra-national values sets, on the basis of homogenies distributions of values, in order to satisfy cultural and/or linguistic considerations

Furthermore, supra-national value sets will be developed by combining a selection of European value sets on the basis of cultural and/or linguistic considerations. For instance, there might be a supra-national value set on the basis of the West Germanic languages, one on the basis of Nord Germanic languages, one on the Slavonic languages etc. In other words, we would aim to provide the best proxy possible, using as much information possible from comparable countries. Grouping of comparable countries will be decided using a Delphi panel method utilising expertise from the consortium, SAB and stakeholder experts. For feasibility and expert network aspects, work will be divided on a regional basis between the WP partners. Both the pan-European and the supra-national value sets will be validated in comparison to national value sets in WP6.

D5.2 Report on supra-national values sets for the EQ-5D-5L, EQ-5D-3L, and EQ-5D-Y (Youth)  
Partners involved: EUR*, MUW  
Duration: month 1 – 27

**Task 5.3:** To identify, define and compile generic PROMs and their meta-data suitable for economic evaluations with specific guidance on applicability

Although several literature reviews collecting information of PROMs exist and relevant databases have been developed (e.g. Patient Reported Outcomes Measurement Group, http://phi.uhce.ox.ac.uk/, Registry of Outcome measures, http://www.treat-nmd.eu/resources/outcome-measures/registry-of-outcome-measures/), currently none of these provide a systematic overview and meta-data guiding researchers and decision makers on the best possible choices for outcome measurement in multi-sectoral, multi-national and multi-person economic evaluations. We will identify, define and compile existing generic (non-disease specific) PROMs and their meta-data on 1) psychometric robustness, 2) potential for measuring multi-person/family/lifespan outcomes (e.g. availability of children and adult versions), 3) coverage...
of HRQoL or broader concepts (e.g. non-health outcomes, capabilities), 4) multi-sectoral aspects, 5) availability of preference-based valuations, 6) country coverage (e.g. language versions, available utility value sets) for the measurement and valuation of outcomes in economic evaluations across and within countries. To harvest already existing information and avoid duplication of previous efforts, identification will focus on three major activities: Relevant expert consortia will be contacted and existing PROM databases and individual websites will be searched to identify relevant instruments and their meta-data. In addition, a new/update systematic literature review will be performed to compile all relevant generic PROMs and to answer the following questions: 1) What generic preference-based outcome measures are available? 2) How have they been developed, valued and validated? 3) What is their coverage in terms of languages and countries in which they can be used? 4) Are there different versions suitable for use across different age groups, i.e. children, adolescent, adults, elderly? Meta-data extraction will follow a template based on expert focus group discussions within the consortium and the SAB. Findings will be synthesised in the form of a dynamic electronic compendium allowing regular, low resource updating.

D5.3: Electronic compendium of generic PROM instruments and their meta-data suitable for economic evaluations.

Partners involved: MUW*, EUR
Duration: month 1-36

* Task Leaders are marked with an asterisk.

## Participation per Partner

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## Description of deliverables

D5.1 : Report on a pan-European value set for EQ-5D [18]
Report on a pan-European value set for EQ-5D
D5.2 : Report on supra-national values sets for EQ-5D [27]
Report on supra-national values sets for EQ-5D
D5.3 : Electronic compendium of generic PROM instruments and their meta-data suitable for economic evaluations [36]
Electronic compendium of generic PROM instruments and their meta-data suitable for economic evaluations

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Objectives

Piloting and validation for feasibility, within- and cross-country transferability, and applicability within an HTA framework of the methods and tools developed in WP1-5 will be conducted in WP6. These activities will be undertaken in Spain, a country without an established national unit cost programme and with a decentralised health care system structure allowing for the assessment of within-country variations. Therefore, we will:

O6.1: Validate the between-country and within-country transferability of unit costing and outcome measurement methods and tools developed in WP1, WP2, WP3, WP4, and WP5 within the selected set of illustrative mental diseases in Spain

O6.2: Validate the applicability of methods and tools developed in WP1, WP2, WP3, WP4, and WP5 in the context of a real-world HTA project framework within one of the selected illustrative mental diseases in Spain

Description of work and role of partners

WP6 - Validation [Months: 1-36]

SESCS, Psicost

Task 6.1: Application/use of methods and tools developed by PECUNIA partners for mental diseases in Spain

This task builds upon the deliverables of WPs1-5. Methods and tools developed in WPs1-5 will be tested for between-country and within-country (in several Spanish regions) transferability and applicability. Each method and tool will be used for the estimation of costs and outcomes of each selected mental disease (depression, schizophrenia, PTSD) in Spain and in four different Spanish regions (i.e. Andalusia, Basque Country, Canary Islands, and Catalonia). Review of literature and databases, and collaboration with experts and other agents will be required to collect data for the application of methods and tools. The selected Spanish regions represent a variety of regions in terms of geography, wealth and development. As a result of this task, we will prepare a report on the between-country and within-country transferability and applicability of the relevant methods and tools (D6.1).

Partners involved: SESCS*, Psicost

Duration: month 1 – 36

Note: Despite the validation of applicability starts in month 24, partners of WP6 will be aware of the progress of activities in the WP1-5 since month 1 and will carry out specific steps as early as possible without interference with the actual validation process.

* Task Leaders are marked with an asterisk.
Participation per Partner

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<td>6 - SESCS</td>
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<td>Confidential, only for members of the consortium (including the Commission Services)</td>
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Description of deliverables

D6.1 : Report on the between-country and within-country transferability and applicability of the unit costing and outcome measurement methods and tools developed by PECUNIA [36]

Report on the between-country and within-country transferability and applicability of the unit costing and outcome measurement methods and tools developed by PECUNIA

D6.2 : Report on the HTA applicability of the unit costing and outcome measurement methods and tools developed by PECUNIA [36]

Report on the HTA applicability of the unit costing and outcome measurement methods and tools developed by PECUNIA

Schedule of relevant Milestones

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## Schedule of relevant Milestones

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<td>MS14</td>
<td>HTA applicability report</td>
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</table>
WP7 will provide clear organisational and scientific frameworks and all necessary support mechanisms to enable a smooth project workflow in PECUNIA and to ensure that all contractual commitments will be met in time. Particular attention will be paid to enhancing the close organisational and scientific integration of all partners into the consortium and to integrating all deliverables into a cohesive scientific framework through unified concept development and ongoing support and guidance. Therefore, we will:

O7.1: Provide optimal guidance and support to all partners through a quick set-up of effective management and communication structures

O7.2: Provide transparency for consortium partners and the EC through proper project documentation

O7.3: Maximise effectiveness of project activities: ensure the timely and qualitative achievement of project results through scientific and administrative coordination

O7.4: Integrate all deliverables into a cohesive scientific framework through unified concept and methods development and ongoing support and guidance

O7.5: Ensure sound data management to make the research data findable, accessible, interoperable and reusable (FAIR)

Description of work and role of partners

WP7 - Project management, coordination and integration [Months: 1-36]
MUW, UKE, CUB, UM, EUR, SESCS, Psicost, LSE, UnivBris, EURICE

The coordinator will be responsible for the fulfilment of all her tasks as set out in the Grant Agreement and in the work plan, thus ensuring the overall management of the PECUNIA project. She will be strongly supported by the project management partner EURICE. Together, the coordinator and EURICE will constitute the project’s Management Team.

While the coordinator is the intermediary for all communications and interactions with the EC (e.g. submission of reports and deliverables, processing of EC payment to the partners, communication of risks and events that will affect the implementation of the project), EURICE’s emphasis will be on assisting the coordinator in the aforementioned tasks and on facilitating a smooth management of the project at consortium level. With its long-standing experience in managing EU projects and its strong track record in steering international consortia, EURICE complements the coordinator’s activities through a holistic approach that combines grants management, project management, communication management and innovation management.

Task 7.1: Implementation of efficient management and support structures
EURICE will support the coordinator in the quick set-up of the project’s organisational and internal communication structure in order to safeguard a smooth project start and enable an immediate uptake of activities. Each partner will be informed on H2020 rules and regulations as well as on specific project internal workflows. A booklet compiling the most relevant basic project documents will be provided at the occasion of the kick-off meeting. This will be complemented by an electronic storage of the project framework on the password-protected, web-based project management platform ‘ProjectAngel’, specifically developed for EU projects, which will be set up and readily available at the project start. ProjectAngel will provide all partner staff members with an up-to-date overview of the project status at all times and facilitate comprehensive project management. The platform can be used for data storage and file sharing and will support the compilation of periodic reports as well as the preparation and documentation of deliverables.

In addition, personalised practical guidance and support provided by EURICE to all partners will ensure a smooth project implementation.

Partners involved: EURICE*, MUW
Duration: month 1 – 36

Task 7.2: Contractual issues
The coordinator (supported by EURICE) will be responsible for the preparation, collection and maintenance of contractual documents (Grant Agreement, GA, and Consortium Agreement, CA) and will ensure that project partners are aware of the project’s legal framework at all times. The CA, based on a recognised model agreement such as e.g. the DESCA 2020 model CA and adapted to the project specifics, will be negotiated in parallel to GA negotiations with the EC to ensure that an agreed and signed version is ready at the project start. Should the need arise, contract amendments...
will be prepared and requested immediately to minimise delays in project implementation. Clear rules laid out in the CA will facilitate management workflows when quick decisions are needed. Moreover, EURICE will guide the consortium in IP related issues in close connection with its tasks in WP8.

Partners involved: MUW*, EURICE
Duration: month 1 – 36

Task 7.3: Reporting, financial management & controlling
Following an 18-months reporting schedule, two periodic reports (P1: M1-18, P2: M19-36) will be submitted to the EC. Compilation of these reports will be managed by EURICE and the coordinator. Moreover, the PECUNIA consortium will implement internal progress reports in M9 and M27 to monitor the project’s progress steadily and to ensure a quick uptake of activities. In close cooperation with the partners’ Grants Offices EURICE will compile and regularly provide individual financial records (updated budgets and cash flow overviews) to each partner individually. While the partners’ financial departments administer their own resources, EURICE coordinates the collection and monitoring of periodic cost claims on consortium level, checks that the declared costs are appropriately justified, provides a follow-up of EC payments and collects audit certificates where necessary. Deviations from the planned use of resources will be discussed with the affected partners and brought to the attention of the responsible WP leader and/or the coordinator.

Within the first half year of the project, a webinar on H2020 financial management will be offered by EURICE to familiarise all individuals involved in the financial reporting process (scientists and administrators) with the relevant H2020 rules and regulations and related project internal procedures.

Partners involved: EURICE*, MUW
Duration: month 1 – 36

Task 7.4: Scientific coordination, quality assurance & risk management
High quality outputs are the basis for an effective project implementation as well as for a successful exploitation strategy in the project. To ensure that all project outputs fulfill the best possible quality standards, deliverables will be prepared by the responsible partner, quality controlled by the WP leader, reviewed by the Management Team for formal and scientific completeness and correctness and finally submitted to the EC by the coordinator. EURICE will be responsible for the organisation and follow-up of periodic project meetings which will be held every 6 months.

A main task of the Management Team will be the monitoring of WP status measured against deliverable and milestone planning. The progress of each WP will be presented by the WP leaders at meetings. Quality assessment by the Steering Committee (i.e. all WP leaders) will enable a close work plan follow-up, leading to a timely identification of bottlenecks or delays, allow for informed decision making, thorough risk review and, if needed, prompt conflict resolution. Furthermore, the Management Team will initiate appropriate contingency planning on project level, resulting in timely adjustments of the work plan whenever necessary and their translation into contract amendments where needed. Should any conflict arise, EURICE as a mediating partner will consolidate arguments, and strive to find the best solution to suit all partners’ interests, e.g. when it comes to exploiting the project’s results (see also WP8). To this end, EURICE will liaise actively with all responsible bodies, e.g. all partners’ technology transfer offices.

Partners involved: MUW*, EURICE, all
Duration: month 1 – 36

Task 7.5: Close integration of partners and deliverables
Particular attention will be given to enhancing the close integration of all PECUNIA partners. Thus, to ensure that all partners will be able to take up their planned activities quickly and smoothly, including close support of less experienced partners by EURICE with particular efforts immediately preceding and following the start of the project. During the kick-off meeting, there will be a specific workshop on H2020 project administration and management, covering scientific, legal and organisational issues. All necessary support and guidance will be provided to the partners during the whole project duration. Scientific integration of all partners, WP activities and deliverables into a cohesive, unified conceptual framework with particular attention to user and stakeholder needs will be led by the coordinator.

Partners involved: EURICE*, MUW
Duration: month 1 – 36

Task 7.6: Scientific integration of PECUNIA methods and tools
In the first six months of the projects a methodological, taxonomical and conceptual framework in the form of a concept paper (D7.1) will be established by the coordinator and the HA leads providing the basis for the standardised procedure in setting-up country reports (D7.2) for each of the selected EU countries. A core group of experts from the PECUNIA consortium, each one responsible for one country, will be formed. The reports will identify and map services across the selected EU-countries. Country reports will be established between month 6 and month 12 of the project. Containing comprehensive country-specific, multi-sectoral service information relevant for the illustrative disease areas they will
form the basis of necessary service lists for WPs1-4. The standardised, pilot, English-language, sector specific RUM instruments will be consolidated, translatability assessed, consortium forward translated and piloted through focus group discussions involving adult volunteers (patients, family members, carers), health economists and health care professionals in all PECUNIA development countries in order to develop an integrated, multi-lingual, multi-sectoral instrument for service and resource use measurement (D7.3). The final pilot version will be consented between the participating partners and stakeholders.

Partners involved: MUW*, all  
Duration: month 1 – 36

Task 7.7: Open Research Data Pilot (ORDP) and Data Management Plan
Following the requirements of the Open Research Data Pilot (ORDP) to make the research data findable, accessible, interoperable and reusable (FAIR), a first version of a Data Management Plan (DMP) will be delivered within the first 6 months of the project (D7.4) based on Annex 1 of Horizon 2020 FAIR Data Management Plan (DMP) Template[1]. The DMP will be updated over the course of the project whenever significant changes arise, such as (but not limited to) new data, changes in consortium policies or composition. It shall be updated as a minimum in time with the periodic evaluation/assessment of the project (P1: M1-18, P2: M19-36).

Partners involved: MUW*, UM, all  
Duration: month 1 - 36


* Task Leaders are marked with an asterisk.

<table>
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<tr>
<th>Participation per Partner</th>
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<tbody>
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### Description of deliverables

- **D7.1**: Concept paper [6]
- Concept paper
- **D7.2**: Country reports [12]
- Country reports
- **D7.3**: Integrated, multi-lingual, multi-sectoral instrument for service and resource use measurement [36]
  - Integrated, multi-lingual, multi-sectoral instrument for service and resource use measurement
- **D7.4**: Data Management Plan [6]
  - Data Management Plan

### Schedule of relevant Milestones

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### Objectives

WP8 will ensure consistent dissemination and communication, ensuring optimal visibility, a wide outreach to and involvement of all relevant stakeholders, as well as strategic planning and operational support of project exploitation through dedicated innovation management. Innovation management is supported by proper project management (WP7) to ensure that high-quality results are created, captured, assessed and used.

- **O8.1**: Communication, creating visibility and encouraging project outreach
- **O8.2**: Disseminating results to targeted stakeholders and the scientific community
- **O8.3**: Involvement of stakeholders for cross-country transferability
- **O8.4**: Fostering innovation capacity and exploitation of results within regulatory framework

### Description of work and role of partners

**WP8 - Communication, dissemination & exploitation [Months: 1-36]**

**EURICE, MUW**

**Task 8.1: Project Communication**

Following a multidimensional, integrated and impact-oriented outreach approach, PECUNIA and its results will be promoted by professional communication measures providing targeted information via different channels to multiple audiences (incl. the media and general public) in a strategic and effective manner.

1) **Strategic Planning, Management and Monitoring of Project Communication**

Communication Committee (CC): A CC, comprising EURICE, the coordinator and key representatives of the PECUNIA stakeholder group, will be elected at the kick-off meeting and will be in charge of guiding external project communication, content production and quality assurance for all communication measures.

Communication Concept: As a basis for all communication measures, EURICE will elaborate a basic communication concept in close cooperation with the CC, defining key messages and appropriate communication means to address the major stakeholder groups (health economists, decision makers, payers/insurance companies, industry (pharma, biotech), health care providers, health care professionals, patients & families as well as the media/general public).

Communication Activity Plan (CAP): A CAP systematically outlining envisaged communication activities will be set up and regularly updated. The CAP will serve as an internal communication monitoring tool complementing the periodically updated Plan for the dissemination and exploitation of project results (PDE) (see also Task 8.2)

2) **Project Branding & Communication Material**

Visual Design: Based on the communication concept EURICE will conceive key design elements, i.e. project logo, colour scheme, fonts, to define the project’s ‘visual identity’ and create a distinct branding that will ensure a professional, consistent visual appearance of the project across all outreach activities.

Communication Toolkit: A Communication Toolkit (D8.1) will be provided through the internal management platform ProjectAngel, allowing all partners to easily access and use the material. The toolkit will include core communication material such as logo and templates (e.g. posters, presentations, reports, internal documents), and may be further expanded during the course of the project by leaflets, fact sheets or infographics.

Project Website: EURICE will set-up and maintain the public project website (D8.2), including the development of a content structure, web design, and web hosting. The website will serve as a central showcase for the project’s activities and achievements. All partners will regularly provide new content to keep the website up-to-date.

3) **Outreach Activities**

Media Relations: The CC will identify research results of special interest and trigger press releases to be published on the project website and relevant international science information platforms (e.g. CORDIS, Eurekalert). Moreover, press releases will be distributed to press departments of all partners and representatives of stakeholder groups to stimulate decentralised communications and a broad addressing of media outlets/journalists on a regional and national level.

Public Events: The participation in popular scientific events with a health economic focus will be encouraged and supported with appropriate communication material (e.g. leaflet, posters).

Partners involved: EURICE*, MUW

Duration: month 1 – 36
Task 8.2: Dissemination to Target Communities

Effective dissemination of project outcomes will ensure the use of results and maximise impact.

Plan for the Dissemination and Exploitation of Project Results (PDE): Planned and implemented dissemination and exploitation activities and scientific publications will be summarised in the periodically updated PDE (D8.3). Scientific publications: A relevant PECUNIA publication strategy will encourage timely open-access dissemination of results in peer-reviewed journals while ensuring that no conflicts with IPR issues arise. Main results from the project may be published in special issues of relevant, leading health economics journals (e.g. Value in Health, PharmacoEconomics, European Journal of Health Economics) to increase impact and visibility.

Open Access (OA): At the kick-off meeting, EURICE will inform about the different possibilities to publish OA. Each partner is aware of the obligation to make PECUNIA publications publicly available within twelve months after publication. The PDE will also include a current overview of the project’s open access publication status.

e-Newsletter: PECUNIA will publish a six-monthly e-newsletter that will actively promote project-related news, activities and results (e.g. recent publications). The newsletter will be distributed via e-mail to all PECUNIA partners’ and stakeholders’ press departments and additional stakeholders such as related initiatives, projects, associations (e.g. IHEA, EuHEA, INAIHTA, EURnetHTA) and official societies (e.g. ISPOR) both inside and outside Europe.

Networking including scientific events: PECUNIA results will be presented at international conferences and symposia including main health economics and health technology assessment relevant meetings (e.g. IHEA, euHEA, ISPOR, HTAi). This will provide a platform for immediate presentation of results, fostering an active dialogue and direct interaction with other members of the scientific community, and prepare scientific collaborations in the future. To foster networking within and outside the scientific community, particular attention will also be paid to liaising with other related initiatives on national and international level; particularly relevant previous or ongoing EU-funded initiatives e.g. EuroHOPE, MHEEN, eDESDE, REFINEMENT (see Table 3).

Partners involved: MUW*, EURICE

Duration: month 1 – 36

Task 8.3: Involvement of Stakeholders

Each member of the core group of experts, who will set-up the country reports (D7.6), will identify and invite additional leading specialists from their country with a similar scientific standing to extend and complement a) the stakeholder group (Table 8), b) the members of the SAB (Table 7), as well as c) the core group’s experience in the 1st satellite workshop in M18 (D8.4). Bringing together all important stakeholders (national and pan European) the workshop will present an ideal forum to present and discuss the country reports, and the strategies for cross-country harmonisation/transferability for a unified unit cost approach, taking into account the perspectives of patients/families/decision makers/payers etc. Based on the country reports and discussions the core group of experts will establish a roadmap with essential conditions that will be directly realised/exploited/considered during the development of the new methods (WPs1-4) and applied in WP6 (validation of transferability, generalisability & applicability).

A 2nd satellite workshop together with a large outreach event will take place towards the end of the project (D8.5), connected to an international health economics/HTA conference (e.g. IHEA, EuHEA or ISPOR). Experts and stakeholders will come together again to present and discuss the final roadmap. Additional experts from related EU-funded projects will participate as keynote speakers on research challenges and opportunities for future collaborations. The event will help to disseminate project results as well as synergies between EU-funded projects to experts and the public, and pave the way for a sustainable uptake of established procedures.

Partners involved: EURICE*, MUW, all

Duration: month 1 – 36

Task 8.4: IP Management and Exploitation Strategies

A large part of the results generated within PECUNIA will be freely accessible for non-commercial purposes, e.g. for decision makers and economists in the health care systems of the selected European countries. However, some results will have the potential to lead to commercially exploitable results, provided to the bio- and pharma industry and payers. Therefore, strategic planning as well as operational support activities to identify and manage key project outputs with high potential for further exploitation and implementation will be pursued from the very beginning and throughout the project lifetime. The Consortium Agreement will provide the basic legal framework for IP-Management, with a detailed section with specific innovation-related clauses on ownership, access rights, decision making procedures, publications, IP-Management, and will include reference documents for Material Transfer Agreements and Background-IP of all consortium partners. A confidentiality agreement to be signed by the SAB members and potential other participants in non-public project activities will be readily available at the project start. IP management activities will also include guidance and support in case of conflict of IP-related interests among the consortium members, or interfacing with technology transfer offices at partner institutions to prepare exploitation of results.

In addition, proactive monitoring of outputs is the basis for increasing innovation potential and capacity on consortium and individual partner level. IP & Innovation Management will focus on the use of acknowledged tools and strategy
workshops to develop and implement successful exploitation strategies. The timing of these activities is closely aligned to major milestones and project outputs to ensure an efficient and quick uptake of promising project outputs.

1) Innovation Management Toolkit
Innovation-related questionnaires (IRQ): In order to clearly define each partner’s exploitation plans and expectations individually, and to assess the expected uptake of results at partner level, IRQ will be collected by EURICE at the beginning of the project to ensure optimal transparency among the consortium partners, and to help identify potential conflicts of interests or bottlenecks.

Key exploitable Results (KER) Term Sheet (KERTS): The expected exploitable results identified in Table 5 (section 2.2) will be updated based on the IRQ’s clear definition of individual partners’ exploitation interests and the expected uptake of generated results by different members of the consortium. The update serves as a basis for a project-wide exploitation strategy which will be developed in the Capacity building seminars (CBS, see below).

2) Innovation-related Events
A number of innovation-related events will be organised and aligned with the achievement of major milestones to ensure that the planned innovation-related activities match the progress of work and level of maturity of results.

Capacity building seminars (CBS): A dedicated session at the kick-off meeting will serve to reflect on and potentially revise foreseen initial exploitation plans as well as the partners’ roles and tasks regarding innovation-related activities. A webinar on the basic legal framework and IP rules under Horizon2020 will be organised by EURICE to ensure a common level of knowledge on relevant IP issues among the partners.

Partners involved: EURICE*, MUW
Duration: month 1 – 36

* Task Leaders are marked with an asterisk.

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#### Description of deliverables

- **D8.1**: Dissemination toolkit [9]
- **D8.2**: Public project website [4]
- **D8.3**: Plan for the dissemination and exploitation of project results (PDE) [18]
- **D8.4**: Report on PECUNIA satellite workshop I [18]
- **D8.5**: Report on PECUNIA satellite workshop II and outreach event [36]

#### Schedule of relevant Milestones

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<tr>
<td>MS1</td>
<td>Concept paper</td>
<td>1 - MUW</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>MS2</td>
<td>Country reports</td>
<td>1 - MUW</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>MS5</td>
<td>Workshop I</td>
<td>10 - EURICE</td>
<td>18</td>
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</tr>
<tr>
<td>MS10</td>
<td>Multi-sectoral, multi-lingual RUM</td>
<td>1 - MUW</td>
<td>36</td>
<td></td>
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<tr>
<td>MS15</td>
<td>Workshop II (outreach event)</td>
<td>10 - EURICE</td>
<td>36</td>
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</table>
## 1.3.4. WT4 List of milestones

<table>
<thead>
<tr>
<th>Milestone number</th>
<th>Milestone title</th>
<th>WP number</th>
<th>Lead beneficiary</th>
<th>Due Date (in months)</th>
<th>Means of verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS1</td>
<td>Concept paper</td>
<td>WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8</td>
<td>1 - MUW</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>MS2</td>
<td>Country reports</td>
<td>WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8</td>
<td>1 - MUW</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>MS3</td>
<td>List of services</td>
<td>WP1, WP2, WP3, WP4, WP6</td>
<td>2 - UKE</td>
<td>18</td>
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</tr>
<tr>
<td>MS4</td>
<td>List of units for services</td>
<td>WP1, WP2, WP3, WP4, WP6</td>
<td>7 - Psicost</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>MS5</td>
<td>Workshop I</td>
<td>WP8</td>
<td>10 - EURICE</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>MS6</td>
<td>Pan-European utility value set</td>
<td>WP5</td>
<td>5 - EUR</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>MS7</td>
<td>Costing templates</td>
<td>WP1, WP2, WP3, WP4</td>
<td>1 - MUW</td>
<td>24</td>
<td></td>
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<tr>
<td>MS8</td>
<td>Pilot sectoral RUMs</td>
<td>WP1, WP2, WP3, WP4</td>
<td>4 - UM</td>
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<td>MS9</td>
<td>Supra-national utility value sets</td>
<td>WP5</td>
<td>5 - EUR</td>
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<tr>
<td>MS10</td>
<td>Multi-sectoral, multilingual RUM</td>
<td>WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8</td>
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<td>36</td>
<td></td>
</tr>
<tr>
<td>Milestone number</td>
<td>Milestone title</td>
<td>WP number</td>
<td>Lead beneficiary</td>
<td>Due Date (in months)</td>
<td>Means of verification</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------------------------</td>
<td>-----------</td>
<td>-----------------</td>
<td>----------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>MS11</td>
<td>Electronic compendium of unit costs</td>
<td>WP1, WP2, WP3, WP4</td>
<td>1 - MUW</td>
<td>36</td>
<td></td>
</tr>
<tr>
<td>MS12</td>
<td>Electronic compendium of PROMs</td>
<td>WP5</td>
<td>1 - MUW</td>
<td>36</td>
<td></td>
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<tr>
<td>MS13</td>
<td>Transferability report</td>
<td>WP6</td>
<td>6 - SESCS</td>
<td>36</td>
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<tr>
<td>MS14</td>
<td>HTA applicability report</td>
<td>WP6</td>
<td>6 - SESCS</td>
<td>36</td>
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<tr>
<td>MS15</td>
<td>Workshop II (outreach event)</td>
<td>WP8</td>
<td>10 - EURICE</td>
<td>36</td>
<td></td>
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</table>
### 1.3.5. WT5 Critical Implementation risks and mitigation actions

<table>
<thead>
<tr>
<th>Risk number</th>
<th>Description of risk</th>
<th>WP Number</th>
<th>Proposed risk-mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Medium: Definitions of existing services, resources and unit prices are not comparable across countries. Medium: Availability of data differs substantially by country, hence impairing the composition of a complete compendium of harmonised unit costs and service costs (D1.5).</td>
<td>WP1</td>
<td>- Partners with experience in developing internationally transferable definitions are part of the consortium. - Services and resources will not just be listed but described as part of D1.1, allowing for a comparison of services delivered in different national set-ups. - A standardised costing template taking into account different levels of data availability and alternative costing approaches will be developed (D1.4), allowing for user-friendly update based on newly available data in the future. Only publicly available data will be used for sustainability and reproducibility reasons.</td>
</tr>
<tr>
<td>2</td>
<td>Low: Systematic Review of the RUM Low to Medium: Same items are asked differently by different RUMs Availability of all relevant items of good psychometric quality Medium: Availability of data differs substantially by country, hence impairing the composition of a complete compendium of harmonised unit costs and service costs (D2.5)</td>
<td>WP2</td>
<td>- Partners with experience in developing RUMs are part of the consortium. - Items or the RUMs will not just be selected, but we rephrase the items together with the expert consortium (partners, SAB and advisory stakeholders) in order to get standardised format. - Although diverse RUMs exist for the health sector, for other sectors PECUNIA might lead to the first ever instrument, psychometric aspects will also be assessed following PECUNIA. - A standardised costing template taking into account different levels of data availability and alternative costing approaches will be developed (D2.4), allowing for user-friendly update based on newly available data in the future. Only publicly available data will be used for sustainability and reproducibility reasons.</td>
</tr>
<tr>
<td>3</td>
<td>Low: Review of the measurement instruments and valuation methods. Low to Medium: Availability of national data on the average value of production per hour, unemployment rate and vacancy rate.</td>
<td>WP3</td>
<td>For most EU-countries national data on economic variables will be available at EUROSTAT.</td>
</tr>
<tr>
<td>4</td>
<td>Medium: Cultural differences between countries related to family cost and informal care  Medium: Availability of data differs substantially by country, hence impairing the composition of a complete compendium of harmonised unit costs and service costs (D3.5)</td>
<td>WP4</td>
<td>- Systematic literature search on cross-country differences in valuation of family costs. - A standardised costing template taking into account different levels of data availability and alternative costing approaches will be developed (D3.4), allowing for user-friendly update based on newly available data in the future. Only publicly available data will be used for sustainability and reproducibility reasons.</td>
</tr>
<tr>
<td>5</td>
<td>Low: EQ-5D data will not be available for the cross-country utility value set development.</td>
<td>WP5</td>
<td>EuroQoL is part of the PECUNIA SAB with explicit commitment to the task so risk is low. Relevant written consent has been sought. No other tasks in PECUNIA are inter-dependent with this specific task, so even in case of failure the...</td>
</tr>
<tr>
<td>Risk number</td>
<td>Description of risk</td>
<td>WP Number</td>
<td>Proposed risk-mitigation measures</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>-----------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>6</td>
<td>Medium: Limited time to validate the relevant methods and tools developed by WP1-5 in only one year. Low: Difficulties in selecting the intervention for the HTA project, which should represent a remedy to a relevant health problem related to one of the mental health diseases, accepted by the Consortium.</td>
<td>WP6</td>
<td>- Several resources will be concentrated in a short period to face the validation of the tools and methods in parallel and with strong teamwork to exploit economies of scale. Specific steps (e.g. systematic literature reviews) and HTA model structure development will be carried out as early as possible without interference with the actual validation process. - Several rounds of discussion will be held among all partners, the SAB and advisory stakeholders to prioritise relevant themes. Delphi technique could be implemented to reach a consensus.</td>
</tr>
<tr>
<td>7</td>
<td>Medium: WP leaders not coordinating activities properly or timely. Medium: Individual partners not performing the assigned tasks on time. Low: Conflicts arising between partners over division of labour. Medium: Individual partners/key staff leaving the consortium</td>
<td>WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8</td>
<td>- A robust project management structure will be implemented to enable pro-active management. - Regular internal progress reports will allow close monitoring. - Project meetings will be carried out at a regular basis to discuss and solve problems by consensus. - A clear work plan has been elaborated specifying “who does what”, and responsibilities for individual tasks have been allocated to experienced partners. - A Consortium Agreement defining responsibilities and obligations of all partners will be jointly concluded before the start of the project, binding the actions and commitment of the partners. - An experienced management team and professional project management office will implement risk reflection strategies at a problem-oriented level. Hence, it is expected that conflicts become apparent very quickly in day-to-day communication and thus severe discordances will be excluded. By doing so, conflict resolution will not affect the consortium nor has any implications on the work plan. - Partners are established research groups/SME and several partners have experience in multiple areas of work. There is possibility for timely new recruitment or within partner or between partner reallocation of tasks if necessary.</td>
</tr>
<tr>
<td>8</td>
<td>Medium: Partners not engaged in all aspects of project dissemination and/or exploitation. Low: Conflicts over IP management.</td>
<td>WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8</td>
<td>- Open access planning for scientific publications will be implemented jointly by all partners. - The periodically updated PDE will include a current overview of the project’s (open access) publication status. - The Consortium Agreement will provide the legal framework for IP-management, with a specific section dealing with innovation-related clauses (ownership, access rights, decision making procedures, etc.) - A capacity building seminar and webinar will be organised to identify and plan exploitation opportunities, and the project’s IPR strategy, consolidating the interests of all partners will be</td>
</tr>
<tr>
<td>Risk number</td>
<td>Description of risk</td>
<td>WP Number</td>
<td>Proposed risk-mitigation measures</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------</td>
<td>-----------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>drafted. - Wide stakeholder outreach activities including SAB, webinar for ASG in which stakeholders receive detailed information on the project, timeline, and two stakeholder workshops. The societal benefit for Europe will be highlighted in order to consolidate their engagement.</td>
</tr>
</tbody>
</table>
### 1.3.6. WT6 Summary of project effort in person-months

<table>
<thead>
<tr>
<th>WP</th>
<th>WP1</th>
<th>WP2</th>
<th>WP3</th>
<th>WP4</th>
<th>WP5</th>
<th>WP6</th>
<th>WP7</th>
<th>WP8</th>
<th>Total Person/Months per Participant</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MUW</td>
<td>33.60</td>
<td>0.90</td>
<td>0.90</td>
<td>0.90</td>
<td>20.70</td>
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<tr>
<td>2</td>
<td>UKE</td>
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<td>2</td>
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<td>1</td>
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<td>0</td>
<td>7</td>
<td>0</td>
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<td>3</td>
<td>CUB</td>
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<td>0</td>
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<td>4</td>
<td>UM</td>
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<td>0</td>
<td>5.50</td>
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<tr>
<td>5</td>
<td>EUR</td>
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<td>0</td>
<td>35</td>
<td>0</td>
<td>18.50</td>
<td>0</td>
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<tr>
<td>6</td>
<td>SESCS</td>
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<td>24.30</td>
<td>1.50</td>
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</tr>
<tr>
<td>7</td>
<td>Psicost</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>15</td>
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<td>8</td>
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<td>0</td>
<td>0</td>
<td>2</td>
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<tr>
<td>9</td>
<td>UnivBris</td>
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<td>0</td>
<td>0</td>
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</tbody>
</table>

**Total Person/Months** 78.40 55.30 40.70 49.10 39.20 39.30 76.70 20.90 399.60
1.3.7. WT7 Tentative schedule of project reviews

<table>
<thead>
<tr>
<th>Review number</th>
<th>Tentative timing</th>
<th>Planned venue of review</th>
<th>Comments, if any</th>
</tr>
</thead>
<tbody>
<tr>
<td>RV1</td>
<td>18</td>
<td>Brussels</td>
<td>Review w external experts, to be confirmed</td>
</tr>
</tbody>
</table>
1. Project number
The project number has been assigned by the Commission as the unique identifier for your project. It cannot be changed. The project number should appear on each page of the grant agreement preparation documents (part A and part B) to prevent errors during its handling.

2. Project acronym
Use the project acronym as given in the submitted proposal. It can generally not be changed. The same acronym should appear on each page of the grant agreement preparation documents (part A and part B) to prevent errors during its handling.

3. Project title
Use the title (preferably no longer than 200 characters) as indicated in the submitted proposal. Minor corrections are possible if agreed during the preparation of the grant agreement.

4. Starting date
Unless a specific (fixed) starting date is duly justified and agreed upon during the preparation of the Grant Agreement, the project will start on the first day of the month following the entry into force of the Grant Agreement (NB: entry into force = signature by the Commission). Please note that if a fixed starting date is used, you will be required to provide a written justification.

5. Duration
Insert the duration of the project in full months.

6. Call (part) identifier
The Call (part) identifier is the reference number given in the call or part of the call you were addressing, as indicated in the publication of the call in the Official Journal of the European Union. You have to use the identifier given by the Commission in the letter inviting to prepare the grant agreement.

7. Abstract

8. Project Entry Month
The month at which the participant joined the consortium, month 1 marking the start date of the project, and all other start dates being relative to this start date.

9. Work Package number
Work package number: WP1, WP2, WP3, ..., WPn

10. Lead beneficiary
This must be one of the beneficiaries in the grant (not a third party) - Number of the beneficiary leading the work in this work package

11. Person-months per work package
The total number of person-months allocated to each work package.

12. Start month
Relative start date for the work in the specific work packages, month 1 marking the start date of the project, and all other start dates being relative to this start date.

13. End month
Relative end date, month 1 marking the start date of the project, and all end dates being relative to this start date.

14. Deliverable number
Deliverable numbers: D1 - Dn

15. Type
Please indicate the type of the deliverable using one of the following codes:
- **R** Document, report
- **DEM** Demonstrator, pilot, prototype
- **DEC** Websites, patent fillings, videos, etc.
- **OTHER**
- **ETHICS** Ethics requirement
- **ORDP** Open Research Data Pilot

16. Dissemination level
Please indicate the dissemination level using one of the following codes:

- PU Public
- CO Confidential, only for members of the consortium (including the Commission Services)
- EU-RES Classified Information: RESTREINT UE (Commission Decision 2005/444/EC)
- EU-CON Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC)

17. Delivery date for Deliverable
Month in which the deliverables will be available, month 1 marking the start date of the project, and all delivery dates being relative to this start date.

18. Milestone number
Milestone number: MS1, MS2, ..., MSn

19. Review number
Review number: RV1, RV2, ..., RVn

20. Installation Number
Number progressively the installations of a same infrastructure. An installation is a part of an infrastructure that could be used independently from the rest.

21. Installation country
Code of the country where the installation is located or IO if the access provider (the beneficiary or linked third party) is an international organization, an ERIC or a similar legal entity.

22. Type of access
- VA if virtual access,
- TA-uc if trans-national access with access costs declared on the basis of unit cost,
- TA-ac if trans-national access with access costs declared as actual costs, and
- TA-cb if trans-national access with access costs declared as a combination of actual costs and costs on the basis of unit cost.

23. Access costs
Cost of the access provided under the project. For virtual access fill only the second column. For trans-national access fill one of the two columns or both according to the way access costs are declared. Trans-national access costs on the basis of unit cost will result from the unit cost by the quantity of access to be provided.
<table>
<thead>
<tr>
<th>Version/ Date</th>
<th>Work Packages</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0/20-09-2017</td>
<td>WP1</td>
<td>Task 1.1: The end month has been changed to 18 (see also explanation below for Deliverables WP1).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP1</td>
<td>Task 1.2: Minor change in description.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP1</td>
<td>Task 1.3: Minor change in description. The end month has been changed to 24 (see also explanation below for Deliverables WP1).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP1</td>
<td>Task 1.4: Numbering of Deliverables adjusted (see also explanation below for Deliverables WP1).</td>
</tr>
<tr>
<td>2.0/12-10-2017</td>
<td>WP1</td>
<td>1 person month of P2-UKE was shifted from WP1 to WP7 due to the creation of Deliverable D7.5.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP2</td>
<td>Task 2.1: The end month has been changed to 18 (see also explanation below for Deliverables WP2).</td>
</tr>
<tr>
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<td>WP2</td>
<td>Task 2.2: Minor adjustment in description.</td>
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<tr>
<td>1.0/20-09-2017</td>
<td>WP2</td>
<td>Task 2.3: Minor change in description due to the combination of deliverables (see explanation below for Deliverables WP2). The end month has been changed to 24 to be consistent with the deliverables delivery date.</td>
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<tr>
<td>2.0/12-10-2017</td>
<td>WP2</td>
<td>1 person month of P4-UM was shifted from WP2 to WP7 due to the creation of Deliverable D7.5.</td>
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<td>WP3</td>
<td>Task 3.2: Numbering of deliverable adjusted (see explanation below for Deliverables WP3). The end month has been changed to 24 to be consistent with the deliverables delivery date.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP3</td>
<td>Task 3.3: Numbering of deliverable adjusted (see explanation below for Deliverables WP3).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP4</td>
<td>Task 4.1: The end month has been changed to 18 (see also explanation below for Deliverables WP4).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP4</td>
<td>Task 4.3: Minor adjustment in description. The end month has been changed to 24 to be consistent with the deliverables delivery date.</td>
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<tr>
<td>2.0/12-10-2017</td>
<td>WP4</td>
<td>1 person month of P3-CUB was shifted from WP4 to WP7 due to the creation of Deliverable D7.5.</td>
</tr>
<tr>
<td>2.0/06-10-2017</td>
<td>WP5</td>
<td>The end month of WP5 has been changed to M36 to be in line with the duration of the respective tasks.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP5</td>
<td>Task 5.2: The duration of the task has been changed to 1-27 (see also explanation below for Deliverables WP5).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP5</td>
<td>Task 5.3: The end month has been changed to 36 (see also explanation below for Deliverables WP5).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP6</td>
<td>Objective 6.1: Minor change of description.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP6</td>
<td>Task 6.1: Minor change of description due to the combination of deliverables (see also explanation below for Deliverables WP6).</td>
</tr>
<tr>
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<td>WP6</td>
<td>Task 6.2: Numbering of deliverable adjusted (see explanation below for Deliverables WP6). Minor change in description.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP7</td>
<td>Task 7.3: Slight addition to description to be consistent with Annex 1. Deletion of D7.3 and D7.4 (see explanation below for Deliverables WP7).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP7</td>
<td>Task 7.6: Numbering of deliverable and respective delivery dates adjusted (see explanation below for Deliverables WP7). Slight change of description due to the combination of Deliverables and...</td>
</tr>
<tr>
<td>Version/ Date</td>
<td>Work Packages</td>
<td>Changes</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------</td>
<td>---------</td>
</tr>
<tr>
<td>2.0/ 10-10-2017</td>
<td>WP7</td>
<td>Objective <strong>O7.5</strong>, addressing the data management in PECUNIA, has been added. Additionally, Task <strong>7.7</strong> has been added describing the participation of PECUNIA in the Open Research Data Pilot (ORDP) and the creation of a Data Management Plan.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP8</td>
<td>Task <strong>8.2</strong>: Deliverable D8.4 deleted (see explanation below for Deliverables WP8).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP8</td>
<td>Task <strong>8.3</strong>: Numbering of deliverable adjusted (see explanation below for Deliverables WP8).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP8</td>
<td>Task <strong>8.4</strong>: Minor additions to description.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>WP9</td>
<td>As requested by the EC, an additional work package, WP9, addressing Ethics requirements, has been added. The work plan has been adapted accordingly.</td>
</tr>
<tr>
<td>2.0/12-10-2017</td>
<td>WP9</td>
<td>WP 9 has been deleted by the EC as all the ethical comments have been addressed in the DoA and the requested documents are only to be kept available upon request.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Version/ Date</th>
<th>Deliverables</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP1</td>
<td>Deliverable <strong>D1.1</strong>: “health and social care” has been added to the title, the dissemination level was changed to “confidential” (CO) and the delivery date has been changed to M18 to make it consistent with the reporting periods.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP1</td>
<td>Deliverable <strong>D1.2</strong>: “health and social care” has been added to the title and the dissemination level has been changed to “confidential” (CO).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP1</td>
<td>Deliverable <strong>D1.3</strong> has been renamed to “Pilot instrument for service and resource use measurement: health and social care”. The dissemination level has been changed to “confidential” (CO) and the delivery date has been changed to M24 to make it consistent with the reporting periods.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP1</td>
<td>Deliverable <strong>D1.4</strong> has been deleted and integrated in D7.5 following the request by the EC officer to combine smaller reports.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP1</td>
<td>Due to the removal of D1.4, the numbering of Deliverable D1.6 “Electronic compendium of harmonised unit costs and service costs” has been altered to <strong>D1.4</strong>. “health and social care” has been added to the title.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP1</td>
<td>Due to changes in precedent deliverables, numbering of D1.6 “Electronic compendium of harmonised unit costs and service costs” has been altered to <strong>D1.5</strong>. “health and social care” has been added to the title. The dissemination level has been changed to “confidential” (CO).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP2</td>
<td>Deliverable <strong>D2.1</strong>: “criminal justice and education” was added to the title, the dissemination level has been changed to “confidential” (CO) and the delivery date has been changed to M18 to make it consistent with the internal reporting periods.</td>
</tr>
<tr>
<td>Version/ Date</td>
<td>Deliverables</td>
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<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP2</td>
<td>Deliverable <strong>D2.2</strong>: “criminal justice and education” has been added to the title and the dissemination level has been changed to “confidential” (CO).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP2</td>
<td>Deliverable <strong>D2.3</strong> was renamed to “Pilot instrument for service and resource use measurement: criminal justice and education”. The dissemination level has been changed to “confidential” (CO) and the delivery date has been changed to M24 to make it consistent with the reporting periods.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP2</td>
<td>Deliverable <strong>D2.4</strong>: “criminal justice and education” has been added to the title.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP2</td>
<td>Deliverable <strong>D2.5</strong>: “criminal justice and education” has been added to the title. The dissemination level has been changed to “confidential” (CO).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP3</td>
<td>Deliverable <strong>D3.1</strong>: The title was slightly adapted, the dissemination level has been changed to “confidential” (CO) and the delivery date has been changed to M18 to make it consistent with the reporting periods.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP3</td>
<td>Deliverable <strong>D3.2</strong> was changed to <strong>D3.3</strong> and the title has been changed to “Pilot Standardised measuring template instrument: production loss of paid and unpaid work” to make it consistent with the logical order of the Deliverables in WP1 and 2. The dissemination level has been changed to “confidential” (CO).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP3</td>
<td>Deliverable <strong>D3.3</strong> has been changed to <strong>D3.2</strong> (explanation see above) and the title has been changed slightly. The dissemination level has been changed to “confidential” (CO).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP3</td>
<td>Deliverable <strong>D3.4</strong>: The title has been adapted to “Standardised costing template for selected costing approaches: production loss of paid and unpaid work”</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP3</td>
<td>The dissemination level of Deliverable <strong>D3.5</strong> has been changed to “confidential” (CO).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP4</td>
<td>Deliverable <strong>D4.1</strong>: “patient, family and informal care” has been added to the title. The dissemination level was changed to “confidential” (CO). The delivery date has been changed to M18 to make it consistent with the reporting periods.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP4</td>
<td>Deliverable <strong>D4.2</strong>: “patient, family and informal care” has been added to the title. The dissemination level has been changed to “confidential” (CO).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP4</td>
<td>Deliverable <strong>D4.3</strong> has been renamed to “Pilot instrument for service and resource use measurement: patient, family and informal care” to make it consistent with the logical order of the Deliverables in WP1-3. The dissemination level has been changed to “confidential” (CO) and the delivery date has been changed to M24 to make it consistent with the reporting periods.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP4</td>
<td>Deliverable <strong>D4.4</strong>: “patient, family and informal care” has been added to the title.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP4</td>
<td>Deliverable <strong>D4.5</strong>: “patient, family and informal care” has been added to the title. The dissemination level has been changed to “confidential” (CO).</td>
</tr>
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<td>Version/ Date</td>
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<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP5</td>
<td>The dissemination level of Deliverable D5.1 has been changed to “confidential” (CO).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP5</td>
<td>The dissemination level of Deliverable D5.2 has been changed to “confidential” (CO) and the delivery date has been changed to M27 to make it consistent with the internal reporting periods.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP5</td>
<td>The dissemination level of Deliverable D5.3 has been changed to “confidential” (CO) and the delivery date has been changed to M36 to make it consistent with the reporting periods.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP6</td>
<td>D6.1-D6.4 have been deleted and combined, following the request by the EC to reduce the number of reports. Instead, D6.5 has been changed to D6.1 and has been renamed “Report on the between-country and within-country transferability and applicability of the unit costing and outcome measurement methods and tools developed by PECUNIA”. The dissemination level has been changed to “confidential” (CO). The new Deliverable D6.2 has been titled “Report on the HTA applicability of the unit costing and outcome measurement methods and tools developed by PECUNIA”.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP7</td>
<td>The Deliverables D7.3 and D7.4 (Management status reports) have been deleted following the request by the EC.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP7</td>
<td>Due to changes in precedent deliverables, numbering of D7.5 “Concept paper” has been altered to D7.3. The delivery month has been changed to month 6.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP7</td>
<td>Due to changes in precedent deliverables, numbering of D7.6 “Country reports” has been altered to D7.4. The delivery month has been changed to month 12.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP7</td>
<td>Deliverable D7.5 has been created, combining other deliverables from previous work packages. It was named “Integrated, multi-lingual, multi-sectoral instrument for service and resource use measurement”.</td>
</tr>
<tr>
<td>2.0/13-10-2017</td>
<td>Deliverables WP7</td>
<td>Deliverable D7.1 and D7.2 have been deleted as requested by the EC.</td>
</tr>
<tr>
<td>2.0/13-10-2017</td>
<td>Deliverables WP7</td>
<td>The Deliverables D7.3, D7.4 and D7.5 have been re-numbered due to the deletion of D7.1 and D7.2.</td>
</tr>
<tr>
<td>2.0/10-10-2017</td>
<td>Deliverables WP7</td>
<td>Deliverable D7.4 Data Management Plan has been created.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP8</td>
<td>Following the request by the EC Deliverable D8.4 has been deleted.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP8</td>
<td>Deliverable D8.5 has been split into two separate ones: D8.4 has been titled “PECUNIA satellite workshop I” and consequently, D8.5 has been renamed “PECUNIA satellite workshop II and outreach event”.</td>
</tr>
<tr>
<td>2.0/13-10-2017</td>
<td>Deliverables WP8</td>
<td>Deliverables D8.4 and D8.5 (satellite workshops) have been renamed as requested by the EC.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP9</td>
<td>Following the newly created work package 9 addressing Ethics requirements, the Deliverable D9.1 “H - Requirement No. 1” has been created.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP9</td>
<td>Following the newly created work package 9 addressing Ethics requirements, the Deliverable D9.2 “H - Requirement No. 2” has been created.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP9</td>
<td>Following the newly created work package 9 addressing Ethics requirements, the Deliverable D9.3 “H - Requirement No. 3” has been created.</td>
</tr>
<tr>
<td>Version/ Date</td>
<td>Deliverables</td>
<td>Changes</td>
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<tr>
<td>1.0/20-09-2017</td>
<td>Deliverables WP9</td>
<td>Following the newly created work package 9 addressing Ethics requirements, the Deliverable D9.3 “H - Requirement No. 3” has been created.</td>
</tr>
<tr>
<td>2.0/12-10-2017</td>
<td>Deliverables WP9</td>
<td>The deliverables in WP9 have been deleted by the EC (see explanation above).</td>
</tr>
</tbody>
</table>

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<tr>
<th>Version/ Date</th>
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</thead>
<tbody>
<tr>
<td>1.0/20-09-2017</td>
<td>MS1</td>
<td>Due date has been changed to Month 6.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>MS2</td>
<td>Due date has been changed to Month 12.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>MS3</td>
<td>Due date has been changed to Month 18.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>MS4</td>
<td>The numbering of M4 and M5 has been reversed. The due date of MS5 “Workshop I” has been changed to M18 to be consistent with the work plan.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>MS5</td>
<td>See above (MS4).</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>MS8</td>
<td>MS8 has been deleted to be consistent with the work plan.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>MS9</td>
<td>To follow the order, MS9 has been changed to MS8 and the title was slightly adapted. The due date has been changed to Month 24.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>MS10</td>
<td>Following the order, MS10 has been changed to MS9 and the due date has been changed to Month 27.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>MS11</td>
<td>MS11 has been deleted to be consistent with the work plan. Instead, three new Milestones were created: MS10 “Multisectoral, multi-lingual RUM”, MS11 “Electronic compendium of unit costs” and MS12 “Electronic compendium of PROMs”.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>MS12</td>
<td>MS12 has become MS14 and the title has slightly been adapted to “HTA applicability report”.</td>
</tr>
<tr>
<td>1.0/20-09-2017</td>
<td>MS14</td>
<td>MS14 “Workshop II (outreach event)” has become MS15.</td>
</tr>
</tbody>
</table>

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<tr>
<th>Version/ Date</th>
<th>Summary of project efforts in person months</th>
<th>Changes</th>
</tr>
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<tbody>
<tr>
<td>2.0/12-10-2017</td>
<td>P2-UKE</td>
<td>1 PM has been shifted from WP1 to WP7 due to creation of D7.5 (12/10/17).</td>
</tr>
<tr>
<td>2.0/12-10-2017</td>
<td>P3-CUB</td>
<td>1 PM has been shifted from WP4 to WP7 due to creation of D7.5 (12/10/17).</td>
</tr>
<tr>
<td>2.0/12-10-2017</td>
<td>P4-UM</td>
<td>1 PM has been shifted from WP2 to WP7 due to creation of D7.5 (12/10/17).</td>
</tr>
<tr>
<td>2.0/12-10-2017</td>
<td>P9-UnivBris</td>
<td>1 PM has been shifted from WP2 to WP7 due to creation of D7.5 (12/10/17).</td>
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</table>

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<tr>
<th>Version/ Date</th>
<th>Section 1: Excellence</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0/21-09-2017</td>
<td>1.2 Relation to the work programme</td>
<td>As requested by the EC officer, it has been highlighted that the research results of PECUNIA will be transferable to other disease areas (see paragraph 2 and Table 1).</td>
</tr>
<tr>
<td>Version/ Date</td>
<td>Section 1: Excellence</td>
<td>Changes</td>
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</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>1.2 Relation to the work programme</td>
<td>As requested by the EC, it has been pointed out that PECUNIA will also rely on the expertise of a psychiatric expert: A psychiatric expert was included as member of the SAB and will also be part of the stakeholder workshops (see Table 1 and Table 7).</td>
</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>1.2 Relation to the work programme</td>
<td>To ensure a multidisciplinary approach, it was pointed out that the Advisory Stakeholder Group (ASG) will also include the health care sector (see Table 1).</td>
</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>1.2 Relation to the work programme</td>
<td>More information has been added regarding the methods applied taking into account the diversity of health systems within and across countries (see Table 1).</td>
</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>1.2 Relation to the work programme</td>
<td>The newly funded projects IMPACT-HTA and COMED were added to the list of projects with which PECUNIA will work together (see Table 1).</td>
</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>1.2 Relation to the work programme</td>
<td>More information on the translatability assessment and focus group validation has been added. The research will also be conducted in WP7 (see Table 1 and WP7 description).</td>
</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>1.3 Concept and methodology</td>
<td>It has been highlighted that the stakeholder communication and dissemination of results will be on a pan-European level.</td>
</tr>
<tr>
<td>Version/ Date</td>
<td>Section 2: Impact</td>
<td>Changes</td>
</tr>
<tr>
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</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>2.1 Expected impacts</td>
<td>As requested by the EC officer, it has been clarified throughout the text that the research will be based on publicly available data.</td>
</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>2.1 Expected impacts</td>
<td>Health economists and HTA have been added to the scientific community, which will be involved in PECUNIA, to achieve maximum impact in the society.</td>
</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>2.2 Measures to maximise impact</td>
<td>HTA was included in the list of relevant stakeholders for PECUNIA. Additionally, it has been highlighted that specialists from all European countries will be involved.</td>
</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>2.2 Measures to maximise impact</td>
<td>Exploitation: It has been clarified that the project results will be freely accessible for non-commercial use and that some expected results will have potential for commercial exploitation.</td>
</tr>
<tr>
<td>1.0/14-09-2017</td>
<td>2.2. Measures to maximise impact</td>
<td>Payers and policy makers have been added to the list of target customers (see Table 5).</td>
</tr>
<tr>
<td>2.0/11-10-2017</td>
<td>2.2. Measures to maximise impact</td>
<td>A paragraph on Open research data has been added.</td>
</tr>
</tbody>
</table>

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>1.0/21-09-2017</td>
<td>3.1 Work plan</td>
<td>Figure 10 has been updated, integrating WP9, Ethics requirements, as requested by the EC officer.</td>
</tr>
<tr>
<td>2.0/12-10-2017</td>
<td>3.1 Work plan</td>
<td>Figure 10 has been updated, deleting WP9.</td>
</tr>
<tr>
<td>1.0/22-09-2017</td>
<td>3.1 Work plan</td>
<td>To be consistent with the changes of Work packages, deliverables and milestones, the Gantt Chart has been adapted (Table 6, see also WP descriptions).</td>
</tr>
<tr>
<td>2.0/13-10-2017</td>
<td>3.1 Work plan</td>
<td>To be consistent with the changes of Work packages, deliverables and milestones, the Gantt Chart has been adapted.</td>
</tr>
<tr>
<td>3.0/19-10-2017</td>
<td>3.1 Work plan</td>
<td>To be consistent with the changes in the delivery dates of deliverables and task descriptions, the Gantt Chart has been adapted.</td>
</tr>
<tr>
<td>1.0/14-09-2017</td>
<td>3.2. Management structures and procedures</td>
<td>As requested by the EC officer psychiatric expertise was integrated in PECUNIA by adding a psychiatric expert as member of the SAB (see also Table 7).</td>
</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>3.2. Management structures and procedures</td>
<td>Slight change in description regarding the ASG, also highlighting the inclusion of health economists and HTA and the Pan-European scope.</td>
</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>3.2. Management structures and procedures</td>
<td>The 1st satellite workshop was moved to month 18 to be in line with the work plan (see also D8.4).</td>
</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>3.2. Management structures and procedures</td>
<td>To ensure consistency with the description of WP8, it was highlighted that the project’s progress will be monitored by internal progress reports throughout the project.</td>
</tr>
<tr>
<td>2.0/13-10-2017</td>
<td>3.2. Management structures and procedures</td>
<td>Figure 11, Management bodies, has been updated (colour of SAB-bubble) to reflect the management structure correctly.</td>
</tr>
<tr>
<td>2.0/13-10-2017</td>
<td>3.4. Resources to be committed</td>
<td>A declaration regarding other direct costs was added in Section 3.4b.</td>
</tr>
<tr>
<td>Version/ Date</td>
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<td>Changes</td>
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<tr>
<td>2.0/12-10-2017</td>
<td>3.4. Resources to be committed</td>
<td>Other direct cost’ items of P1-MUW: Due to the fact that the subcontracting costs were increased to 9,000 Euro, the costs for the stakeholder workshops were reduced to 49,400 Euro.</td>
</tr>
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<tr>
<th>Version/ Date</th>
<th>Section 4: Members of the consortium</th>
<th>Changes</th>
</tr>
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<tbody>
<tr>
<td>1.0/21-09-2017</td>
<td>4.1. Participants</td>
<td>The profile of Nataša Perić was added to the staff members involved from P1-MUW.</td>
</tr>
<tr>
<td>1.0/21-09-2017</td>
<td>4.1. Participants</td>
<td>The profile of Dr Vera Schneider was added to the staff members involved from P10-Eurice.</td>
</tr>
<tr>
<td>1.0/21-09-2017; 4.0/10-11-2017</td>
<td>4.2. Third Parties involved</td>
<td>As requested by the EC officer, further information on subcontracting (P1-MUW) was added.</td>
</tr>
<tr>
<td>1.0/22-09-2017</td>
<td>4.2. Third Parties involved</td>
<td>It was clarified that the EuroQol Group as third party of beneficiary P5-EUR will provide in-kind contributions free of charge.</td>
</tr>
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<tr>
<th>Version/ Date</th>
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<tbody>
<tr>
<td>1.0/21-09-2017</td>
<td>5.1 Ethics</td>
<td>The information on data collection and the use of data in PECUNIA has been specified as requested by the EC officer.</td>
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<tr>
<td>1.0/21-09-2017</td>
<td>5.1 Ethics</td>
<td>Information on WP9 and the respective deliverables (D9.1-9.4) has been added, as requested by the EC officer.</td>
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<td>2.0/13-10-2017</td>
<td>5.1 Ethics</td>
<td>Information on WP9 and the respective deliverables (D9.1-9.4) has been deleted</td>
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<td>3.0/19-10-2017</td>
<td>5.1 Ethics</td>
<td>Minor changes to text.</td>
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ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluations

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Problem setting
Adequate health care provision – with equal quality, accessibility, and efficiency for each citizen in each country – is still missing in the European Union (EU). The Programme in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluations (PECUNIA) is highly ambitious to change this by establishing standardised costing and outcome assessment systems that directly enable comparability, applicability, and transferability of cost-effectiveness evidence for health-related interventions within and across countries. The need for such harmonised cost and outcome evidence in Europe is urgent as needs increasingly outweigh resources while health care systems are challenged by rapidly ageing societies with growing populations, and consequently prolonged disease burden due to long-term chronic and mental health problems and multi-morbidities. In addition, the growing demand for new expensive health care technologies further increases health care costs.

The cost of mental health diseases alone is one of the main health expenditure contributors worldwide, currently they account for up to 14% of health expenditure across OECD countries (Hewlett and Moran 2014). Between 1972 and 2010, public health expenditure has risen in absolute terms by 80% across the EU (Medeiros and Schwierz 2013). Currently it is 8% of the annual national income (GDP) with total health expenditure at 10%. It is foreseen that by 2060 public health expenditure will rise further to about 9.3%-11.7% of the GDP without more cost containment efforts (Medeiros and Schwierz 2013).

Yet another challenge of the EU health care systems is the growing availability and complexity of health information for evidence-based health care decision making. Health economic evaluation provides an explicit framework for the comparative assessment of both costs and outcomes of alternative health care interventions to determine cost-effectiveness and support efficient care provision (Drummond et al. 2015). The requirement to demonstrate cost-effectiveness evidence in addition to quality, safety and efficacy of interventions has been introduced in many health care systems as a ‘fourth hurdle’ for the reimbursement of pharmaceutical, medical technology or biotech products (Rawlins 2012). This greatly increases the necessity to present nationally relevant but methodologically standardised and comparable cost, outcome and cost-effectiveness estimates (Drummond et al. 2009) posing additional burden on clinical study sponsors and researchers. Lack of standardised tools, limited transparency and comparability of the applied methods and limited implementation opportunities due to fragmented funding arrangements are barriers for the acceptance and use of economic evaluations by decision makers (Evers et al. 2015). Opportunities to disentangle cost, outcome and cost-effectiveness variations in services due to differences in systems, provisions, analytical methods and actual costs/outcomes are inadequate.

The need for actions in terms of achieving greater cost-effectiveness and basing policy making on evidence in the health system is also explicitly emphasised in the EU Health Strategy ‘Investing Health’ (European Commission 2013) which underlines that as well as being a value in itself, health is a precondition for economic prosperity. Efficient spending on health can promote growth and thereby directly contribute to the Commission’s 2014-2019 priority on growth and jobs. However, harmonised methods and standardised tools for the comprehensive measurement and valuation of these broader inter-sectoral economic, societal and wellbeing impacts (Leggett et al. 2016; Coast et al. 2008a) and the integration of relevant data from different sources within a multi-sectoral economic evaluation, are lacking. This greatly hinders cost-effectiveness estimations from a fully societal perspective. While economic evaluation from a health and social care perspective is still the primary requirement in many countries (e.g. UK, AT, BE, DE, FI, PL), conducting evaluations from a societal perspective is becoming more and more common either as the primary perspective (e.g. DE, NL, FR, PT, ES) or as a secondary analysis.

Vision
PECUNIA aims at establishing direct solutions to the challenges outlined above. It will promote equal feasibility of multi-sectoral (health care, social care, employment, education, criminal justice, patient/family and informal care),
multi-national, and multi-person (patient and family as unit) economic analyses across Europe. It is our vision that by refining guidance and developing new harmonised, efficient and sustainable methods, tools and information for resource use, unit cost and outcome assessment from a societal perspective, we will significantly improve the methodological quality, comparability, feasibility and acceptance of economic evaluations. Ultimately, this will enhance efficient, evidence-based collaborative care models and inter-sectoral funding arrangements necessary to improved chronic and mental health care in all EU health care systems.

**Mission**

The PECUNIA consortium is a unique network of ten partners from six countries with relevant complementary methodological expertise. They represent different types of health care systems. Three out of four EU countries with established national reference unit cost information for economic evaluations and relevant expertise are part of PECUNIA (UK, NL, DE), albeit the methodological approaches vary. The other three partner countries are at early stages of such initiatives (AT, ES, HU). The countries also vary in the availability of national health utility value sets for common outcome measurement in economic evaluations and in their ability to produce high quality, robust cost-effectiveness evidence. PECUNIA will primarily tackle the unnecessary variations in the input cost and (health) outcome data of economic evaluations which limit the comparability, transferability and applicability of cost-effectiveness results within and across countries. It will address the scarcity of internationally standardised, generic tools for the assessment of both costs and outcomes focusing on the lack of harmonised multi-sectoral, multi-national and multi-person resource use measurement (RUM) instrument, harmonised reference unit cost information, and outcome assessment tools in the form of cross-national health utility value sets and guidance on broader wellbeing assessment, across many EU countries (Figure 1).

**Objectives**

Specific objectives of PECUNIA over its 36-month work plan are therefore to develop:

1. New, internationally standardised, harmonised and validated, generic, self-reported, multi-sectoral resource use measurement (RUM) instrument consistent with a harmonised unit cost approach.
2. New, internationally standardised, harmonised and validated multi-sectoral unit costing templates and a multi-national electronic compendium of core resource and service reference unit costs for selected mental health diseases.
3. Methods for estimating cross-national utility value sets (pan-European and supra-national) allowing increased comparability and transferability of health outcomes across Europe.
4. An electronic compendium of existing, generic, patient-reported outcome measures (PROMs) and their metadata suitable for health and broader wellbeing assessment in multi-sectoral, multi-national, multi-person economic evaluations.
5. Increased stakeholder awareness and engagement to ensure rapid adoption of the developed methods, tools and information, and exploit (business) opportunities for their long-term sustainability and further expansion.

**1.2 Relation to the work programme**

Specific changes health systems face include demographics and burdens of disease, advances in biomedical research, health technologies and personalised medicine as well as the availability of large datasets. These challenges highlight the need to develop e.g. new methods for economic evaluation in the context of HTA. Currently, health economics research has generated evidence of differences between costs and health outcomes within and across countries but the understanding of major drivers of these differences is still limited. The work programme SC1-PM-20-2017 ‘Methods research for improved health economic evaluation’ calls for 1) new or improved methods to understand variations in costs and health outcomes within and across countries including methods for measuring broader
economic and societal impacts, and as an alternative or additional area of scope 2) the integration of data on costs and health outcomes from different sources.

PECUNIA is entirely aligned with the above challenges. Firstly, the main focus is to develop new and harmonised methods and tools aiming at capturing costs and outcomes from a broad, multi-sectoral perspective. These tools will also capture effects on productivity and patients and their families in particular, which are largely neglected in economic evaluations. Secondly, it will substantially improve the quality and feasibility of data inputs for economic evaluations by developing harmonised and transferable methods. These will promote the methodological quality of economic evaluations and their value and validity for use in decision making across EU countries. Thirdly, mental health disease areas (depression, schizophrenia, post-traumatic stress disorders (PTSD)) with high disease, societal and economic burdens were selected as illustrative disease areas for service identification and reference unit cost development to not only address methodological issues at their maximum, but to also contribute to major public health challenges with highly needed applied evidence. All PECUNIA methods and tools will be, however, generic and applicable to any disease area.

New methods for cost assessment (WPs [Work Packages] 1-4) will integrate both resource use and cost data from various sources, e.g. routine administrative databases, surveys and registries including four cross-cutting horizontal methodological tasks (HAs [Horizontal Axes] 1-4) for the identification, definition, measurement and valuation of health-related resource use in multiple sectors: 1) health and social care, 2) education and criminal justice, 3) employment and productivity, and for 4) patients and families including informal care. By developing costing templates, which explicitly take into consideration the heterogeneity of existing data, a step towards harmonisation will be made. In addition, more efficient methods to develop outcome estimates that are comparable across EU countries will be developed integrating data from different geographical regions (WPS). Limitations of all data will be acknowledged through validation (WP6) and through continuous input from stakeholders (WPs7-8). Ongoing, informative assessment will be facilitated by developing all tools in a way that allows low-threshold update by the user, e.g. based on new technologies (e.g. e-health) or more current data. For a more detailed conceptual structure of PECUNIA, see Figure 6. Table 1 presents the specific challenges and scope of this call, as set out in the SC1 work programme, and how it is addressed by PECUNIA.

Table 1. PECUNIA’s relation to the work programme

<table>
<thead>
<tr>
<th>Specific challenges and scope of the topic</th>
<th>How PECUNIA addresses the challenge/scope</th>
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<tbody>
<tr>
<td>Proposals should address which factors on the supply and demand side of a health system have major effects on the costs and outcomes of health-related interventions, which includes understanding variations in costs and health outcomes including methods for more robust measures of wellbeing and quality of life, patient preferences and experience, patient-reported outcomes</td>
<td>Together with relevant stakeholders and based on rigorous scientific methods, lists of vital services in the different sectors (health and social care, education and criminal justice, employment, and patient/family and informal care) (WPs1-4) will be developed and resource use valued to capture the most important factors on the demand and supply side of national health systems. By developing cross-national utility estimates using the most commonly used outcome measurement instrument (EQSD) and collating meta-data on existing PROMs with specific guidance on multi-sectoral, multi-national and multi-person applications, more comparable and robust outcome measurement will be established (WPS).</td>
</tr>
<tr>
<td>Understanding variations in costs and health outcomes including methods for measuring broader economic and societal impacts such as productivity</td>
<td>By adopting a fully multi-sectoral approach, broad economic and societal impacts will be captured. It is one of the main pillars of our concept to improve the measurement and costing methods for health-related interventions in multiple sectors, education and criminal justice (WP2), employment and productivity (WP3), patient, family and informal care (WP4) in addition to the health and social care (WP1).</td>
</tr>
<tr>
<td>In the development of these methods, the perspectives of different important stakeholder groups in the health system and broader economy should be taken into account</td>
<td>The development of these methods is closely supported by an Expert Scientific Advisory Board (SAB) which includes: methodological and decision making experts; health professionals; psychiatrists; key stakeholders located at European HTA institutions; health insurance institutions; EC Joint Actions on Mental Health and Wellbeing, and the European Federation of Associations of Families of People with</td>
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### Mental Illness (EUFAMI)

In addition, **two pan-European stakeholder workshops** will be organised. Firstly, the **roadmap of planned methods and tools will be discussed** with a wide range of stakeholders including main health economist and HTA associations, payers, decision makers from multiple sectors of the economy, industry, health care professionals, psychiatrists, and patient and family representatives. Secondly, **final results will be presented to promote the uptake of the methods and tools across Europe (WP8)**.

<table>
<thead>
<tr>
<th>Research design should be developed by means of a multidisciplinary approach</th>
<th>The consortium consists of members with <strong>multi-disciplinary academic backgrounds</strong> in medicine, economics, public health, health economics, psychology and sociology. <strong>Mixed-methods approach combining quantitative and qualitative research will be adopted across all scientific WPs (WPs1-6)</strong>. SAB and Advisory Stakeholder Group (ASG) represent a wide portfolio of applied disciplines (e.g. health care, communication, policy, management).</th>
</tr>
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</table>
| Rigorous standards of health economic research should be applied including the analysis of underlying assumptions | **Standards, underlying assumptions and previous theoretical work** relevant to costing and outcome measurement will be **synthesised and developed** into an overarching conceptual, terminological and methodological framework in the form of a ‘**Methods and concept paper**’ (WP7, D7.1, M1). This will be **implemented** by all scientific WPs (WPs1-6) and form the basis of all developmental work in WPs1-5.  
  - **Normative** (i.e. economic theory) and **positive** (i.e. from an applied perspective) **states of the art** will be considered when developing resource use measurement and cost valuation methods in **WPs1-4**. Feasibility will be considered using **scenario analysis** based on differing **costing perspectives** and implementation of the opportunity cost approach. Possible ranges rather than point estimates will be established using **fuzzy logic techniques** (HA4).  
  - For existing RUM instruments, their **psychometric validity** will be explicitly investigated using standard valuation methods and checklists (COSMIN). For the new RUM instrument, **focus group technique** and formal **translatability assessment** will be used (HA3, WP1).  
  - Developed methods and applied cross-national **utility value sets** will use the EQ-5D data derived through multiple **direct preference elicitation techniques**. The assessment of broader outcome measurement options will consider economic theories such as Sen’s capability approach. (WP5)  
  - **Systematic literature reviews** will be performed consistent with the methods proposed by the Cochrane Collaboration, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement, and the standards developed for economic evaluation by our partners. (WPs1-6)  
  - **Health Technology Assessment (HTA)** methods consistent with national and international **guidelines** will be used to validate the developed tools and frameworks. (WP6) |
| Research should consider aspects related to gender, socioeconomic status and other health determinants as well as issues related to data protection and relevant regulatory developments, as relevant | The **three illustrative disease areas** selected for PECUNIA (WPs1-4, 6), i.e. depression, schizophrenia and PTSD, have **specific age relevant aspects** (e.g. schizophrenia starting in early adulthood, depression impacting all age groups), **gender relevance** (e.g. depression more common in women), have **major educational, criminal, work and family impacts** and are associated with **severe comorbidities**. Typically, mental health diseases are **more common in individuals with lower socio-economic status**. **Unemployment, poorer living conditions** including homelessness are major factors to consider. In line with ongoing socio-demographic changes, **depression is predicted to become the leading cause for disability** with growing public health importance together with PTSD where **ongoing political** (e.g. refugee health) and **environmental changes** (e.g. flooding) are particularly influential. Potential impacts on variations in the **developed unit costs and outcomes** will be explicitly considered. **In addition**, synthesis of meta-data on existing **PROMs** will include aspects of **life span and/or multi-person measurement (WP5)**.  
Developed methods will not rely on big, individual-level datasets, keeping **data protection issues** to the minimum while ensuring easy sustainability. The underlying concept of PECUNIA is greatly in **line with the increasing regulatory**
<table>
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<th>Developed methods applicable to a wide range of health-related interventions, spanning prevention and treatment</th>
<th>Investigated core services for the three illustrative mental health disease areas will cover all levels of service provision spanning prevention and treatment to long-term care and beyond to include also inter-sectoral services (WPs1-4, 6, HA1-2, country reports WP7). All PECUNIA methods and tools will be generic and applicable to any disease area.</th>
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<tr>
<td>Methods taking into account the diversity of health systems within and across countries</td>
<td>By including both dominantly social insurance health care systems (Bismarck type) (e.g. AT, DE), tax-funded health care systems (Beveridge type) (e.g. UK) and health care systems with a more prominent role of private providers (e.g. NL), the full range of health care systems is captured by the five partner countries within which new methods will be developed (AT, DE, HU, NL, UK). Selected health care systems also differ in their level of centralisation. Validation in a sixth partner country (ES) permits further consideration of diversity within and across countries. In addition, the constitution of the SAB allows the close inclusions of some direct country-specific system aspects from Portugal and Belgium and some pan-European considerations during development. The ASG satellite workshops and outreach activities support the ultimate validation and dissemination of results at an extended pan-European level (WP8).</td>
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<tr>
<td>Synergies with other relevant research projects and initiatives are to be established</td>
<td>Methods and results of relevant previous/ongoing/starting research projects (e.g. MHEEN I-II, REFINEMENT, eDESDE, HealthBASKET EUnetHTA, EU Joint Action on Mental Health and Wellbeing, EUnetHTA Joint Action III, IMPACT-HTA, COMED) will directly feed into the PECUNIA programme through common partners, inclusion of representatives in our SAB, and/or invitation to our ASG (WP8). In addition, a joint follow-up COST Action application to establish an International Unit Cost Network is planned to expand the scope of countries which can benefit from the methods and tools developed in this project.</td>
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<td>Methods and approaches should be validated</td>
<td>Translatability assessment and focus group validation of the newly developed self-reported multi-sectoral RUM instrument will be conducted (WPs1-4, WP7, HA3). All developed methods and approaches will be validated for within and across country transferability, feasibility and applicability within an HTA framework in the sixth partner country (ES) in WP6, and via the ASG satellite workshops with an extended pan-European focus in WP8.</td>
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### 1.3 Concept and methodology

#### 1.3.1 Concept, main idea

**Cost assessment**

**Identification and definition**

Many countries have now established organisations to develop economic evaluations to inform policy making either within or outside a health technology assessment (HTA) framework (www.inahta.org, www.htai.org, www.eunethtaa.eu). Despite the resulting significant increase in the number of economic evaluation studies (Chisholm and Evans 2007) policy concerns about the quality of these studies remain. In response, several international and national guidelines have been developed to set general methodological standards and assess the quality and reporting of economic evaluation studies (Drummond and Jefferson 1996; Husereau et al. 2013).

Curiously enough, all the efforts made in the development of national and international guidelines for conducting health economic studies have not been accompanied by a similar effort to identify standard units of analysis of health care activities/interventions. The first international classification of interventions developed by the WHO (International Classification of Health Interventions – ICHI) (Paviot et al. 2010) will not be available until 2018. This lack of harmonisation is particularly relevant for the evaluation of the assessment of waste in health care interventions in the context of local health systems, which could tackle inefficiencies, costs and consequences of...
unnecessary health expenditure and unexplained clinical practice variation. National and international comparisons to reduce waste in health care delivery and improve health interventions have recently turned into a major driver to better health care planning (President's Council of Advisors on Science and Technology 2014).

A few studies have developed mapping tools for the international comparison of services/resources for the area of mental health care. Johnson et al. (2000) developed a framework for the classification of mental health services, the European Service Mapping Schedule (ESMS). In the ESMS mental health services are mapped according to different criteria (e.g. setting, inpatient or outpatient, intensity). ESMS was incorporated in the MHEEN II project as the elective tool for measuring service availability at local level in financing studies in Europe. Based on ESMS, Salvador-Carulla et al. (2015) developed a toolkit to map adult mental health care provision in Europe (REMAST) that incorporated new units of analysis of the micro-organisation of health care delivery systems (Basic Stable Inputs of Care-BSICs) coded according to their most salient activity of “main type of care” (MTCs). These units of analysis of service availability at local level provide a valuable basis to generate internationally comparable coding and maps of services/resources. Costs so far were allocated to these units of care availability (Moreno et al. 2008) to assess relative efficiency, benchmarking and waste in small health areas (Torres-Jiménez et al. 2015). However, they were primarily developed to compare the inputs of care. Therefore they cannot be used for measurement and monetary valuation of the utilisation of these inputs in health interventions (process of care) to calculate costs in the framework of economic evaluation.

There are similar problems to the above mentioned in the analysis of productivity losses and other broader societal impacts of health care interventions. There is growing evidence that at least a quarter of the total direct cost impact of health care interventions may fall onto other sectors (i.e. criminal justice, housing), see Figure 2 for an example of the distribution of health care costs in early psychosis (Dewa et al. 2016). Indirect costs due to lost productivity often represent an even bigger impact than direct costs. Yet no methods and tools exist for the harmonised identification, definition, measurement and valuation of inter-sectoral impacts of health interventions.

Measurement

For economic evaluations to inform efficient resource allocation, they need robust cost input data (Xu et al. 2014). Generally, this issue has received comparatively little scientific attention so far (Drummond et al. 2015), and it often remains unclear if variations in costs are due to differences in methodology or differences attributable to the underlying health care services (Tan et al. 2012). Essential in any costing methods is the robust measurement of resource use. In the literature there are patient self-reports (e.g. cost questionnaires, diaries, interviews) or administrative records (e.g. administrative systems of care providers or insurance companies) used for resource use measurement. Both methods have advantages and disadvantages as described in Table 2, and have been used frequently in economic evaluations.
A systematic review of instruments measuring health care resource use by Noben et al. (2016) supports the exchangeability of both, the self-reported and administrative RUMs in health care. However, a major limitation of administrative data for economic evaluation from a societal perspective is that they can never include all societal costs (formal and informal, reimbursed and non-reimbursed), next to the ethical dilemmas of merging several administrative data for research purposes. Therefore self-reported RUMs are often the only method which can measure the health care consumption and the consumption of goods in other sectors in natural units from a societal perspective.

In the last decades, a large number of self-reported RUMs have been developed (Noben et al. 2014; Ridyard et al. 2012; Thorn et al. 2013). The Database of Instruments for Resource-Use Measurement (DIRUM) is a Web-enabled database, accessible via www.DIRUM.org, which serves as a practical resource for health economic evaluators, to search for self-reported RUMs and shows the measurement properties of these self-reported measures (Ridyard et al. 2012). Although a large number of self-reported RUMs are available, e.g. the commonly used CSRI (Beecham and Knapp 1992), there is a lack of gold standard and little research has been done on the measurement properties of these instruments such as feasibility including practicality (time to complete, responsiveness, completion rate etc.), reliability (test-retest reliability, inter-rater reliability), and validity (content validity, face validity, construct validity, etc.).

Taking into account these measurement properties, Thorn et al. (2013) developed a method for improving the design and administration of RUMs. This results in an ideal way of approaching RUMs development, encompassing planning, development, piloting, analysis and deployment of instruments. The method of Thorn et al. (2013) also takes into consideration all the steps represented in the methodological tasks adopted by PECUNIA (identification, definition, measurement and valuation of impacts), and shows that they are interlinked. For example, sources of unit costs should be identified at the outset of a study to help with specifying questions with the appropriate level of detail in the RUM, which makes many RUMs inherently country-specific as the granularity of unit costs varies between settings (Thorn et al. 2013).
Valuation

Another crucial step is the monetary valuation of the identified resource use in the form of unit costs. Currently, unit cost estimates between studies and countries are not comparable to differences in their units of measurement (granularities) and costing methodologies (Frappier et al. 2015). Resulting decision makers’ lack of confidence in general methodology is often considered an important barrier to the uptake of economic evaluation results (Barnett 2009). Also existing national costing guidelines provide little guidance in terms of specific unit costing methods (Adam et al. 2003). It was thus recommended recent editorial that an independent group should be mandated for the production of standard country-specific unit costs available to national and international researchers and decision makers (Frappier et al. 2015). As of now, collections of estimates are not routinely available for services across countries. If available, it is unclear whether differences in cost estimates stem from differences in the service composition, intensity of service delivery or differences in input costs (Busse et al. 2008).

In some countries (e.g. NL, DE, AU), sets of national reference unit cost estimates have been published as part of national costing guidelines, mostly capturing the health and social care sectors. These have greatly enhanced the feasibility of robust cost-effectiveness evidence development (Wagstaff and Culyer 2012). In other countries, such as the UK, the PSSRU Unit Cost compendium is downloaded at least 600 times per month (http://www.pssru.ac.uk/research-current.php) even though its use is only recommended. So far only four EU countries have established national health and social care reference unit cost programmes applying various costing methodologies (Figure 3), which makes international study comparisons highly problematic (Drummond et al. 2015).

Indeed, several comparisons have shown that unit cost estimates in the health care sector are sensitive to the applied costing methods (e.g. Clement et al. 2009; Heerey et al. 2002; Shrestha et al. 2012). For example, an ongoing research study into national cost variations caused by differing unit cost methods/sources in Austria revealed a 170% difference in unit cost estimates for General Practitioner (GP) consultation costs (Simon and Mayer 2017) (Figure 4).

From a global viewpoint, such differences can alter the cut-off point between an efficient versus a non-efficient intervention in an economic evaluation. Also different valuation methods come with different strengths, limitations and assumptions. It is generally agreed that depending on the specific service and its role in the economic evaluation, different costing methods are appropriate. For example, micro-costing, which is rather labour intensive, is potentially the right method for the core intervention in an economic evaluation, whereas the other, less detailed costing approaches can be used for other services (Barnett 2009). Hence, the level of accuracy that makes sense also
depends on the actual importance of the cost item, which is why a ‘one size fits all’ type costing methodology that is applied to every single service is usually not suitable. This choice should be driven by the needs of the respective analysis (Clement et al. 2009) as well as country-specific guidelines. However, more transparency and standardisation is needed in the calculation methods and the included cost ingredients. Moreover, further advancements and geographical coverage in the above respects are limited. This is due to the substantial efforts and resources needed to develop such information sets without harmonised methods and tools.

**Outcome assessment**

In terms of outcome assessment, the EuroQol EQ-5D questionnaire is the most frequently used generic, preference-based outcome measure in economic evaluations and HTAs in Europe (EuroQol Group 1990; Wille et al. 2010). This measure can be used for the estimation of Quality Adjusted Life Years (QALYs) (Brazier et al. 2016), the currently preferred outcome measure in economic evaluations, but it is also a generic measure of patient preferences both in the adult and the youth populations. Recently, the EuroQol Group improved the EQ-5D by increasing the number of answer levels from 3 (EQ-5D-3L) to 5 levels (EQ-5D-5L). Crosswalk datasets exist to convert national value sets from the 3L to the 5L, but the full benefit of the EQ-5D-5L can only be achieved when new national value sets are generated. As with the EQ-5D-3L version, however, it is unlikely that all EU countries will be able to invest in newly derived national value sets for the new EQ-5D-5L. Currently national utility value sets based on the EQ-5D-3L instrument exist in ten EU countries. For the EQ-5D-5L only three official country-specific utility value sets are available. Additional 5L value-sets are currently being developed for Germany, France, Poland and some other EU countries. An effort for an European value set has been made for the old EQ-5D-3L (Greiner et al. 2003), and this article has been referred to massively, but the ‘Single European Currency’ was developed based on Visual Analogue Scale (VAS) values instead of the preferred Time Trade-Off (TTO) values. So, there is a need to develop a state-of-the-art ‘Single European Currency’ for the new 5 level version of the EQ-5D. Central-Eastern European countries, particularly lack relevant information and measures that further decreases the opportunities for transparent and efficient health care planning in these countries (Renz et al. 2016; Mayer et al. 2016) (Figure 5).

The validity and adequacy of health utility measurement with EQ-5D, however, has been questioned in several disease areas including some major mental health problems. While some studies have found the EQ-5D remarkably sensitive, notably in depression and anxiety disorders, other studies have found that the instrument is not sensitive enough to change and therefore underestimates the effects of interventions (e.g. bipolar disorder, schizophrenia) (Saarni et al. 2010). It is also proven that for many people with mental or chronic health problems broader wellbeing aspects beyond health are at least as important and therefore such outcome aspects should not be ignored in economic evaluations. These findings are in line with Sen’s capability approach pointing to basic needs beyond health such as freedom of choice (Sen 1982). Numerous relevant PROM instruments have now been developed using these alternative concepts (e.g. ICECAP (Coast et al. 2008b), OxCAP-MH (Simon et al. 2013), ASCOT (Netten et al. 2012)). Especially in multi-sectoral economic evaluations, these alternative or additional outcome measurement methods may have specific relevance. In addition, for disease areas with major impact on the health and wellbeing of carers and families (e.g. mental health problems or chronic diseases), multi-person outcomes may have to be measured and valued jointly, preferably within the same framework and with the same method. Harmonised and comprehensive information and guidance on the methods and tools for the assessment of broader wellbeing from a societal perspective, however, are lacking. Furthermore, the potential double counting of broader economic and societal

![Figure 5. Availability of official national EuroQol EQ-5D value sets across the EU](https://example.com/figure5)

Note: Spanish (ES) and Polish (PL) value sets not produced as part of the EuroQol Group, crosswalk datasets not included

Source: Own illustration (Simon et al.) based on [www.euroqol.org](http://www.euroqol.org) and expert input
impacts on both the costs and outcomes sides (Johannesson 1997) may also contribute to unnecessary variations in cost-effectiveness results and specific aspects of existing PROMs have not been investigated yet.

PECUNIA follows a systematic approach to address the above issues in cost and outcome assessments, illustrated in Figure 6 (PECUNIA CUBE) and outlined below. Further methodological details are described in section 1.3.4 and in the WP descriptions in section 3.

PECUNIA’s research and developmental activities for cost assessment will be multi-sector oriented. They will address all important sectors of the economy in four WPs (WP1 Health and social care, WP2 Education and criminal justice, WP3 Employment and productivity, and WP4 Patient, family and informal care). Cross-cutting methodological tasks for WPs1-4 will be harmonised across four horizontal axes (HA): Identification HA1, Definition HA2, Measurement HA3, Valuation HA4. WP5 Outcomes will focus on improving the methods and tools for comparable and broader health and wellbeing impact assessment in economic evaluations. Relevant tools will be developed in five countries (AT, DE, NL, HU, UK). Piloting and validation for feasibility, within- and cross-country transferability, and applicability within an HTA framework will be conducted in a sixth country (ES) (WP6: Validation). WP7 will support PECUNIA with management, coordination and integration, while WP8 will be responsible for the wide pan-European stakeholder communication and dissemination of results including exploitation of their innovation potentials.

Illustrative mental health disease areas
Mental health conditions account for up to 14% of health expenditure across OECD countries (Hewlett and Moran 2014). Considering the scope of the call, the main concepts, objectives and expertise of PECUNIA, relevant existing knowledge base, and the given time and resource limitations, three mental health disease areas were selected (depression, schizophrenia and PTSD) as illustrative examples for WPs1-4. Depression is a very common often recurring or chronic condition affecting around 30 million people in Europe, with aggregated economic costs of approximately €92 billion. Currently it is the third leading cause of disability due to morbidity and mortality in Europe and by 2030 it is predicted to become the leading cause of disease burden (WHO 2012). Schizophrenia has life-long multi-sectoral aspects that require complex packages of care (Killaspy et al. 2016). PTSD’s burden is increasing with great relevance to the ongoing socio-political changes (e.g. refugees) in Europe (Langlois et al. 2016). In addition to posing major public health burdens, they are characterised by complex services, major inter-sectoral economic and social consequences, and broader wellbeing impacts in all ages. All these issues present major methodological challenges in economic evaluations and are among those addressed by the main objectives of PECUNIA. In general, however, all the developed costing methods and tools (i.e. RUM instrument and unit costing templates) as well as the tasks focusing on outcome assessment will be generic and not limited to specific disease areas.
Cost assessment

In order to develop valid international comparisons, cost-consequence, cost-effectiveness and cost-utility analyses require the identification of standard, transferable units of analysis of resource utilisation. For such a purpose, a mapping algorithm of interventions/services must structurally incorporate several specific aspects. Firstly, a list of core services has to be identified. Secondly, services/resource use must be defined in such a hierarchical way (‘service atom’, Figure 7) that standardised units of measurement (granularities) can be attached to the endpoints of the taxonomy. These in turn can then be developed further into a generic, multi-sectoral RUM questionnaire usable in any patient sample. Thirdly, the endpoints of the taxonomy should internally be as homogeneous as possible regarding the costs of the services/resources described in order to allow the valuation of monetary unit costs corresponding to these granularities. To meet these conditions, they must be incorporated into the description of services/resources and the development of any mapping algorithm ab initio, which will be the purpose of PECUNIA to extend suitable mapping tools that already exist (see section 1.3.1).

Based on the above concepts and ideas, **PECUNIA will develop for cost assessment:**

1. New, internationally standardised, harmonised and validated, generic, self-reported, multi-sectoral resource use measurement (RUM) instrument consistent with a harmonised unit cost approach.
2. New, internationally standardised, harmonised and validated multi-sectoral unit costing templates and a multi-national electronic compendium of core resource and service reference unit costs for selected mental health diseases.

Outcome assessment

In the absence of a national utility value set, investigators tend to use a value set from a neighbouring country as a proxy (Knies et al. 2009). The validity of the use of such proxies can be increased if values sets from multiple countries were combined. This also gives more clarity about real outcome differences versus methods driven variations across countries. The aim therefore is to develop cross-national value sets (pan-European and supra-national) on the basis of existing datasets. For this, the EQ-5D will be used as an illustrative example. The task will not only generate new, unified cross-national health utility value sets using data owned by the the EuroQol group which is a third party and member of the SAB in PECUNIA, but may also serve as an illustrative example with generalisable methods to other utility valuation instruments.

In order to provide guidance on the methods and tools for the assessment of broader wellbeing from a societal perspective and advice on a harmonised and standardised framework for the joint assessment of costs and outcomes in multi-sectoral economic evaluations, PECUNIA will systematically collate and synthesise existing, publicly available generic PROM information suitable for outcome measurement in economic evaluations together with specific meta-data on validity and applicability in multi-sectoral, multi-national, multi-person economic evaluations.

Based on the above concepts and ideas, **PECUNIA will develop for outcome assessment:**

3. Methods for estimating cross-national utility value sets (pan-European and supra-national) allowing increased comparability and transferability of health outcomes across Europe.

It is within our concept to take results beyond the initial 36 months and the six partner countries. Ultimately, we aim to establish new
PECUNIA will do this with maximum EU-level **stakeholder awareness and engagement** to ensure **rapid adoption** of the developed methods, tools and information, and exploit business opportunities for their **long-term sustainability** and further expansion.

### 1.3.2 Positioning of the project

The project comprises several concepts for innovative tools and electronic platforms that will be developed to more advanced **technology readiness levels (TRL)** as shown in **Figure 8** (expected improvements during the project indicated by arrows, improvements envisaged after the project indicated as dotted arrows). We aim at advancing the **multi-sectoral RUM instruments to TRL4** (component validation in lab) in WPs1-4. Work in WPs1-4 and WP6 will advance **multi-sectoral unit cost templates and electronic compendium, cross-national utility value sets**, as well as **electronic compendium of generic PROM instruments with meta-data** from TRL2 to TRL6, demonstration in relevant environment.

![Figure 8. Positioning of the distinctive developmental processes](image)

If the PECUNIA application is successful, the consortium plans a follow-up international project on the multi-country linguistic, cultural and psychometric validation of the **multi-sectoral RUM instrument increasing its TRL to level 7**. A planned **joint follow-up COST Action application** to establish an **International Unit Cost Network** with expanded country coverage would eventually lead to the **unit costing system being proven in a Europe-wide operational environment at TRL7** (demonstration in operational environment). Beside the expected increased impact of the developed methods and tools in Europe, these steps would also set new standards in multi-sectoral costing methods internationally. Relevant research interests for transferring the PECUNIA system to Australia and Canada have already been expressed and received.

### 1.3.3 Relation to ongoing national and international research, and synergies

PECUNIA is the first European project to focus on comprehensive harmonisation of valuation of services/resource utilisation for use in economic evaluation. The MHEEN projects I-II, which approached the topic from a health system perspective, applied e.g. activity-based costing methods for mental health services for one country only. The applicability and transferability of this costing approach will be tested as a part of this project depending on data availability. The HealthBASKET project conducted a cross-country comparison of unit costs for nine health services in 2005 and developed the ‘case vignette’ approach to costing (Busse et al. 2008). Correlation between costs calculated based on this method and reimbursement information was found to be low for four services, pointing out the need for further harmonisation and costing development in this area. The main methodological issues in costing identified in HealthBASKET will be considered in the course of WP1. One of the main conclusions of the project was that mutually accepted methodological costing standards are a prerequisite for international cost comparison and detailed costing guidelines should be developed. These challenges will be addressed by PECUNIA within and beyond
the health and social care sector. Several partners participated in the above mentioned projects or are currently collaborating with relevant researchers in other projects (e.g. the BRIDGE Health project).

**Partner involvement in ongoing research**

Following the introduction of the first costing manual in 2000 and a first update in 2004, EUR was responsible for the updates of the Dutch costing manuals in 2009 (Hakkaart-van Roijen et al. 2010; Tan et al. 2012) and 2015 (Hakkaart-van Roijen et al. 2015). For inter-sectoral costs and benefits in the Dutch health care system UM explored the feasibility of several costing methods in the Dutch education and criminal justice sector (Drost et al. 2017a). The derived estimates were included in the most recent national Dutch costing manual (Drost et al. 2014). For psychiatric residential care provided in Spain, unit costs relying on activity-based costing methodology were calculated by Psicost as part of the MHEEN II project (Moreno et al. 2008). For a wide range of services related to mental disorders delivered in the German health care sector, unit costs were derived based on top down approaches by UKE (Grupp et al. 2017). In Austria, as a first step towards systematically accessible cost data, MUW has setup a publicly available online database collating unit costs used in published economic evaluations (DHE 2017). MUW is also intensively involved in broader wellbeing measurement for mental health (OxCAP-MH, Simon et al. 2013) and multi-national economic evaluation methods development (PReDiCT). In the UK, a comprehensive library of unit costs in the health and social care sectors is published annually by LSE/PSSRU, co-authored by a member of the SAB (PSSRU 2017). LSE also authored the recent WHO report on ‘Evidence on financing and budgeting mechanisms to support inter-sectoral actions between health, education, social welfare and labour sectors’ (McDaid and Park 2016). The question of how to value lost productivity was addressed by UM based on a systematic review of pharmacoeconomic guidelines (Knies et al. 2010). The state of the art of valuation of informal care for inclusion in economic evaluation was recently assessed by EUR (Hoefman 2015). EUR also recently developed the iMTA Productivity Cost Questionnaire (iPCQ), capturing lost productivity in the employment and patient/family sectors (Bouwmans et al. 2015). Furthermore, EUR developed the iMTA valuation of informal care questionnaire, including the CarerQol for measurement of caregiver costs and burden (Hoefman et al. 2011; Hoefman et al. 2013; Brouwer et al. 2006; Hoefman et al. 2011). The Dutch valuation set of the EQ-5D-5L was estimated by EUR (Versteegh et al. 2016). In Hungary, costs and benefits in several chronic diseases including mental disorders were explored by CUB (Pentek et al. 2012; Pulay et al. 2016). UnivBrıs is co-founder of the DIRUM database, while SESCS is partner of the EUnetHTA Joint Action III. In addition, methods and results of the newly funded EU projects such as IMPACT-HTA and COMED will feed into PECUNIA through invitation to our ASG.

In order to facilitate and benefit from synergies and knowledge sharing with other relevant EU-funded projects, notably IMPACT-HTA and COMED, several meetings and a symposium or workshop (at a time and place to be agreed with the Commission) will be planned. This will allow for sharing project results and discuss with other peer projects about facilitators and barriers faced by the project. The EC wishes to strengthen cooperation and exchange of experiences between projects dealing with the same areas. This will bring together different project teams to increase the impact of their research and ensure better visibility and popularisation of research results.

**PECUNIA is therefore perfectly placed to avoid duplication of previous efforts and progress existing multi- and transdisciplinary knowledge** in the areas of national unit cost programmes for economic evaluations, health services research and mapping, resource use measurement, health technology assessment, mental health research, outcomes research and health information and systems research. Given that some partner countries have established costing guidelines and collections of standardised unit costs that are mandatory when submitting evidence for e.g. pharmaceutical reimbursement decisions, implementation of one single ‘gold standard’ across countries is not the aim of PECUNIA. Instead, by providing different methodological approaches within the developed costing templates and feeding these with publicly available national data from several countries, the foundation will be laid for future update as necessary. Availability of national-level data and within- and between-country differences in e.g. accounting standards might hamper the feasibility of some of the methodological approaches and these gaps and the limitations of the relevant input data (regional level only or expert estimate) will be made explicit in PECUNIA. Nevertheless, the methodological foundations will be provided through PECUNIA and the templates will have a dynamic set-up allowing necessary updates in the future. PECUNIA’s relation to ongoing and previous relevant national and international research, its synergies and complementary characteristics are summarised in Table 3.
### Table 3. Relation of PECUNIA to previous and ongoing national and international research

<table>
<thead>
<tr>
<th>Project (and EU funding programme)</th>
<th>Duration</th>
<th>Partners involved</th>
<th>Relevance/Synergies</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMPACT-HTA &amp; COMED (planned H2020 projects)</td>
<td>2018 onwards</td>
<td>-</td>
<td>Social costing methods, EQ-5D subgroup preferences, observational data bias, real world data sources</td>
</tr>
<tr>
<td>UK unit cost programme, e.g. PSSRU Unit Costs of Health and Social Care (PSSRU 2017)</td>
<td>Ongoing (1993-)</td>
<td>LSE Member of the SAB</td>
<td>PECUNIA will benefit from developed costing guidelines, experiences with different stakeholder interests, costing methods and data availabilities stemming from ongoing national unit cost initiatives in the partner countries.</td>
</tr>
<tr>
<td>German unit cost initiative for mental disorders (Grupp, König, and Konnopka 2017)</td>
<td>2011-2015</td>
<td>UKE</td>
<td></td>
</tr>
<tr>
<td>Dutch unit cost list on health and social care services (Hakkaart-van Roijen et al. 2015)</td>
<td>Ongoing (2009-)</td>
<td>EUR</td>
<td></td>
</tr>
<tr>
<td>Dutch unit cost list on inter-sectoral costs and benefits (Drost et al. 2017a; Drost et al. 2014)</td>
<td>Ongoing (2015-)</td>
<td>UM</td>
<td></td>
</tr>
<tr>
<td>Austrian unit cost initiative based on publicly available unit costs across sectors (DHE 2017)</td>
<td>Ongoing (2014-)</td>
<td>MUW</td>
<td></td>
</tr>
<tr>
<td>PReDict (EC H2020) – Predicting Response to Depression Treatment</td>
<td>Ongoing (2015-2018)</td>
<td>MUW</td>
<td>The needs for a multi-national, multi-sectoral RUM and aligned reference unit costs have been highlighted in the ongoing multi-national PReDict study on depression. Relevant experience will feed into PECUNIA.</td>
</tr>
<tr>
<td>BRIDGE Health (EC 3rd Health Programme) – Bridging Information and Data Generation for Evidence-based Health policy and research</td>
<td>Ongoing (2015-2017)</td>
<td>MUW</td>
<td>BRIDGE Health led to the planning of a Joint Action on Health Information towards a sustainable EU health information system that supports country knowledge, health research and policy making followed up by a HIREP-ERIC (European Research Infrastructure Consortium on Health Information for Research and Evidence-based Policy). PECUNIA may contribute to these with the establishment of methods and tools for standardised and harmonised reference unit cost information for Europe.</td>
</tr>
<tr>
<td>EUnetHTA Joint Action III</td>
<td>Ongoing (2016-2020)</td>
<td>SESCS, member of the SAB</td>
<td>EUnetHTA is established to create an effective and sustainable network for HTA across Europe. PECUNIA will contribute to EUnetHTA Joint Action-III aims of developing reliable, transparent and transferable information to contribute to HTAs in EU countries and regions.</td>
</tr>
<tr>
<td>JA MH-WB – Joint Action on Mental Health and Wellbeing</td>
<td>2013-2016</td>
<td>Leader of this JA is member of the SAB</td>
<td>This JA established knowledge on the situation of mental health and well-being in EU countries. Outputs relevant to PECUNIA were produced (e.g. on mental health and schools) and will be taken into consideration (e.g. to inform the list of services in the education sector in WP2).</td>
</tr>
<tr>
<td>MHEEN (EU Health Programme 2008-2013) – Mental Health Economics European Network Phase I-II</td>
<td>2005-2007</td>
<td>3 PIs (MUW, Psicost, UM) partners Chair of SAB was PI</td>
<td>The project took a health system perspective and applied activity-based costing methods for mental health services in Spain. The applicability and transferability of this costing approach will be tested as a part of PECUNIA depending on data availability (WP1).</td>
</tr>
<tr>
<td>REFINEMENT (FP7-HEALTH) – Research on financing systems’ effect on the quality of mental health care</td>
<td>2011-2013</td>
<td>Psicost, LSE</td>
<td>The project, which explored the impact of funding on outcomes, examined mental health pathways through the service system. This information will be fed into HA1/2 to define and identify relevant mental health services in PECUNIA.</td>
</tr>
<tr>
<td>eDESDE-LTC (FP7-HEALTH) – Description and evaluation of services for long term care in Europe</td>
<td>2008-2010</td>
<td>Psicost, LSE</td>
<td>The project aimed at developing an operational system for coding, mapping and comparing services for Long-Term Care across Europe. This attempt to facilitate semantic interoperability is also relevant for PECUNIA, where joint definitions will be developed as part of HA2.</td>
</tr>
<tr>
<td>HealthBASKET (FP6-POLICIES) – Health benefits and service</td>
<td>2004-2007</td>
<td>-</td>
<td>The HealthBASKET project conducted a cross-country comparison of unit costs for nine health services in 2005 and developed the ‘case vignette’</td>
</tr>
</tbody>
</table>
1.3.4 Methodology

Systematic literature reviews (WPs1-6)

To identify relevant evidence for WPs1-6, PECUNIA will carry out several systematic literature reviews. The reviews will be conducted such that they are in line with the proposed methods by the Cochrane Collaboration (Higgins and Green 2011) and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al. 2009). Several databases will be searched including ASSIA; CINAHL; Cochrane library including DARE, NHS EED, HTA; Econlit; Embase; PsychINFO; and MEDLINE. Languages will be limited to those of the partner countries. Study protocols will be registered in PROSPERO – an international database of prospectively registered systematic reviews where feasible. The consortium and the SAB will act as expert advisors for the scoping and the discussion of results for systematic literature reviews according to van Mastrigt et al. (2016) (Figure 9).

Cost assessment (WPs1-4)

WPs1-4 will focus on the assessment of costs across multiple sectors alongside four horizontal methodological tasks/axes (HAs) following the steps of Identification (HA1), Definition (HA2), Measurement (HA3) and Valuation (HA4). Relevant methods are described below.

Identification (HA1) and Definition (HA2)

The aim of the horizontal methodological tasks/axes Identification (HA1) and Definition (HA2) are to set up a standardised framework to generate internationally comparable lists and descriptions of services used to handle the consequences of and/or societal resources consumed by the illustrative mental health disorders. The relevant task will be based on publicly available data and can be divided into two main steps:

**Step 1: Identification of relevant services/resources in the national contexts**

1a) Step 1 starts with an initial search in publicly available sources, e.g. literature, guidelines, official publications from ministries, etc., relevant for the topics of WPs1-4. The specific description of relevant sources will be produced by the WPs. The focus of this search will be on high sensitivity to ensure no relevant service/resource is overlooked. To ensure this, a wide definition of inclusion criteria will be provided by WPs1-4.

1b) Following the initial search, a first round of expert interviews will be conducted by the partners regarding their national findings contributing to WPs1-4, if necessary. The focus of these interviews will be a first validation of comprehensiveness. Services/resources identified as irrelevant at this stage of process may be excluded.

1c) After initial validation, all partners will establish a list of the services/resources in English language, in conjunction with a description of the services/resources. Those lists and descriptions belonging to the work packages of other groups will then be transmitted to those groups leading the respective WPs, which will use the lists and descriptions as input for Step 2.
Step 2: Development of a classification system for costing purposes to which the services can be mapped and main cost drivers can be defined

2a) Parallel to conducting step 1a), WPs1-4 will conduct a literature search on international classification/mapping systems regarding the sectoral service/resource utilisation analysed in the given WP (e.g. ESMS/DESDE-LTC, REMAST, ICHI). If applicable these systems can be used as a basis for the classification of services/resources identified by the partners. If they cannot be applied, they can be used as a basis for amendment or the development of a new classification system.

2b) After receiving the lists produced in step 1c), each WP (1-4) will first clarify wordings and descriptions, if necessary. The services/resources identified will then be analysed regarding the classification systems identified in step 2a). If such systems cannot be adopted from the literature, these will be developed following two main principles: 1) the resulting classification must be useable to define measurable units of service utilisation (granularities), 2) if different services/resources are combined into one cell of the classification system, these must, in first place, represent relatively homogenous costs.

2c) After establishing classification systems for WPs1-4, all partners will group the national services/resources provided by the other working groups in work step 1) according to the classification system for their WP. The resulting lists will be sent back to the partners who will validate these lists for correctness.

The feasibility analysis of the tool will inform on: 1) accuracy (or face validity), i.e., apparent precision of the units of analysis of service/resource utilisation; 2) acceptability, i.e., language and display is acceptable to end-users; 3) user-friendliness, i.e., did users have difficulty understanding and/or using the chart, the extent of additional explanation required, training requirements and time taken to get the intended information; and 4) practicality, i.e., how useful the tool might be in real-life conditions in health economics studies, and in routine practice, and on training/experience required to collect the information. Respondents will be asked to identify content which proved problematic or confusing; 5) applicability (whether the content seemed appropriate for the assessment of the resources); 6) efficiency (the value of the information derived from the tool in relation to the effort required to use it), and 7) cultural transferability to be applicable in different European countries. Each of these will be rated from 1 to 4, where lower ratings indicated greater feasibility in each respect. The previous experience in the development in international units of service availability and capacity (Salvador-Carulla et al. 2010) and on mental health indicators of service utilisation in Spain (Salvador-Carulla et al. 2010) will be used for this analysis.

Measurement (HA3)
The purpose of horizontal methodological task/axis Measurement (HA3) is to quantify the health care consumption and the consumption of goods in all relevant sectors in natural units. It will develop and standardise generic (covering each relevant aspect) self-reported RUMs that measure health and social care (WP1), education and criminal justice (WP2), employment and productivity (WP3), and patient, family and informal care (WP4) in a practical, reliable, and valid way. These sector specific RUMs will then be integrated into a standardised, multi-sectoral, multi-lingual pilot RUM as one of the final PECUNIA tools (WP7). Ethical considerations and issues relevant to primary data collection, analysis and management related to the planned focus group discussions with adult volunteers will be addressed. In order to achieve the above, we will have the following steps:

Steps 1 and 2: Identifying existing relevant self-reported RUM instruments
Following the common method (Figure 9), an expert consortium (step 1) will be established to help us identify and further develop a RUM for each WP. In step 2, in order to identify existing relevant self-reported RUMs, a systematic review will be performed in each WP according to the standards (van Mastrigt et al. 2016; Thielen et al. 2016; Wijnen et al. 2016) of systematic reviews and consistent with methods proposed by the Cochrane Collaboration and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al. 2009). The main sources for identifying relevant self-reported RUMs will be DIRUM (Ridyard et al. 2012), Medline, Embase, Econlit, PsychInfo and Web of Science. In this systematic review the quality of the instrument, based on its psychometric properties, will be taken into account. Appraisal of the psychometric properties of the existing self-reported RUMs will be done by criteria used in the DIRUM database and by COSMIN elements (Mokkink et al. 2010a; Mokkink et al. 2010b; Mokkink et al. 2010c). Additionally the stakeholders can suggest other RUMs. Findings of the systematic review will be included in the DIRUM database.
### Valuation (HA4)

The horizontal methodological task/axis **HA4 Valuation** will address the final step in the costing process of a service/resource use. Valuation implies that the different resources used for the production of a unit of a service are multiplied with their cost and summed up to derive the cost of one service unit. From a health economics perspective, there is a general consensus that the derived costs should ideally capture the opportunity cost (Drummond et al. 2015), also referred to as the true ‘economic cost’. Several approaches to value resources and services in the health and social care sectors (WP1) are applied in practice, including e.g. micro-costing, cost-accounting methods, utilization of standard unit costs, fees, charges and/or market prices (Busse 2007). The methodology for the valuation of health-related resource use in the education and criminal justice sector (WP2) is less established, the exception being the recently developed approach by Drost et al. (2017a). Health impairments can also affect the individual’s activities in paid and unpaid work (Brouwer et al. 1997) (WP3) but the relevant valuation methodology is not harmonised across countries (Noben et al. 2014). Resource use in the family sector (WP4) includes e.g. informal care and out-of-pocket costs (Hoefman 2015). Other relevant cost components are e.g. reductions in household activities, need for domestic help or homelessness. Presumably due to difficulties associated with the valuation of items, they are currently, however, not commonly included in economic evaluations (Drost et al. 2017b). These issues will be addressed using publicly available data in four steps:

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1:</strong></td>
<td>Methodological synthesis is planned in terms of the costing methods that are currently applied in the selected countries. A review of relevant costing guidelines, unit cost programmes and relevant documents will be conducted. Selected costing methods will be tested to derive unit costs for all sectors.</td>
</tr>
<tr>
<td><strong>Step 2:</strong></td>
<td>Development of pilot-tested, standardised and validated multi-sectoral templates for different costing approaches for use across countries. This will set the foundation for harmonised costing in the EU. In practice, this will allow for flexibility in adopting the most appropriate costing method for different services while making differences due to e.g. data availability in different countries transparent.</td>
</tr>
<tr>
<td><strong>Step 3:</strong></td>
<td>Stakeholder involvement&lt;br&gt;&lt;br&gt;<em>Focus group 1: Health economists and other expert stakeholders</em>&lt;br&gt;In the third step, experts in the field of health economics will be involved in order to prioritise the items which agree with the cost drivers identified in HAs1-2. This will lead to a first draft instrument in English with input from WPs1-4 in a modular format. In the experience of DIRUM, it is unlikely that we will be able to use all items directly from existing RUMs, as there are many different ways that authors can ask essentially the same question. We will list all items and bring them back to the same description. PECUNIA partners, the SAB and relevant ASG members will be involved in this step which is intended to prioritise items for inclusion, as well as prepare a draft of the actual questions. Standardised methods for health questionnaire development will be followed (Edwards 2010, McColl et al. 2001, Streiner et al. 2014).</td>
</tr>
<tr>
<td><strong>Step 4:</strong></td>
<td>Translatability assessment&lt;br&gt;A formal translatability assessment of the draft instrument to 10-11 international languages will be subcontracted to Oxford University Innovations to help finalising the items and the wording of the pilot instrument which will then be forward translated within the consortium for further assessment.</td>
</tr>
<tr>
<td><strong>Step 5:</strong></td>
<td>Final development of a pilot RUM&lt;br&gt;&lt;br&gt;<em>Focus group 2: Adult volunteers</em>&lt;br&gt;In the fourth step, representatively selected adult volunteers using focus group techniques will be included in the development of the RUMs in order to see which items of the RUM are valid, reliable and practical from an end user perspective. This will result in a final pilot RUM for WPs1-4 in the five developing partner countries.</td>
</tr>
</tbody>
</table>
Step 3: Creation of an online database with calculated unit costs for core services applying the costing templates. This will make comparable unit costs for the health and social care sectors, the education and criminal justice sectors, the employment sector and the patient and family readily available for several countries. At the same time, it will allow for easy update and extension in the future. This will provide a transparent aid to understand cost calculations for services (e.g. for directors of relevant institutions, politicians, researchers) and will ultimately also allow for better service planning based on more accurate cost data. No cross-country synthesis is currently planned on the level of derived cost data. The necessity and feasibility of imputation of missing data will e.g. be explored in Task 1.3 (WP1). Correlation between different results of different costing approaches will be tested.

Step 4: Since health services evolve over time, resource use questionnaires and unit costs will be updated as new methods of delivering care (e.g. e-consultations) become available supported by a long-term business plan.

OUTCOME ASSESSMENT (WP5)

WP5 will focus on the harmonised assessment of outcomes in multi-sectoral, multi-national, and (where relevant) multi-person economic evaluations. It will carry out two parallel activities, one addressing cross-country and methodological variations in utility measurement, the other one synthesising and harmonising methods information for broader wellbeing measurement. No limitations to disease areas will be used.

**EQ-5D pan-European and supra-national utility value sets**

EQ-5D value sets can be developed on the basis of a Visual Analogues Scale (VAS) or Time Trade-Off (TTO) methods. TTO is the preferred and most often used in HTA. At this moment, March 2017, there are ten EQ-5D-3L European national value sets (Belgium, Denmark, Finland, France, Germany, Netherlands, Poland, Slovenia, Spain, UK) and three EQ-5D-5L European national value sets (Netherlands, Spain, UK) published. Additionally, 5L value-sets are currently being developed for Germany, France, Poland and several other EU countries. Through the direct involvement of the EuroQol Group (third party, SAB), the owner of these data, we have access to these data and we will cooperate with the original authors, to get maximal information and acceptation. The data typically exits out of national values for 86 of the 3125 possible health states of the EQ-5D-5L. The data of the 86 health states has to be combined and then a new model has to be estimated in order to arrive at a pan-European value set of all 3125 states. The EuroQol Group is experimenting to combine TTO with Discrete Choice Experiments (DCE) data, which are collected alongside the TTO values as these are less vulnerable for interviewer effects. Given that national values are nested with possible interviewer effects, the combination of DCE and TTO can help to unravel the two different sources of variance. The pan-European data set offers a unique opportunity to see how the earlier data sets would have benefited from better quality control. If so, this would also help other values set collections for other health-related quality of life (HRQoL) questionnaires. Furthermore, supra-national values sets will be developed by combining a selection of European value sets on the basis of cultural and/or linguistic considerations. For instance, there might be a supra-national value set on the basis of the West Germanic languages, and another one on the basis of Nord Germanic languages, and again another one for on the Slavonic languages etc. In other words, we would aim to provide the best proxy possible, using as much information possible from comparable countries. Grouping of comparable countries will be decided by an expert focus group consisting of relevant members of the consortium, SAB (e.g. COSMIN, EuroQol) and stakeholder experts using Delphi panel methods.

**Electronic compendium of generic, validated PROM instruments and meta-data suitable for economic evaluations**

For this objective, a systematic search of publicly available data will be carried out to identify relevant generic, validated PROM instruments suitable for economic evaluations. Several literature reviews collecting information on PROMs exist and PROM databases have been developed. To avoid duplication of existing work, multiple distinctive tasks will be performed using both top-down and bottom-up approaches.

Step 1: Relevant PROM databases, e.g. Patient Reported Outcomes Measurement Group, Registry of Outcome measures will be identified and searched.
VALIDATION (WP6)

WP6 has two main objectives: to validate the cross-country and within-country transferability of methods and tools developed in WPs1-5 (O6.1), and to validate the applicability of those methods and tools in the context of a real-world HTA project in Spain using publicly available data (O6.2). Due to the predominance of regional planning and governance, the regional-level HTA network, the lack of harmonised national reference unit costs, and the forthcoming official national EQ-5D-5L value set, Spain has been chosen as the best country to validate both cross-country and within-country transferability.

The first objective will be addressed by means of the direct application of the costing templates to estimate costs related to the three illustrative mental diseases, taking a national-level perspective as well as from the subnational/regional perspective of four regions in Spain. This will comprise of the following steps:

**Step 1:** Identification and definition of services/resources included in the templates in Spain. The potential difficulties related to inexistence or differences in the definition of services/resources will require extra-estimations, the adaptation of the templates if possible, or the assumption of approximate equivalencies and their limitations. Psicost’s experience and interviews with other Spanish experts will be used to validate the existence and definition of the services/resources included in the tools and methods, and to make decisions in order to progress with the application of the templates.

**Step 2:** Measurement of services/resources utilisation by means of the systematic review of Spanish studies and clinical guidelines, search and data extraction from other sources such as statistics, databases and registries, and the consultation with experts if needed. The quality of the sources/data will be explicitly reported as it is clear that it would affect the results in comparison to the potential use of the RUM. Although the RUM templates are not foreseen to be translated into Spanish nor used in Spain, activities in Step 1 will help the posterior international validation of the instrument.

**Step 3:** Main health economics research groups, societies and developers of identified PROMs will be surveyed for relevant instruments and their meta-data.

**Step 4:** Results of the reviews will be followed by focus group discussions with an expert group consisting of consortium partners and SAB members to identify the most important instrument characteristics and meta-data that will be later reported in a form of a ‘matrix’ as an electronic compendium.

**Step 5:** Meta-data extraction will follow a template that will be designed to inform on the selection of generic PROMs with respect to their special characteristics for multi-sectoral, multi-national, multi-person economic evaluations. It will focus on identifying information about an instrument in terms of: 1) whether it can be used to assess utilities, 2) does it focus on HRQoL or cover broader dimensions of wellbeing, 3) can there be double counting in terms of inter-sectoral costs and outcomes, and 4) does it allow to assess multiple-persons, e.g. family units, children, adolescents, adults or elderly? The screening of information on psychometric properties of included PROMs will be conducted for reliability (internal consistency), convergent and discriminative validity, reproducibility, and responsiveness. The COSMIN checklist will be used to evaluate the methodological quality of the validation studies. We will also look at the transferability of the identified PROMs, i.e. which languages and countries are covered by each instrument (Mokkink et al. 2010b).

**Step 6:** An electronic compendium will be created to make results and relevant guidance publicly available. The compendium will be regularly updated supported by a long-term business plan developed as part of PECUNIA.
Step 3: Valuation of services and resources use. The application of the cost templates in a different country from where they were designed will help to validate their transferability. The results of the valuation and the analysis of the process will be included in a report on the usability, flexibility and limitations of the use of the templates in Spain.

Step 4: In parallel with the validation of the costing templates, the validation of the cross-national (pan-European and supra-national) utility values sets estimated during the PECUNIA project (WP5) will be addressed. These value sets will be compared to the Spanish value sets from the EQ-5D-5L which will be publicly available in short. The correlation between both value sets will be one of the statistical measures of the goodness of the cross-national utility values developed by PECUNIA.

The second objective will be achieved in the context of an HTA project where a relevant technology for one of the three illustrative diseases will be evaluated. The HTA project will consist of 1) a systematic review of the effectiveness (and meta-analysis), safety and cost-effectiveness of the technology according to EUnetHTA (EUnetHTA Guidelines) and Cochrane Collaboration methodology standards (Higgins and Green 2011), 2) a de novo model-based economic evaluation where the technology will be compared in terms of costs and QALYs with a comparator representative of usual care, from both the societal and the Spanish NHS perspectives, and following robust methods (Drummond et al. 2015), and 3) a budget impact analysis from the NHS perspective. The unit costs obtained after the application of the costing templates will be used in the base case. The previously available unit costs in the Spanish context will be used in the deterministic sensitivity analyses. Similarly, utility weights for relevant health states obtained from literature and based on EQ-5D and equivalent weights obtained from the new value sets developed by PECUNIA will be used in the analyses. The results of the base case and the results of the sensitivity analyses will be contrasted. The time constraints and the limitation of standardised and available data on unit costs, resources and utilities are common in real-world HTA projects. This exercise will allow us to reflect on the feasibility of the new methods and tools, and their (dis)advantages in comparison with the usual procedures in HTA.

1.3.5 Sex and/or gender analysis

Although the focus of the call and PECUNIA is methodological, the chosen mental health disease areas have specific sex/gender relevant epidemiology and sex/gender may also impact on prototype care pathways, core service distributions, and causes variations in the economic and societal impacts at sectoral level (e.g. female dominance in informal caring role). These impacts will be taken into account in the full programme of PECUNIA. For example, relevant sex/gender epidemiology will be represented in the composition of focus groups. Balanced participation of women and men is also present at all levels in the research and innovation teams and in the management structures. PECUNIA has a 50%-50% female-male ratio at PI level.

1.4 Ambition

Advance beyond the state-of-the-art and innovation potential

No gold standard international, self-reported, multi-sectoral RUM questionnaire exists for economic evaluations, although the need is immense with the increasing number of multi-national studies and inclusion of societal perspective. PECUNIA has the UnivBris as partner. They are one of the founders of the DIRUM database which is the broadest compendium of such instruments. Several other partners (MUW, CUB, EUR, UM, LSE) have participated in the development of diverse RUM instruments and are experts of the existing variations and limitations. Developing a comprehensive, standardised, harmonised, modular, multi-sectoral, internationally transferable RUM instrument has great innovation potential as it is likely to set new standards in resource use measurement for economic evaluations across Europe. PECUNIA aims to develop the pilot version of such a RUM. Further relevant resources will then be sought to progress the TRL process. Currently only four countries (DE, FI, NL, UK) have established national reference unit cost programmes in the EU, all focusing on the health and social care sectors (Figure 3). Similar compendiums for inter-sectoral impacts of health interventions do not exist. Three (DE, NL, UK) out of these countries are part of PECUNIA. All these unit cost programmes have improved immensely the feasibility, transparency and comparability of national-level economic
evaluations in the given countries. In the Netherlands, it is now compulsory to use the relevant unit cost evidence in any reimbursement submissions. In the UK, more than two-third of all published economic evaluations have used information from the PSSRU Unit cost collection since its inception even though it is only a recommended source. Nevertheless, the costing approaches vary substantially between these programmes limiting their impact at international level. The commitment of these early developer partners from the DE, NL and UK to the harmonised PECUNIA methods, tools and information for multi-sectoral and multi-national reference unit cost development show the immense need for further international harmonisation. PECUNIA will contribute to the establishment of comparable, low resource need and sustainable unit cost programmes in some of the partner countries. Complemented with a follow-up COST Action application, it has the potential to achieve full impact across the EU and even beyond based on relevant expressions of interest for further international collaborations from Australia and Canada. Overall, it is not overstatement to say that the costing templates and reference cost information have a disruptive innovation potential. If adopted as compulsory or recommended parts of future national and EU costing guidelines, they will bring a much higher level of transparency into evidence-informed decision making and reimbursement decisions on both the decision makers’/payers’ side and on the industry’s side about costs in most EU health care systems. See also Letters of Commitments from SAB members in this respect. Overall, health economists and HTA developers (end-users) will be provided with harmonised tools for each costing step substantially improving the feasibility of comparable cost-effectiveness evidence generation also from a societal perspective while reducing necessary efforts.

The cross-national utility value sets and the electronic compendium of PROM instruments and their meta-data are also expected to progress harmonised, comparable outcome assessment in Europe substantially. They are seen as products with complementary innovation potentials to existing national methods of utility measurement and the existing limited guidance on broader wellbeing measurement.

Wide-ranging, continuous stakeholder engagement and partnering with an Small and Medium-sized Enterprise (SME) specialised in innovation management is therefore key in the success of PECUNIA. Several licensing and other IPR management issues are foreseen. The strengths, weaknesses, opportunities and threats (SWOT) of PECUNIA are analysed in Table 4 below. In how far and to which extend the four dimensions (strength/opportunities/weaknesses/threats) determine that the envisaged PECUNIA impacts will be achieved is described below in the following section, 2.1 Expected impacts.

Table 4. SWOT analysis for PECUNIA

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
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<tbody>
<tr>
<td><strong>Consortium expertise:</strong> Key experts with longstanding complementary experience in the area of costing and outcomes research, questionnaire development and project and innovation management</td>
<td><strong>Ambitious work plan</strong> (may be seen also as strength): develop new standards alongside all steps of the costing processes and for some steps of outcome measurement within 36 months, shortage of resources/time may happen → careful planning, active risk management, central consortium budget to allow for redistribution if necessary</td>
</tr>
<tr>
<td><strong>Consortium composition:</strong> Established work relationships and successful scientific collaborations within consortium, gender balance</td>
<td><strong>Interdependency of WPs1-4, high level of collaboration needed</strong> (may be seen also as strength) → WP7 has specific steps and deliverables planned to support integration</td>
</tr>
<tr>
<td><strong>Partner institutions:</strong> Established academic and research institutes working in the fields of economic evaluations and HTA and an SME, all with clear understanding of the problems and needed solutions</td>
<td><strong>New RUM to be developed until pilot stage</strong> due to resource constraints → follow-up project planned</td>
</tr>
<tr>
<td><strong>Partner countries:</strong> Heterogeneity in composition of health systems will allow for international transferability of any developed tools</td>
<td><strong>Long-term sustainability and wide outreach of methods is needed</strong> to achieve expected impact → careful innovation management, development of business plan to support sustainability, and wide stakeholder outreach as part of the programme; COST Action application</td>
</tr>
<tr>
<td><strong>Efficiency and transparency of methods:</strong> reduced efforts needed by clinical study sponsors and researchers to conduct economic evaluations and facilitate acceptance by decision makers</td>
<td><strong>Limited issues with data protection:</strong> no use of individual-level data for reference unit cost development</td>
</tr>
<tr>
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<tr>
<td><strong>Stakeholder involvement</strong> (e.g. decision makers, patients): Tailoring of newly developed methods and tools according to broad stakeholder needs and thereby bridging gap between academic research and feasibility and practicability</td>
<td><strong>Heterogeneity in health systems</strong> (e.g. regarding the delivery of services in different sectors) hampering comparability of e.g. services → detailed descriptions of services will be developed in WPs1-4 to allow for cross-country comparisons</td>
</tr>
</tbody>
</table>

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- Generalised introduction of the ‘fourth hurdle’ to pricing and reimbursement decisions for new health care technologies in Europe
- **Societal perspective**: Countries across Europe are increasingly recommending the societal perspective for economic evaluations, hence creating a clear need for multi-sectoral tools for resource use and outcome measurement and valuation
- **Multi-national economic evaluations**: Increasing number of multi-national studies calls for harmonised methods to make cross-country comparisons valid
- PECUNIA is completely aligned with the objectives of several EU and international initiatives/projects: EU Health Strategy ‘Investing Health’, the EC Joint Action for Mental Health and Wellbeing, EUnetHTA Joint Action III, the EC Joint Action for Health Information preceding a future HIREP-ERIC, and the ongoing WHO International Classification of Health Interventions (ICHI).
- **Lack of data**: limited data availability within some countries does not allow for a complete picture based on different costing methodologies → developed costing template will allow for low-threshold, user-friendly update in the future
- **Existing national guidelines in costing/valuation**: For countries with established unit cost initiatives, the introduction of newly developed methods, tools and estimates might prove more difficult → current unit cost lists not exhaustive; current costing standards will be identified in HA4 and complemented with additional approaches with potentially better fit depending on research question; costing guidelines get updated regularly and given the relevant stakeholder involvement, aligned update as an option
- **Increased transparency** about costs and outcomes may be seen as threat by decision makers, payers and industry (disruptive innovation) → inclusion of relevant stakeholders in development process, professional innovation management

Overall, most of PECUNIAs potential weaknesses may be also seen as strengths. We feel that with careful planning, right consortium composition, wide stakeholder outreach and relevant resource allocation PECUNIA is well-prepared to face the challenges and the potential threats.

**References**


Drost RMWA, Paulus ATG, Ruwaard D, Evers SMAA. 2014. [Manuel on intersectoral costs and benefits of (preventive) interventions: Classification, identification and cost prices.] (Maastricht University).


Hoefman RJ, van Exel NJ, Brouwer WB. 2011. iVICQ, iMTA valuation of informal care questionnaire (Rotterdam: iBMG/iMTA).


2. Impact

2.1 Expected impacts

Contribution to expected impacts mentioned in the work programme, under the relevant topic

1) Validated improved or new approaches for the collection and analysis of data for health economic evaluation, resulting in high-quality and comparable information within and across countries

The main objectives of PECUNIA focus on the development of new standardised, harmonised and validated methods, tools and information for multi-sectoral, multi-national and multi-person assessment of costs and outcomes for economic evaluations. All main products including 1) a new, modular, generic, self-reported RUM instrument; 2) generic unit costing templates and an electronic compendium of resulting reference unit costs for core services and resource use for illustrative mental health disease areas; 3) pan-European and supra-national utility value sets for Europe based on the EQ-5D, and 4) an electronic compendium and guidance for existing, generic, PROMs and their meta-data suitable for health and broader wellbeing assessment in economic evaluations will contribute to improved feasibility, comparability and transferability of economic evaluations across and within countries. Due to scarcity of similar tools, new standards in costing methods and multi-sectoral economic evaluations will be set.

2) Validated improved or new approaches for integration of data from all relevant sources, to facilitate an informative and continuous assessment of health interventions and systems

New methods for cost assessment (WPs1-4) will integrate both resource use and cost data from various publicly available data sources, e.g. routine administrative databases, surveys and registries including four cross-cutting horizontal methodological tasks (HAS1-4) for the identification, definition, measurement and valuation of health-related resource use in multiple sectors: 1) health and social care, 2) education and criminal justice, 3) employment and productivity, and for 4) patients and families including informal care. By developing costing templates, which explicitly take into consideration the heterogeneity of existing data, a step towards harmonisation will be made. In addition, more efficient methods to develop outcome estimates that are comparable across EU countries will be developed integrating data from different geographical regions. Ongoing, informative assessment will be facilitated by developing all tools in a way that allows low-threshold update by the user, e.g. based on new or more current data.

3) Validated improved or new indicators, measures and tools, to be used by decision makers for resource allocation in health systems that are patient-centered, efficient and sustainable

PECUNIA will develop and validate low resource, sustainable methods and templates for reference unit cost calculations. Based on existing evidence from DE, NL and the UK, the improved feasibility, comparability and standardisation of costing methods will lead to greater acceptance and usability of cost-effectiveness evidence by decision makers and payers. With the PECUNIA methods and tools, the needed level of investment into new country-specific reference unit cost programmes will be reduced while system efficiency will increase substantially. With their wide-ranging impacts, they even have a disruptive innovation potential in the case of decision makers, payers and the industry if introduced in countries where currently no reference unit cost programmes are in place (currently 24 out of 28 EU countries). They will also promote the feasibility of evidence-informed collaborative care models further increasing system-level efficiency. The multi-sectoral concept of PECUNIA leading to a harmonised, multi-sectoral self-reported RUM will capture effects on productivity (WP3) and patients and their families (WP4) in particular, which currently are largely neglected in economic evaluations. New methods and tools for outcome assessment will address the specific issue of multi-person outcome measurement (e.g. families) within one framework.

Substantial impacts not mentioned in the work programme

Impact on users (health economists, HTA, decision/policy makers, payers)

Beyond numerous open-access scientific publications and presentations of PECUNIA results at scientific meetings, outreach to users is also planned via our SAB (Table 7) and Advisory Stakeholder Group (ASG, Table 8). Based on current experience in DE, NL and the UK, it is highly likely that PECUNIA methods, tools and information will become...
compulsory or recommended new standards in future national and EU costing guidelines in adoptive countries. To achieve this, we will liaise with all relevant major international and national professional organisations and associations (see Table 8). PECUNIA will contribute to EUnetHTA Joint Action-III, which aims of developing reliable, transparent and transferable information to contribute to HTAs in European countries and regions. The tools provided by PECUNIA will help to facilitate efficient use of a set of new resources available for HTA, creating a valid and sustainable system of HTA knowledge sharing and promoting good practice in HTA methods and processes along the economic evaluation and budget impact estimations.

**Impact on industry**
With the growing importance of the fourth hurdle for reimbursement decisions, PECUNIA has substantial impact potential for the (pharma)industry and related consultancy. This may also reach the level of disruptive innovation if relevant methods, tools and reference unit cost information becomes required standards in national and EU-level costing guidelines as for example in the Netherlands.

**Impact on patients, health professionals, health care providers and public health**
Mental health disease areas (depression, schizophrenia, PTSD) with high disease, societal and economic burdens were selected as illustrative disease areas for service identification and reference unit cost development to not only address methodological issues at their maximum (mix of health and non-health (social, education, employment, justice) services and interventions) and therefore make relevant methods and tools also applicable for other disease areas, but contribute also to high priority medical and public health challenges in Europe and worldwide with highly needed applied evidence. The feasibility of evidence-informed collaborative care models will be increased leading to better patient care.

**Impact on broader society**
Due to its multi-sectoral concept, it is expected that the methods and tools developed in PECUNIA will be also relevant to the evaluation of non-health care interventions/services, e.g. in the employment or educational sectors. The feasibility of evidence-informed inter-sectoral funding arrangements will be increased.

In order to achieve maximum impact, EURICE, an SME specialised in project and innovation management, has joined the consortium. Wide-ranging stakeholder engagement beyond the scientific community (decision makers, payers, health economists, HTA, patients and families, health care professionals, etc.) with relevant dedicated resources is one of the main objectives of PECUNIA (see WP8 for detailed description).

**Barriers/obstacles and framework conditions determining impact achievements**
The SWOT analysis including information on all expected barriers and obstacles and other framework conditions determining impact achievements and the planned remedial actions including future follow-up projects is presented for PECUNIA in section 1.4, Table 4. Based on this, the most important barrier to impact achievement is the potential resistance of decision makers, payers and industry to greater transparency about costs and efficiency brought by the harmonised reference unit cost information at national level. PECUNIA addresses this by intensive relevant stakeholder outreach and inclusion. Another important obstacle is the need for additional resources and follow-up projects to achieve sustainability and full impact of developed tools and information across Europe. Relevant scientific plans have already been outlined (e.g. COST Action for International Unit Cost Network) and a tailored business plan will be formulated as part of the project to ensure sustainability and prepare potential future commercialisation.

2.2 **Measures to maximise impact**
A pan-European initiative, such as PECUNIA, which mainly aims at developing new methods for an integrative, standardised and harmonised measurement of resource use and its unit cost valuation for multiple sectors, can achieve its desired impact only if the project obtains the required visibility through targeted communication measures, and if dissemination and exploitation of results are thoroughly planned. The required regulatory
framework for dissemination and exploitation has been discussed and created during the proposal phase, and a draft plan for the dissemination and exploitation of project results has been agreed on by the consortium (see below, ‘Specific activities before the start of the project’). Specific measures to identify, manage, protect, exploit and disseminate project results will be an integral part of the project work plan. Special efforts will be devoted to ensuring that the project’s ideas and findings are communicated to and understood by a diversity of actors, inside and outside the health economic community. Specific dissemination and communication activities will thus target a wide array of stakeholders relevant to PECUNIA: Health economists, HTA, decision/policy makers, payers/insurance companies, industry (pharma, biotech), consultancy, health care providers, health care professionals, patients & families. Moreover, as PECUNIA aims at implementing the developed, harmonised methods into the health care systems in the EU, user needs and regulatory aspects across EU countries are crucial to be identified and considered. Therefore, representatives of each relevant stakeholder group (Advisory Stakeholder Group (ASG), see Table 8) as well as additional leading specialists from all European countries will be involved throughout the project. Bringing together all important stakeholders (national and pan European levels) in dedicated satellite workshops and round table discussions, strategies for cross-country harmonisation/transferability for a unified unit cost approach will be discussed. The perspectives of patients/families/decision makers/payers etc. will directly be considered during method development in WPs1-4. Please see below a description of outreach strategies for each ASG.

All activities to maximise the long-term impact of PECUNIA are summarised in WP8, ensuring that:

- A clear regulatory framework will be set up at the beginning of the project;
- Innovation management (communication, dissemination and exploitation) activities are thoroughly planned, follow a clear strategy and are closely monitored;
- A consortium-wide innovation management strategy will be jointly elaborated considering all individual partner interests;
- Expected contributions from each partner are defined, together with their potential benefit for other partners, to clarify lines of collaboration and interactions and optimise uptake of individual results;
- Professional communication measures provide targeted information to multiple audiences;
- Scientific outcomes will be disseminated at scientific conferences and in the form of high quality peer-reviewed journals, while ensuring that IP rights are not infringed;
- Open access to scientific publications will be guaranteed and provided as early as possible;
- Proactive monitoring of results to increase the innovation potential and enhance innovation capacity are implemented;
- Newly emerging IP with a potential for commercialization is assessed and captured;
- Early stage key exploitable results are identified continuously throughout the project and described in a standardised format, allowing easy uptake by Technology Transfer Offices;
- Effective exploitation strategies for each key exploitable result are in place and are followed;
- Stakeholder needs are properly considered and appropriately addressed during method development for optimal implementation opportunities.

EURICE acting as a neutral, independent, and non-biased partner being not involved in the achievement of scientific results, will centrally organise and document all innovation management measures, guide and support their planning, coordinate strategy development, provide or arrange for legal support where needed, collect input from all consortium partners, and compile related documents on consortium level. Thus, EURICE will provide fair and transparent innovation management decision support relying on proper project management activities (WP7) to ensure that high-quality results are created, captured, assessed and properly used.

Specific activities before the start of the project

Establishing a regulatory framework for dissemination and exploitation

The consortium members have been made aware of the general conditions under which all Horizon2020 projects are executed, laying out the basic rules for intellectual property rights, as well as the exploitation and dissemination of project results:
Unless it goes against their legitimate interests, each project partner must disseminate its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications.

Results that are generated under the project are to be regarded as the property of the partner(s) who have generated it, and who shall provide for their adequate and effective protection.

All results shall be used and exploited by the partner who carried out the work leading to the results without any restriction.

Where two or more partners have jointly carried out work generating project results, they shall have joint ownership of such project results according to their respective intellectual and financial contributions. In such a case, the co-owners shall establish a specific agreement regarding the allocation and terms of exercising that joint ownership (Joint Ownership Agreement).

Open access (free of charge, online access for any user) must be ensured to all peer-reviewed scientific publications relating to project results at the latest within 12 months of publication.

All project-specific rules and regulations for management of IP (specifically joint inventions), and more detailed provisions regarding confidentiality, dissemination and exploitation will be defined in the consortium agreement (CA). This additional agreement will complement the Grant Agreement (GA) to be concluded with the European Commission, will be negotiated in parallel to GA preparations, and signed by all partners before the project start. The document will specify the pre-existing intellectual property and know-how that each partner will bring into the project (‘Background’), and clarify access rights to both Background and Results for different purposes, such as use for the implementation of the project, use for further research, or use for commercial exploitation during and after the end of the project.

It is understood by the consortium that a wide outreach to different target communities and the strategic planning of exploitation activities are paramount to optimise project impact. The partners have therefore discussed and agreed on a draft Plan for the dissemination and exploitation of project results (PDE), which comprises a set of dedicated dissemination, exploitation and communication measures that are outlined below.

Specific activities during project implementation

‘Dissemination’ means disclosing results to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

‘Communication’ means the promotion of the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

‘Exploitation’ means the use of results in further research activities other than those covered by the action concerned, or in creating and providing a service, or in standardisation activities.

a) Dissemination and exploitation of results

Dissemination and exploitation measures will address the full range of potential users and different uses including research, commercial, investment, social, environmental, policy and decision making within the health care sector. The draft PDE as presented is to be refined during the first few months of the project and approved by the consortium. The document will be extended and updated continuously throughout the project, to help the strategic and systematic planning of dissemination and use of results as well as to properly document the implementation of all planned activities. For that purpose, an update of the PDE will be compiled and submitted to the EC after 18 months. The exploitation section of the PDE will contain a list of Key Exploitable Results for commercialization that are clearly defined, an exploitation strategy for each of those results, and a lead partner that is responsible for the implementation and possibly adaptation of the strategy per result.

1 Definition from Rules for Participation, see Article 2 (Definitions) §9.
**Targeted dissemination measures**

The following dissemination activities will ensure optimal visibility of progress and achievements, as well as a wide outreach and involvement of all relevant stakeholders (as defined above).

- **PECUNIA Concept Paper**: To ensure 
  a) a standardised approach in setting-up PECUNIA country reports and 
  b) maximal visibility very early on in the project, a concept paper about PECUNIA's main aims and methodological approach will be set-up in the first three months of the project and published immediately thereafter.

- **Scientific Publications**: As part of the PDE, a relevant PECUNIA publication strategy will be developed including a list of envisaged peer-reviewed publications (paper tracker). It will encourage timely open-access dissemination of results in peer-reviewed journals while ensuring that no conflicts with IPR issues arise. It will safeguard that fair credit is given to all individuals (including junior researchers) who have contributed to the research and authorships are based on international principles for example The International Committee of Medical Journal Editors Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (ICMJE Recommendations 2013). It is planned that main results from the project will be published in special issues of relevant, leading health economics journals (e.g. Value in Health, PharmacoEconomics, European Journal of Health Economics) to increase impact and visibility.

- **Open Access (OA) strategy**: All consortium partners have been familiarised with the two main routes that they can follow to make their research articles available as open access, namely by publishing directly in an open access journal (i.e. the ‘gold’ route) or by self-archiving, i.e. by depositing their final peer-reviewed publication into an appropriate institutional or a subject-based or a centralised repository, such as the Zenodo repository set up by the OpenAIRE project (i.e. the ‘green’ route). EURICE will actively inform the project partners about the different possibilities to publish open access at the kick-off meeting, help direct partners to their locally available repositories as well as the Zenodo repository of the infrastructure project OpenAIRE2020 (‘Open Access Infrastructure for Research in Europe’), and distribute information on the open access policies of the most frequently used journals for this consortium. Furthermore, the issue will be an integral component of WP8 presentations at each progress meeting. These actions should raise awareness that there are significant economic, social and educational benefits to making research outputs available without financial, legal and technical barriers. In the periodically updated PDE, an updated overview of the current OA status of all PECUNIA publications will be provided after each reporting period.

- **PECUNIA e-Newsletter**: PECUNIA will publish a six-monthly e-newsletter that will actively promote project-related news, activities and results (e.g. recent publications). The newsletter will be distributed via e-mail to all PECUNIA partners’ and stakeholders’ press departments and additional stakeholders such as related initiatives, projects, associations (e.g. IHEA, EuHEA, INAHTA, EUnetHTA) and official societies (e.g. ISPOR) both inside and outside Europe.

- **Scientific events**: PECUNIA results will be presented at international conferences and symposia including main health economics and health technology assessment relevant meetings (e.g. IHEA, EuHEA, ISPOR, HTAi). This will provide a platform for immediate presentation of results, fostering an active dialogue and direct interaction with other members of the scientific community, and prepare scientific collaborations in the future.

- **Networking**: To foster further networking within and outside the scientific community, particular attention will also be paid at liaising with other related initiatives on national and international level; particularly relevant ongoing EU-funded initiatives, such as EuroHOPE (see Table 3).

- **Stakeholder outreach strategy and involvement**: The ASG (see Table 8) consists of European-level and national-level representatives from MSs of health economists, HTA, health professionals, industry, decision makers, payers, and family organisations. Beside the SAB, they are the second body for advisory input throughout the PECUNIA project, representing the needs of end-users and interest groups. Each member of the ASG will use their institutional channels in order to disseminate project results and promote the action among their network and events in their European country. European stakeholders will use their European wide dissemination channels and events. This will provide the widest outreach to target groups among Europe possible. Additionally, two outreach events in the form of satellite workshops will be implemented. The 1st satellite workshop aims at bringing together the ASG, the SAB, as well as additional country experts (thus representatives of all important stakeholders, national and European) to present and discuss country reports on the selected EU countries, and the strategies for cross-country harmonisation/transferability for a unified unit cost approach. Taking into
account the perspectives of patients/families决策 makers/payers, etc. will ensure that the developed methods in WP 1-4 will be tailored to the needs of the end-users and guarantees proper implementation into the regulatory frameworks of the different health care systems of the selected European countries. The 2nd satellite workshop together with a large outreach event will take place towards the end of the project, connected to an international health economics/HTA conference (e.g. IHEA, EuHEA, ISPOR). Experts and stakeholders will present and discuss a final roadmap. Additional experts from related EU-funded projects will participate as keynote speakers on research challenges and opportunities for future collaborations. The event will help to disseminate project results and identify synergies between EU-funded projects to experts and the public, and pave the way for a sustainable uptake of established procedures.

**Exploitation**

While taking into account that a large part of the PECUNIA activities will lead to results that are to be made freely accessible for non-commercial purposes, it is clearly expected that some results will have the clear potential to lead to new electronic platforms and questionnaires/services that will provide the partners in the consortium with a competitive edge for commercial exploitation. The consortium agrees that centralised, early planning of exploitation activities can greatly enhance the impact achieved. It will ensure a clear follow up of each and every planned action, and provide transparency towards all members of the consortium. Raising awareness of IP rules and protection measures, in addition to an assessment of exploitation interests by all partners at the beginning of the project, will help to ensure that the results can be exploited by carrying out further research and seizing market opportunities, both collectively and at the individual partner level.

The current project work plan foresees the generation of results that will be exploited commercially by the consortium. Table 5 below summarises the expected results at this stage and respective envisaged (preliminary) exploitation strategies that will be further elaborated in the plan for dissemination and exploitation (PDE).

<table>
<thead>
<tr>
<th>Expected result</th>
<th>Exploitable by</th>
<th>Envisaged product</th>
<th>Exploitation model</th>
<th>Target customer</th>
</tr>
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<tbody>
<tr>
<td>WPs1-4 Multi-sectoral RUM instruments</td>
<td>All partners</td>
<td>Questionnaires</td>
<td>Licensing</td>
<td>Pharma and Biotech industries</td>
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<tr>
<td>WPs1-4, 6 Multi-sectoral unit cost templates and</td>
<td>All partners</td>
<td>Electronic</td>
<td>Licensing</td>
<td>Consultancy, payers and policy makers</td>
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<td>electronic compendium</td>
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<td>WPs5, 6 Electronic compendium of generic PROM</td>
<td>All partners</td>
<td>Questionnaires</td>
<td>Licensing</td>
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<td>instruments with meta-data</td>
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**IP Management: Strategy for knowledge management and protection**

In order to achieve the impacts of the project most efficiently, exploitation activities will combine established work processes for anticipatory innovation planning to capture, protect and assess key exploitable results including strategic support, and very concrete measures to commercialise market-ready products and implement new, standardised methods and strategies into the regulatory framework of the health care systems. This approach will safeguard that questionnaires and electronic databases will be quickly introduced as a health care service to both the market for commercial use and health care systems of the selected EU countries for non-commercial use. Innovation and IP management activities will also include supportive measures and guidance in case of conflict of IP-related interests arise among the partners, or interfacing with technology transfer offices at partner institutions to prepare exploitation of results.

The following two steps of professional IP management measures are foreseen in PECUNIA in order to increase the innovation potential and enhance innovation capacity during the project fully. The customised approach will include strategic planning as well as operational support activities using acknowledged tools and workshops to develop and implement successful exploitation strategies.

1) **Innovation Management Toolkit**

Innovation-related questionnaires (IRQ) are designed to collect detailed information on expected results, preferred exploitation routes and the intended role in the exploitation process at partner level, serving to clearly define each
partner’s exploitation plans and expectations individually. This will ensure optimal transparency among the partners, support the assessment of expected uptake of results and help identify potential conflicts of interests or bottlenecks early-on in the project. With the use of the IRQ, the first assessment that was done during the proposal phase (see Table X above) will be updated defining the ‘exploitation baseline’ from which each partner starts into the project. Based on the information extracted from the IRQ, expected Key Exploitable Results (KER) can be derived and the associated expected uptake by different members of the consortium can be defined using a standardised, Key exploitable Results Term Sheet (KERTS), serving as a sound basis for a project-wide exploitation strategy.

**Implementation and updating of exploitation strategy:** The joint exploitation strategy making use of all relevant Innovation Management Tools as mentioned above, will be fixed in writing, facilitating its stringent implementation. However, the consortium will regularly revise and adapt the document as necessary, factoring in e.g. changing health care and market needs and demands, or novel scientific findings and technological developments. At the occasion of PECUNIA progress meetings, a status update will be presented for each element of the KER, and respective exploitation strategies and next steps will be updated where appropriate. As a supportive tool to visualise, document and regular update key parameters of the KERs, such as value propositions and market segments, an adapted version of the Business Model Canvas template will be used. It helps the consortium members to already tackle and define major IP and innovation parameters early-on and to adapt each parameter as needed during the entire project life time.

**ii) Innovation-related Events:**
A number of innovation-related events will be organised during the project’s lifetime and aligned with the achievement of major milestones to ensure that the planned innovation-related activities match the progress of work and level of maturity of results. During these seminars and workshops consortium partners have the chance to exchange interests and define goals on consortium level in a confidential atmosphere and with the input of invited IP & exploitation experts: Guided by EURICE, a Capacity building seminars (CBS) is foreseen as a dedicated session at the kick-off meeting, and will be used to return initial exploitation plans to mind as defined during the proposal stage to reflect on the plans of partners’ roles and responsibilities regarding exploitation activities. Furthermore, a webinar on the basic legal framework and IP rules under Horizon2020 will be offered by EURICE to ensure a common level of knowledge on relevant IP issues among the partners.

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**Open research data**
The majority of the data PECUNIA will use are publicly available except 1) the secondary analysis of an existing anonymised dataset owned by the EuroQol group for cross-national utility value sets development (WP5), and the individual-level data which will be collected primarily via focus group discussions of the draft RUM instrument (WP7). The consortium wishes to participate in the pilot study on Open Research Data in Horizon 2020. For all research data the principle of FAIR data management will be applied as broadly as possible. A detailed first version of the ‘Data Management Plan’ (DMP) compliant with the Data Protection Directive 95/46/EC and the Information Security Standards BS ISO/IEC 27002: 2013 will be developed as part of WP7 activities (D7.4). PECUNIA results will be made available for non-commercial use via dedicated electronic platforms. A business plan outlining both non-commercial and commercial options for the preservation and updating of the results beyond the primary project timeframe will be exploited (see below).

**Business Plan**
Beside poor innovation management, many scientific projects lack plans for long-term sustainability and further development options for their exploitable results. PECUNIA is different. We will consider both non-commercial and commercial ways of securing sustainability and potential for expansion. Beside a joint follow-up COST Action application, we will actively explore the opportunities to incorporate the generated electronic compendiums on outcome and unit cost evidence into the planned HIREP-ERIC. Commercial exploitation of the tools and methods will target the pharma and biotech industries and consultancies. Relevant plans will be developed through direct industry stakeholder engagement and in consensus with the consortium as part of the project.
b) Communication activities

Transparent and continuous internal communication will ensure that partners will be kept fully informed about any developments throughout the course of the project. Project-specific external communication will be promoted by professional communication measures providing targeted information via different channels to multiple audiences safeguarding the widest outreach possible.

Communication measures will be customised towards the individual target audiences outlined below in order to optimally inform and involve stakeholders as well as the general public. All partners will invest in communication of project results based on a clear strategy which will be further developed during the project, adapted to and considering the timing of major milestones and the progress of work to guarantee an efficient uptake of promising project outputs.

All PECUNIA partners have demonstrated excellent communication skills in previous national, European and international research and innovation projects, including EU-funded projects, in which they have participated or coordinated. Relevant projects are indicated, for example, in Table 3, section 1.3.4. or in the partner descriptions in section 4 of this proposal. Each of these projects implemented a variety of communication activities such as central events, teachings and trainings, and numerous high-level publications that jointly resulted in a high visibility of the individual initiatives.

The aims of the PECUNIA communication activities are to promote knowledge sharing, greater public awareness, transparency and education.

The overall strategy to implement communication measures will encompass four major areas:

i) To systematically identify central target groups and appropriate communication channels

As a basis for an effective communication management, a Communication Committee will be elected consisting of key representatives of the PECUNIA core activities, who will be in charge of guiding external project communication as well as content production and quality assurance for all communication measures. Furthermore, a Communication Concept as well as a Communication Activity Plan will be elaborated in order to define key messages and appropriate communication means to individually address major target audiences as well as to systematically outline the various activities envisaged. Representatives of the ASG will be involved, and their channels and networks used for communicating progress and results of PECUNIA.

ii) To develop a specific project branding for the project and create, design and produce informative and promotional material

Based on the Communication Concept and the Communication Activity Plan, visual design elements i.e. colour scheme, fonts, etc., will be conceived in order to define the project’s ‘visual identity’ and to create a distinct branding, ensuring a professional, consistent visual appearance of the project across all outreach activities. These elements will be adopted for a number of templates to be used for presentations, reports, and posters, tailored to target-group specific information needs and serve as a Communication Toolkit. The Communication Toolkit will allow all partners to easily access and use these project-specific communication and dissemination templates and material, facilitating project-related communication and dissemination

iii) To set-up a project website

The public website will be generated and used as the predominant tool to communicate the scientific concept, project achievements, related background information and publications, including a condensed overview of the work plan, recent developments, individual partner descriptions, contact details, conferences of interest, etc. Content for the website will be provided by the Communication Committee but also by all partners, will be collected regularly by EURICE and will be uploaded to the website in a timely manner in order to ensure that information remains fully up to date. Thus, non-confidential information will be made widely available to the scientific community, patient organisations, the broad public, and to other stakeholders as outlined in Table 8. The website will furthermore contain the restricted password-protected internal communication and management platform called the ‘ProjectAngel’ that is accessible for PECUNIA members only, to exchange confidential and project internal information (file sharing).
iv) **Target communication measures**

The need for the existence of an integrated European approach will be addressed in order to highlight the importance of concerted actions and European funding. PECUNIA will convey its results to the European Commission and relevant Member State platforms. We will do so – among other activities - within the scope of a new EU initiative which aims at forming a European Research Infrastructure Consortium (HIREP-ERIC) to collect, process, analyse, report, and communicate health information across EU countries. The PECUNIA consortium plans for a joint COST Action proposal in order to extend the usage of the developed methods in further national unit cost programmes.

Furthermore, **media relations** will be used to actively promote the project and its results by providing targeted information to the multiple audiences identified in a strategic and effective manner: Project activities and outputs will be monitored closely to identify research results of special interest aiming to trigger press releases on a regular basis. The **press releases** will be published on the project website and relevant international science information platforms (e.g. CORDIS, Eurekalert) and will be distributed to all partners’ press departments, to stimulate decentralised communications and a broad addressing of media outlets/journalists on a regional and national level. Rounding up the multifaceted communication portfolio, popular **public events** with a health economic focus will be actively used to inform about the objectives and progress of the PECUNIA project to experts and the interested public and to help establishing synergies with other EU-funded projects.

3. **Implementation**

3.1 **Work plan — Work packages, deliverables**

**Brief presentation of the overall structure of the work plan**

PECUNIA’s research and developmental activities for cost assessment will be sector-relevant and will address all important sectors of the economy in four WPs (WP1 Health and social care, WP2 Education and criminal justice, WP3 Employment and productivity, and WP4 Patient, family and informal care). Cross-cutting methodological tasks for WPs1-4 will be harmonised across four horizontal axes (HA): Identification HA1, Definition HA2, Measurement HA3, Valuation HA4. WP5 Outcomes will focus on improving the methods and tools for comparable and broader health and wellbeing impact assessment in economic evaluations. Relevant tools will be developed in 5 countries (AT, DE, NL, HU, UK). Piloting and validation for feasibility, within- and cross-country transferability, and applicability within an HTA framework will happen in a sixth country (ES) (WP6: Validation). WP7 will support PECUNIA with management, coordination and integration, while WP8 will be responsible for the wide stakeholder communication and dissemination of results including exploitation of their innovation potentials (Figure 10).

Considering the scope of the call, the main concepts of PECUNIA, relevant existing research and knowledge base, common expertise and interest of the consortium and time and resource limitations, three mental health disease areas were selected (depression, schizophrenia and PTSD) as illustrative examples for the tasks considering cost assessment (WPs1-4). In general, however, all the developed costing methods and tools (i.e. RUM instrument and unit costing templates) as well as the tasks focusing on outcome assessment will be generic and not limited to specific disease areas.
**Figure 10:** Graphical presentation of components showing how they inter-relate (Pert chart).
### Table 6. Timing of the different work packages and their components (Gantt chart)

*T=Task, Milestone=MS, Deliverable=

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<th>N°</th>
<th>Title</th>
<th>start month</th>
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<th>1st Period</th>
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**WP1 Health and social care**

- **T1.1** Identification of services and resources
  - 1: MS1
  - 18: MS18

- **T1.2** Definition of measurable and internationally transferable units of service use (granularities)
  - 1: MS1
  - 18: MS18

- **T1.3** Measurement of services and resources
  - 1: MS1
  - 24: MS24

- **T1.4** Valuation of services and resources
  - 1: MS1
  - 36: MS36

**WP2 Criminal justice and education**

- **T2.1** Identification of relevant services in criminal justice and education
  - 1: MS1
  - 18: MS18

- **T2.2** Definition of measurable services and resources in criminal justice and education (granularities)
  - 1: MS1
  - 18: MS18

- **T2.3** Measurement of services and resources in criminal justice and education
  - 1: MS1
  - 24: MS24

- **T2.4** Valuation of services and resources in criminal justice and education
  - 1: MS1
  - 36: MS36

**WP3 Employment and productivity**

- **T3.1** Approaching the expert consortium
  - 1: MS1
  - 4: MS4

- **T3.2** Measuring instruments of productivity loss of paid and unpaid work
  - 1: MS1
  - 24: MS24

- **T3.3** Valuation methods of productivity loss of paid and unpaid work
  - 1: MS1
  - 24: MS24

- **T3.4** Electronic compendium for measuring and valuation of productivity loss of paid and unpaid work
  - 1: MS1
  - 36: MS36

**WP4 Patient, family and informal care**

- **T4.1** Identification and mapping of services and resources
  - 1: MS1
  - 18: MS18

- **T4.2** Definition of measurable and transferable units of patient and family specific resource input
  - 1: MS1
  - 18: MS18

- **T4.3** Measurement of patient and family specific services and resources
  - 1: MS1
  - 24: MS24

- **T4.4** Valuation of patient and family specific services and resources
  - 1: MS1
  - 36: MS36

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<table>
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<th>WP5 Outcomes</th>
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<tr>
<td>T5.1 To develop a pan-European value set for the EQ-5D-5L, EQ-5D-3L and EQ-5D-Y (Youth)</td>
<td>1 18</td>
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<tr>
<td>T5.2 To develop supra-national value sets, on the basis of homogeneities distributions of values, in order to satisfy cultural and/or linguistic considerations</td>
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<tr>
<td>T5.3 To identify, define and compile generic PROMs and their meta-data suitable for economic evaluations with specific guidance on applicability</td>
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<thead>
<tr>
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<tr>
<td>T6.1 Application/use of methods and tools developed by PECUNIA partners for mental diseases in Spain</td>
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<tr>
<td>T6.2 Valuation of results of methods and tools developed by PECUNIA partners within a real-world HTA project</td>
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<thead>
<tr>
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<tr>
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<td>T7.2 Contractual issues</td>
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<td>T7.3 Reporting, financial management and controlling</td>
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<td>T7.4 Scientific coordination, quality assurance and risk management</td>
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<td>T7.5 Close integration of partners and deliverables</td>
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<td>T7.6 Concept paper and country reports</td>
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<tr>
<td>T7.7 Open Research Data Pilot (ORDP) and Data Management Plan</td>
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<td>T8.1 Project Communication</td>
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<tr>
<td>T8.4 IP Management and Exploitation Strategies</td>
<td>1 36</td>
</tr>
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</table>
3.2 Management structure, milestones and procedures

Organisational structure and decision making

The PECUNIA project management component will: (i) provide support for individual scientists to ensure that project objectives are achieved; (ii) monitor and control the progress of each WP; (iii) coordinate project activities; (iv) implement quality control mechanisms by defining appropriate project standards; and (v) ensure targeted dissemination of knowledge. A wide array of activities will be undertaken, including scientific and administrative management, guidance of decision making, contractual management, financial management, supervision of and compliance to ethical standards, management of knowledge and IPR issues, and coordination of communication activities.

The PECUNIA consortium consists of ten partners from EU28 (7 universities, 2 research organisations, 1 SME), of which the majority have extensive experience with EU funded collaborative projects, while some partners are new to the funding scheme. Thus, the management of PECUNIA will be tailored to the different needs and requirements of our academic and industry partners.

The organisational structure as illustrated in the schematic below (Figure 11) was jointly agreed on by the PECUNIA consortium. It is adapted to the size and composition of the consortium and the tasks and duties of all partners involved.

Figure 11. Management bodies

Management bodies

The Coordinator (COO) is represented by Professor Judit Simon at the Medical University Vienna. Prof. Simon has longstanding experience in the implementation and management of regional, national and international multi-disciplinary grants, including EU grants as a partner, country-lead, WP co-lead, or PL lead. The tasks of the COO will be the overall monitoring and coordination of any scientific, technical, dissemination as well as exploitation related activity at consortium level. In close collaboration with the WP Leaders (WPLs), she will be responsible for the overall management of scientific results, monitor WP status measured against deliverable and milestone planning, carry out risk assessment and contingency planning in order to ensure a timely and accurate follow-up of the work plan, and monitor the implementation of the project.
The **Project Management Office (PMO)** EURICE has longstanding experience as management and dissemination partner in international collaborative projects. EURICE has been involved in EU-Framework Programmes since FP4 and has been supporting researchers in over 250 EU funded projects to date. In PECUNIA, EURICE will be in charge of administrative, contractual, financial and organisational management tasks. Furthermore, EURICE will serve as a ‘helpdesk’ for all partners, giving guidance in any administrative, financial and EC regulatory questions in day-to-day work. Requests at consortium level will be consolidated and channelled by EURICE before forwarding them to the COO to reduce their administrative workload to a minimum. Reliable communication standards are of utmost importance for a smooth workflow in collaborative projects. EURICE will coordinate and monitor project communication, information management as well as reporting via ‘Project Angel’, a web-based project management and communication platform which has been developed for the management of projects funded under EU Framework Programmes and specially adapted to Horizon2020 regulations. EURICE will help in organising project meetings, provide support in preparing the agenda and minutes of the meeting, collect documentation to enable monitoring of activities within all WPs, coordinate reporting activities including financial reports and the preparation of audit certificates from all partners, and collect deliverables and reporting documents in a timely fashion.

The **Management Team (MT)** is composed of the Coordinator and the **Project Management Office** and will be in charge of all management tasks in PECUNIA. The MT will assume the role of an interface between the consortium and the European Commission and as such be responsible for the delivery of reports as well as uptake and implementation of EC suggestions and requests.

The **Steering Committee (SC)** is composed of the WP Leaders (WPLs) who are responsible for coordination of the research activities from all partners involved in the 8 WPs. The SC represents the interface between the General Assembly (GA, see below) and the MT. The SC will arrange for the timely execution and preparation of deliverables to assure the attainment of objectives. Thus, the SC allows for focused and comprehensive monitoring of the WP status measured against deliverable and milestone planning, control of deliverable timeliness and quality in order to ensure a timely and accurate work plan follow-up, early identification of possible technical and organisational problems and for trouble shooting. Should this be considered necessary, the SC can request another member of the consortium to join the SC to represent a particular area of work or expertise. The SC shall keep the MT informed of the development and progress status on a regular basis.

The **General Assembly (GA)** will be composed of one representative per partner and will be chaired by the COO Judit Simon. The GA will act as the ultimate democratic decision making body in PECUNIA. Decisions will comprise any technical or scientific changes to be made to the objectives and the overall work plan, project management related matters including re-allocation of tasks or resources or actions with regard to a defaulting party, resolving administrative or organisational issues, modifications to the consortium agreement and conflict management in general. Decisions will be made regularly at project meetings or when the need arises. Each partner will have one vote but may define an authorised deputy in order to guarantee that the GA is quorate at any time. In case of parity the COO will have the casting vote. Detailed rights and obligations of the GA will be laid down in the consortium agreement, which will be concluded jointly by all partners before the start of the project.

The **Scientific Advisory Board (SAB)** will not be part of the consortium officially, but its scientific input for strategic decisions will be valuable on a consultative level. The SAB will be invited to join the project meetings and satellite workshops to give targeted input on the scientific progress. However, the SAB will not be involved in administrative project management discussions (financial, organisational or contractual issues) and will not have voting rights. The SAB will be comprised of renowned scientists, health economic experts, psychiatrists, health system decision makers and one patient organisation, representing the interests of families of people with mental illness. The SAB members from eight European countries are chosen to complement the (country specific) consortium’s expertise and to maximise benefits of the project. However, the composition of the SAB will remain flexible during the project duration to allow for goal oriented exchange of information. The following individuals (highlighted in green in Table 7 below) have already agreed to support the implementation and steering of PECUNIA as members of a SAB, their Letter of Commitments (LoC) are attached to this proposal.

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Table 7. Members of the Scientific Advisory Board (SAB)

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
<th>Country</th>
<th>Expertise</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Martin Knapp (chair)</td>
<td>Personal Social Services Research Unit, London School of Economics and Political Science</td>
<td>United Kingdom</td>
<td>Economics, mental health, social care, policy analysis</td>
<td>confirmed, see letter of commitment</td>
</tr>
<tr>
<td>Jennifer Beecham</td>
<td>Personal Social Services Research Unit, University of Kent</td>
<td>United Kingdom</td>
<td>Unit costs, resource use instrumentation, economic evaluation</td>
<td>confirmed, see letter of commitment</td>
</tr>
<tr>
<td>János Kálmán</td>
<td>University of Szeged</td>
<td>Hungary</td>
<td>Psychiatry, child and adolescent psychiatry, forensic psychiatry, clinical pharmacology, rehabilitation in psychiatry, health services management</td>
<td>confirmed, see letter of commitment</td>
</tr>
<tr>
<td>Claudia Wild</td>
<td>Ludwig Boltzmann Institute for Health Technology Assessment</td>
<td>Austria</td>
<td>Health economics, health Quality assessment, health policy</td>
<td>confirmed, see letter of commitment</td>
</tr>
<tr>
<td>Antoni Dedeu Baraldés</td>
<td>Agency for Health Quality and Assessment of Catalonia (AQAs)</td>
<td>Spain</td>
<td>Health care decision/policy making, reimbursement of new health care technologies, EU projects</td>
<td>confirmed, see letter of commitment</td>
</tr>
<tr>
<td>Christiane Roick</td>
<td>Federal Association of the AOK (AOK-Bundesverband)</td>
<td>Germany</td>
<td>Health system decision making, Germany’s health care system, mental health services, implementation and evaluation of innovative health care models, analyses based on routinely collected health data/secondary data, health care and health economic research</td>
<td>confirmed, see letter of commitment</td>
</tr>
<tr>
<td>José Miguel Caldas de Almeida</td>
<td>Lisbon Institute of Global Mental Health (LIGMH)</td>
<td>Portugal</td>
<td>Global mental health policy, services development and implementation, mental health systems, development of innovative payments models for mental health systems</td>
<td>confirmed, see letter of commitment</td>
</tr>
<tr>
<td>Aagje leven</td>
<td>European Federation of Associations of Families of People with Mental Illness (EUFAMI)</td>
<td>Belgium</td>
<td>Deinstitutionalisation and transformation of services, research and policies</td>
<td>confirmed, see letter of commitment</td>
</tr>
<tr>
<td>Jan J. van Busschbach</td>
<td>Chairman EuroQol –Board and Head Section Medical Psychology and Psychotherapy Erasmus MC (EMC)</td>
<td>Netherlands</td>
<td>Health economic outcomes in mental health, questionnaire developments</td>
<td>confirmed, see letter of commitment</td>
</tr>
<tr>
<td>John Geddes</td>
<td>University of Oxford</td>
<td>United Kingdom</td>
<td>Mood disorders, psychiatry, epidemiology, clinical trials, research synthesis, meta-analysis</td>
<td>confirmed, see letter of commitment</td>
</tr>
</tbody>
</table>

The Advisory Stakeholder Group (ASG) (see Table 8) consists of European-level and national-level MS representatives of health economists, HTA, health professionals, industry, decision makers, payers, and family organisations. Beside the SAB (see Table 7 above) they are the second body for advisory input throughout the PECUNIA project with a pan-European scope, representing the needs of end-users and interest groups at EU level. They will provide their expertise about their national unit cost system and regulatory requirements and communicate their interests and needs with respect to the methods that will be developed within PECUNIA during two dedicated satellite workshops to which they will be invited: The 1st satellite workshop organised by month 18 aims at bringing together the ASG, the SAB, as well as additional country experts to present and discuss the country reports of the selected EU countries that will be compiled during the first project months, as well as possible strategies for cross-country harmonisation/transferability for a unified unit cost approach. Taking the perspectives of patients/families/decision makers/payers, etc. into account will ensure that the developed methods in WP 1-4 will be tailored to the needs of the end-users and guarantees proper implementation into the
regulatory frameworks of the different health care systems in Europe afterwards. The 2nd satellite workshop towards the end of the project will bring together all experts and stakeholders again for presentation and discussion of the final roadmap. The workshop provides the opportunity to discuss regulatory hurdles that are not yet solved and to formulate strategies how to overcome these hurdles.

As PECUNIA aims at a joint encompassing unit cost approach among Europe, we need this diverse sector- and country specific expertise in order to find the best overarching solutions that are easily applicable in each country and sustainable over time. Table 8 summarises the identified stakeholders at European level and from all PECUNIA partner countries as illustration. Relevant stakeholders from all EU countries will be identified during the project and invited to the satellite workshops. The outreach strategy for each stakeholder group is outlined in section 2.2, Measures to maximise impact.
Table 8. Advisory Stakeholder Group (ASG), illustration of stakeholders at EU-level and for PECUNIA partner countries

<table>
<thead>
<tr>
<th>STAKEHOLDER GROUP</th>
<th>European Stakeholders</th>
<th>AT Stakeholders</th>
<th>DE Stakeholders</th>
<th>ES Stakeholders</th>
<th>HU Stakeholders</th>
<th>NL Stakeholders</th>
<th>UK Stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health economists</td>
<td>International Health Economics Association (IHEA) European Health Economics Association (euHEA)</td>
<td>Austrian Health Economics Association (ATHEA) ISPOR Austrian Chapter</td>
<td>German Health Economics Association (DGGO)</td>
<td>Asociación de Economía de la Salud (AES)</td>
<td>ISPOR Hungarian Chapter</td>
<td>The Dutch Association for Health Technology Assessment (NVTAG) The Dutch Association of Health Economist (VGE)</td>
<td>Health Economists’ Study Group UK</td>
</tr>
<tr>
<td>HTA &amp; public health institutes</td>
<td>European network for Health Technology Assessment (EUnetHTA) International Network of Agencies for Health Technology Assessment (INAHTA) International Association of National Public Health Institutes (IANPHI)</td>
<td>Ludwig Boltzmann Institute Health Technology Assessment (LBI HTA) Austrian Public Health Institute (GÖG)</td>
<td>German Institute for Medical Documentation and Information (DIMDI) Institute for Quality and Efficiency in Health Care (IQWiG)</td>
<td>Red Española de Agencias de Evaluación de Tecnologías Sanitarias y Prestaciones del Sistema Nacional de Salud</td>
<td>Department of Health Technology Assessment, National Institute of Pharmacy and Nutrition</td>
<td>National Institute for Public Health and the Environment (RIVM) Erasmus Medical Centre (iMGZ) Institute of Health policy and Management (iBMG) Institute for Medical Technology Assessment (iMTA)</td>
<td>National Institute for Health Research (Health Technology Assessment and Public Health Research boards) Scottish Health Technologies Group Medical Research Council (Methodology Research Programme Panel)</td>
</tr>
</tbody>
</table>

779292 PECUNIA – Part B
<table>
<thead>
<tr>
<th>STAKEHOLDER GROUP</th>
<th>European Stakeholders</th>
<th>AT Stakeholders</th>
<th>DE Stakeholders</th>
<th>ES Stakeholders</th>
<th>HU Stakeholders</th>
<th>NL Stakeholders</th>
<th>UK Stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Payers - Social/private insurance</strong></td>
<td>European Social Insurance Partners Association (ESIP)</td>
<td>Association of Austrian social insurance carrier</td>
<td>National Association of Statutory Health Insurance Funds (GKV-Spitzenverband)</td>
<td>Ministry of Health 17 Regional Health Services</td>
<td>National Health Insurance Fund Administration</td>
<td>National Health Institute</td>
<td>As above</td>
</tr>
<tr>
<td>(Users, data and funding)</td>
<td></td>
<td>Insuranc Association Austria (VVO)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Health care professionals</strong></td>
<td>Mental Health Europe (MHE)</td>
<td>Austrian Association of Political Consultants (OGPP)</td>
<td>German Association for Psychiatry, Psychotherapy and Psychosomatics (DGPPN)</td>
<td>Federación de Asociaciones Científico Médicas Españolas Sociedad Española de Farmacia Hospitalaria</td>
<td>Hungarian Psychiatric Association</td>
<td>The Dutch Association for Psychiatry (nvvp)</td>
<td>British Medical Association</td>
</tr>
<tr>
<td>(Users, data)</td>
<td></td>
<td>Medical Association Vienna</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patients and families</strong></td>
<td>European Federation of Associations of Families of People with Mental Illness (EUFAMI)</td>
<td>Club D&amp;A</td>
<td>Irre menschlich Hamburg e.V. (Irre menschlich)</td>
<td>Plataforma de pacientes Foro Español de Pacientes</td>
<td>Hungarian Association of Patient Organizations</td>
<td>National Platform Mental Health (Nationaal Platform GGz)</td>
<td>Healthwatch, The Patients’ Association</td>
</tr>
<tr>
<td>(Data)</td>
<td></td>
<td>Socio-psychiatric services (PSD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Help for Relatives of People with Mental Illness (HEP)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Data)</td>
<td></td>
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</tr>
</tbody>
</table>
Management aims

The project management activities will provide a clear organisational framework and all necessary support mechanisms and ensure a smooth project workflow and that all contractual commitments are met on time. To achieve this, both scientific and organisation project management must go hand in hand, and particular attention will be paid to individualised practical support, reaching out to all relevant individuals at partner sites, including scientific and administrative team members at various levels.

The main aims of PECUNIA management are

- to provide optimal orientation to all partners, quick set-up of effective management and communication structures, guidance and support
- to safeguard maximal transparency for all partners and the EC through proper project documentation and targeted pro-active provision of information
- to maximise effectiveness of project activities: Ensure timely and qualitative achievement of project results through scientific and administrative coordination.
- to ensure efficiency: Enabling the consortium to use resources wisely, avoid duplication of efforts, and reduce loss or waste of time and energy to a minimum.

Management procedures

Monitoring project progress and reporting

The PECUNIA work plan is arranged in 8 WPs and 31 tasks. The SC will monitor and direct the WP research activities: Each WPL will monitor the status of deliverables, milestones and financials of his WP and will inform the SC on the status quo during the regular project meetings and also ad hoc by personal communication if the need arises. To assist the WPL in their tasks, EURICE will collect relevant administrative and financial information from each partner involved and compile an overview on WP level at regular intervals. Following an 18-months reporting schedule, two periodic reports (P1: M1-18, P2: M19-36) will be submitted to the EC. Compilation of these reports will be managed by the MT, with the finalised report being transferred into the EC reporting systems by EURICE. Besides these contractual obligations, the project’s progress is steadily monitored through internal progress reports to ensure a quick uptake of activities and proper use of resources and adhere to guidelines immediately from the project start. Internal and official/contractual reporting will be implemented based on the following procedure:

A) Team Leader report (TLR): Each partner will prepare team leader progress reports for each WP he is involved in, in order to inform the relevant WPLs of progress towards achievement of the particular deliverables in compliance with the work plan, including deviations from the work plan and incidents.

B) Work Package Leader report (WPLR): Based on the input of each partner given in the individual team leader reports, each WPL will then prepare a WPLR, summarizing the activities of all partners within the respective WP and related deviations from the work plan.

Both TLR and WPLR will comprise a description of tasks carried out and technical progress, and the related overview of manpower effort compiled by EURICE, based on the information collected from each partner. The overall project progress will be monitored by the MT based on these WPL reports.

EURICE will monitor the financial reporting process, support the partner institutions in ensuring the compliance of reported costs with all applicable EC rules and regulations, and strive to achieve a harmonised format of the explanations of the use of the resources provided by each partner institution.

Project meetings will be held twice a year (once a year in person, and once a year via telephone conferencing), wherever possible at one of the partner institutions. Meetings will be divided into a scientific progress section and an administrative project management section. Additional work group meetings or video/telephone conferences will be held whenever necessary, for example to co-ordinate individual WP progress, the preparation of reports, or to discuss any critical issues that may emerge in the course of PECUNIA.

Decision making, remedial action, and appropriateness of organisational structure

Decisions will be made by the different project bodies as described above; however, detailed rules for decision making and risk management will be laid down in the PECUNIA consortium agreement, to be jointly agreed on by
all partners before the start of the project. The document will be the basis for the legal, administrative, financial and organisational management of PECUNIA and will include regulations on:

- Technical provisions (technical resources made available, maximum efforts, modification procedures)
- Rules for dissemination and use (particularly confidentiality, ownership of results, legal protection of results, pre-existing knowledge of partners (background))
- Organisational provisions (committees, cooperation supervision, revision of the agreement)
- Financial provisions (financing plan, modification procedures, mutual payments, etc.)
- Legal provisions (legal cooperation status, terms of the agreement, penalties for non-compliance with obligations, applicable law)

The organisational structure of PECUNIA has been designed to provide for maximum efficiency in project management issues. WPs are headed by experienced WPLs who will function as primary responsible persons for the smooth implementation of their WP, or for quick and efficient trouble shooting should the need arise. WPLs will be closely supported by an experienced management team, which has implemented effective management structures and procedures in comparable initiatives before. It must remain the responsibility of each individual project partner to report any risk situations that may conflict with the project objectives or their successful completion immediately to the WPL concerned as well as to the MT. However, a number of potential risks to which particular attention will be paid right from the start of the project have been identified already and are described in detail in section 3.2.b, and experience has shown that a close and trustful interaction between the management team and each consortium member helps reveal critical issues quickly in the context of day-to-day communication, allowing for speedy remedial action. Upon reporting of an occurring risk, the COO will consult with the concerned WPL or the entire SC according to the gravity of the problem. Possible mitigation measures, including changes in the scheduling of deliverables and or allocated budget will be discussed immediately and decided on in a timely manner. The MT and SC are aware of organisational and technical challenges of this planned large-scale multi-national initiative, and well prepared to initiate quick action whenever needed. Sufficient personnel resources were allocated to these crucial tasks, given the size, complexity and scale of the project. The work plan follow-up and decision making process designed for PECUNIA has taken these factors into account, and the MT as well as all selected WP leaders are well experienced in dealing with the managerial tasks they were assigned. In case of a need for remedial action, the MT will set the schedule for finding solutions and the COO will chair all discussions. In the case of critical deviations from the work plan the EC will be informed and consulted immediately. Every issue will be managed in accordance with the provisions of the Grant Agreement and the Consortium Agreement. General Assembly meetings will be called, whenever necessary.

Innovation management

Innovation management is considered an important task by the PECUNIA consortium. To be able to guarantee that the innovation potential of the project results is identified and respective measures can be taken, WP8 and specifically Task 8.4 ‘IP-management and exploitation strategies’, will deal with innovation-related activities. While taking into account that a large part of the PECUNIA activities will lead to results that are to be made freely accessible, it is clearly expected that some results will have the clear potential to lead to new electronic platforms and questionnaires/services that will provide the industrial partner and end users in the consortium with a competitive edge. A dedicated session at the kick-off meeting in form of a Capacity building seminars (CBS) will serve to reflect on and potentially revise foreseen initial exploitation plans as well as the partners’ roles and tasks regarding innovation-related activities. Thus, the project work plan foresees that individual exploitation strategies will be collected and depicted right at the beginning of the project (building on what has already been collected and discussed on the proposal phase) and merged to a coherent exploitation strategy on consortium level. EURICE will collect respective information through innovation-related questionnaires that are to be filled out by each partner before the first progress meeting. An exploitation planning session will then be part of every progress meeting to discuss exploitation interests documented, and to define exploitation opportunities and strategies, both on individual and on consortium level. The task leader of Task 8.4, EURICE, will be the individual in charge of monitoring all innovation-related progress, working very closely with the scientific project manager implemented by the coordinator (bringing in the market and technical perspective), and will serve as a contact person for all consortium members for any innovation and IP related questions that may arise during the course
of the project. This will allow the consortium not only to pursue their exploitation aims defined at the project start, but also to respond appropriately to any external or internal opportunity that may come up during project implementation. As one of three members of the European IPR helpdesk initiative, EURICE is providing training to EC staff on IP management issues, and is well experienced in guiding IP and innovation management in the context of large EU funded projects, with a network of experts readily at hand for in depth consultancy and advice whenever needed.

The exploitation section of the PDE will include a table detailing each identifiable project result with potential economic value, the owner(s) of such result, sectors of potential application and an overall plan for the protection and exploitation of the result, to be updated regularly as the project progresses.

**Risks and mitigation measures**

All PECUNIA consortium members have long-standing experience in scientific research as well as participation in or coordination of projects at international levels. Thus, the consortium is capable to identify and deal with potential risks due to the fact that partners are experienced in planning and implementing appropriate contingency measures. Already established tight links and well-functioning communication lines through earlier and ongoing cooperation in other projects is a strong asset that will help reduce complications and ensure short reaction time should quick action be needed.

Furthermore, efficient management structures will be implemented in PECUNIA, allowing for close monitoring of WP status, early identification of possible scientific, technological, experimental, organisational and administrative problems, trouble shooting and conflict resolution.

Taken together, the consortium is convinced that risks that may arise during the project are kept to a minimum. However, since scientific research and work flows are not fully predictable, the project will be subject to a certain number of risks that are inherent to the nature of an international collaborative project with ambitious objectives and efficient time planning. After thorough risk analysis, carried out jointly by all partners, the consortium lists below the most important risks together with proposed mitigation measures.

3.3 **Consortium as a whole**

**Consortium description**

The PECUNIA consortium covers ten partners from six European countries (AT, ES, DE, HU, NL, UK) corresponding to 45% of the current EU-28 population. Seven academic departments, two research institutes and one SME are involved. At PI level, a 50%-50% female-male gender ratio is given. All PECUNIA partners have long-standing bilateral and multilateral collaboration histories on different levels (Figure 12). Specifically, partners have successfully worked together in 17 projects, including several EU projects (e.g. MHEEN, eDESDE-LTC, BURQOL-Rd, EQUIP, ASSPRO CEE). A total of 69 joint manuscripts were published, and 29 joint events such as workshops, symposia, talks and exchange stays were organised. In addition, six other collaboration activities took place between PECUNIA partners including e.g. memberships in review boards and honorary professorships. The experience of the PECUNIA consortium in relation to the PECUNIA objectives (section 1.1) is summarised in Table 9.
Table 9. PECUNIA consortium experience in relation to PECUNIA objectives

<table>
<thead>
<tr>
<th>Objective No.</th>
<th>Content of objective (see also section 1.1)</th>
<th>PECUNIA experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Developing multi-sectoral resource-use and impact measurement instruments</td>
<td>UnivBris as one of the founders of the DIRUM database, LSE with its most often used CSRI (Client Service Receipt Inventory) questionnaire, UKE, UM, EUR, MUW, CUB and LSE with its activities on health-related resource use measurement, inter-sectoral resource use measurement and work productivity measurement, respectively, cover all current key initiatives in resource-use measurement expertise in Europe</td>
</tr>
<tr>
<td>2</td>
<td>Developing multi-sectoral unit costing templates</td>
<td>EUR, UM, UKE, LSE and PSICOST with extensive experience based on earlier EU projects or long-standing national costing initiatives in various sectors. MUW is developing a relevant national project in Austria.</td>
</tr>
<tr>
<td>3</td>
<td>Developing cross-national utility value sets for health outcome valuation with EQ-5D</td>
<td>EUR, MUW and CUB have gathered relevant experience in the past, which will be complemented by EuroQol as part of the SAB</td>
</tr>
<tr>
<td>4</td>
<td>Promoting broader wellbeing measurement and setting up an electronic compendium on existing PROMs and their meta-data</td>
<td>MUW and EUR with a track-record of highly relevant project experience</td>
</tr>
<tr>
<td>5</td>
<td>Increasing stakeholder awareness and ensuring long-term sustainability of developed outputs</td>
<td>The SAB, the ASG including the pharmaceutical industry and EURICE will help ensure successful realisation of this aim; SESC pert brings in practical real-life HTA expertise complemented by relevant knowledge within the SAB</td>
</tr>
</tbody>
</table>

Industrial/Commercial involvement

The (pharmaceutical) industry, as one of the potential future users of the developed results, will be involved via the ASG and will be invited to the relevant workshops. This will ensure both relevant stakeholder input and promote the potential for commercial exploitation of relevant results. For more, see section 2.2 Business plan.

Other countries and international organisations: not applicable
3.4 Resources to be committed

Total cost for the PECUNIA project: 2,999,943.75 Euro. Total EU requested contribution: 2,999,943.75 Euro. The different budgets allocated to the participants reflect and justify their different contributions to the project, as described in the proposal.

The project will mobilise the resources necessary to carry out the work for the overall duration. The resources will be integrated and used to form a coherent project within the overall financial plan. Moreover, the participants will complement the EC Contribution with their own resources such as personnel whose costs are not charged to the project (e.g. research services, project management), facilities (e.g. offices, library), equipment (e.g. computers), softwares, data (e.g. all existing EuroQoL EQ-5D-5L data), databases (e.g. DIRUM) and PROMs (e.g. OxCAP-MH). 7 academic departments, 2 research institutes and 1 SME are involved. All partners are experienced at collaborating between industry and academia, and most have previously been involved in EU funded projects. The details of staff efforts and cost categories are reported below and in the administrative forms.

### 3.4.b Other direct cost’ items (travel, equipment, other goods and services, large research infrastructure)

The participants will ensure that other direct costs are conform to H2020 rule and to applicable national law on public procurement for public contracting authorities while respecting applicable rules on conflict of interest (see Art. 10 and Art. 35 of the Grant Agreement).

<table>
<thead>
<tr>
<th>P1-MUW</th>
<th>Cost (€)</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Travel</td>
<td>50,000.00</td>
<td>1 kick-off + 3 annual meetings, conferences (10,000 €), travel costs for SAB members (40,000 €)</td>
</tr>
<tr>
<td>Equipment</td>
<td>1,500.00</td>
<td>MUW PC</td>
</tr>
<tr>
<td>Other goods and services</td>
<td>144,400.00</td>
<td>Mandatory audit/Certificate on Financial Statement (CFS) (5,000 €), MUW training (3,000 €), Open access publications (30,000 €), Project meetings (20,000 €), SAB meetings (20,000 €), Stakeholder workshops (49,400 €), Data collection (5,000 €), Ethics approvals (12,000 €)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>195,900.00</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>P2-UKE</th>
<th>Cost (€)</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Travel</td>
<td>9,000.00</td>
<td>1 kick-off + 3 annual meetings, conferences</td>
</tr>
<tr>
<td>Equipment</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Other goods and services</td>
<td>5,000.00</td>
<td>Data collection</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>14,000.00</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>P3-CUB</th>
<th>Cost (€)</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Travel</td>
<td>9,000.00</td>
<td>1 kick-off + 3 annual meetings, conferences</td>
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<tr>
<td>Equipment</td>
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<tr>
<td>Other goods and services</td>
<td>7,000.00</td>
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<td><strong>Total</strong></td>
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<th>P4-UM</th>
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<td>Other goods and services</td>
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<td><strong>Total</strong></td>
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### Methods research for improved health economic evaluation

#### P5-EUR

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<td>Equipment</td>
<td>-</td>
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<td>Other goods and services 5,000.00</td>
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#### P6-SECS

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<tr>
<td>Other goods and services 5,000.00</td>
<td>Access to data such as eSalud database and bibliography (2,000 €), consulting services with experts (3,000 €)</td>
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<td><strong>Total</strong></td>
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#### P7-Psicost

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<tr>
<td>Equipment 2,000.00</td>
<td>Personnel computer for junior researcher, all equipped (1,000 €), Personnel computer for project manager, all equipped (1,000 €)</td>
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<td>Other goods and services 5,000.00</td>
<td>Data collection (Data based licenses, ...)</td>
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#### P8-LSE

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<td>Other goods and services 5,000.00</td>
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#### P9-UnivBris

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<tr>
<td>Equipment</td>
<td>-</td>
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<td>Other goods and services 1,150.00</td>
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#### P10-EURICE

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<th>Cost (£)</th>
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<td>Equipment</td>
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<td>Other goods and services 7,500.00</td>
<td>Website set-up and maintenance, printing materials (flyers, leaflets)</td>
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<td><strong>Total</strong></td>
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4. Members of the consortium

4.1. Participants (applicants)

<table>
<thead>
<tr>
<th>P1</th>
<th>Medizinische Universitaet Wien (MUW)</th>
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</table>

**Description of the legal entity**

The Medical University of Vienna (MUW) is one of the most traditional medical training and research facilities in Europe. It is today the largest medical training institute in the German-speaking area. With its 27 university hospitals, three clinical institutes, twelve theoretical medicine centres and numerous highly specialised laboratories, it is included among the most important cutting-edge research institutes of Europe in the area of biomedicine ([https://www.meduniwien.ac.at/web/](https://www.meduniwien.ac.at/web/)). The Department of Health Economics (DHE) was founded in 2013 as the first dedicated health economics department in Austria and is a dynamically growing international research unit. It is part of the Centre for Public Health with over 70 employees and aims to support efficiency and equity concerning health and health care through relevant interdisciplinary collaborations within the university and with other national and international research and decision-making institutions. Major research areas include the synthesis of evidence and appraisal of the socioeconomic burden of diseases, the costs, benefits and cost-effectiveness of preventative, diagnostic and treatment interventions both alongside clinical studies and using modelling techniques ([https://healtheconomics.meduniwien.ac.at/?L=1](https://healtheconomics.meduniwien.ac.at/?L=1)).

**Main tasks in the project**

Main tasks in the project include i) coordination of the project (WP7), ii) co-lead on WP1, iii) lead on WP5, iv) lead on HA4 and v) provision of country-specific contributions for Austria to all relevant WPs. The profile of the legal entity matches these tasks insofar as the DHE is an academic unit of the MUW with all the relevant resources and experience to support legal and research services aspects, manage research projects, carry out literature reviews and evidence synthesis, conduct surveys and qualitative research, arrange local and national ethics approval, provide direct access to patients, health care professionals and their relevant representative organisations and access national health-care decision-makers. The DHE has an established research team, a broad European research network, experience with European project participation, and is in an intensive growth phase. The main focus of the DHE is applied economic evaluations and relevant methodological development with specific expertise in outcomes research including measurement of broader well-being and resource use valuation, and costing methods including being the initiator of the Austrian Unit Cost Programme.

**Profile of staff members involved**

**Prof. Dr Judit Simon** (female), Professor of Health Economics, Head of Department is a health economist and public health expert. Prof Simon has been involved in several relevant European projects as partner (MHEEN II), WP co-lead (BRIDGE) or HE lead (PreDict), and HE PI on numerous relevant mental health clinical studies (e.g. ACTIONS, OXTENT, OCTET, CEQUEL, POMET). Her main research interests and expertise lie in applied economic evaluations and relevant methods development including broader well-being measurement for mental health outcomes (OxCAP-MH), multi-national cost-effectiveness analyses (Magpie, PreDict), the development of cost-effective clinical guidelines (UK NICE guidelines for schizophrenia, depression, eating disorders), broader health services (MHEEN II) and systems research (BRIDGE), and is the initiator of the Austrian Unit Cost Programme. She also holds a Visiting Professorship in Cognitive Health Economics at the Department of Psychiatry of the University of Oxford and is Research Associate at the Health Economics Research Centre (HERC), Nuffield Department of Population Health at the University of Oxford.

**Dr Susanne Mayer** (female), Assistant Professor. Dr Mayer holds a PhD in Health Economics and a Master’s degrees in Socio-Economics and Economics from Vienna University of Economics and Business. She has methodological expertise, project experience and a track record of peer-reviewed publications in qualitative and quantitative research, trial-based economic evaluations (e.g. OCTET, CEQUEL, PreDict), systematic literature reviews, resource-use measurement instruments in the education and criminal justice sector and resource use valuation (costing).

**Nataša Perić MSc** (female), PhD student of Applied Medical Science at the Medical University of Vienna. She holds a Master’s degree in International Business Administration from the University of Vienna. She has a comprehensive background in health system performance assessment with focus on health system efficiency, qualitative research (e.g. SROI of mobile care services in Vienna, Ashoka Globalizer) and European project experience (e.g. BRIDGE Health).
Agata Łaszewska MPH (female), PhD student of Applied Medical Science at the Medical University of Vienna, has a comprehensive background in the field of public health and health economics. She has been involved in multiple projects in the area of mental health. Her main research expertise lies in costing of community-based mental health care services and PROMs (e.g. OxCAP-MH).

Margit Leeb (female), Scientific Assistant with experience in research administration and project management. She will support the day-to-day coordination of the consortium at MUW (WP7).

Relevant publications, and/or products, services


Relevant previous projects or activities

| 2. NIHR Programme Grant OCTET (RP-PG-0606-1006): ‘Oxford Community Treatment Order Evaluation Trial (OCTET)’, 2008-2013; development of a nouveau patient-reported outcome (PROM) instrument, the OxCAP-MH (Oxford CAPabilities questionnaire-Mental Health) measuring broader well-being in mental health as part of the programme. |
| 3. EU H2020 project PreDicT (H2020-SMEINST-2-2015 - 696802): ‘Predicting Response to Depression Treatment’, 2015-2019; testing a machine learning algorithm in five European countries to provide a rapid, objective measure of a patient’s response to antidepressant treatment to stratify care and accelerate their recovery from the illness and return to normal quality-of-life and functioning with full economic evaluation. |
| 4. EU HP-PJ project BRIDGE (HP-PJ-2014 - 664691): ‘Bridging information and Data Generation for Evidence-based health policy and research’, 2015-2017; BRIDGE Health aims to develop a comprehensive, integrated and sustainable Health Information System, to support policy and research in the EU and in Member States, e.g. by developing a blueprint for country fact sheets on health system performance assessment. |
| 5. Austrian Unit Cost Programme, 2014- : Following the kick-off of the initiative with national stakeholders in 2014, two workshops with international experts were held, funded by the Austrian Research Association. The DHE Unit Cost Online Database based on a systematic review of existing published information from costing studies was launched in 2016 (internal resources) http://healtheconomics.meduniwien.ac.at/science-research/dhe-unit-cost-online-database/. Second phase to develop harmonised national reference cost information is in progress. |

Significant infrastructure and/or any major items of technical equipment

779292 PECUNIA – Part B
**DHE Unit cost website:** The DHE has set up a website allowing for free download of the DHE Unit Cost Online Database, including user guides and user tracking. It aims to provide readily available unit costs for services in the Austrian health and social care sector retrieved from published economic evaluations and increase awareness of different unit cost sources and their limitations, both among researchers and policy-makers. It is available for free download at [http://healtheconomics.meduniwien.ac.at/science-research/dhe-unit-cost-online-database/](http://healtheconomics.meduniwien.ac.at/science-research/dhe-unit-cost-online-database/).

**OxCAP-MH:** Multi-dimensional, self-reported instrument measuring broader wellbeing in mental health. Judit Simon as the main author and guardian has responsibility for dissemination and access issues, and holds permission for relevant further developments of the instrument. It is accessible via [http://healtheconomics.meduniwien.ac.at/science-research/oxcap-mh/](http://healtheconomics.meduniwien.ac.at/science-research/oxcap-mh/).

<table>
<thead>
<tr>
<th>P2</th>
<th>Universitaetsklinikum Hamburg-Eppendorf (UKE)</th>
</tr>
</thead>
</table>

**Description of the legal entity**

The University Medical Centre Hamburg-Eppendorf was founded in 1889 and is the largest hospital in Hamburg, incorporating 14 centres with 80 departments and more than 1,400 hospital beds. The medical school associated with the centre is among the largest in Germany, providing medical training for 3,500 MD students. With more than 10,000 employees, the UKE is the third-largest employer in the Free and Hanseatic City of Hamburg. About 2,400 of them are medical specialists and researchers, while more than 3,100 work as nurses and therapists ([www.uke.de](http://www.uke.de)). The Department of Health Economics and Health Services Research is part of the Centre for Psychosocial Medicine of the UKE and of the inter-faculty Hamburg Centre for Health Economics (HCHE) of the University of Hamburg. The HCHE is Germany’s largest health economic research centre with approximately 70 researchers ([www.hche.de](http://www.hche.de)). Major research areas of the Department of Health Economics and Health Services Research of the UKE include cost-of-illness and cost-effectiveness analyses and the measurement of preferences for health and health care, with a special focus on mental health care. Since 2010, the Department has received about 40 externally funded research grants and published approximately 300 peer-reviewed research articles ([www.uke.de/kliniken-institute/institute/gesundheitsökonomie-und-versorgungsforschung/index.html](http://www.uke.de/kliniken-institute/institute/gesundheitsökonomie-und-versorgungsforschung/index.html)).

**Main tasks in the project**

Main tasks in the project include i) lead on WP1, ii) lead on HA2 and iii) provision of country-specific contributions for Germany to all relevant WPs. The Department of Health Economics and Health Services Research has access to the necessary infrastructure to fulfil the task described above. As an academic unit of the UKE, the Department can use all relevant resources of this institution to support project management and research implementation. Access to the research infrastructure facilitates the preparation of literature reviews and the synthesis of evidence as well as the conduction of surveys and qualitative research. Furthermore, assistance for the obtaining of ethical approval on local and national levels, and support to gain access to patients, health care professionals, their relevant representative organisations and national health-care decision-makers will be granted. Additionally, the Department has a well-established research team. The research focus of the Department includes cost-of-illness and cost-effectiveness analyses and relevant methodological development with specific expertise in measurement of costs and preferences for health and health care. The Department has developed an instrument for measuring resource utilisation and unit costs for mental health care in Germany.

**Profile of staff members involved**

**Prof. Dr Hans-Helmut König** (male), Professor (Chair) of Health Services Research and Health Economics, Head of the Department of Health Economics and Health Services Research at the University Medical Centre Hamburg-Eppendorf. Before joining the Medical Faculty of the University of Hamburg in 2010, he was Professor of Health Economics at the University of Leipzig (2003-2010). Before, he was a senior researcher in the Department of Health Economics at the University of Ulm (1996-2003) where he received the venia legendi (Habilitation) in 2003. From 1995-1996 he was a research fellow at Department of Health Care Systems Research of the University of Tübingen. Hans-Helmut König first studied Economics (1985-1986), then Medicine at the Universities of Tübingen, London and Oxford (1986-1992), received his doctoral degree from the University of Tübingen in 1993 and a Master’s degree in Public Health from Yale University in 1995. His main research fields are cost-of-illness studies, empirical and model-based cost-effectiveness analyses, as well as the measurement of preferences for health and health care, with a special focus on mental health care.

**Dr Alexander Konnopka** (male), senior researcher. Dr Konnopka has university degrees in medicine and...
Dr Christian Brettschneider (male), Junior-Scientists-Group Leader, has a Doctoral Degree from the University of Hamburg and a Diploma in Health Economics from the University of Cologne. His fields of expertise are trial-based economic evaluations, cost-of-illness studies, the development and validation of assessment instruments for resource-use and quality-of-life, and the valuation of resource use (unit cost calculation). Dr Brettschneider has been referee for 29 scientific journals and is Associate Editor of BMC Psychiatry.

Relevant publications, and/or products, services

Relevant previous projects or activities
1. Health economic evaluations within the German Psychotherapy Research Network funded by the German Ministry of Education and Research, 2007-2014.
2. Hamburg Centre for Health Economics: Young researcher group focusing on methods for the economic evaluation of mental health care, funded by the German Ministry of Education and Research, 2012-2016.
4. Health economic evaluation of collaborative care of late-life depression: Implementation of the IMPACT program in Germany (GermanIMPACT), funded by the German Ministry of Education and Research, 2012-2015.
5. Late-life depression in primary care: needs, health care utilisation and costs (AgeMooDe), funded by the German Ministry of Education and Research, 2012-2015.

Significant infrastructure and/or any major items of technical equipment
Research at The Department of Health Economics and Health Services Research is based on substantial preparatory work in the field of the development of resource use measures and calculation of unit costs. Researchers from the Department of Health Economics and Health Services Research participated in the development of the FIMA questionnaire, a resource use measure for the use in elderly populations, and developed the FIMPsy, a questionnaire for the assessment of resource utilization in populations with mental health problems. Additionally, researchers of the Department calculated and published unit costs to complement the FIMA and the FIMPsy.

P3 Budapesti Corvinus Egyetem (CUB)

Description of the legal entity
Corvinus University of Budapest (CUB) is the largest economic university in Hungary and offers educational programmes in business administration, economics and social sciences. The excellence of these departments assures the university a leading position in Hungarian higher education (www.uni-corvinus.hu). The Department of Health Economics (DHE) was founded in 1999 as the first dedicated health economics department in Hungary.
DHE regularly takes part in international research programmes financed by the European Commission. DHE has experience and scientific results in the following research areas: quality of life, cost-of-illness and burden of disease analysis, health care utilisation, health technology assessment, systematic reviews, cost-effectiveness analysis (hecon.uni-corvinus.hu).

**Main tasks in the project**

Main tasks in the project include i) lead on WP4, ii) provision of country-specific contributions for Hungary to all relevant WPs. The DHE has all the relevant resources, equipment and experiences to perform relevant research tasks in the project. It has extensive research experience in conducting cost-of-illness studies, including resource use measurement and costing. Additionally, the Department has experience in the field of systematic literature review, outcome research, cost-effectiveness research and health technology assessment.

**Profile of staff members involved**

Prof. László Gulácsi (male), Professor of Health Economics, Head of the Department of Health Economics, Corvinus University Budapest. Prof. Gulácsi is a physician, having university degrees of programming mathematics, mathematical economics and sociology, and health economics. To date (March 2017) he (co)authored more than 200 articles in peer-reviewed journals, published twelve books, 64 book chapters on health economics, public health, health technology assessment, health policy and quality improvement.

Dr Valentin Brodzsky (male), Associate Professor at the Department of Health Economics. He has research expertise in the field of cost-of-illness, health technology assessment, cost-effectiveness modelling, and outcome research. He has participated in several national or international cost-of-illness studies and conducted analyses on direct and indirect costs related to different diseases. His publication activity includes 45 English and 37 Hungarian publications, 14 book chapters and 74 published conference abstracts.

**Relevant publications, and/or products, services**


**Relevant previous projects or activities**

2. EC/DG Sanco project **EUNethTA**: European Network for Health Technology Assessment, 2006-2009.
5. EU FP7 project **BURQOL-RD** (A/101205): ‘Social Economic Burden and Health-Related Quality of Life in patients with Rare Diseases in Europe’, 2010-2013. (Contract nº 2009 12 04). The main aim of BURQOL-RD was to develop a disease based model (instrument) to quantify the Economic Burden and Health-Related Quality of Life (HRQOL) for patients and their caregivers, from a macro societal perspective. ([http://www.burqol-rd.com/](http://www.burqol-rd.com/))

**Significant infrastructure and/or any major items of technical equipment**

DHE has all software (statistical packages, modelling software etc.) that is necessary to accomplish research objectives. Additionally, the Department has access to a cost-of-illness study database that comprises data of 16 studies including informal care costs.
Maastricht University (UM) is the most international university in the Netherlands, and stands out for its innovative approach to learning and international outlook. With almost 16,000 students and 4,000 staff members, UM offers a wide choice of academic programmes, among others in the field of participation and health economics (www.maastrichtuniversity.nl). Within the UM, the Care and Public Health Research Institute (CAPHRI) provides high quality multidisciplinary research and teaching aimed at the improvement of the individual's quality of life, participation and the population's health through (cost-effective) innovation in public health and health care (www.caphri.nl).

Main tasks in the project
Main tasks in the project include i) lead on WP2, ii) co-lead on HA3 and iii) provision of country-specific contributions for Netherlands together with EUR. The UM has a long history in the methodological development of economic evaluation tools as and also a longstanding tradition in coordinating and participating in European projects. In summary, the UM has the relevant resources and experience to support and manage the research, and to carry out all dimensions of the research required. Furthermore the UM has direct access to patient groups, health care professionals and their relevant representative organisations and to national health-care decision-makers. The Health Economics/HTA research group within CAPHRI consists of a well-known research team, which aims to methodologically develop and study the functioning of the health care system from an economic perspective. The research group also seeks to perform and methodologically develop human/patient oriented research economic evaluation studies, studying costs, effects, and cost-effectiveness of health care in order to support decision makers when deciding about health care innovations.

Profile of staff members involved
Prof. Silvia Evers (female), Professor of Public Health Technology Assessment at Maastricht University, Netherlands, in the Department of Health Services Research of the Faculty of Health, Medicine and Life Science. Next to that, she is working at the Trimbos Institute, Netherlands, Institute of Mental Health and Addiction, Centre of Economic Evaluation. At Maastricht University, Prof Evers is leader of the programme ‘Creating value-based health care’ and profile coordinator of the HTA-trace of the Health Sciences Research Master at CAPHRI, Research School of Public Health and Primary Care. Currently, she has been the co-supervisor of more than 20 PhD students and more than 100 Bachelor and Master Students. She has co-authored up to 200 (peer-reviewed) publications (Google’s H-index 34). Her chief current research efforts are directed towards the methodology of economic evaluation of (preventive) interventions, meta-analysis, transferability and quality of life analysis. Prof. Evers has a special interest in the application of these methods, looking at innovative interventions in the field of public health.

Prof. Carmen Dirksen (female), professor in Health Technology Assessment (HTA) of clinical interventions at the Care and Public Health Research Institute (CAPHRI), Maastricht University, and head of the department Clinical Epidemiology and Medical Technology Assessment (KEMTA), Maastricht UMC+. She chairs the Dutch Society for Technology Assessment in Health Care (NVTAG). She has over 20 years of experience in HTA, and has been involved in many economic evaluation studies covering various disciplines, among them (youth) mental health. Recently, Prof. Dirksen, together with Prof. Evers, was commissioned to perform a broad consultation among Dutch experts regarding the need for standardisation of economic evaluations in the youth mental health sector by the Netherlands Organisation for Health Research and Development (ZonMw). She has supervised 14 PhD students in the past, and is currently supervisor of 12 PhD students. Additionally, she (co-)authored over 140 peer reviewed journal articles.

Dr Aggie T.G. Paulus (female), Associate Professor in Health Economics, Chair of Program Committee Health, Program Director Master Healthcare Policy, Innovation and Management (Maastricht University – Faculty of Health, Medicine and Life Sciences). Since 1990, Dr Paulus has gained ample experience in conducting research and acting as a co-promotor and/or supervisor of PhD students, researchers and postdocs. She has an interest and has been involved in various multidisciplinary researches, combining health economics with other disciplines, including policy and organisational sciences. Besides an interest in multidisciplinary and qualitative research, Dr Paulus is also interested in more fundamental, theory driven, research. She (co-)authored over 170 publications, including scientific articles, reports, book chapters and books. Her academic focus is particularly on inter-sectoral
costs and benefits of interventions in health care, the broader economic impacts of interventions and policy measures in health care, intra-organisational care arrangements, health care reform and innovations in health care.

### Relevant publications, and/or products, services


### Relevant previous projects or activities

1. Paulus ATG. **Identifying and Valuing Intersectoral Cost and Benefits**. Grant: 200400010 from the Dutch Organisation for Health Research and Development (ZonMw).
2. The **INFORMEH (an INstrument FOR outcome Measurement in Economic evaluations of Health promotion)** project. Grant number: 200400007 from the Netherlands Organization for Health Research and Development (ZonMw).
3. Dirksen CD, Evers SMAA. Broad Consultation as Part of the **Standardization of Economic Evaluation Research in the Youth Sector**. Maastricht University, funded by Dutch Organisation for Health Research and Development (ZonMw). 2016.
4. EC FP7 project **EQUIPT** (Grant no. 602270): ‘protocol of a comparative effectiveness research study evaluating cross-context transferability of economic evidence on tobacco control’.

### Significant infrastructure and/or any major items of technical equipment

**UM website**: The UM has compiled a freely downloadable handbook on the *valuation of intersectoral costs and benefits*. It provides cost prices for the intersectoral costs and benefits for the Netherlands with a special focus on education and criminal justice. The report which included standard cost prices is available for free download at [https://hsr.mumc.maastrichtuniversity.nl/node/13155](https://hsr.mumc.maastrichtuniversity.nl/node/13155).

The UM has set several standards for *systematic reviews of economic evaluation*, besides an series of articles on how to do a systematic review for economic evaluation, the UM has set the standard (according to the Cochrane) for quality assessment in economic evaluation, called the Consensus Health Economic Criteria (CHEC) list, information about how to perform a systematic reviews and the CHEC is available at [https://hsr.mumc.maastrichtuniversity.nl/consensus-health-economic-criteria-chec-list](https://hsr.mumc.maastrichtuniversity.nl/consensus-health-economic-criteria-chec-list).

Finally the Maastricht University has largely been involved in *economic evaluation in the field of mental health*, making secondary data analysis feasible.

<table>
<thead>
<tr>
<th>P5</th>
<th>Erasmus Universiteit Rotterdam (EUR)</th>
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**Description of the legal entity**

Erasmus University Rotterdam is a highly ranked, international research university, based in the dynamic and diverse city of Rotterdam. Founded in 1913, it is currently one the biggest universities of the Netherlands with a student population of 23,000 and a research community of circa 1,400. Scholars and students in seven faculties and two institutions work on global social challenges in the areas of health, wealth, governance and culture.
As part of a large global network of academic partnerships, a unique collaboration with city and port, the dynamic city of Rotterdam serves as our laboratory. The quality of research at Erasmus University is reflected in its consistent top-100 position in most major universities rankings. On the lively, modern campus, students and scholars of more than 100 nationalities are constantly encouraged to develop their talents and meet their ambition. The Institute of Health Policy and Management (iBMG) based at Erasmus University Rotterdam is leading in the fields of policy and organisational sciences with a focus on health care, health economics, medical technology assessment, social medical sciences, health law and health insurance. iBMG educates students for several jobs in health care varying from management functions in health care organisations to health insurance, consultancy and governmental jobs related to health care. The institute offers an initial bachelor programme, two master programmes and post academic education. The programme on economic evaluations of health care at (iBMG) has achieved a leading European position. iBMG is involved in ten EU-projects in the Horizon 2020 - research and innovation framework programme and was beneficiary in nine studies for the 7th research framework programme. Herewith, the iBMG has the largest number of EU-Projects at the Erasmus University Rotterdam.

Main tasks in the project
Main tasks in the project include i) lead on WP3 ii) co-lead on WP5. The profile of the legal identity matches these tasks insofar, as iBMG contributed to important methodological innovations for improved health economic evaluations, which resulted in influential methodology developments. iBMG offers expertise in economic evaluations, cost analysis, and outcomes research and is dedicated to the use of cost-effectiveness information in healthcare decision making. iBMG was at the forefront of developments in the societal perspective for economic evaluation in health, including the development of the friction cost-method for estimating productivity losses, the development of the cost-effectiveness acceptability curves, measurement of presenteeism, questionnaires for productivity costs and questionnaires to estimate costs of illness, measurement of caregiver costs and burden and the valuation of the EQ-5D-5L. iBMG developed a preference-based measure that focuses on benefits beyond health, by assessing well-being in adolescents. Recently, iBMG was involved in the update and replacement of guidelines for economic evaluation, outcomes research as well as the costing manual issued by the Dutch National Healthcare Institute (ZiN). This methodological knowledge dovetails seamlessly with the necessary experience and international knowledge to form a state-of-the art assessment of outcome measures and measuring and valuing the impact of health on employment (WP3).

Profile of staff members involved
Dr Leona Hakkaart-van Roijen (female), Associate Professor Health Economic and Economic Evaluations in Health Care. Dr Hakkaart was involved in the development of questionnaires to measure cost from a societal perspective, the iMTA Medical Cost Questionnaire (iMCQ), the iMTA Productivity Cost Questionnaire (iPCQ) and the inventory of Costs in Psychiatric Patients (TIC-P). Dr Hakkaart works closely together with a large number of national and international institutions. Recently, she supervised the update of the Dutch manual for costing studies in economic evaluations which is part of the new Dutch guidance for economic evaluations in healthcare of the National Health Institute (ZiN).

Frederique van Krugten MSc. (female). She is a highly talented and award winning PhD student (NIHES-award Erasmus Medical Centre) and recently started her PhD in development and validation of HTA instruments in Mental Health Care. She has large expertise in systematic literature reviews as well as in the development and validation of instruments in health economics. She has excellent writing and presentation skills in Dutch and English.

Relevant publications, and/or products, services

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**Relevant previous projects or activities**


2. Update and replacement of guidelines for economic evaluation (2015) commissioned by the Dutch National Health Care Institute (ZIN). These guidelines ensure the comparability and quality of such evaluations, which should facilitate making well informed policy decisions regarding reimbursement of interventions.

3. Development and validation of measurement instruments for productivity costs due to absence from work and efficiency loss at paid and unpaid work, e.g. the IMTA productivity Costs Questionnaire (iPCQ). It was designed to cover all domains of productivity losses, thus allowing quantification and valuation of all types of productivity losses. (https://www.bmg.eur.nl/english/imta/publications/questionnaires_manuals/)

4. EU H2020 project AEGLE: ‘An analytics framework for integrated and personalized healthcare services in Europe’. It will provide a framework for Big Data analytics for healthcare that will overall enable and promote innovation activities that place “health” at the spotlight. (http://www.aegle-uhealth.eu/en/about/the-aegle-approach.html)

5. EU H2020 project COMPARE: ‘Collaborative Management Platform for detection and Analyses of (Re-) emerging and foodborne outbreaks in Europe’. It establishes a multidisciplinary research network which aims at becoming the enabling analytical framework and globally linked data and information sharing platform for the rapid identification, containment and mitigation of emerging infectious diseases and foodborne outbreaks. (http://www.compare-europe.eu/Project-organisation/Work-packages/Workpackage-14).

**Significant infrastructure and/or any major items of technical equipment**

The Dutch costing manual (2016): The Dutch costing manual has set-up a website allowing for free download of the unit cost Online excel database, including user guides and user tracking. It provides reference unit costs for services in the Dutch health and social care sector and costs outside the health care and patients and family costs. It is available for free download at https://www.zorginstituutnederland.nl/.

The ‘Patient Reported Outcomes Measurement Information System’ (PROMIS) is a validated and reliable measurement system. It is a set of person-centred measures that evaluates and monitors physical, mental, and social health in adults and children (http://www.dutchflemishpromis.nl/).

### P6 Servicio Canario de la Salud (SESCS)

**Description of the legal entity**

Servicio Canario de la Salud (SESCS) is a regional governmental organisation responsible for the provision of public health services and promoting, funding and managing research health activities on the Canary Islands (Spain). The HTA Unit of SCS (SESCS) is part of 1) the Spanish network of Health Technology Assessment (HTA) funded by the Spanish Ministry of Health to support national decision making (RedAETS); and 2) the European Network of HTA (EUnetHTA). SESC has been part of several national research networks funded by the Instituto de Salud Carlos III (ISCIII): the former Research Network on Telemedicine Based Services, the Health Services Research Network (Red IRySS), and the Biomedical Research Network on Epidemiology and Public Health (CIBERESP). Currently SESC leads the Scientific Committee of the Spanish Network in Health Services Research for Chronic Diseases (REDISSEC). At international level, SESC has participated (P) or coordinated (C) several research projects and Joint Actions funded by the EC, such as BURQOL-RD (C), IC-Health (C), EUnetHTA I-III (P), EUROPLAN (P), ASDEU (P), EMPATHIE (P), RARE BestPractices (P), Mastermind (P) or CHRODIS (P). SESC has developed an intense research activity in cost of illness and cost-effectiveness studies of health interventions, usually linked to the assessment of health related quality of life. The SESC research team is multidisciplinary (medical doctors, health economists, statisticians, sociologists, psychologists, anthropologists, engineers, etc.) with experience in HTA.
methods, from quantitative to qualitative, such as systematic reviews, meta-analysis, budget impact analysis and economic evaluations. Besides, the group has scientific experience on methods to promote patients participation on scientific activities and HTA.

**Main tasks in the project**

Main tasks in the project include i) lead on WP6. SESCS is committed to the validation of methods and tools previously developed in WP1, WP2, WP3, WP4 and WP5 of the PECUNIA project, testing their cross-country transferability as well as testing their validity within health sectors not related to mental health and in the framework of an HTA project.

**Profile of staff members involved**

**Dr Pedro Serrano-Aguilar** (MD, PhD, MPH) (male), Head of the Health Technology Assessment (HTA) Unit at the Canary Islands (SESCS) and President of the board of Directors of the Spanish Network for HTA (Ministry of Health). He is also part of the EUnetHTA Joint Action-III. He was coordinator of the scientific program on Health Services Research in CIBER of Epidemiology and Public Health research network. Currently, he is leading the Scientific Committee and its own research team at REDISSEC (Spanish Network of Health Services Research for Chronic Diseases). At International level, Dr Serrano-Aguilar participated in several research projects funded by the EC, such as EUnetHTA, EUROPLAN, BURQOL-RD, RARE BestPractices. Apart from his administrative responsibilities, he has published more than 100 scientific papers in international journals (EMBASE). He has been member of the E-Rare JTC Scientific Evaluation Committee from 2011-2014, of the COST calls from 2013-2014, and of the Romanian Executive Agency for Higher Education, Research, Development and Innovation (UEFISCDI) since 2014.

**Dr Laura Vallejo-Torres** (BSc, MSc, PhD) (female) has a PhD in Health Economics from University College London (UCL) and a MSc in Health Economics from the University of York. She has worked at the Health Economics Research Group at Brunel University, as senior health economist at UCL and as senior researcher at University of la Laguna within the EU-funded project IMBRAIN. She is currently employed at SESCS leading research on methodological issues around economic evaluation and conducting health technology assessment reports. She also holds a part-time position at UCL. She has published more than 25 publications in peer-reviewed international journals. She is vice-president of the Spanish Association of Health Economics.

**Lidia García-Pérez** (BSc, MSc) (female), health economist with 13 years of experience in health services research and HTA at SCS. She has conducted several projects that included economic evaluation, systematic review of effectiveness, systematic review of cost-effectiveness and primary studies (observational and experimental studies).

**Dr Lilisbeth Perestelo-Pérez** (MPsych, PhD) (female), leading investigator in the development, evaluation and implementation of decision support interventions for shared decision making in Spain. With a PhD in Clinical and Health Psychology awarded in 2007, she completed postdoctoral fellowship at the Knowledge and Evaluation Research Unit (Mayo Clinic) (2008-2009) and at Health Decision Sciences Center (Massachusetts General Hospital) (2015) on shared decision making. She works at SESCS, collaborating with others Agencies for Health Technologies Assessment in Spain. She is also member of REDISSEC in Spain and a co-founder of the Latin American Network for Medical SDM and Patients’ Participation.

**Renata Linertová** (female), senior researcher in the field of HTA. She is specialises in systematic reviews and economic evaluations and she has a recent experience as a project manager of the European project BURQOL-RD.

**Relevant publications, and/or products, services**


**Relevant previous projects or activities**

1. **EUnetHTA Project** funded by European Commission from 2006-2008 (2005110), and EUnetHTA Joint Action 2 from 2012-2015. Currently SCS is a partner in the EUnetHTA Joint Action 3. Both, the project and the Joint Actions are setting standards to improve the quality and the efficiency of the HTA process in the European Union. [http://www.eunethta.eu/](http://www.eunethta.eu/)


3. **ICT PSP project MasterMind** (CIP-ICT-PSP-2013-7-621000): ‘MAnagement of mental health diSorders Through advancEd technology and seRvices – telehealth for the MIND’, 2014-2017. The objective of this project is to make high quality treatment for depression more widely available for adults suffering from the illness by the use of ICT (computerised Cognitive Behavioural Therapy). SESC is a subcontractor of partner with tasks related to qualitative assessment and estimation of costs. [https://mastermind-project.eu/](https://mastermind-project.eu/)


5. Valuation and modelling of EQ-5D-5L health states for the Spanish population using a hybrid approach (DOI: 10.1097/MLR.0000000000000283): 1st Pilot assessment commissioned by the Spanish Ministry of Health to support Health Policy Decisions (report SESC 2010/05) [https://goo.gl/Qjd8eW](https://goo.gl/Qjd8eW); 2nd Project supported by the EuroQol Group.

**Significant infrastructure and/or any major items of technical equipment**

SCS has access to expert documentalists, as part of its own research team, to most biomedical bibliographic resources usually needed for Health Technology Assessment reports, and to specific software for cost-effectiveness analysis based on modelling (TreeAge Pro Health 2013, Stata MP 2012, Microsoft Office Access 2013). SCS developed the BURQOL-meter, an automated tool to measure the socio-economic and health related quality of life impact of chronic diseases on patients and their caregivers. The BURQOL-meter was validated among patients (adults and children) with ten different rare diseases in eight European Union countries, along the BURQOL-RD project. The BURQOL-meter integrates the EQ-5D-5L with a questionnaire designed to measure resource utilisation from a societal perspective.
development of Main Type of Care and Basic and related methodology; REFINEMENT Project: development of a toolkit that includes service mapping with MTC and BSIC (REMAST), financing systems (FINCENTO), pathways of care (REPATO) and quality of care (REQUALIT) will be used for the development of units of analysis for resources utilization and interventions.

Profile of staff members involved

Dr Luis Salvador-Carulla (PhD) (male), honorary president and active member of Psicost. He is an expert on service research in disability and mental health and he has been a consultant on several projects to the World Health Organisation. He is currently professor of Disability and Mental Health (MH) in the Faculty of Health Sciences of the University of Sydney, where his major role is to develop connections between MH research and policy within Europe. In 2016 he moved to a part-time position to facilitate his role in Psicost and the collaboration in EC projects. He has a career total of over 200 scientific publications on MH care, conceptual frameworks and decision support tools for evidence-informed planning, and has been the leader of several national and international research projects. He was coordinator of the international project eDESDE-LTC project (eHealth Project No. 2007116) funded by the Executive Agency for Health and Consumers (EAHC). Besides, he was principal researcher of the Psicost partner in the REFINEMENT project (7FP Project No. 261459) funded by the 7th Framework Program of the European Commission.

Prof. Juan Cabasés (male), PhD in Economics, University of the Basque Country, Professor of Applied Economics at the Public University of Navarra, working in Public Sector Economics and Health Economics. He is the Director of the Health Economics research group at the Public University of Navarra, very active in research projects at national and international levels, doctoral theses and in the participation and organisation of national and international conferences. He has multiple publications in Health Economics in books and scientific journals on Economic Evaluation of Health Care Technology, Regional Health Care Financing, Mental Health, and Equity. Prof Cabases is also referee of scientific journals and research projects.

Prof. Carlos R. García-Alonso (PhD) (male), Professor of Operational Research and Quantitative Methods. He holds a Ph.D in Engineering. He focuses his research on mental health problems and models of simulation related with efficiency. He has supervised researchers in several Spanish funded projects, and participated as a researcher in different European funded projects.

Dr Mencía R. Gutierrez-Colosia (PhD) (female), psychologist. She is an expert in the DESDE-LTC and on mental health services research. As a member of Psicost, she has participated in European and national funded projects focusing on the evaluation of services and financing systems.

Dr Cristina Romero, PhD in Psychology (female). President of Psicost. Expert on service evaluation research in disability and mental health. Specialist in clinical psychology.

Dr Juan Luis González-Caballero, PhD in Mathematics (male). His main research interests are in biostatistics, in methods of multivariate analysis (in particular on those related to the classification and dimension reduction), in generalised linear models, and in multilevel models to explain the relationships between variables within populations.

Dr Eduardo Sánchez-Iriso (male), PhD in Economics from the Public University of Navarra. His main research focus is on economic evaluation of health technologies as well as measures of health related quality of life (QALY).

Relevant publications, and/or products, services

Relevant previous projects or activities

1. EC FP7 project REFINEMENT: ‘RE-search on FIN-ancing systems’ E- ffect on the Quality of MENT-al health care’, 2011-2013. Financing systems’ effects on the Quality of Mental health care in Europe. Brief description: Made international comparisons across the European Union on mental health financing systems and the outcomes of mental health care services. Psicost was a member of the consortium.


Significant infrastructure and/or any major items of technical equipment

In order to develop their tasks for this project, the team at Psicost is going to use different computer programs, such as SPSS, ARCGIS, STATA. They are also going to create a specific data base.

They are also going to employ the DESDE-LTC (Description and Evaluation of Services and Directories for Long Term Care): it is an open-access international tool coordinated by PSICOST that provides detailed descriptions of the coding and characteristics of services from all relevant sectors (health, social, education, employment, housing and justice), including their utilisation and staffing. DESDE-LTC is the extended version of the European service mapping schedule (ESMS-I) for the assessment of services in adult mental health care. It uses a tree system for the classification of services in a defined catchment area according to the main care structure/activity offered as well as their level of availability (section B) and utilization (section C). To ensure reliable comparisons across areas, it identifies the minimal unit of care with organisational and temporal stability (BSIC, basic stable input of care) that is coded using its main activity or typology of care (MTC Main Type of Care). PSICOST has also produced benchmarking and efficiency analysis tools that are currently being used for health planning in the Basque Country and Catalonia (Spain).
substantial impact on UK and international policy discussion. In 2009 LSE Health and Social Care (of which PSSRU at LSE is a substantial part) was awarded a Queen’s Anniversary Prize for Higher and Further Education for ‘applying research to the advancement of global health and social care policy’. PSSRU has particular expertise in economic evaluations in social care and mental health (and increasingly also in other public health and healthcare areas). A lot of research has been undertaken since 2009 on the cost-effectiveness of care and support services (such as telecare and telehealth, coping strategies for family carers of people with dementia, befriending), funding arrangements (such as personal budgets, and broader financing options for social care), organisational arrangements (such as community navigators) and preventive strategies (such as for child neglect and abuse, for falls, for loneliness, and for social care needs in old age). A significant body of research has been undertaken on unpaid care, most recently focusing on employment and the economic costs of replacement care. PSSRU research has provided evidence to underpin developments in policy and practice discussions, feeding into Government Green and White Papers, Parliamentary debates, evidence and advice to Parliamentary Select Committees and – internationally – to the OECD, World Health Organisation (WHO), and various international government bodies. PSSRU also hosts the International Long-term Care Policy Network which aims to promote the global exchange of evidence and knowledge on long-term care policy.

Main tasks in the project
LSEs main tasks include i) co-lead on WP4, and ii) provision of county-specific support to all relevant WPs. WP4 will develop internationally standardised methods and tools to allow the consistent measurement of resource use of informal care giving activities. This will facilitate multinational comparative analyses for costs and economic evaluations across the countries identified in the proposal. Specifically this will include identification of services and resources required, and measurement and validation of harmonised approaches. PSSRU’s expertise in the development of measurements includes development of the CSRI (Client Services Receipt Inventory) resource use schedule by Jennifer Beecham and Martin Knapp, which has been used in over 500 evaluations across the world, and a number of toolkits and accompanying guidance to provide costing mechanisms to support commissioners to allocate resources more cost-effectively. PSSRU’s expertise in economic evaluations and modelling, as well as research on unpaid careers, will be applied to the proposed project.

Profile of staff members involved
A-La Park (female), Assistant Professorial Research Fellow within the Personal Social Services Research Unit at the LSE. Her work focuses on the economics of mental health and well-being promotion across the life-course, as well as wider research to make the economic case beyond health sector from a societal perspective. She focuses in particular on systematic reviewing and decision analytical modelling at the national and international levels. She has worked on European Commission-funded studies on mental health research in Europe, suicide prevention interventions, promoting health of residents in psychiatric and social care institutions, the economic case for promotion of mental health and prevention of mental disorders, and strategies and best practices for the reduction of injuries. Her current work includes economic evaluations and modelling on studies looking at dementia and autism. She has worked as an external consultant for the WHO, the OECD and the EC.

Relevant publications, and/or products, services
2. Inter-sectoral issues in financing mechanisms at international levels, e.g. McDaid, D, Park, A (2016). Financing and budgeting mechanisms to support the inter-sectoral actions to promote health. *The World Health Organization (WHO) regional office for Europe*.


Relevant previous projects or activities
5. EC, DG Health and Consumers, European network for promoting health of residents in psychiatric and social care institutions, 2008-2011.

Significant infrastructure and/or any major items of technical equipment
The project will benefit from wider PSSRU resources, including office space, equipment and IT support, and PSSRU’s expertise in, and resources for, knowledge exchange and impact activities. Senior PSSRU researchers have links to a number of funded projects that have particular relevance to this proposal. Wider significant infrastructure at the LSE includes the Library, known as the British Library of Political and Economic Science, one of the largest libraries in the world devoted to the economic and social sciences. LSE colleagues are fully experienced in supporting EU research grants.

P9 University of Bristol (UnivBris)

Description of the legal entity
The University of Bristol is a Russell Group University and one of the most prestigious universities in the UK. It is a thriving international community combining excellence in research and innovation with a vibrant entrepreneurial culture. Research is at the heart of the University’s mission and accounts for its international reputation. The University organises its academic affairs across six faculties: Engineering, Science, Biomedical Sciences, Health Sciences, Social Sciences and Law, and Arts. In the 2014 UK Research Excellence Framework (REF2014) confirms its position in the top ten UK research universities, measured by both research output and research impact. Over 33% of the University’s research was judged to be ‘world leading’, and over 80% of publications were judged to be ‘internationally excellent’. The university was placed in the top five institutions for research impact in ten areas. In 2009-10 the University was allocated the 8th highest share of government research funding in the UK. The University participates in hundreds of international collaborations both within and outside of Europe, including 286 projects under the last framework programme, FP7, and measured by the share of funding to date is ranked in the top 20 participating institutions within the EU under Horizon 2020. REF2014 also confirmed the School of Social and Community Medicine’s position as a leading centre for research in population health sciences in the UK and internationally. Fifty per cent of our research was rated as 4* (world leading), and 86% as 4* or 3* (world leading or internationally excellent). 100% of our research impact case studies were rated as world-leading, as was 100% of our research environment.

Main tasks in the project
Our main tasks within the project will be to support specific methodological aspects of the proposal across WPs1-4 along the HA3 axis. In particular, we will contribute to the measurement of services and resources task in WP2, (Task 2.3), drawing on our extensive experience in the area of costing methodology research. The profile of the legal entity closely matches these tasks as follows. The School of Social and Community Medicine (SSCM) has excellent facilities for the conduct of world class research, providing the relevant resources and training opportunities to allow the tasks to be carried out effectively. Centres hosted within SSCM also provide access to a wide range of methodological expertise on which we can draw, including the ConDuCT-II Hub (one of five Medical
Research Council (MRC) Hubs for Trials Methodology Research), and the National Institute for Health Research (NIHR) Schools of Public Health Research and of Primary Care Research. The Health Economics at the University of Bristol (HEB) group is a dynamic, supportive and rapidly expanding group numbering around 20 researchers with expertise including costing methodology and qualitative research.

Profile of staff members involved

Prof. William Hollingworth (male), Professor of Health Economics. Prof. Hollingworth leads the Health Economics at the University of Bristol (HEB) group, and is deputy director of the MRC Network of Hubs for Trials Methodology Research ConDuCT-II Hub. He has extensive experience of conducting economic evaluations alongside clinical trials, particularly in the areas of diagnostic testing. He has been a co-applicant on numerous successful clinical trial funding bids (e.g. RAFT, MIR, CEDAR, NHS FITNET), and a partner and WP lead on the EU H2020 project ULTRADIAN.

Dr Sian Noble (female), Senior Lecturer in Health Economics. Dr Noble is chair of the MRC Health Economic Resource Use and Costs Working Group. She has extensive experience of economic evaluation alongside clinical trials, particularly in the areas of orthopaedics and urology. She has been a co-applicant on numerous successful clinical trial funding bids (e.g. ProtecT, CAP, UNBLOCS, UPSTREAM, APEX, INFORM, STAR).

Dr Joanna Thorn (female), Senior Research Associate in Health Economics. Dr Thorn has a master’s degree in Health Economics and Health Policy. Her research focuses on improving the methods by which we collect resource-use data from patients in randomised controlled trials and on improving costing methodology in general. She has been a co-applicant and lead applicant on a number of MRC methodology funding bids, and has experience of working on applied economic evaluations (e.g. 3D, RAFT, CAP).

All three staff members contributed to the creation of DIRUM (the Database of Instruments for Resource-Use Measurement), an initiative that has been well used by health economists.

Relevant publications, and/or products, services


Relevant previous projects or activities

1. MRC Network of Hubs for Trials Methodology Research (N57): ‘Identification of items for inclusion in a standardised resource-use measure (ISRUM)’, 2015-2016: Delphi methodology was used in the project to gain a consensus view on the key items of resource use that should be measured in an economic evaluation; a comprehensive review of existing instruments generated the initial list of potentially suitable resource-use items.

2. MRC Network of Hubs for Trials Methodology Research (R38): ‘Creating guidance for the costing methodology
with clinical trials’, 2013-2014: The project was set up to explore current practice in costing methodology through a workshop involving practising health economists.

3. MRC Network of Hubs for Trials Methodology Research (R5): ‘Development of a central repository of resource-use data collection instruments for trial-based health economic evaluations’, 2011–2012: A freely accessible database of data collection instruments (DIRUM) was designed, developed and populated with relevant instruments. Instruments are added on an ongoing basis.

4. MRC (MR/K025643/1): ‘Collaboration and innovation in Difficult and Complex randomised controlled Trials Invasive procedures (ConDuCT-II) Hub’, 2014-2019: One of five Hubs, ConDuCT-II carries out a wide range of health economic methodological research within the ‘Prioritisation and design of trials for cost effectiveness analysis’ theme; researchers benefit from the interdisciplinary expertise available. The ConDuCT-II Hub is a continuation of the ConDuCT Hub, one of the eight original Hubs.


Significant infrastructure and/or any major items of technical equipment

Database of Instruments for Resource-Use Measurement (DIRUM): Funded by the Medical Research Council Network of Hubs for Trial Methodology Research, DIRUM is an open-access expanding database of resource-use questionnaires and other instruments. Instruments are freely available for use by health economists in trial-based economic evaluations (subject to permissions set by authors) and for methodological research purposes. DIRUM also houses a repository of methodological papers related to resource use and cost measurement. It is accessible via www.dirum.org.

P10 EURICE - European Research and Project Office GmbH (EURICE)

Description of the legal entity

Founded in 2000, European Research and Project Office GmbH (EURICE) provides comprehensive support services for the planning, initiation, and implementation of international collaborative research and innovation projects. EURICE ranks among Europe’s largest project management offices, with a dedicated team of >40 staff members with different professional and scientific background and expertise, such as law, medicine, biology, chemistry, communications, social and computer sciences. **Within Horizon 2020, EURICE has been successfully involved in the coordination of 21 collaborative projects** – among them coordination & support actions (Fit for Health), and health projects focusing on new and innovative therapies for chronic diseases. Our portfolio also comprises related funding programmes, e.g. the ‘European and Developing Countries Clinical Trials Partnership’ (EDCTP) programme or public-private partnership initiatives, like the ‘Innovative Medicines Initiative’ (IMI). Our portfolio ranks from collaborative projects in the field of experimental research (TRL 2-4) up to demonstration and technology validation projects in an operational environment (TRL 5-8). According to the most recent Horizon 2020 monitoring report published in 2016, EURICE belongs to the **Top 3 of SMEs in Europe** regarding the number of signed Horizon 2020 agreements.

Consortium partners benefit from our extensive expertise gathered from more than 100 project co-ordinations in EU Funding Programmes and profit of our mature Project Management Office infrastructure. We offer backbone services for a successful project management approach by providing fair, transparent and neutral decision support information. EURICE is specialised in managing impact and innovation in all areas of research and innovation projects. We offer expert knowledge to brief EC staff, evaluators and proposers how to maximise the impact and exploitation of research outcomes. In order to pave the route for successful project exploitation, we support consortia in identifying, capturing, protecting and nurturing the Intellectual Property (IP) generated in research collaborations. Thus, EURICE accompanies researchers and innovative companies through the entire life cycle of a project – from the first idea to successful project implementation – and beyond.

We developed specific training modules (on-site, webinars, audio-visual) for successful innovation and project management in collaborative Horizon 2020 research and innovation projects. We welcomed over 4,000 users (Researchers, SMEs, EC project monitoring staff, Reviewers) in our extensive training programme in 2016 alone.

Furthermore, EURICE provides expert knowledge to several ‘Innovation Support Actions’ aiming at maximising values of Horizon 2020 and focusing on the exploitation of Horizon 2020 results:
- European IPR Helpdesk which provides hands-on assistance in the field of IP & innovation management for researchers and SMEs involved in Horizon 2020;
- **Fit for Health 2.0** which aims at maximising impact of health-related projects in Horizon 2020;
- **Inno-Coaching** which offers **high-level innovation audits** for European SMEs;
- **IP4Business**, which offers training for EU SMEs in the field of IP diagnostics and commercialisation of innovative ideas (bilateral co-operation with the European Patent Office);
- **Common Exploitation Booster**, which supports Horizon 2020 consortia to develop exploitation strategies and analyse related risks and opportunities;
- **Innovation Radar**, which focuses on the identification of high potential innovations and the key innovators in Horizon 2020 projects.

### Main tasks in the project

**Grants and Project Management:**
EURICE will support the coordinator in all aspects of project management, including administrative, legal and financial matters, to ensure a smooth project implementation. As key partner of WP7 EURICE will assist the coordinator in project- and progress monitoring, risk mitigation, and decision making. EURICE will facilitate the project workflow, stimulate interaction between the different project management bodies, and together with the coordinator, assume the role of a liaison between the project consortium and the European Commission.

**Innovation-related activities:**
In WP8, together with the coordinator, EURICE will ensure the synthesis of the results from WPs1-6, and support innovation-related activities such as dissemination and exploitation of results, to maximise project impact. EURICE will provide advice concerning Horizon 2020-specific rules and regulations regarding Intellectual Property Rights (IPR)-issues to all partners throughout the project. Tailored to the different phases and specific needs of PECUNIA, EURICE offers **structured innovation support through well-defined measures**, such as Exploitation Strategy Workshops, innovation questionnaires, lean Canvas-Method of Exploitation Planning and/or IP portfolio management tools.

**Communication:**
Together with all partners, EURICE will ensure coherent external communication of the project and its results towards relevant target groups. In addition, EURICE will support all partners in networking activities and in questions concerning stakeholder and media relations throughout the project.

### Profile of staff members involved

**Jörg Scherer** (male), Managing Director. He has been working as a licensed innovation manager and business advisor in both the academic and industrial sector for over 20 years. He has an outstanding track record of participation/coordination in over sixty European research and innovation projects, spanning FP4-Horizon 2020. He acts as a senior innovation management expert for different EC units, Executive Agencies and EU business associations. In 2016, he provided over 50 lectures and training sessions in the field of IP management and exploitation strategies in Horizon 2020.

**Dr Ina Filla** (female), Project Manager. Dr Filla has experience with EU-funded research projects since 2015 including formal, contractual, managerial and organisational aspects, as well as dissemination and exploitation of project outcomes. Her project portfolio is particularly focusing on Life Sciences projects.

**Dr Vera Schneider** (female), Senior Research & Innovation Manager. Vera has been working in international collaborative projects since 2003 and has built up an extensive track record in the successful management of life science, health and biotech projects. Additionally, she provides training sessions and workshops on knowledge transfer and innovation management and has been serving as a project evaluator to the European Commission. She has a strong personal interest in clinical trials, ethical and regulatory issues as well as the innovation potential and value-chain of medical products.

**Lisa Heinemann** (female), Project Officer. Her professional expertise is in the administrative management of EU-funded research projects, including day-to-day management and coordination of project activities, contractual and financial management, decision making management, communication & reporting.

**Stephanie Weber** (female), M.A., Communication Manager/Head of Communication. She has experience with strategic communication management in EU-funded projects since 2011 incl. development of communication strategies, stakeholder & media relations, planning & implementation of events, conception of marketing materials.
Relevant EURICE services and publications
1. Strategic and operational Project Management and Project Administration services.
2. Communication & dissemination activities, including Open Access strategies.
3. Training Modules: “Maximising impact of Horizon 2020 projects” & “IP and Innovation Management in Horizon 2020”.
5. Publications, such as “Creating values: IP exploitation in Horizon 2020”; Jörg Scherer; published by the European Technology Platform for Water, September 2014.

Relevant previous projects or activities
1. EU FP7 project Fit for Health 2.0 (FP7-HEALTH-2013-INNOVATION-1 -602428): Supporting sustainable participation of industry, in particular hightechnology, research-intensive SMEs in EU-funded research in the Health Sector
2. EU H2020 project CARAT (H2020/PHC-16-2015 -667980): Chimeric Antigen Receptors (CARs) for Advanced Therapies
5. EC-H2020 (INNOSUP): European IPR Helpdesk. 2011-2018

Significant infrastructure and/or any major items of technical equipment
EURICE - based in Saarbrücken, Berlin and Brussels - offers full professional Project Management Office (PMO) services for research networks and collaborative research and innovation projects on national and particularly international level. The highly qualified team provides a comprehensive set of expertise, tools and experiences in grants management (including legal and financial affairs), project management (strategic & operational), communication, exploitation management and training activities (online/onsite) - which are crucial for the smooth and successful management of PECUNIA.

4.2. Third parties involved in the project (including use of third party resources)

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P1-MUW
Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)

YES

Oxford University Innovation will be sub-contracted to do the translatability assessment including an exclusive proprietary service called QuesTReview which shall ease the burden of any further piloting/validation procedures substantially (saving time and costs) of the initial draft of the multi-sectoral RUM instrument (WP1, HA3). Oxford University Innovation is a subsidiary of the University of Oxford providing a wide range of academic consultancy and services, including e.g. the coordination of PROM translation processes in a very competitive and highly professional manner. They are the only provider of QuesTReview, hence no other provider could be commissioned.
to do the above package of services. The fact that the name of the subcontractor is indicated in Annex 1 does not imply the approval of the European Commission of the subcontract. If the subcontractor was not selected based on best-value-for-money (in compliance with Article 13 of the Grant Agreement), the Commission may reject the costs even if its name was indicated in Annex 1. Foreseen amount to be subcontracted in WP7/Task 7.6: EUR 9,000.

<table>
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<th>Question</th>
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<tbody>
<tr>
<td>Does the participant envisage that part of its work is performed by linked third parties</td>
<td>NO</td>
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<tr>
<td>Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)</td>
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**PS-EUR**

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<tr>
<td>Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)</td>
<td>YES</td>
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The EuroQol Group will support WP5 in-kind free of charge with statistical expertise and all existing European EQ-5D data gathered previously for national value set developments. The EuroQol Group comprises a network of international, multilingual, multi-disciplinary researchers, with currently more than 75 members worldwide. Their aim is to improve decisions about health and health care throughout the world by developing, promoting and supporting the use of instruments (e.g. EQ-5D) with the widest possible applicability for the measurement and valuation of health.

**P6-SESCS**

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<td>Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)</td>
<td>YES</td>
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**FUNCANIS** is a public foundation, established by the Government of the Canary Islands, for the financial and administrative management of most research operations of its Public Health Service (Servicio Canario de la Salud, SCS). SESCS is the Evaluation and Planning Unit of the SCS. The aim of FUNCANIS is to promote and support research in the field of health sciences in order to contribute to disease prevention, health promotion and protection on the Canary Islands. FUNCANIS is responsible for the financial and administrative management of any research and innovation activities, including European and national projects, of SCS. FUNCANIS is funded by SCS and its board is mainly composed by Canarian Public Health Service’s executives. One of its aims, stated in the foundational rules, is “to manage the research, funded through private or public resources, to be led by researchers of the SCS and performed in its premises.”

FUNCANIS will provide in-kind contributions free of charge (after art. 12 of the AMGA) to handle the administrative/financial tasks of the beneficiary, including issues related to employment and payment of new personnel, payment of travel expenses, purchase of equipment, consumables, etc. Administrative and financial management will be at all times under the technical direction of the beneficiary.
5. Ethics and Security

5.1 Ethics

The PECUNIA project will adhere to all relevant legislation relating to ethics and security coming from the separate countries, as well as the ethical standards and guidelines from Europe, such as the Charter of Fundamental Rights of the European Union. These rules will be strictly applied in each country, and in each setting. Looking at the ethical issues table the PECUNIA project does not involve any research with Human Embryos/Foetuses, Human Cells/Tissues, Personal data, Animals, Third countries, Environment & Health and Safety, and Dual Use.

The PECUNIA project will only involve research with human adult volunteers through focus group discussions, and will not include patients. The data collection will not interfere with any treatment or intervention. The data collection will relate to one single measurement where participants have to complete a generic, multi-sectoral RUM instrument (WP7). All other data used in PECUNIA project are either publicly available or are secondary, anonymised data relating to the EuroQol Group.

It goes without saying that the PECUNIA study will be conducted, if applicable in compliance with applicable regulatory requirements (REGULATION (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC) and in accordance with the international ethical principles of the Declaration of Helsinki.

The data coming from the human adult volunteers will be unidentifiable to a natural person (according to Article 2(a) of EU Directive 95/46/EC). For the recruitment process we will use an open population which we will include by leaflets and advertisements, next to that a convenience sample (students and colleagues) will be included if applicable. The inclusion criteria will be adults of 18 years and over, exclusion criteria will be not native speaker of the given language, or not able to give informed consent. For this part we will apply, if needed, for any ethical approval for each country, where data collection is done. Even if ethical approval is not needed we will apply an informed consent procedure according to the national and international standards (e.g. World Health Organisation standards (www.who.int/rpc/research_ethics/informed_consent/en/). The PECUNIA Informed Consent Form, and detailed Information Sheet provided to the participants, will be in the relevant languages and in terms understandable to the participants. Aims, methods and implications of the PECUNIA research, the nature of the participation and any benefits, risks or discomfort that might be involved, are described. It is explicitly stated that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation or data at any time — without any consequences. It is indicated how the data will be collected, protected during the project and either destroyed or reused subsequently. We will ensure that the potential participant has fully understood the information and does not feel pressured or forced to give consent. Consent will be given in writing (e.g. by signing the ‘informed consent form’ and ‘information sheets’). If the consent cannot be given in writing, for example because of illiteracy, the non-written consent will be formally documented and independently witnessed.

We will prospectively provide the European Commission with a detailed description of the informed consent procedures. Any copies of approvals coming from ethical and legal bodies, templates of informed consent forms, and approvals for the authorisation to use the EuroQol data, will be provided upon request.

Data storage and data management will be done according to the (inter)national standards and if possible the data storage and management will be done conjointly with the appropriate local data protection agencies (EU Directive 95/46/EC and country-specific regulations) All data will be stored in routine data files. Both quantitative and qualitative will be collected and stored anonymously. At the end of the project PECUNIA data and

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documentation will be archived centrally at the Medical University of Vienna in accordance with Austrian regulations. We will store data for 20 years. All data will be treated anonymously and stored in safe digital environments. During, and after the study neither confidential, nor privacy sensitive information will be archived.

5.2 Security

The PECUNIA project will not conduct any activities or produce results raising security issues, and will not use 'EU-classified information' as background or results.

- activities or results raising security issues: (NO)
- 'EU-classified information' as background or results: (NO)
Letters of Commitment
PECUNIA: Letter of Commitment

Dear Professor Simon, Dear Judit

I would be honoured and delighted to be a Scientific Advisor to the PECUNIA team.

As you know, I have worked for many years in research, teaching and policy advice in the mental health field, particularly using economics evidence and methods. In particular, I have been Director of a large research centre at the LSE for more than 20 years, and was also Director of the Centre for the Economics of Mental Health at King’s College London for 20 years. I would want to use that experience to support and advise the PECUNIA project if it is funded.

By developing standardised methods to explore the reasons for cost and outcome variation across a number of European countries, the PECUNIA project would greatly add to the evidence platform from which policy options can be discussed and practice developments can be built. For that reason, I think your proposed project holds enormous promise for the field.

Best wishes.

Professor Martin Knapp
Director of PSSRU

4 April 2017
Prof. Judit Simon  
Department of Health Economics/Center for Public Health  
Medical University of Vienna  
Kinderspitalgasse 15  
1090 Vienna  
Austria

PECUNIA: letter of commitment

Dear Prof. Simon,

I am writing this letter to express my commitment to the proposal titled *Programme in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluations.*

I am Professor of Health and Social Care Economics and Deputy Director at the PSSRU, University of Kent (www.pssru.ac.uk). Since 1974 PSSRU has undertaken high-quality, independent research in social and health care, which has had an important influence on theory, and policy development and reform in England and elsewhere. Our work is underpinned by the production of welfare framework and focuses on needs, resources and outcomes. We continue to work in the fields of adult and children's social and health care, including mental health, long-term care funding, cost and outcome measurement, and cost-effectiveness evaluation.

Within PSSRU I lead the well-established Unit Costs Programme and am responsible for the annual publication of the *Unit Costs of Health and Social Care* (www.pssru.ac.uk/project-pages/unit-costs/). Since 1993, these volumes have been the primary source of unit costs for both policy makers and academics; the volumes are cited in 68% of economic evaluations published in the UK between 2008 and 2015. Key to our Programme is the development of unit costs that are robust and theoretically sound. It is this basis in economic theory and the high level of well-respected expertise that will provide one set of supports for PECUNIA.

The second set of expertise comes from long-term experience in conducting economic evaluations, particularly in exploring interventions for people with mental health problems. This work includes development of the *Client Service Receipt Inventory*, a resource use schedule used in more than 600 economic evaluations across the world (www.pssru.ac.uk/blogs/csri/). I can provide in-depth knowledge of conducting economic evaluations in a wide range of circumstances.
Given the different service arrays and financing systems across European countries – set alongside the increasing need for health and social care, and constraints on budgets – aiming for standardisation and validation of methods and tools in economic evaluation across countries is an important step. This project aims to improve the ability of the research community to support health care decision-making, both within and between countries, by improving the quality of economic evaluations.

I heartily support this proposal.

Yours sincerely,

Jennifer Beecham
Professor of Health and Social Care Economics
PSSRU, University of Kent and London School of Economics, www.pssru.ac.uk
Senior Fellow, NIHR School for Social Care Research
http://www.pssru.ac.uk/publications-for-author.php?id=1
http://scholar.google.co.uk/citations?user=a-CnBTkAAAAJ&hl=en
Letter of Commitment to the PECUNIA proposal

Dear Prof. Simon,

The reason why I’m writing you this letter because I was referred to be an external advisor in the PECUNIA consortial Scientific Advisory Board.

I’m a professor of psychiatry and head of the Psychiatry Department of the University of Szeged. I have 32 years practice in the field of clinical psychiatry. During my clinical work I specialized in psychiatry, child and adolescent psychiatry, forensic psychiatry, clinical pharmacology, rehabilitation in psychiatry and health services management. Since my graduation I was continuously involved in psychiatry-related teaching activities of undergraduate and postgraduate students. In my more than 30 years of professional background I expertise in the clinical practice in the acute inpatient treatment of mood disorders, schizophrenia and other psychotic disorders and stress-related conditions. My special clinical interest is neurocognitive disorders, preclinical and clinical aspects of Alzheimer’s dementia and related disorders. I was the elected vice president in the Hungarian Psychiatric Association for two times and as the president of the former Hungarian Alzheimer’s Association I organized several national scientific meetings and in 2016 I was the local organizer and the local head of the scientific committee of the world congress of ADI (Alzheimer’s Disease International) 2016, Budapest.

Since 2014 when I was appointed to the head of the psychiatry department with 170 beds I had the possibility to introduce a novel nosological category-based in- and outpatient system in our department.

I have clinical and research experience in the development of psychiatric assessment scales and screening methods. In the last couple of years our research group is involved the development of screening tools for amnestic disorders (paper based and telemedicine).

As mental health disorders - depression, schizophrenia and post-traumatic stress disorder – will be used as illustrative disease in PECUNIA project, my clinical and research expertise might help in identification and classification of mental health services, development of resource use measurement tools and planning surveys in mental health diseases.

I think that the PECUNIA proposal would give an excellent opportunity for the contributing countries to learn more about the health economic issues in mood disorders, schizophrenia and PTSD, and therefore to provide novel data and approaches for the decision-makers in Europe.

This is a big honour for me to participate in the PECUNIA proposal.

Yours sincerely,

János Kálmán MD, PhD, DSC
Head of Department
University of Szeged, Department of Psychiatry

06. 03. 2017.
March 31st, 2017

Subject: Letter of Commitment (LoC) to participate as SAB-member in PECUNIA

Dear Prof. Simon,

In my role as Director of the Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA) supporting evidence-based decisions on resource allocation in the Austrian health care system I know how challenging it is to conduct value-analysis without detailed data on costs or validated costing methods. I feel honored to be asked to contribute as a member of the Scientific Advisory Board (SAB) to this highly relevant project (PECUNIA) seeking 1.) to understand the drives of cost variations, 2.) to improve the comparability, quality and transferability of health economic data, 3.) to promote harmonized cost evidence for core services and 4.) to support feasibility of measurement and valuation.

The specific contribution I can offer is to give advice on existing data-pools in Austria and to evaluate their validity as well as to support in decisions which data are of most relevance (needed) for HTA on innovative therapies be it drugs or (high-risk) interventions in hospitals. But the project PECUNIA is not only relevant for national decision-making in health care based on solid data and methods, but also for benchmarking and comparing across borders.

I sincerely express my support for the project and my commitment to contribute with my expertise on Austrian health policy decision-making.

Yours sincerely,

[Signature]

Priv. Doz. Dr. phil. Claudia Wild
Director LBI-HTA
Letter of Commitment

Dear Prof. Simon,

I am pleased to write you to express my commitment with PECUNIA’s project external board.

As AQuAS Director, my role is to lead and represent the health assessment agency of the Ministry of Health of Catalonia. AQuAS is the organisation in charge of yielding knowledge for Catalan Public Healthcare System from different perspectives. AQuAS’ expertise fields ranges from research and Innovation policies, HTA, health data analytics to system outcomes reporting.

As AQuAS’ representative, I can contribute to the project with a multidisciplinary approach to health-related policy evaluation and incorporating to the project the experience of the Catalan Healthcare System, a complex and innovative ecosystem that prioritises accountability, safety and efficiency within its performance.

PECUNIA fits perfectly into AQuAS aim of providing scientific evidence to the health system regarding the health outcomes and the cost to produce them.

Therefore, AQuAS fully supports PECUNIA and is completely engaged to the project in its role of member of the external board. As AQuAS’ Director, I will participate to the board activities when requested by the coordinator.

Yours sincerely,

Antoni Dedeu Baraldés
Director
Agency for Health Quality and Assessment of Catalonia – AQuAS
Dear Prof. Simon,

it is a pleasure for me to express my support for your project regarding the development of standardized and validated methods for health economic evaluations in Europe. In my opinion, the project is very important to improve the quality, comparability and transferability of health economic research in Europe. This is especially necessary, since we have in Europe different types of health care systems with different reimbursement structures on the one hand, but a growing standardization of legal frame conditions, for example regarding the approval of drugs or medical devices, one the other hand.

I’m working at the Federal Association of the AOK (AOK-Bundesverband), the political umbrella organization of the AOK system. The AOK system is the largest of Germany’s 113 statutory health insurance funds. Around 25 million people are insured under the 11 regional AOKs – close to a third of the German population. As assistant head of the medical department I’m familiar with the structure, the legal and economic frame conditions and the quality of Germany’s health care system. I advise the AOKs regarding development, implementation and evaluation of innovative health care models. Furthermore, I’m a member of the Federal Joint Committee (Gemeinsamer Bundesausschuss). The Federal Joint Committee is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany. It issues directives for the benefit catalogue of the statutory health insurance funds (GKV) and specifies which services in medical care are reimbursed by the GKV. I’m experienced in analyses based on routinely collected health data / secondary data. Together with the Scientific Institute of the AOK I’ve published several analyses about service utilization and costs of medical health care in Germany.
Besides, I'm a visiting scientist and lecturer for health care and health economics at the Institute of Social Medicine, Occupational Health and Public Health at the Medical Faculty, University of Leipzig.

With my expertise regarding the German health care system as well as health care and health economic research and analysis of secondary data I could contribute to the project as scientific advisor. Therefore, it would be a pleasure and honour for me to be one of the members of the scientific advisory board in the PECUNIA project.

Yours sincerely,

PD Dr. med. Christiane Roick, MPH
AOK-Bundesverband
Letter of commitment

Dear Prof. Simon,

I am delighted to accept you invitation to be part of the scientific advisory board of the PECUNIA project. I believe this is a project that may contribute to respond to some of the main challenges mental health systems reforms are currently confronted with worldwide. During the last two decades I have been closely involved in mental health policy development and research, both at the national and international levels.

In my country, Portugal, I was responsible for the coordination of the national mental health plan (2008-2016), which included a deep transformation of the mental health financing and governance models. As chief of the Mental Health Unit at the Pan American Health Organization, the Regional Office of WHO for the Americas (2000-2006), I was responsible for the technical cooperation provided to countries of the Americas in the implementation of mental health systems reform and coordinated a NIMH funded project to increase research capacity of Latin American countries in this field.

As coordinator of the EU Joint Action on Mental Health and Well-Being (2013-2016), I was specifically responsible for the work focused on the transition to integrated and socially inclusive community-based care for people with severe mental disorders, which included a study of the organization of mental health systems in Europe, with a special emphasis on understanding the ingredients that explain the best outcomes.

6 April 2017
My main current interests in research, at the Lisbon Institute of Global Mental Health and at the Nova Medical School, are in the areas of mental health systems and outcomes research, and I am specially interested in studies leading to innovative financing models that may contribute to overcome the barriers usually found in mental health systems reforms. I am also leading a consortium that has just submitted a proposal aiming at developing and implementing a standard MH care operational navigation chart (MChart toolbox), based on a multi-applicable framework, that allows navigation of local MH systems by consumers and health professionals across 6 European countries to optimise access to MH care in collaboration with public health agencies and other relevant stakeholders, and to assess its impact on implementation and MH care literacy in Europe.

Based on my experience and research I am firmly convinced that the new methods and tools PECUNIA aims to develop to better understand the factors that explain the variations in relevant costs and outcomes within and across countries, and to improve the quality, comparability and transferability of health economic evaluations in Europe, are very much needed worldwide. I believe that my expertise in mental health systems implementation, and in the development of innovative financing models of mental health services, may contribute to the success of the project.

For all these reasons, I would like to express my entire support for the PECUNIA project and to reiterate my interest in working with the PECUNIA consortium as member of the advisory board.

Yours sincerely,

José Miguel Caldas de Almeida, MD, PhD
President, Lisbon Institute of Global Mental Health
Prof. Judit Simon  
Department of Health Economics/Center for Public Health,  
Medical University of Vienna,  
Kinderspitalgasse 15,  
1090 Vienna,  
Austria  


Dear Prof. Simon,

I am delighted to confirm the support of European Federation of Associations of Families of People with Mental Illness (EUFAMI) for the Horizon 2020 PECUNIA proposal and join the scientific advisory board. As you are aware, EUFAMI facilitates dialogue with patients and their families and dissemination to policy makers.

EUFAMI will act to give families a voice in the development of the costing tools and methods. EUFAMI has 36 member organisations from 23 countries; most of which are national organisations but some are regional organisations. Together, they represent hundreds of thousands of people with mental ill health, their family and carers Europe-wide. EUFAMI has an ongoing commitment to improving care and welfare for people affected by mental illness and is delighted to see increased research into the cost drivers behind healthcare costs in the form of PECUNIA. The methods and tools may allow policymakers to reduce the costs of mental healthcare, directly benefiting the children and their families we represent.

EUFAMI also enables its member organisations to act jointly at a European Level, combining their efforts and sharing experience. We have a number of programmes supporting people affected by severe mental ill health and the organisations representing them across Europe which renders us in a position to a) judge the added value for family members and b) if it proves successful, communicate the results with our community and policy makers at European Union level. EUFAMI will participate as a scientific advisor to the project, representing the voice of family caregivers. We are convinced that the directed that the development of tools and methodology to better asses healthcare costs is beneficial to service users as it may yield lower healthcare costs in the long-run.

We anticipate that PECUNIA can successfully utilise the expertise of the EUFAMI infrastructure and network to develop costing tools and methods with family members in mind. We are hopeful that this proposal will enable this.

With kind regards,

Aagje Ieven  
Secretary General
Prof. Judit Simon  
Department of Health Economics/Center for Public Health  
Medical University of Vienna  
Kinderspitalgasse 15  
1090 Vienna  
Austria  

10 April 2017  

Commitment to the PECUNIA Scientific Advisory Board  

Dear Prof. Simon,  

With this letter I want to confirm my intention to serve as a member of the Scientific Advisory Board (SAB) of the PECUNIA project. The PECUNIA project aims to develop standardized, validated methods and tools to 1) better understand the drivers behind the variations in relevant costs and (health) outcomes within and across countries; 2) improve the quality, comparability and transferability of health economic evaluations in Europe; 3) promote the establishment of harmonized, efficient and sustainable country-specific unit cost evidence for core services in health care, social care and other relevant economic sectors (i.e. employment, education, criminal justice, patient/family and informal care), and 4) support the feasibility of broader economic and societal impacts measurement and valuation in multi-sectoral economic evaluations within and outside the HTA framework. Considering feasibility and relevant societal challenges in the European health systems, selected mental health disease areas will be used as illustrative examples. This is an important project, which I gladly want to share my knowledge and experience with by participating to the SAB. As full professor of health related quality of life and Head of the Section Medical Psychology and Psychotherapy of the department of Psychiatry at the Erasmus Medical Centre I can provide added value to the PECUNIA project. Furthermore, as the chairman of The Board of the EuroQol Research Foundation I can provide the necessary link to the EuroQol Group, one of the work packages on health outcomes. As a member of the SAB of PECUNIA I will participate in a mutually agreed number of consultations of the SAB and can provide feedback on the specific part of the PECUNIA project related to my expertise and knowledge.

Yours sincerely,  

Prof. dr. Jan J van Busschbach  
Head Section Medical Psychology & Psychotherapy  
Department of Psychiatry  
Erasmus MC: University Medical Center Rotterdam, The Netherlands  
j.vanbusschbach@erasusmc.nl
Dear Prof. Simon,

As requested, I am writing to confirm my enthusiasm for the PECUNIA project and to explain my areas of experience and expertise.

I am Head of the Department of Psychiatry at Oxford University, Director of R&D at Oxford Health NHS Foundation Trust (OH), Director of the NIHR Oxford Cognitive Health Research Facility and Director of the NIHR Oxford Health Biomedical Research Centre.

I have been Chief and Principal Investigator on a wide range of clinical trials ranging from phase 1b industry-sponsored trials (Sunovion, P1vital), through to high intensity phase II/III trials. I designed and was PI on multicentre clinical trials trials e.g BALANCE (PI) RCT comparing combination of lithium plus valproate with lithium and valproate monotherapy in bipolar disorder, CEQUEL (PI); RCT investigating lamotrigine vs placebo in combination with quetiapine in bipolar depression. My research synthesizing efficacy/safety data has clarified the extent of knowledge, and has identified leads for future discovery work. It has had major impact on research, guidelines and clinical practice. I have always endeavoured to include health economic evaluations in the assessment of health technologies from earliest phase of clinical trial.

I was a member of the National Institute for Health and Clinical Excellence (NICE) Technology Appraisal Committee from 2003-2011 and was involved in the work of NICE at a time of intense methodological development. For example, I was the Committee lead on the TA of acetylcholinesterase inhibitors for dementia where the key decisions hinged on HE analyses.

I can therefore bring a wide range of relevant experience from academic studies through to real-world decisionmaking.

Yours sincerely,

Professor John Geddes
Professor of Epidemiological Psychiatry
### ESTIMATED BUDGET FOR THE ACTION

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<td><strong>Total</strong></td>
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<td><strong>9,800.00</strong></td>
<td>0.00</td>
<td><strong>295,875.00</strong></td>
</tr>
</tbody>
</table>

### Notes

1. See Article 6 for the eligibility conditions.
2. Indirect costs already covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.5(b)) are ineligible under the GA. Therefore, a beneficiary-linked third party that receives an operating grant during the action's duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant, unless it can demonstrate that the operating grant does not cover any costs of the action (see Article 6.2.E).
3. This is the theoretical amount of EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This theoretical amount is capped by the ‘maximum grant amount’ (that the Commission/Agency decided to grant for the action) (see Article 5.1).
4. The ‘maximum grant amount’ is the maximum grant amount decided by the Commission/Agency. It normally corresponds to the requested grant, but may be lower.
5. Depending on its type, this specific cost category will or will not cover indirect costs. Specific unit costs that include indirect costs are: costs for energy efficiency measures in buildings, access costs for providing trans-national access to research infrastructure and costs for clinical studies.
6. See Article 5 for the forms of costs.
7. Unit : hours worked on the action; costs per unit (hourly rate) : calculated according to the beneficiary's usual accounting practice.
8. A. Direct personnel costs
   - A.1 Employees (or equivalent)
   - A.2 Natural persons under direct contract
   - A.3 Seconded persons
   - A.4 SME owners without salary
   - A.5 Beneficiaries that are natural persons without salary
   - A.6 Personnel for providing access to research infrastructure
9. B. Direct costs of subcontracting
10. C. Other direct costs
11. D. Indirect costs
   - D.1 Travel
   - D.2 Equipment
   - D.3 Other goods and services
   - D.4 Costs of large research infrastructure
   - D.5 Costs of internally invoiced goods and services

### Calculation

\[ h = 0.25 \times \left( a + b + c + f + g + \frac{[e][d][f][g]}{[n]} \right) \]

\[ j = a + b + c + \frac{[e][d][f][g]}{[n]} \]

\[ k = a + b + c \]

\[ l = a + b + c + \frac{[e][d][f][g]}{[n]} \]

\[ m = a + b + c + \frac{[e][d][f][g]}{[n]} + h + i \]

\[ n = \begin{cases} 0 & \text{Yes/No} \end{cases} \]

### Estimation

- **Estimated costs of beneficiaries**
- **Declaration of costs under Point D.4**
- **Estimated costs of beneficiaries/linked third parties not receiving funding/ international partners**
- **Information for indirect costs**
- **Information for auditors**
- **Other information**

---

**Grant Agreement number:** 779292 — **PECUNIA** — H2020-SC1-2016-2017/H2020-SC1-2017-Single-Stage-RTD
ANNEX 2a

ADDITIONAL INFORMATION ON THE ESTIMATED BUDGET

- Instructions and footnotes in blue will not appear in the text generated by the IT system (since they are internal instructions only).
- For options [in square brackets]: the applicable option will be chosen by the IT system. Options not chosen will automatically not appear.
- For fields [grey in square brackets] (even if they are part of an option as specified in the previous item): IT system will enter the appropriate data.

Unit cost for SME owners/natural beneficiaries without salary

1. Costs for a [SME owner]//beneficiary that is a natural person/ not receiving a salary

Units: hours worked on the action

Amount per unit (‘hourly rate’); calculated according to the following formula:

\[
\text{EUR 4,650 / 143 hours} \times \text{country-specific correction coefficient of the country where the beneficiary is established}
\]

Country-specific correction coefficient (in force at the time of the call):

### EU Member States

<table>
<thead>
<tr>
<th>Country</th>
<th>Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>AT</td>
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</tr>
<tr>
<td>BE</td>
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<td>BG</td>
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<td>FR</td>
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<td>HR</td>
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<td>IE</td>
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<td>LT</td>
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<tr>
<td>MT</td>
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### H2020 associated countries

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<tr>
<td>TR</td>
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### Other countries

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<td>KH</td>
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</table>
H2020 Model Grant Agreements: H2020 General MGA: v4.0

<table>
<thead>
<tr>
<th>Grant Agreement number: [insert number] [insert acronym] [insert call identifier]</th>
</tr>
</thead>
</table>

For the following beneficiaries/linked third parties, the amounts per unit (hourly rate) are fixed as follows:

- Beneficiary/linked third party [short name]: EUR [insert amount]
- Beneficiary/linked third party [short name]: EUR [insert amount]

[same for other beneficiaries/linked third parties, if necessary] /

Estimated number of units: see Annex 2

**Energy efficiency measures unit cost**

**OPTION if specific unit cost applicable to the grant:** 2. Costs for energy efficiency measures in buildings

Unit: m² of eligible ‘conditioned’ (i.e. built or refurbished) floor area

Amount per unit*: see (for each beneficiary/linked third party and BEST table) the ‘unit cost table’ attached

* Amount calculated as follows:

\[
\text{EUR 0.1 x estimated total kWh saved per m² per year x 10}
\]

Estimated number of units: see (for each beneficiary/linked third party and BEST table) the ‘unit cost table’ attached

Unit cost table (energy efficiency measures unit cost)¹

<table>
<thead>
<tr>
<th>Short name beneficiary/linked third party</th>
<th>BEST No</th>
<th>Cost Amount per unit</th>
<th>Estimated No of units</th>
<th>Total unit cost (cost per unit x estimated no of units)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ Data from the ‘building energy specification table (BEST)’ that is part of the proposal and Annex 1.
Research infrastructure unit cost

|OPTION if specific unit cost applicable to the grant: 3. Access costs for providing trans-national access to research infrastructure |

Units²: see (for each access provider and installation) the ‘unit cost table’ attached

Amount per unit*: see (for each access provider and installation) the ‘unit cost table’ attached

* Amount calculated as follows:
  average annual total access cost to the installation (over past two years³)
  average annual total quantity of access to the installation (over past two years³)

Estimated number of units: see (for each access provider and installation) the ‘unit cost table’ attached

Unit cost table (access to research infrastructure unit cost)⁵

<table>
<thead>
<tr>
<th>Short name access provider</th>
<th>Short name infrastructure</th>
<th>Installation</th>
<th>Unit of access</th>
<th>Amount per unit</th>
<th>Estimated No of units</th>
<th>Total unit cost (cost per unit x estimated no of units)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Clinical studies unit cost

|OPTION if specific unit cost is applicable to the grant: 4. Costs for clinical studies |

Units: patients/subjects that participate in the clinical study

Amount per unit*: see (for each sequence (if any), clinical study and beneficiary/linked third party) the ‘unit cost table’ attached

Estimated number of units: see (for each clinical study and beneficiary/linked third party) the ‘unit cost table’ attached

* Amount calculated, for the cost components of each task, as follows:

For personnel costs:

² Unit of access (e.g. beam hours, weeks of access, sample analysis) fixed by the access provider in proposal.
³ In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.
⁴ In exceptional and duly justified cases, the Commission/Agency may agree to a different reference period.
⁵ Data from the ‘table on estimated costs/quantity of access to be provided’ that is part of the proposal and Annex 1.
For personnel costs of doctors: ‘average hourly cost for doctors’, i.e.:

\[
\frac{\text{certified or auditable total personnel costs for doctors for year N-1}}{(1720 \times \text{number of full-time-equivalent for doctors for year N-1})}\times \text{estimated number of hours to be worked by doctors for the task (per participant)}
\]

For personnel costs of other medical personnel: ‘average hourly cost for other medical personnel’, i.e.:

\[
\frac{\text{certified or auditable total personnel costs for other medical personnel for year N-1}}{(1720 \times \text{number of full-time-equivalent for other medical personnel for year N-1})}\times \text{estimated number of hours to be worked by other medical personnel for the task (per participant)}
\]

For personnel costs of technical personnel: ‘average hourly cost for technical personnel’, i.e.:

\[
\frac{\text{certified or auditable total personnel costs for technical personnel for year N-1}}{(1720 \times \text{number of full-time-equivalent for technical personnel for year N-1})}\times \text{estimated number of hours to be worked by technical personnel for the task (per participant)}
\]

‘total personnel costs’ means actual salaries + actual social security contributions + actual taxes and other contributions + actual social security contributions + actual taxes and other costs included in the remuneration, provided they arise from national law or the employment contract/equivalent appointing act.

For **consumables**:  
For each cost item: ‘average price of the consumable’, i.e.:

\[
\frac{\text{certified or auditable total costs of purchase of the consumable in year N-1}}{\text{total number of items purchased in year N-1}}\times \text{estimated number of items to be used for the task (per participant)}
\]

‘total costs of purchase of the consumable’ means total value of the supply contracts (including related duties, taxes and charges such as non-deductible VAT) concluded by the beneficiary for the specific service delivered in year N-1, provided the contracts were awarded according to the principle of best value-for-money and without any conflict of interests.

For **medical equipment**:

For each cost item: ‘average cost of depreciation and directly related services per unit of use’, i.e.:

\[
\frac{\text{certified or auditable total depreciation costs in year N-1} + \text{certified or auditable total costs of purchase of services in year N-1 for the category of equipment concerned}}{\text{total capacity in year N-1}}\times \text{estimated number of units of use of the equipment for the task (per participant)}
\]

‘total depreciation costs’ means total depreciation allowances as recorded in the beneficiary’s accounts of year N-1 for the category of equipment concerned, provided the equipment was purchased according to the principle of best value for money and without any conflict of interests + total costs of renting or leasing contracts (including related duties, taxes and charges such as non-deductible VAT) in year N-1 for the category of equipment concerned, provided they do not exceed the depreciation costs of similar equipment and do not include finance fees.

For **services**:

For each cost item: ‘average cost of the service per study participant’, i.e.:

\[
\frac{\text{certified or auditable total costs of purchase of the service in year N-1}}{\text{total number of patients or subjects included in the clinical studies for which the service was delivered in year N-1}}
\]

‘total costs of purchase of the service’ means total value of the contracts concluded by the beneficiary (including related duties, taxes and charges such as non-deductible VAT) for the specific service delivered in year N-1 for the conduct of clinical studies, provided the contracts were awarded according to the principle of best value for money and without any conflict of interests.

For **indirect costs**:
\[
\{ [\text{cost component ‘personnel costs’} + \text{cost component ‘consumables’} + \text{cost component ‘medical equipment’}] \}
\]

minus
\[
\{ \text{costs of in-kind contributions provided by third parties which are not used on the beneficiary’s premises} + \text{costs of providing financial support to third parties (if any)} \} \}
\]

multiplied by
\[
25\%
\]

The estimation of the resources to be used must be done on the basis of the study protocol and must be the same for all beneficiaries/linked third parties/third parties involved.

The year N-1 to be used is the last closed financial year at the time of submission of the grant application.

Unit cost table: clinical studies unit cost

<table>
<thead>
<tr>
<th>Task, Direct cost categories</th>
<th>Resource per patient</th>
<th>Costs year N-1 Beneficiary 1 [short name]</th>
<th>Costs year N-1 Linked third party 1a [short name]</th>
<th>Costs year N-1 Beneficiary 2 [short name]</th>
<th>Costs year N-1 Linked third party 2a [short name]</th>
<th>Costs year N-1 Third party giving in-kind contributions 1 [short name]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequence No. 1</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Task No. 1</td>
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<tr>
<td>Blood sample</td>
<td></td>
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</tr>
<tr>
<td>(a) Personnel costs:</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Doctors</td>
<td>n/a</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- Other Medical Personnel</td>
<td>Phlebotomy (nurse), 10 minutes</td>
<td>8,33 EUR</td>
<td>11,59 EUR</td>
<td>10,30 EUR</td>
<td>11,00 EUR</td>
<td>9,49 EUR</td>
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<tr>
<td>- Technical Personnel</td>
<td>Sample Processing (lab technician), 15 minutes</td>
<td>9,51 EUR</td>
<td>15,68 EUR</td>
<td>14,60 EUR</td>
<td>15,23 EUR</td>
<td>10,78 EUR</td>
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<tr>
<td>(b) Costs of consumables:</td>
<td>Syringe</td>
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<td>XX EUR</td>
<td>XX EUR</td>
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<td></td>
<td>Cannula</td>
<td>XX EUR</td>
<td>XX EUR</td>
<td>XX EUR</td>
<td>XX EUR</td>
<td>XX EUR</td>
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<tr>
<td></td>
<td>Blood container</td>
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<td>XX EUR</td>
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<td>(c) Costs of medical equipment:</td>
<td>Use of -80° deep freezer, 60 days</td>
<td>XX EUR</td>
<td>XX EUR</td>
<td>XX EUR</td>
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<td></td>
<td>Use of centrifuge, 15 minutes</td>
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<td>XX EUR</td>
<td>XX EUR</td>
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<td>(d) Costs of services</td>
<td>Cleaning of XXX</td>
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<td>(e) Indirect costs (25% flat-rate)</td>
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<td>XX EUR</td>
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6 Same table as in proposal and Annex 1.
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<tr>
<td>Amount per unit (unit cost sequence 1):</td>
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<td>XX EUR</td>
<td>XX EUR</td>
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(a) Personnel costs:
- Doctors | XXX | XX EUR | XX EUR | XX EUR | XX EUR | XX EUR |
- Other Medical Personnel | XXX | XX EUR | XX EUR | XX EUR | XX EUR | XX EUR |
- Technical Personnel | XXX | XX EUR | XX EUR | XX EUR | XX EUR | XX EUR |
(b) Costs of consumables: | XXX | XX EUR | XX EUR | XX EUR | XX EUR | XX EUR |
|   | XXX | XX EUR | XX EUR | XX EUR | XX EUR | XX EUR |
(c) Costs of medical equipment: | XXX | XX EUR | XX EUR | XX EUR | XX EUR | XX EUR |
|   | XXX | XX EUR | XX EUR | XX EUR | XX EUR | XX EUR |
(d) Costs of services | XXX | XX EUR | XX EUR | XX EUR | XX EUR | XX EUR |
(e) Indirect costs (25% flat-rate) | XX EUR | XX EUR | XX EUR | XX EUR | XX EUR | XX EUR |

Task No. 2 |   |   |   |   |
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<tbody>
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<tr>
<td>Amount per unit (unit cost sequence 2):</td>
<td>XX EUR</td>
<td>XX EUR</td>
<td>XX EUR</td>
<td>XX EUR</td>
</tr>
<tr>
<td>Amount per unit (unit cost entire study):</td>
<td>XX EUR</td>
<td>XX EUR</td>
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</tr>
</tbody>
</table>
ACCESSION FORM FOR BENEFICIARIES

UNIVERSITAetsklinikum Hamburg-Eppendorf (UKE), established in Martinistrasse 52, Hamburg 20246, Germany, VAT number: DE218618948, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('2')

in Grant Agreement No 779292 ('the Agreement')

between MEDIZINISCHE UNIVERSITAET WIEN and the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled ‘ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluations (PECUNIA)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Sigrid MEYER with ECAS id nmeyersi signed in the Participant Portal on 29/11/2017 at 11:40:06 (transaction id SigId-252504-ezI64DLZwsxRUX0cfQrmm/qa45629b34YyBd1hQZYotUKiA-dsD0XyIR50s6MV0mBFZVz7ezWnPEXuGld281JwK-PHsUMVQXycwK0JgUV9y-bP6ovXwG8QLMeEwWJoUdMoHL1m9pMkHsUwanu9E Nyl). Timestamp by third party at Wed Nov 29 11:40:17 CET 2017
ACCESSION FORM FOR BENEFICIARIES

BUDAPESTI CORVINUS EGYETEM (CUB), established in FOVAM TER 8, BUDAPEST 1093, Hungary, VAT number: HU15329743, (‘the beneficiary’), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

**to become beneficiary** No (‘3’)

in Grant Agreement No 779292 (‘the Agreement’)

between MEDIZINISCHE UNIVERSITAET WIEN and the European Union (‘the EU’), represented by the European Commission (‘the Commission’),

for the action entitled ‘ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluaTions (PECUNIA)’.

and mandates

the **coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

András LÁNCZI with ECAS id nrostozs signed in the Participant Portal on 28/11/2017 at 08:08:12 (transaction id SigId-228406-
0eFgyyVFkgdEpo1Tib4xkhJydoMQh7g5fzZ8ccFKT7uzkr9s
nj1Izk7PCI/czyJwmg7k8D6zK47N3DApeJLGaKW-
PHeiUMVXCY CamwkoJgLV9y-
5mtrzMSeUdscXmcyCo4pBpzQar2YI21ZCJNVizoguubK).
Timestamp by third party at
Tue Nov 28 08:08:23 CET 2017
ACCESSION FORM FOR BENEFICIARIES

UNIVERSITEIT MAASTRICHT (UM), established in Minderbroedersberg 4-6, MAASTRICHT 6200 MD, Netherlands, (‘the beneficiary’), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No (‘4’)  
in Grant Agreement No 779292 (‘the Agreement’)  
between MEDIZINISCHE UNIVERSITÄT WIEN and the European Union (‘the EU’), represented by the European Commission (‘the Commission’),  
for the action entitled ‘ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluations (PECUNIA)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Maurice ZEEGERS with ECAS id nzeemaur signed in the Participant Portal on 30/11/2017 at 15:12:01 (transaction id Sigldd-276371- jywczgviMSnxZILNNvXm8HzY2TnArBhLzljxhV0wQzwqiv 5G0Sld5TjhsqoNDA7y00K4FCcjLT8SuBwbsQ9vm- PHeiUMVvXYCawvkJjLUV9y- s7vXe0AyMrKH2Kg1jB9TGlipZK42KjtI3hZlWwoi).  
Timestamp by third party at Thu Nov 30 15:12:12 CET 2017
ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ERASMUS UNIVERSITEIT ROTTERDAM (EUR), established in BURGEMEESTER OUDLAAN 50, ROTTERDAM 3062 PA, Netherlands, VAT number: NL804735529B02, (‘the beneficiary’), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No (‘5’) in Grant Agreement No 779292 (‘the Agreement’) between MEDIZINISCHE UNIVERSITÄT WIEN and the European Union (‘the EU’), represented by the European Commission (‘the Commission’),

for the action entitled ‘ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluAtions (PECUNIA)’. and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

werner BROUWER with ECAS id nbrouwwe signed in the Participant Portal on 27/11/2017 at 16:54:40 (transaction id SigId=224405-BcoZMaMBTms3tJ0k9YR4VxQ2e9Y5sqaqkNswWNNST2HTmQgR262jpxVhDiGJdungfK7EsqyMuc0yrE8jm-PHeUjMV5XYCamwkoJgUV9y-hcX0pwvK4UEm8VSTxRKS8Xh7TjV3mstzzj8f6HKXHm). Timestamp by third party at Mon Nov 27 16:54:50 CET 2017
ACCESSION FORM FOR BENEFICIARIES

SERVICIO CANARIO DE LA SALUD (SESCS), established in PÉREZ DE ROZAS, 5, 4 PLANTA, SANTA CRUZ DE TENERIFE 38006, Spain, VAT number: ESQ8555011I, (‘the beneficiary’), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No (‘6’)
in Grant Agreement No 779292 (‘the Agreement’)
between MEDIZINISCHE UNIVERSITÄT WIEN and the European Union (‘the EU’), represented by the European Commission (‘the Commission’),

for the action entitled ‘ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluations (PECUNIA)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Conrado DOMÍNGUEZ TRUJILLO with ECAS id ndoconna
signed in the Participant Portal on 08/12/2017 at 00:02:33
(transaction id Sigld-15926-TGL0jLzgeyMlzrX1tQ8TMxPDBkSkGyWuREJMoPVcH-
FjJiszkKjYWwPsPmRrlbZROH0kFUE61vcCiaKjGOMAD-
PHsUmv5xYClmSRslEdOqzH-WyazsbEZSHdR8o9ItTnKdZCEQ5sLHtXczRydARaa2LWj).
Timestamp by third party at Fri Dec 08 00:06:47 CET 2017.
ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ASOCIACION CIENTIFICA PSICOST (Psicost), established in CALLE ENERGIA SOLAR BLOQUE G 1, SEVILLA 41014, Spain, VAT number: ESG11729571, (‘the beneficiary’), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No (‘7’)

in Grant Agreement No 779292 (‘the Agreement’)

between MEDIZINISCHE UNIVERSITÄT WIEN and the European Union (‘the EU’), represented by the European Commission (‘the Commission’),

for the action entitled ‘ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluAtions (PECUNIA)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Carlos Ramón GARCIA ALONSO with ECAS id ngaclosr
signed in the Participant Portal on 28/11/2017 at 09:40:54

transaction id SigId-229967- bvHzsC8zqObzVQsXYqkEbzzHkbOxkyL2agzzYfifDq19rb
XWTOblizSn1xgto71u1f1zLP4EMDo8zqocC4X8b4mG-
PHaiUMVXYCawmk2JqLV9y-
X4gRhlHghxxkeQBNbzK9N49eObGwEnSxITC6YusHf2zvD4
Wl. Timestamp by third party at Tue Nov 28 09:41:05 CET 2017
ACCESSION FORM FOR BENEFICIARIES

LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE (LSE), established in Houghton Street 1, LONDON WC2A 2AE, United Kingdom, VAT number: GB629588094, (‘the beneficiary’), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No (‘8’) in Grant Agreement No 779292 (‘the Agreement’) between MEDIZINISCHE UNIVERSITAET WIEN and the European Union (‘the EU’), represented by the European Commission (‘the Commission’),

for the action entitled ‘ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluAtions (PECUNIA)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

David COOMBE with ECAS id ncoombea signed in the Participant Portal on 30/11/2017 at 11:50:17 (transaction id SigId:270135-SBFZIl2dzmszplgk3nYPWb3M2BiJNSKhqIzepthiDWXc kJ4RZWISA+JzlazQvTGR2zzg92NZ6POJUznN1nHfq- PHeuUMVXSXYCamwkoUgLqLV9y- lZtEwqzj9VpcsIl7xnJwHG3&Y6GRSHxRdkFIFSzeSkHe). Timestamp by third party at Thu Nov 30 11:50:30 CET 2017
ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITY OF BRISTOL (UnivBris), established in TYNDALL AVENUE SENATE HOUSE, BRISTOL BS8 1TH, United Kingdom, VAT number: GB991261800, (‘the beneficiary’), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No (‘9’)
in Grant Agreement No 779292 (‘the Agreement’)

between MEDIZINISCHE UNIVERSITAET WIEN and the European Union (‘the EU’), represented by the European Commission (‘the Commission’),

for the action entitled ‘ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluAtions (PECUNIA)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Rachel EVANS with ECAS id nevanrac signed in the Participant Portal on 28/11/2017 at 16:18:52 (transaction id SigId-242467-v4KMNC1KBezRvZLo6SNzzahC4rDCYCG9OWaH8aaMNisXZ9SYTBIAVBul9zya6xa8k0UdXjqqnas3n2kymQxAj9ym-PHiUUMVSYCawkoJgUUY9y-3Eemd4ZWzJwe4SyXIdhyg2frX8TbR0H7b8yFqwJbOLu). Timestamp by third party at Tue Nov 28 16:19:05 CET 2017
ACCESSION FORM FOR BENEFICIARIES

EURICE EUROPEAN RESEARCH AND PROJECT OFFICE GMBH (EURICE), established in STUHLSATZENHAUSWEG 69, SAARBRUCKEN 66123, Germany, VAT number: DE210372698, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary No ('10')

in Grant Agreement No 779292 ('the Agreement')

between MEDIZINISCHE UNIVERSITAET WIEN and the European Union ('the EU'), represented by the European Commission ('the Commission'),

for the action entitled ‘ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluA tions (PECUNIA)’. 

and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Jörg SCHERER with ECAS id nacherej signed in the Participant Portal on 28/11/2017 at 11:56:55 (transaction id SigId-234520-
QCkhhSmqRnZbSVKjkeSkUcAFPBdwwkki2ExPCNdqZPd LzGgGybrXjUcbA2xAlzhlPlkDolnsG9BUZbTzy-
PHHiUMVXSNYcanwk0JgUV9y-
6Bj69MVX2PCZueJnSnDzWdKFCedNq77wUs2DNN)
, Timestamp by third party at Tue Nov 28 11:57:08 CET 2017
### Table: Financial Statement

<table>
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<th>Actual</th>
<th>Unit</th>
<th>Actual</th>
<th>Actual</th>
<th>Actual</th>
<th>Actual</th>
<th>Unit</th>
<th>Flat rate</th>
<th>Unit</th>
<th>[Lump sum]</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>Total b</td>
<td>No hours</td>
<td>Total c</td>
<td>d</td>
<td>f</td>
<td>g</td>
<td>Total h</td>
<td>&gt;=0.25 a (a+b+c+d+e+f+g+ h)</td>
<td>Total [j1]</td>
<td>Total [j2]</td>
</tr>
</tbody>
</table>

The beneficiary/linked third party hereby confirms that:

The information provided is complete, reliable and true.

The costs declared are eligible (see Article 6).

The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

1. Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account later, in order to replace other costs that are found to be ineligible.

2. The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim indirect costs unless you can demonstrate that the operating grant does not cover any costs of the action.

3. Costs of in-kind contributions not used on premises.

4. The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim indirect costs unless you can demonstrate that the operating grant does not cover any costs of the action.

5. Flat rate: 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E)

6. Only specific unit costs that do not include indirect costs.
ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- For options [in italics in square brackets]: choose the applicable option. Options not chosen should be deleted.
- For fields in [grey in square brackets]: enter the appropriate data

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TERMS OF REFERENCE FOR AN INDEPENDENT REPORT OF FACTUAL FINDINGS ON COSTS DECLARED UNDER A GRANT AGREEMENT FINANCED UNDER THE HORIZON 2020 RESEARCH FRAMEWORK PROGRAMME

INDEPENDENT REPORT OF FACTUAL FINDINGS ON COSTS DECLARED UNDER A GRANT AGREEMENT FINANCED UNDER THE HORIZON 2020 RESEARCH FRAMEWORK PROGRAMME
Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the ‘Terms of Reference (ToR)’ under which

[OPTION 1: insert name of the beneficiary] ('the Beneficiary')

[OPTION 2: insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary

[insert name of the beneficiary] ('the Beneficiary')

agrees to engage

[insert legal name of the auditor] ('the Auditor')

to produce an independent report of factual findings (‘the Report’) concerning the Financial Statement(s) drawn up by the [Beneficiary] [Linked Third Party] for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements’ (‘CFS’) referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and [OPTION 1: the European Union, represented by the European Commission ('the Commission')]

[OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')]

[OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]

The [Commission] [Agency] is mentioned as a signatory of the Agreement with the Beneficiary only. The [European Union][Euratom][Agency] is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the [Commission]/[Agency] the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement.

The CFS is composed of two separate documents:

- The Terms of Reference (‘the ToR’) to be signed by the [Beneficiary] [Linked Third Party] and the Auditor;

---

1 By which costs under the Agreement are declared (see template ‘Model Financial Statements’ in Annex 4 to the Grant Agreement).
The Auditor’s Independent Report of Factual Findings (‘the Report’) to be issued on the Auditor’s letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures (‘the Procedures’) to be performed by the Auditor, and the standard factual findings (‘the Findings’) to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the Commission [ Agency,] the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The [Beneficiary] [Linked Third Party]:
- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the [Beneficiary’s] [Linked Third Party’s] accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the [Beneficiary’s] [Linked Third Party’s] staff and accounting as well as any other relevant records and documentation.

The Auditor:
- [Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].
- [Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].

The Auditor:
- must be independent from the Beneficiary [and the Linked Third Party], in particular, it must not have been involved in preparing the [Beneficiary’s] [Linked Third Party’s] Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the [Beneficiary] [Linked Third Party].
The Commission sets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with ²:

- the International Standard on Related Services (‘ISRS’) 4400 Engagements to perform Agreed-upon Procedures regarding Financial Information as issued by the International Auditing and Assurance Standards Board (IAASB);
- the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the [Commission]/[Agency] requires that the Auditor also complies with the Code’s independence requirements.

The Auditor’s Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary [and the Linked Third Party], and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the Commission[, the Agency], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [the European Union] [Euratom] budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the Commission [, the Agency], the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by /dd Month yyyy/.

1.6 Other terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor’s fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

² Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services (‘ISRS’) 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.
Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor’s letterhead)

To

[ name of contact person(s)], [Position]

[ Beneficiary’s] [Linked Third Party’s] name

Address

[ dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with [OPTION 1: [insert name of the beneficiary] (‘the Beneficiary’)] [OPTION 2: [insert name of the linked third party] (‘the Linked Third Party’), third party linked to the Beneficiary [insert name of the beneficiary] (‘the Beneficiary’),

we

[name of the auditor] (‘the Auditor’),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)\(^3\) of the [Beneficiary] [Linked Third Party] concerning the grant agreement [insert grant agreement reference: number, title of the action and acronym] (‘the Agreement’),

with a total cost declared of

[total amount] EUR,

and a total of actual costs and unit costs calculated in accordance with the [Beneficiary’s] [Linked Third Party’s] usual cost accounting practices’ declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the [Beneficiary’s] [Linked Third Party’s] usual cost accounting practices] EUR

and hereby provide our Independent Report of Factual Findings (‘the Report’) using the compulsory report format agreed with you.

The Report

Our engagement was carried out in accordance with the terms of reference (‘the ToR’) appended to this Report. The Report includes the agreed-upon procedures (‘the Procedures’) carried out and the standard factual findings (‘the Findings’) examined.

\(^3\) By which the Beneficiary declares costs under the Agreement (see template ‘Model Financial Statement’ in Annex 4 to the Agreement).
The Procedures were carried out solely to assist the [Commission] [Agency] in evaluating whether the [Beneficiary’s] [Linked Third Party’s] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The [Commission] [Agency] draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the [Beneficiary’s] [Linked Third Party’s] Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

**Not applicable Findings**

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

---

**List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.**

---

**Exceptions**

Apart from the exceptions listed below, the [Beneficiary] [Linked Third Party] provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

---

**List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.**

---
Example (to be removed from the Report):

1. The Beneficiary was unable to substantiate the Finding number 1 on ... because ....
2. Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: ...
3. After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____________ EUR. The difference can be explained by ...

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because ...
2. In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ....

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the [Beneficiary] [Linked Third Party] and the [Commission] [Agency], and only to be submitted to the [Commission] [Agency] in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the [Beneficiary] [Linked Third Party] or by the [Commission] [Agency] for any other purpose, nor may it be distributed to any other parties. The [Commission] [Agency] may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the [Commission] [Agency] by the [Beneficiary] [Linked Third Party] for the Agreement. Therefore, it does not extend to any other of the [Beneficiary’s] [Linked Third Party’s] Financial Statement(s).

There was no conflict of interest\(^4\) between the Auditor and the Beneficiary [and Linked Third Party] in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR ____________ (including EUR ____________ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

---

\(^4\) A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.
Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to ‘the Beneficiary’ is to be considered as a reference to ‘the Linked Third Party’.

The ‘result’ column has three different options: ‘C’, ‘E’ and ‘N.A.’:

- ‘C’ stands for ‘confirmed’ and means that the auditor can confirm the ‘standard factual finding’ and, therefore, there is no exception to be reported.
- ‘E’ stands for ‘exception’ and means that the Auditor carried out the procedures but cannot confirm the ‘standard factual finding’, or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- ‘N.A.’ stands for ‘not applicable’ and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for ‘beneficiaries with accounts established in a currency other than the euro’ the Procedure related to ‘beneficiaries with accounts established in euro’ is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

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<th>Ref</th>
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<th>Result (C / E / N.A.)</th>
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<tbody>
<tr>
<td>A</td>
<td><strong>ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE</strong></td>
<td></td>
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<td></td>
<td>The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A.</td>
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<td></td>
<td><em>(The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)</em></td>
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</table>
The Auditor sampled _____ people out of the total of _____ people.

A.1 PERSONNEL COSTS

For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs)

To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary:

- a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract;
- the payslips of the employees included in the sample;
- reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system;
- information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent;
- the Beneficiary’s usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay);
- applicable national law on taxes, labour and social security and
- any other document that supports the personnel costs declared.

The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA)

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<tr>
<td></td>
<td>The Auditor sampled _____ people out of the total of _____ people.</td>
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<tr>
<td>A.1</td>
<td>PERSONNEL COSTS</td>
<td>1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary’s sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary’s usual practices.</td>
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<td></td>
<td>For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs)</td>
<td>2) Personnel costs were recorded in the Beneficiary’s accounts/payroll system.</td>
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<td></td>
<td>To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary:</td>
<td>3) Costs were adequately supported and reconciled with the accounts and payroll records.</td>
<td></td>
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<td></td>
<td>- a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract;</td>
<td>4) Personnel costs did not contain any ineligible elements.</td>
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<td>- the payslips of the employees included in the sample;</td>
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<td></td>
<td>- reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system;</td>
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<td></td>
<td>- information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent;</td>
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<td></td>
<td>- the Beneficiary’s usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay);</td>
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<td></td>
<td>- applicable national law on taxes, labour and social security and</td>
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<td>- any other document that supports the personnel costs declared.</td>
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and recalculated the personnel costs for employees included in the sample.

5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.

Further procedures if ‘additional remuneration’ is paid

To confirm standard factual findings 6-9 listed in the next column, the Auditor:

- reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory obligations, the Beneficiary’s usual policy on additional remuneration, criteria used for its calculation, the Beneficiary's usual remuneration practice for projects funded under national funding schemes...);
- recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, usual remuneration paid for projects funded by national schemes) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 ‘Productive hours’ and A.4 ‘Time recording system’).

‘ADDITIONAL REMUNERATION’ MEANS ANY PART OF THE REMUNERATION WHICH EXCEEDS WHAT THE PERSON WOULD BE PAID FOR TIME WORKED IN PROJECTS FUNDED BY NATIONAL SCHEMES.

If any part of the remuneration paid to the employee qualifies as "additional remuneration" and is eligible under the provisions of Article 6.2.A.1, this can be charged as eligible cost to the action up to the following amount:

(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;
(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE

6) The Beneficiary paying “additional remuneration” was a non-profit legal entity.

7) The amount of additional remuneration paid corresponded to the Beneficiary’s usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.

8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used.

9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the
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<td><strong>FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR</strong>&lt;br&gt;(C) <strong>IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.</strong></td>
<td>equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).</td>
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<td></td>
<td>Additional procedures in case “unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices” is applied:</td>
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<td></td>
<td>Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard factual findings 10-13 listed in the next column:</td>
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<td>o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;</td>
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<td></td>
<td>o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS;</td>
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<td></td>
<td>o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records;</td>
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<td>o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts;</td>
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<td>o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.</td>
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<td>For natural persons included in the sample and working with the Beneficiary under a directed</td>
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<td>Ref</td>
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<td>Standard factual finding</td>
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<td><strong>contract other than an employment contract, such as consultants (no subcontractors).</strong> To confirm standard factual findings 14-17 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary:<strong>&lt;br&gt; o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary;</strong>&lt;br&gt; o the employment conditions of staff in the same category to compare costs and;<strong>&lt;br&gt; o any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.).</strong></td>
<td>under conditions similar to those of an employee, in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed.</td>
<td>C</td>
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<td></td>
<td>15) The results of work carried out belong to the Beneficiary, or, if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those results were generated by itself.</td>
<td>E</td>
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<td></td>
<td>16) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.</td>
<td>E</td>
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<td>17) The costs were supported by audit evidence and registered in the accounts.</td>
<td>E</td>
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<td></td>
<td>For personnel seconded by a third party and included in the sample (not subcontractors) To confirm standard factual findings 18-21 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary:<strong>&lt;br&gt; o their secondment contract(s) notably regarding costs, duration, work description, place of work,</strong></td>
<td>18) Seconded personnel reported to the Beneficiary and worked on the Beneficiary’s premises (unless otherwise agreed with the Beneficiary).</td>
<td>E</td>
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work and ownership of the results;
- if there is reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit;
- if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll;
- any other document that supports the costs declared (e.g. invoices, etc.).

19) The results of work carried out belong to the Beneficiary, or, if not, the Beneficiary has obtained all necessary rights to fulfil its obligations as if those results were generated by itself.

**If personnel is seconded against payment:**

20) The costs declared were supported with documentation and recorded in the Beneficiary’s accounts. The third party did not include any profit.

**If personnel is seconded free of charge:**

21) The costs declared did not exceed the third party's cost as recorded in the accounts of the third party and were supported with documentation.

A.2 **PRODUCTIVE HOURS**

To confirm standard factual findings 22-27 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that:

22) The Beneficiary applied method [choose one option and delete the others]

[A: 1720 hours]

[B: the ‘total number of hours']
If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours.

If the Beneficiary applied method C, the auditor verified that the ‘annual productive hours’ applied when calculating the hourly rate were equivalent to at least 90% of the ‘standard annual workable hours’. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts.

**BENEFICIARY’S PRODUCTIVE HOURS’ FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:**

A. 1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)


C. THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS ‘STANDARD ANNUAL PRODUCTIVE HOURS’ IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.

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<th>Result (C / E / N.A.)</th>
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<tr>
<td></td>
<td>o the annual productive hours applied were calculated in accordance with</td>
<td>[C: ‘standard annual productive hours’ used correspond to usual accounting practices]</td>
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<td></td>
<td>one of the methods described below,</td>
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<td>o the full-time equivalent (FTEs) ratios for employees not working full-</td>
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<td>time were correctly calculated.</td>
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<td></td>
<td>If the Beneficiary applied method B, the auditor verified that the</td>
<td>23) Productive hours were calculated annually.</td>
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<td></td>
<td>correctness in which the total number of hours worked was calculated</td>
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<td></td>
<td>and that the contracts specified the annual workable hours.</td>
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<td></td>
<td>If the Beneficiary applied method C, the auditor verified that the</td>
<td>24) For employees not working full-time the full-time equivalent (FTE) ratio was</td>
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<td>‘annual productive hours’ applied when calculating the hourly rate were</td>
<td>correctly applied.</td>
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<tr>
<td></td>
<td>equivalent to at least 90% of the ‘standard annual workable hours’.</td>
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<td></td>
<td>The Auditor can only do this if the calculation of the standard annual</td>
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<td>workable hours can be supported by records, such as national legislation,</td>
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<td></td>
<td>labour agreements, and contracts.</td>
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| 24) For employees not working full-time the full-time equivalent (FTE) | 25) The calculation of the number of ‘annual workable hours’, overtime and absences was verifiable based on the documents provided by the Beneficiary.

25.1) The Beneficiary calculates the hourly rates per full financial year following procedure A.3 (method B is not allowed for beneficiaries calculating hourly rates per month).
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<th>Result (C / E / N.A.)</th>
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<tr>
<td></td>
<td>‘ANNUAL WORKABLE HOURS’ MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER’S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.</td>
<td>If the Beneficiary applied method C.</td>
<td></td>
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<tr>
<td></td>
<td>A.3 HOURLY PERSONNEL RATES</td>
<td>26) The calculation of the number of ‘standard annual workable hours’ was verifiable based on the documents provided by the Beneficiary.</td>
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<td></td>
<td>I) For unit costs calculated in accordance to the Beneficiary’s usual cost accounting practice (unit costs):</td>
<td>27) The ‘annual productive hours’ used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the ‘annual workable hours’.</td>
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<td></td>
<td>If the Beneficiary has a &quot;Certificate on Methodology to calculate unit costs &quot; (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission’s letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary.</td>
<td>28) The Beneficiary applied [choose one option and delete the other]:</td>
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<td></td>
<td>If the Beneficiary does not have a &quot;Certificate on Methodology&quot; (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor:</td>
<td>[Option I: “Unit costs (hourly rates) were calculated in accordance with the Beneficiary’s usual cost accounting practices”]</td>
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<td>[Option II: Individual hourly rates were applied]</td>
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II) For individual hourly rates:

The Auditor:
- reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates;
- recalculated the hourly rates of staff included in the sample (recalculation of all hourly rates if the Beneficiary uses annual rates, recalculation of three months selected randomly for every year and person if the Beneficiary uses monthly rates) following the results of the procedures carried out in A.1 and A.2;
- (only in case of monthly rates) confirmed that the time spent on parental leave is not deducted, and that, if parts of the basic remuneration are generated over a period longer than a month, the Beneficiary has included only the share which is generated in the month.

UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES:

IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.

HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:
IT IS CALCULATED FOLLOWING ONE OF THE TWO OPTIONS BELOW:

A) [OPTION BY DEFAULT] BY DIVIDING THE ACTUAL ANNUAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS

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<tr>
<td>29)</td>
<td>The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding.</td>
<td>For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC):</td>
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<tr>
<td>30)</td>
<td>The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary.</td>
<td>For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission:</td>
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<td>31)</td>
<td>The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary.</td>
<td>For option II concerning individual hourly rates:</td>
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### A.4 TIME RECORDING SYSTEM

To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records:

- description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system);
- its actual implementation;
- time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager;
- the hours declared were worked within the project period;
- there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below);
- the hours charged to the action matched those in the time recording system.

### Standard factual finding

31.1) The Beneficiary used only one option (per full financial year or per month) throughout each financial year examined.

31.2) The hourly rates do not include additional remuneration.

32) All persons recorded their time dedicated to the action on a daily/weekly/monthly basis using a paper/computer-based system. *(delete the answers that are not applicable)*

33) Their time-records were authorised at least monthly by the project manager or other superior.

34) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.
ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).

If the persons are working exclusively for the action and without time records

For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.

35) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.

36) The exclusive dedication is supported by a declaration signed by the Beneficiary and any other evidence gathered.

**B COSTS OF SUBCONTRACTING**

**B.1 The Auditor obtained the detail/breakdown of subcontracting costs and sampled cost items selected randomly** (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest).

To confirm standard factual findings 37-41 listed in the next column, the Auditor reviewed the following for the items included in the sample:

- the use of subcontractors was foreseen in Annex 1;
- subcontracting costs were declared in the subcontracting category of the Financial Statement;
- supporting documents on the selection and award procedure were followed;
- the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment).

37) The use of claimed subcontracting costs was foreseen in Annex 1 and costs were declared in the Financial Statements under the subcontracting category.

38) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money.

(When different offers were not associated with document Ref. Ares(2017)5553433 - 14/11/2017)
In particular,

i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement.

ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement.

For the items included in the sample the Auditor also verified that:

- the subcontracts were not awarded to other Beneficiaries in the consortium;
- there were signed agreements between the Beneficiary and the subcontractor;
- there was evidence that the services were provided by subcontractor;

The Auditor verified that the following minimum conditions were met:

39) The subcontracts were not awarded to other Beneficiaries of the consortium.

40) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.

41) There was evidence that the services were provided by the subcontractors.

C.1 The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled cost items selected randomly (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest).

The Auditor verified that the following minimum conditions were met:

42) All minimum conditions were met.
<table>
<thead>
<tr>
<th>Ref</th>
<th>Procedures</th>
<th>Standard factual finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
<td>the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex 1;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>the financial support to third parties was agreed in Annex 1 of the Agreement and the other provisions on financial support to third parties included in Annex 1 were respected.</td>
<td></td>
</tr>
</tbody>
</table>
**D OTHER ACTUAL DIRECT COSTS**

### D.1 COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES

The Auditor sampled [number] cost items selected randomly (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest).

The Auditor inspected the sample and verified that:

- travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy;
- travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference;
- no ineligible costs or excessive or reckless expenditure was declared (see Article 6.5 MGA).

43) Costs were incurred, approved and reimbursed in line with the Beneficiary's usual policy for travels.

44) There was a link between the trip and the action.

45) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting.

46) No ineligible costs or excessive or reckless expenditure was declared.

### D.2 DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS

The Auditor sampled [number] cost items selected randomly (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest).

For “equipment, infrastructure or other assets” [from now on called “asset(s)"] selected in the sample the Auditor verified that:

- the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures;

47) Procurement rules, principles and guides were followed.

48) There was a link between the grant agreement and the asset charged to the action.

49) The asset charged to the action was traceable to the accounting records and the underlying documents.
Grant Agreement number: [insert number] [insert acronym] [insert call identifier]

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The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary’s country and with the Beneficiary’s usual accounting policy (e.g. depreciation calculated on the acquisition value).

The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).

The Auditor sampled ____ cost items selected randomly (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 items, or 10% of the total, whichever number is highest).

For the purchase of goods, works or services included in the sample the Auditor verified that:

- the contracts did not cover tasks described in Annex 1;
- they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting);
- the goods were not placed in the inventory of durable equipment;
- the costs charged to the action were accounted in line with the Beneficiary’s usual accounting practices;
- no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA).

In addition, the Auditor verified that these goods and services were acquired in conformity with

| 50 | The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary’s country and the Beneficiary’s usual accounting policy. |
| 51 | The amount charged corresponded to the actual usage for the action. |
| 52 | No ineligible costs or excessive or reckless expenditure were declared. |
| 53 | Contracts for works or services did not cover tasks described in Annex 1. |
| 54 | Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment. |
| 55 | The costs were charged in line with the Beneficiary’s accounting policy and were adequately supported. |
| 56 | No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups. |
the Beneficiary's internal guidelines and procedures, in particular:

- if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC (or 2014/24/EU) or of Directive 2004/17/EC (or 2014/25/EU), the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement.

- if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement.

For the items included in the sample the Auditor also verified that:

- the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment);

**SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.**

**D.4 AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE**

The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020.

**57) Procurement rules, principles and guides were followed.** There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money.

*When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption “Exceptions” of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible*

**58) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report.**
**In the cases that a positive ex-ante assessment has been issued** (see the standard factual findings 58-59 on the next column),

The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment;

**In the cases that a positive ex-ante assessment has NOT been issued** (see the standard factual findings 60 on the next column),

The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category;

**In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes** (see the standard factual findings 60 on the next column),

- The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.

### D.5 Costs of internally invoiced goods and services

**The Auditor sampled cost items selected randomly** (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest).

To confirm standard factual findings 61-65 listed in the next column, the Auditor:

- obtained a description of the Beneficiary's usual cost accounting practice to calculate costs of internally invoiced goods and services (unit costs);
- reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS;
- ensured that the methodology to calculate unit costs is being used in a consistent manner, based on objective criteria, regardless of the source of funding;
- verified that any ineligible items or any costs claimed under other budget categories, in particular indirect costs, have not been taken into account when calculating the costs of

| 59) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. |
| 60) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure. |
| 61) The costs of internally invoiced goods and services included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. |
| 62) The cost accounting practices used to calculate the costs of internally invoiced goods and services were applied by the Beneficiary in a consistent manner based on objective criteria regardless of the source of funding. |
| 63) The unit cost is calculated using the actual costs for the good or service recorded in the Beneficiary’s accounts, excluding any ineligible |
internally invoiced goods and services (see Article 6 GA);
- verified whether actual costs of internally invoiced goods and services were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, and correspond to objective and verifiable information.
- verified that any costs of items which are not directly linked to the production of the invoiced goods or service (e.g. supporting services like cleaning, general accountancy, administrative support, etc. not directly used for production of the good or service) have not been taken into account when calculating the costs of internally invoiced goods and services.
- verified that any costs of items used for calculating the costs internally invoiced goods and services are supported by audit evidence and registered in the accounts.

64) The unit cost excludes any costs of items which are not directly linked to the production of the invoiced goods or service.

65) The costs items used for calculating the actual costs of internally invoiced goods and services were relevant, reasonable and correspond to objective and verifiable information.

E USE OF EXCHANGE RATES

E.1 a) For Beneficiaries with accounts established in a currency other than euros

The Auditor sampled [number] cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest):

Costs recorded in the accounts in a currency other than euro shall be converted into euro at the average of the daily exchange rates published in the C series of Official Journal of the European Union (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), determined over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, conversion shall be made at the average of the monthly accounting rates established by the Commission and published on its website (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm).

66) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.
| DETERMINED OVER THE CORRESPONDING REPORTING PERIOD. | 
|---|---|
| b) For Beneficiaries with accounts established in euros | 
| The Auditor sampled ______ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest): | 67) The Beneficiary applied its usual accounting practices. |
| **COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY’S USUAL ACCOUNTING PRACTICES.** | |
MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- For options [in italics in square brackets]: choose the applicable option. Options not chosen should be deleted.
- For fields in [grey in square brackets]: enter the appropriate data.

TABLE OF CONTENTS

TERMS OF REFERENCE FOR AN AUDIT ENGAGEMENT FOR A METHODOLOGY CERTIFICATE IN CONNECTION WITH ONE OR MORE GRANT AGREEMENTS FINANCED UNDER THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME

INDEPENDENT REPORT OF FACTUAL FINDINGS ON THE METHODOLOGY CONCERNING GRANT AGREEMENTS FINANCED UNDER THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME
Grant Agreement number: [insert number] [insert acronym] [insert call identifier]

H2020 Model Grant Agreements: H2020 General MGA — Multi: v4.0 – dd.mm.2017

Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the ‘Terms of Reference (ToR)’ under which

[OPTION 1: [insert name of the beneficiary] (‘the Beneficiary’)] [OPTION 2: [insert name of the linked third party] (‘the Linked Third Party’), third party linked to the Beneficiary [insert name of the beneficiary] (‘the Beneficiary’)]

agrees to engage

[insert legal name of the auditor] (‘the Auditor’)

to produce an independent report of factual findings (‘the Report’) concerning the [Beneficiary’s] [Linked Third Party’s] usual accounting practices for calculating and claiming direct personnel costs declared as unit costs (‘the Methodology’) in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] (‘the Agreement(s)’)

The Agreement(s) has(have) been concluded between the Beneficiary and [OPTION 1: the European Union, represented by the European Commission (‘the Commission’)] [OPTION 2: the European Atomic Energy Community (Euratom, represented by the European Commission (‘the Commission’)] [OPTION 3: the Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] (‘the Agency’), under the powers delegated by the European Commission (‘the Commission’).

The [Commission] [Agency] is mentioned as a signatory of the Agreement with the Beneficiary only. The [European Union] [Euratom] [Agency] is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries [and linked third parties] that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the [Commission] [Agency], for approval, a certificate on the methodology (‘CoMUC’) stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference (‘the ToR’) to be signed by the [Beneficiary] [Linked Third Party] and the Auditor;

- the Auditor’s Independent Report of Factual Findings (‘the Report’) issued on the Auditor’s letterhead, dated, stamped and signed by the Auditor which includes; the standard statements (‘the Statements’) evaluated and signed by the [Beneficiary] [Linked Third Party], the agreed-upon procedures (‘the Procedures’) performed by the Auditor and the standard factual findings (‘the Findings’) assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.
The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the [Beneficiary’s] [Linked Third Party’s] usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the [Beneficiary] [Linked Third Party] and the Auditor.

The [Beneficiary] [Linked Third Party]:
- is responsible for preparing financial statements for the Agreement(s) (‘the Financial Statements’) in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the [Beneficiary’s] [Linked Third Party’s] accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading ‘Statements to be made by the Beneficiary/ Linked Third Party’ in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the [Beneficiary] [Linked Third Party] providing full and free access to the [Beneficiary’s] [Linked Third Party’s] staff and to its accounting and other relevant records.

The Auditor:
- [Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].
- [Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation].

The Auditor:
- must be independent from the Beneficiary [and the Linked Third Party], in particular, it must not have been involved in preparing the Beneficiary’s [and Linked Third Party’s] Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the [Beneficiary] [Linked Third Party].
The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with:

- the International Standard on Related Services (‘ISRS’) 4400 Engagements to perform Agreed-upon Procedures regarding Financial Information as issued by the International Auditing and Assurance Standards Board (IAASB);
- the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code’s independence requirements.

The Auditor’s Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary [and the Linked Third Party] that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, [the Agency], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [the European Union] [Euratom] budget. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission, [the Agency], the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor’s fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

<table>
<thead>
<tr>
<th>[legal name of the Auditor]</th>
<th>[legal name of the [Beneficiary] [Linked Third Party]]</th>
</tr>
</thead>
<tbody>
<tr>
<td>[name &amp; title of authorised representative]</td>
<td>[name &amp; title of authorised representative]</td>
</tr>
<tr>
<td>[dd Month yyyy]</td>
<td>[dd Month yyyy]</td>
</tr>
<tr>
<td>Signature of the Auditor</td>
<td>Signature of the [Beneficiary] [Linked Third Party]</td>
</tr>
</tbody>
</table>

1 Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services (‘ISRS’) 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.
Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary’s] [Linked Third Party’s] name]
[ Address]
[ dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with [OPTION 1: [insert name of the beneficiary] (‘the Beneficiary’)] [OPTION 2: [insert name of the linked third party] (‘the Linked Third Party’), third party linked to the Beneficiary [insert name of the beneficiary] (‘the Beneficiary’)],

we

established at
[full address/city/state/province/country],

represented by
[name and function of an authorised representative],

have carried out the agreed-upon procedures (‘the Procedures’) and provide hereby our Independent Report of Factual Findings (‘the Report’), concerning the [Beneficiary’s] [Linked Third Party’s] usual accounting practices for calculating and declaring direct personnel costs declared as unit costs (‘the Methodology’).

You requested certain procedures to be carried out in connection with the grant(s) [title and number of the grant agreement(s)] (‘the Agreement(s)’).

The Report

Our engagement was carried out in accordance with the terms of reference (‘the ToR’) appended to this Report. The Report includes: the standard statements (‘the Statements’) made by the [Beneficiary] [Linked Third Party], the agreed-upon procedures (‘the Procedures’) carried out and the standard factual findings (‘the Findings’) confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the [Beneficiary] [Linked Third Party].
The Report covers the methodology used from [dd Month yyyy]. In the event that the [Beneficiary] [Linked Third Party] changes this methodology, the Report will not be applicable to any Financial Statement submitted thereafter.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the [Beneficiary’s] [Linked Third Party’s] Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the [Beneficiary] [Linked Third Party] agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

.....

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number ... because...

ii. the Auditor could not carry out the procedure ... established because .... (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number ... because ....

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates ...

Regarding standard Finding 15 it has to be noted that ...

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner:

.....

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;

Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.
2. Brief description of the time recording system in place;
3. An example of the time records used by the [Beneficiary] [Linked Third Party];
4. Description of any budgeted or estimated elements applied, together with an explanation as to why they are relevant for calculating the personnel costs and how they are based on objective and verifiable information;
5. A summary sheet with the hourly rate for direct personnel declared by the [Beneficiary] [Linked Third Party] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [Beneficiary] [Linked Third Party] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:
- is confidential and is intended to be submitted to the Commission by the [Beneficiary] [Linked Third Party] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [Beneficiary] [Linked Third Party] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [Beneficiary] [Linked Third Party].

No conflict of interest exists between the Auditor and the Beneficiary [and the Linked Third Party] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _______ (including EUR _______ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

---

A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.
Statements to be made by the Beneficiary/Linked Third Party (‘the Statements’) and Procedures to be carried out by the Auditor (‘the Procedures’) and standard factual findings (‘the Findings’) to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party’s usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to ‘the Beneficiary’ is to be considered as a reference to ‘the Linked Third Party’.

<table>
<thead>
<tr>
<th>Please explain any discrepancies in the body of the Report.</th>
<th>Procedures to be carried out and Findings to be confirmed by the Auditor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Use of the Methodology</strong></td>
<td><strong>Procedure:</strong></td>
</tr>
<tr>
<td>I. The cost accounting practice described below has been in use since [dd Month yyyy].</td>
<td>✓ The Auditor checked these dates against the documentation the Beneficiary has provided.</td>
</tr>
<tr>
<td>II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy].</td>
<td><strong>Factual finding:</strong></td>
</tr>
<tr>
<td></td>
<td>1. The dates provided by the Beneficiary were consistent with the documentation.</td>
</tr>
<tr>
<td></td>
<td>2. The brief description was consistent with the relevant manuals, internal guidance documents describing the methodology.</td>
</tr>
<tr>
<td></td>
<td>3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.</td>
</tr>
<tr>
<td><strong>B. Description of the Methodology</strong></td>
<td><strong>Procedure:</strong></td>
</tr>
<tr>
<td>III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures.</td>
<td>✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology.</td>
</tr>
<tr>
<td>[Please describe the methodology your entity uses to calculate personnel costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]</td>
<td><strong>Factual finding:</strong></td>
</tr>
<tr>
<td></td>
<td>2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed.</td>
</tr>
<tr>
<td>[If the statement of section “B. Description of the methodology” cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:]</td>
<td>3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.</td>
</tr>
<tr>
<td>- ...</td>
<td></td>
</tr>
</tbody>
</table>
Please explain any discrepancies in the body of the Report.

Statements to be made by Beneficiary

<table>
<thead>
<tr>
<th>C. Personnel costs</th>
<th>Procedures to be carried out and Findings to be confirmed by the Auditor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General</strong></td>
<td><strong>Procedure:</strong></td>
</tr>
<tr>
<td>IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act;</td>
<td>The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.</td>
</tr>
<tr>
<td>V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility;</td>
<td>[The Auditor has drawn a random sample of 10 employees assigned to Horizon 2020 action(s). If fewer than 10 employees are assigned to the Horizon 2020 action(s), the Auditor has selected all employees assigned to the Horizon 2020 action(s) complemented by other employees irrespective of their assignments until he has reached 10 employees. For this sample:</td>
</tr>
<tr>
<td>VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary’s usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s);</td>
<td>✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax, labour and social security law and any other documents corroborating the personnel costs claimed;</td>
</tr>
<tr>
<td>VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice;</td>
<td>✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that:</td>
</tr>
<tr>
<td>VIII. Personnel costs are based on the payroll system and accounting system.</td>
<td>i. they were employed directly by the Beneficiary in accordance with applicable national legislation;</td>
</tr>
<tr>
<td>IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements and were based on objective and verifiable information. [Please describe the ‘budgeted or estimated elements’ and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate].</td>
<td>ii. they were working under the sole technical supervision and responsibility of the latter;</td>
</tr>
<tr>
<td>X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary’s bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action.</td>
<td>iii. they were remunerated in accordance with the Beneficiary’s usual practices;</td>
</tr>
<tr>
<td>XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU budget</td>
<td>iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary’s usual cost accounting practices;</td>
</tr>
</tbody>
</table>


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### Please explain any discrepancies in the body of the Report.

<table>
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<tr>
<td>and grants awarded by bodies other than the Commission/Agency for the purpose of implementing the EU or Euratom budget in the same period, unless the Beneficiary can demonstrate that the operating grant does not cover any costs of the action).</td>
<td>to the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information;</td>
</tr>
<tr>
<td>If additional remuneration as referred to in the grant agreement(s) is paid</td>
<td>if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8,000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s).</td>
</tr>
<tr>
<td>XII. The Beneficiary is a non-profit legal entity;</td>
<td>the Auditor recalculated the personnel costs for the employees in the sample.</td>
</tr>
<tr>
<td>XIII. The additional remuneration is part of the beneficiary’s usual remuneration practices and paid consistently whenever the relevant work or expertise is required;</td>
<td>Factual finding:</td>
</tr>
<tr>
<td>XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding;</td>
<td>4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation.</td>
</tr>
<tr>
<td>XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8,000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action).</td>
<td>5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility.</td>
</tr>
<tr>
<td></td>
<td>6. Their employment contracts were in line with the Beneficiary’s usual policy;</td>
</tr>
<tr>
<td></td>
<td>7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month’s pay, etc.);</td>
</tr>
<tr>
<td></td>
<td>8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records;</td>
</tr>
<tr>
<td></td>
<td>9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values).</td>
</tr>
<tr>
<td></td>
<td>10. Personnel costs contained no ineligible elements;</td>
</tr>
<tr>
<td></td>
<td>11. Specific conditions for eligibility were fulfilled when additional</td>
</tr>
</tbody>
</table>

[If certain statement(s) of section “C. Personnel costs” cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:]

- ...]
Please explain any discrepancies in the body of the Report.

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</table>

remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).

D. Productive hours

XVI. The number of productive hours per full-time employee applied is [delete as appropriate]:

A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time).

B. the total number of hours worked in the year by a person for the Beneficiary

C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours.

If method B is applied

XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave).

XVIII. ‘Annual workable hours’ are hours during which the personnel must be working, at the employer’s disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the

Procedure (same sample basis as for Section C: Personnel costs):

- The Auditor verified that the number of productive hours applied is in accordance with method A, B or C.
- The Auditor checked that the number of productive hours per full-time employee is correct.
- If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts.
- If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90% of the standard number of working hours per year.

Factual finding:

General

12. The Beneficiary applied a number of productive hours consistent with method A, B or C detailed in the left-hand column.

13. The number of productive hours per year per full-time employee was accurate.

If method B is applied
Please explain any discrepancies in the body of the Report.

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<tbody>
<tr>
<td>annual workable hours.</td>
<td>14. The number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary and the calculation of the total number of hours worked was accurate.</td>
</tr>
<tr>
<td>If method C is applied</td>
<td>15. The contract specified the working time enabling to calculate the annual workable hours.</td>
</tr>
</tbody>
</table>

XX. The standard number of productive hours per year is that of a full-time equivalent.

XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary’s usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year.

XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary’s disposal performing the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence.

If certain statement(s) of section “D. Productive hours” cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:

- ...

<table>
<thead>
<tr>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used.</td>
</tr>
<tr>
<td>✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated.</td>
</tr>
</tbody>
</table>

For 10 employees selected at random (same sample basis as Section C: Personnel costs):

<table>
<thead>
<tr>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ The Auditor recalculated the hourly rates.</td>
</tr>
<tr>
<td>✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding.</td>
</tr>
</tbody>
</table>

E. Hourly rates

The hourly rates are correct because:

XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above.

If the statement of section ‘E. Hourly rates’ cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:

- ...
**Please explain any discrepancies in the body of the Report.**

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<tbody>
<tr>
<td><strong>F. Time recording</strong></td>
<td></td>
</tr>
</tbody>
</table>
| XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a daily/weekly/monthly basis [delete as appropriate] using a paper/computer-based system [delete as appropriate]; | Factual finding:  
19. No differences arose from the recalculation of the hourly rate for the employees included in the sample. |
| XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; | Procedure  
- The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. |
| XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; |  
- The Auditor reviewed the time records of the random sample of 10 employees referred to under Section C: Personnel costs, and verified in particular:  
  - that time records were available for all persons with no exclusive assignment to the action;  
  - that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action;  
  - that time records were signed and approved in due time and that all minimum requirements were fulfilled;  
  - that the persons worked for the action in the periods claimed;  
  - that no more hours were claimed than the productive hours used to calculate the hourly personnel rates;  
  - that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period;  
  - the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were... |
| XXVII. Measures are in place to prevent staff from:  
  i. recording the same hours twice,  
  ii. recording working hours during absence periods (e.g. holidays, sick leave),  
  iii. recording more than the number of productive hours per year used to calculate the hourly rates, and  
  iv. recording hours worked outside the action period. | |
| XXVIII. No working time was recorded outside the action period; | |
| XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. | |

*Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present...*
Please explain any discrepancies in the body of the Report.

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<tbody>
<tr>
<td>[If certain statement(s) of section “F. Time recording” cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor: ]</td>
<td>charged to Horizon 2020 actions per person per year than the number of productive hours per year used to calculate the hourly rates, and verified that no time worked outside the action period was charged to the action.</td>
</tr>
</tbody>
</table>

Factual finding:

20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements.

21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available;

22. For the random sample the time records were signed by the employee and the action manager/line manager, at least monthly.

23. Working time claimed for the action occurred in the periods claimed;

24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates;

25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period.

26. Working time claimed is consistent with that on record at the human-resources department.

1. The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.
<table>
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</tr>
<tr>
<td>[official name of the [Beneficiary] [Linked Third Party]]</td>
<td>[official name of the Auditor]</td>
</tr>
<tr>
<td>[name and title of authorised representative]</td>
<td>[name and title of authorised representative]</td>
</tr>
<tr>
<td>[dd Month yyyy]</td>
<td>[dd Month yyyy]</td>
</tr>
<tr>
<td>&lt;Signature of the [Beneficiary] [Linked Third Party]&gt;</td>
<td>&lt;Signature of the Auditor&gt;</td>
</tr>
</tbody>
</table>
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