



EUROPEAN COMMISSION
European Health and Digital Executive Agency

The Director



GRANT AGREEMENT

NUMBER 101035467 — TEHDAS

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Health and Digital Executive Agency (HaDEA)** ('the Agency'), under the powers delegated by the European Commission ('the Commission'), represented for the purposes of signature of this Agreement by Nicolas KRIEGER, Acting Head of Unit, or his/her duly authorised representative,

and

on the other part,

1. 'the coordinator':

SUOMEN ITSENAISYYDEN JUHLARAHASTO (Sitra), established in ITAMERENKATU 11-13, HELSINKI 00180, Finland, VAT number: FI02021323, represented for the purposes of signing the Agreement by Heidi Saario

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 40):

2. **BUNDESMINISTERIUM FUER SOZIALES, GESUNDHEIT, PFLEGE UND KONSUMENTENSCHUTZ (ATNA)**, established in Radetzkystrasse 2, WIEN 1030, Austria,

3. **SCIENSANO (Sciensano)**, established in JULIETTE WYTSMANSTRAAT 14, ELSENE 1050, Belgium, VAT number: BE0693876830,

4. **HRVATSKI ZAVOD ZA ZDRAVSTVENO OSIGURANJE (CHIF)**, established in MARGARETSKA 3, ZAGREB 10000, Croatia, VAT number: HR3580261,

5. **Ministry of Health of the Republic of Cyprus (MoH-CY)**, established in 1 Prodromou Street & 17 Chilonos Street 1 & 17, Nicosia 1448, Cyprus,

6. **MINISTERSTVO ZDRAVOTNICTVI CESKE REPUBLIKY (MZCR)**, established in PALACKEHO NAMESTI 375/4, PRAHA 12801, Czech Republic,

7. **REGION MIDTJYLLAND (RM)**, established in Skottenborg 26, VIBORG 8800, Denmark, VAT number: DK29190925,

8. **SOTSIAALMINISTEERIUM (MoSA)**, established in Suur-Ameerika 1, TALLINN 10122, Estonia,
9. **PLATEFORME DES DONNEES DE SANTE (FR-HDH)**, established in 9 RUE GEORGES PITARD, Paris 75015, France, VAT number: FR66130003783,
10. **BUNDESMINISTERIUM FUER GESUNDHEIT (BMG)**, established in ROCHUSTRASSE 1, BONN 53123, Germany,
11. **DIOIKISI 6IS YGEIONOMIKIS PERIFEREIAS PELOPONNISOU IONION NYSON IPEIROU KAI DYTIKIS ELLADAS (6th Y. PE.)**, established in IPATIS 1, PATRAS 26 441, Greece, VAT number: EL999100797,
12. **ORSZAGOS KORHAZI FOIGAZGATOSAG (OKFÓ)**, established in DIOS AROK 3, BUDAPEST 1125, Hungary, VAT number: HU15845883,
13. **DEPARTMENT OF HEALTH (DoH-IE)**, established in Block 1, Miesian Plaza, 50 – 58 Lower Baggot Street, Dublin D02 XW14, Ireland,
14. **MINISTERO DELLA SALUTE (MINSAL)**, established in Via Giorgio Ribotta 5, ROMA 00144, Italy, VAT number: N/A,
15. **LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA (SAM-LT)**, established in VILNIAUS G 33, VILNIUS LT 01506, Lithuania,
16. **Ministry for Health - Government of Malta (DHIR)**, established in Palazzo Castellania, Merchants Street 15, Valletta VLT 200, Malta, VAT number: MT12979127,
17. **AGENTIA DE TRANSPLANT (ATRM)**, established in STRADA TESTEMITEANU 29, CHISINAU 2025, Moldova,
18. **MINISTERIE VAN VOLKSGEZONDHEID, WELZIJN EN SPORT (VWS)**, established in PARNASSUSPLEIN 5, DEN HAAG 2500 EJ, Netherlands,
19. **THE NORWEGIAN MINISTRY OF HEALTH AND CARE SERVICES (MoH-NO)**, established in R6 Teatergata 9, 0030 Oslo 8011, Norway,
20. **SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE (SPMS)**, established in AVENIDA DA REPUBLICA, 61, LISBOA 1050 189, Portugal, VAT number: PT509540716,
21. **INSTITUT ZA ZASTITU ZDRAVLJA SRBIJEDR MILAN JOVANOVIC BATUT (IPHS "Batut")**, established in DR SUBOTICA STREET 5, BEOGRAD 11000, Serbia, VAT number: RS102000930,
22. **NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ)**, established in TRUBARJEVA CESTA 2, LJUBLJANA 1000, Slovenia, VAT number: SI44724535,
23. **INSTITUTO ARAGONES DE CIENCIAS DE LA SALUD (IACS)**, established in AVENIDA SAN JUAN BOSCO 13, ZARAGOZA 50009, Spain, VAT number: ESQ5000654C,
24. **E-HALSOMYNDIGHETEN (SEHA)**, established in SANK ERIKSGATAN 117, STOCKHOLM 118 60, Sweden, VAT number: SE202100655201,

25. **THE NHS CONFEDERATION (NHSC)**, established in 2ND FLOOR 18 SMITH SQUARE, LONDON SW1P 3HZ, United Kingdom, VAT number: GB788186860,

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
 - Annex 2a Not applicable
- Annex 3 Accession Forms
- Annex 4 Model for the financial statements
- Annex 5 Model for the certificate on the financial statements (CFS)

TERMS AND CONDITIONS

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

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 ‘**Towards the European Health Data Space Joint Action — TEHDAS**’ (‘**action**’), as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **30 months** as of 01/02/2021 (‘**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 affiliated entity) and budget category (see Articles 5, 6 and 11).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted — without an amendment (see Article 39) — 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 10.

CHAPTER 3 GRANT

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

5.1 Maximum grant amount

The ‘**maximum grant amount**’ is **EUR 2 500 000.00** (two million five hundred thousand EURO).

5.2 Form of grant, reimbursement rate and forms of costs

The grant reimburses **60% 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 **4 166 666.67** (four million one hundred and sixty six thousand six hundred and sixty six EURO and sixty seven eurocents).

Eligible costs (see Article 6) must be declared under the following forms (**'forms of costs'** or **'costs forms'**):

- (a) for **direct personnel costs**: as actually incurred costs (**actual costs**);
- (b) for **direct costs of subcontracting**: as actually incurred costs (**actual costs**);
- (c) for **other direct costs**: as actually incurred costs (**actual costs**);
- (d) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2.D (**'flat-rate costs'**);

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 Agency — when the payment of the balance is made — in the following steps:

- Step 1 – Application of the reimbursement rate 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 rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs and flat-rate costs; see Article 6) declared by the beneficiaries and affiliated entities (see Article 15) and approved by the Agency (see Article 16).

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 Agency.

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;
- (b) financial contributions given by third parties to the beneficiary or to an affiliated entity specifically to be used for costs that are eligible under the action.

The following are however **not** considered receipts:

- (a) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);
- (b) 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 in proportion to the final rate of reimbursement of the eligible actual costs approved by the Agency (as compared to the amount calculated following Steps 1 and 2).

5.3.4 Step 4 — Reduction due to substantial errors, irregularities or fraud or serious breach of obligations

If the grant is reduced (see Article 27), the Agency 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 27.2) 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 17) — the Agency rejects costs (see Article 26) or reduces the grant (see Article 27), it will calculate the ‘**revised final grant amount**’ for the action or for the beneficiary concerned.

This amount is calculated by the Agency 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 Agency for the beneficiary concerned;
- in case of **reduction of the grant**: 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 27.2) from the maximum grant amount set out in Article 5.1 or from the maximum EU contribution indicated for the beneficiary in the estimated budget (see Annex 2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount 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 15);
- (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**: not applicable;

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

(d) for **lump sum costs**: not applicable;

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. other direct costs;
- D. indirect costs;

‘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 D 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, 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).

They may also include **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.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract or **seconded by a third party against payment** are eligible personnel costs, if:

- (a) the person works under the beneficiary’s instructions and, unless otherwise agreed with the beneficiary, on the beneficiary’s premises;
- (b) the result of the work carried out belongs to the beneficiary, and
- (c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

- for persons **working exclusively on the action**:
 - {monthly rate for the person
 - multiplied by
 - number of actual months worked on the action}.

The months declared for these persons may not be declared for any other EU or Euratom grant.

The **‘monthly rate’** is calculated as follows:

- {annual personnel costs for the person
- divided by
- 12}

using the personnel costs 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 monthly rate of the last closed financial year available.

- for all **other** persons:

{daily rate for the person

multiplied by

number of actual days worked on the action (rounded up or down to the nearest half-day)}.

The number of actual days declared for a person must be identifiable and verifiable (see Article 13).

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

{number of annual productive days for the year (see below)

minus

total number of days declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The ‘**daily rate**’ is calculated as follows:

{annual personnel costs for the person

divided by

number of individual annual productive days}

using the personnel costs and the number of annual productive days 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 daily rate of the last closed financial year available.

The ‘number of individual annual productive days’ is the total actual days worked by the person in the year. It may not include holidays and other absences (such as sick leave, maternity leave, special leave, etc). However, it may include overtime and time spent in meetings, trainings and other similar activities.

B. Direct costs of subcontracting (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies acting as public authority) are eligible if the conditions in Article 10.1.1 are met.

C. Other direct costs

C.1 Travel costs and related subsistence allowances (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies acting as public authority) are eligible if they are in line with the beneficiary’s usual practices on travel.

C.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 9.1.1 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 beneficiaries that are not public bodies acting as public authority) 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 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.

C.3 Costs of other goods and services (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies acting as public authority) are eligible, if they are purchased specifically for the action and in accordance with Article 9.1.1.

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

D. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 7% of the eligible direct costs (see Article 5.2 and Points A to C above).

Beneficiaries receiving an operating grant¹ financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

6.3 Conditions for costs of affiliated entities to be eligible

Costs incurred by affiliated entities are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 11.1.1.

6.4 Ineligible costs

'**Ineligible costs**' are:

- (a) costs that do not comply with the conditions set out above (Article 6.1 to 6.3), 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;

¹ For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 218, 26.10.2012, p.1) ('**Financial Regulation No 966/2012**'): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

- (v) doubtful debts;
 - (vi) currency exchange losses;
 - (vii) bank costs charged by the beneficiary's bank for transfers from the Agency;
 - (viii) excessive or reckless expenditure;
 - (ix) deductible VAT;
 - (x) costs incurred during suspension of the implementation of the action (see Article 33);
 - (xi) in-kind contributions provided by third parties;
- (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 Agency 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;
- (c) costs for staff of a national (or local) administration, for activities that are part of the administration's normal activities (i.e. not undertaken only because of the grant);
- (d) costs (especially travel and subsistence costs) for staff or representatives of EU institutions, bodies or agencies.

6.5 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 26).

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 27).

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 9);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 10);
- call upon affiliated entities to implement action tasks described in Annex 1 (see Article 11).

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

ARTICLE 8a — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

Not applicable

ARTICLE 9 — PURCHASE OF GOODS, WORKS OR SERVICES

9.1 Rules for purchasing goods, works or services

9.1.1 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 20).

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 17 and 18 also towards their contractors.

9.1.2 Beneficiaries that are ‘contracting authorities’ within the meaning of Directive 2004/18/EC² (or 2014/24/EU³) or ‘contracting entities’ within the meaning of Directive 2004/17/EC⁴ (or 2014/25/EU⁵) must comply with the applicable national law on public procurement.

9.2 Consequences of non-compliance

² Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

³ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).

⁴ Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

⁵ Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).

If a beneficiary breaches any of its obligations under Article 9.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 26).

If a beneficiary breaches any of its obligations under Article 9.1.2, the grant may be reduced (see Article 27).

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

ARTICLE 10 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

10.1 Rules for subcontracting action tasks

10.1.1 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 20).

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 Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 39), 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 Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 17 and 18 also towards their subcontractors.

10.1.2 The beneficiaries must ensure that their obligations under Articles 20, 21, 22 and 30 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.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 26).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 27).

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

ARTICLE 11 — IMPLEMENTATION OF ACTION TASKS BY AFFILIATED ENTITIES

11.1 Rules for calling upon affiliated entities to implement part of the action

11.1.1 The following '**affiliated entities**'⁶ may implement the action tasks attributed to them in Annex 1:

- TEKNOLOGIAN TUTKIMUSKESKUS VTT OY (VTT), affiliated or linked to Sitra
- TERVEYDEN JA HYVINVOINNIN LAITOS (THL), affiliated or linked to Sitra
- CSC-TIETEEN TIETOTEKNIKAN KESKUS OY (CSC), affiliated or linked to Sitra
- HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO (CIPH), affiliated or linked to CHIF
- MIDTJYLLANDS EU KONTOR FORENING (CDEU), affiliated or linked to RM
- UNIVERSITE PAUL SABATIER TOULOUSE III (UT3), affiliated or linked to FR-HDH
- UNIVERSITE D'AIX MARSEILLE (AMU), affiliated or linked to FR-HDH
- INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (Inserm), affiliated or linked to FR-HDH
- HOSPICES CIVILS DE LYON (HCL), affiliated or linked to FR-HDH
- AGENCE DU NUMÉRIQUE EN SANTÉ (ANS), affiliated or linked to FR-HDH
- BUNDESINSTITUT FÜR ARZNEIMITTEL UND MEDIZINPRODUKTE (FDZ), affiliated or linked to BMG
- GEMATIK GMBH (GEMATIK), affiliated or linked to BMG
- SEMMELWEIS EGYETEM (SU), affiliated or linked to OKFŐ
- THE HEALTH RESEARCH BOARD (HRB), affiliated or linked to DoH-IE
- STICHTING NATIONAAL ICT INSTITUUT IN DE ZORG (Nictiz), affiliated or linked to VWS
- DIREKTORAT FOR E-HELSE (E-helse), affiliated or linked to MoH-NO
- FOLKEHELSEINSTITUTTET (FHI), affiliated or linked to MoH-NO
- HELSEDIREKTORATET (Hdir), affiliated or linked to MoH-NO
- FOLKHALSOMYNDIGHETEN (PHAS), affiliated or linked to SEHA

⁶ For the definition, see Article 122 of the Financial Regulation (EU, Euratom) No 966/2012: **entities affiliated to the beneficiary** are:

- (a) entities that form a 'sole beneficiary' (i.e. where an entity is formed of several entities that satisfy the criteria for being awarded a grant, including where the entity is specifically established for the purpose of implementing an action to be financed by a grant);
- (b) entities that satisfy the eligibility criteria and that do not fall within one of the situations referred to in Article 131(4) and that have a link with the beneficiary, in particular a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

- SOCIALSTYRELSEN (NBHW), affiliated or linked to SEHA
- GENOME RESEARCH LIMITED (WSI), affiliated or linked to NHSC

The affiliated entities may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 17 and 18 also towards their affiliated entities.

11.1.2 The beneficiaries must ensure that their obligations under Articles 13, 15, 20, 21 and 22 also apply to their affiliated entities.

11.2 Consequences of non-compliance

If any obligation under Article 11.1.1 is breached, the costs of the affiliated entity will be ineligible (see Article 6) and will be rejected (see Article 26).

If any obligation under Article 11.1.2 is breached, the grant may be reduced (see Article 27).

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

ARTICLE 11a — FINANCIAL SUPPORT TO THIRD PARTIES

Not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 12 — GENERAL OBLIGATION TO INFORM

12.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 25.2 — 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.

12.2 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 36) 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 Agency 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 or those of its affiliated entities and
 - (ii) changes in the name, address, legal form, organisation type of its affiliated entities;
- (b) **circumstances** affecting:
- (i) the decision to award the grant or
 - (ii) compliance with requirements under the Agreement.

12.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

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

ARTICLE 13 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

13.1 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 12) or in the context of checks, reviews, audits or investigations (see Article 17).

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 17), 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 Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

13.1.1 Records and other supporting documentation on the technical implementation

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

13.1.2 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**: not applicable;
- (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;
- (d) for **lump sum costs**: not applicable;

In addition, for **personnel costs** (declared as actual costs), the beneficiaries must keep **time records** for the number of days 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 days worked on the action, the Agency may accept alternative evidence supporting the number of days 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.

For costs declared by affiliated entities (see Article 11), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of its affiliated entities.

13.2 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 26), and the grant may be reduced (see Article 27).

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

ARTICLE 14 — SUBMISSION OF DELIVERABLES

14.1 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.

14.2 Consequences of non-compliance

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

ARTICLE 15 — REPORTING — PAYMENT REQUESTS

15.1 Obligation to submit reports

The coordinator must submit to the Agency (see Article 36) the technical and financial report(s) set

out in this Article. These reports include request(s) for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 36).

15.2 Reporting periods

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

- RP1: from month 1 to month 15
- RP2: from month 16 to month 30

15.2a Request(s) for further pre-financing payment(s)

Not applicable

15.3 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;

- (iii) a **summary** for publication by the Agency;
- (iv) the answers to the ‘**questionnaire**’: covering issues related to the action implementation and its impact;

(b) a ‘**periodic financial report**’ containing:

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

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

The beneficiaries and affiliated entities must declare all eligible costs, even if — for actual 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 Agency.

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 and each affiliated entity 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 13) that will be produced upon request (see Article 12) or in the context of checks, reviews, audits and investigations (see Article 17), 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 10) from each beneficiary and from each affiliated entity, 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**;
- (v) a ‘**certificate on the financial statements**’ (drawn up in accordance with Annex 5) for each beneficiary and for each affiliated entity, if:
- the (cumulative) amount of EU contribution it requests as reimbursement of actual costs (and for which no certificate has yet been submitted) is EUR 150 000 or more and
 - the maximum EU contribution indicated, for that beneficiary or affiliated entity, in the estimated budget (see Annex 2) as reimbursement of actual costs is EUR 200 000 or more.

15.4 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 dissemination;
 - (ii) the conclusions on the action and
 - (iii) the impact of the action;

- (b) a ‘**final financial report**’ containing 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**.

15.5 Information on cumulative expenditure incurred

Not applicable

15.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

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

15.7 Language of reports

All report(s) (including financial statements) must be submitted in the language of the Agreement.

15.8 Consequences of non-compliance

If the report(s) submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 31) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the report(s) and if it fails to comply with this obligation within 30 days following a written reminder, the Agency may terminate the Agreement (see Article 34) or apply any of the other measures described in Chapter 6.

ARTICLE 16 — PAYMENTS AND PAYMENT ARRANGEMENTS

16.1 Payments to be made

The following payments will be made to the coordinator:

- a **pre-financing payment**;
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 15), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 15).

16.2 Pre-financing payment — Amount

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 **1 250 000.00** (one million two hundred and fifty thousand EURO).

The Agency will — except if Article 32 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 42) or from 10 days before the starting date of the action (see Article 3) , whichever is the latest.

16.3 Interim payments — Amount — Calculation

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

The Agency will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 15.3), except if Articles 31 or 32 apply.

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

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

Step 1 – Application of the reimbursement rate

Step 2 – Limit to 90% of the maximum grant amount

16.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs and flat-rate costs; see Article 6) declared by the beneficiaries and the affiliated entities (see Article 15) and approved by the Agency (see above) for the concerned reporting period.

16.3.2 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:

$$\begin{aligned} & \{90\% \text{ of the maximum grant amount (see Article 5.1)} \\ & \text{minus} \\ & \{\text{pre-financing and previous interim payments}\} \}. \end{aligned}$$

16.4 Payment of the balance — Amount — Calculation

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 28).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 90 days from receiving the final report (see Article 15.4), except if Articles 31 or 32 apply.

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

The **amount due as the balance** is calculated by the Agency 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:

$$\begin{aligned} & \{\text{final grant amount (see Article 5.3)} \\ & \text{minus} \\ & \{\text{pre-financing and interim payments (if any) made}\}. \end{aligned}$$

If the balance is positive, it will be paid to the coordinator.

The amount to be paid may however be offset — without the beneficiaries' consent — against any other amount owed by a beneficiary to the Agency, the Commission or another 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).

If the balance is negative, it will be recovered from the coordinator (see Article 28).

16.5 Notification of amounts due

When making payments, the Agency will formally notify to the coordinator the amount due, specifying that 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 27 and 28.

16.6 Currency for payments

The Agency will make all payments in euro.

16.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the Agency 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 90% of the beneficiaries have acceded to the Agreement (see Article 40) and
- (b) to beneficiaries that have acceded to the Agreement (see Article 40).

16.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: NORDEA BANK FINLAND PLC
Full name of the account holder: SUOMEN ITSENAISYYDEN JUHLARAHA
Full account number (including bank codes):
IBAN code: FI2412793000513180

16.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the Agency 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.

16.10 Date of payment

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

16.11 Consequences of non-compliance

16.11.1 If the Agency 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 31 and 32) 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.

16.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 27) and the Agreement or the participation of the coordinator may be terminated (see Article 34).

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

ARTICLE 17 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

17.1 Checks, reviews and audits by the Agency and the Commission

17.1.1 Right to carry out checks

The Agency or 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 Agency or the Commission may be assisted by external persons or bodies.

The Agency or the Commission may also request additional information in accordance with Article 12. The Agency or 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.

17.1.2 Right to carry out reviews

The Agency or 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) and compliance with the obligations under the Agreement.

Reviews may be started **up to five 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 9 to 11a), the beneficiary concerned must inform the third party.

The Agency or 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 Agency or 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 Agency or 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.

17.1.3 Right to carry out audits

The Agency or 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 five 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 9 to 11a), the beneficiary concerned must inform the third party.

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

17.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013⁷ and No 2185/96⁸ (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.

17.3 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 966/2012⁹, 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.

17.4 Checks, reviews, audits and investigations for international organisations

Not applicable

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

17.5.1 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 26), reduction of the grant (see Article 27), recovery of undue amounts (see Article 28) 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 39).

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.

17.5.2 Findings in other grants

⁷ Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 232, 18.09.2013, p. 1).

⁸ 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).

⁹ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

The Agency or 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 five years after the payment of the balance** of this grant.

The extension of findings may lead to the rejection of costs (see Article 26), reduction of the grant (see Article 27), recovery of undue amounts (see Article 28), suspension of payments (see Article 32), suspension of the action implementation (see Article 33) or termination (see Article 34).

17.5.3 Procedure

The Agency or 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.

17.5.3.1 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 Agency or 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 Agency or the Commission in justified cases.

The Agency or the Commission may then start a **rejection procedure** in accordance with Article 26, either on the basis of the revised financial statements, the alternative method or the correction rate announced.

17.5.3.2 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 Agency or 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 Agency or the Commission may then start a **reduction procedure** in accordance with Article 27, either on the basis of the alternative flat-rate or the flat-rate announced.

17.6 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 26).

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

ARTICLE 18 — EVALUATION OF THE IMPACT OF THE ACTION

18.1 Right to evaluate the impact of the action

The Agency or 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 Agency or 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.

18.2 Consequences of non-compliance

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

SECTION 3 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 19 — PRE-EXISTING RIGHTS AND OWNERSHIP OF THE RESULTS (INCLUDING INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS)

19.1 Pre-existing rights and access rights to pre-existing rights

Where industrial and intellectual property rights (including rights of third parties) exist prior to the Agreement, the beneficiaries must establish a list of these pre-existing industrial and intellectual property rights, specifying the owner and any persons that have a right of use.

The coordinator must — before starting the action — submit this list to the Agency.

Each beneficiary must give the other beneficiaries and their affiliated entities access to any pre-existing industrial and intellectual property rights needed for the implementation of the action and compliance with the obligations under the Agreement.

19.2 Ownership of results and rights of use

The results of the action (including the reports and other documents relating to it) are owned by the beneficiaries.

The beneficiaries must give the Agency and the Commission the right to use the results for their communication activities under Article 22.

19.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

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

ARTICLE 20 — CONFLICT OF INTERESTS

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

20.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27) and the Agreement or participation of the beneficiary may be terminated (see Article 34).

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

ARTICLE 21 — CONFIDENTIALITY

21.1 General obligation to maintain confidentiality

During implementation of the action and for **five years after the payment of the balance**, 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’**).

They may use confidential information to implement the Agreement.

The confidentiality obligations no longer apply if:

- (a) the disclosing party agrees to release the other party;
- (b) the information becomes generally and publicly available, without breaching any confidentiality obligation;

(c) the disclosure of the confidential information is required by EU or national law.

21.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

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

ARTICLE 22 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

22.1 Communication activities by the beneficiaries

22.1.1 General obligation to promote the action and its results

The beneficiaries must promote the action and its results.

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

Unless the Agency requests or agrees otherwise, any communication activity related to the action (including at conferences, seminars, in information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via social media, etc.) and any infrastructure, equipment or major results funded by the grant must:

- display the EU emblem and
- include the following text:

“This [insert appropriate description, e.g. report, publication, conference, infrastructure, equipment, insert type of result, etc.] was funded by the European Union’s Health Programme (2014-2020).”

When displayed in association 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 Agency.

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.

22.1.3 Disclaimer excluding Agency and Commission responsibility

Any communication activity related to the action must indicate the following disclaimer:

"The content of this [insert appropriate description, e.g. report, publication, conference, etc.] represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency (CHAFFA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains."

22.2 Communication activities by the Agency and the Commission

22.2.1 Right to use the beneficiaries’ materials, documents or information

The Agency and the Commission may use 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 21, which still apply.

The right to use the beneficiary's materials, documents and information includes:

- (a) **use for its own purposes** (in particular, making them available to persons working for the Agency, 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 1049/2001¹⁰, 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 Agency or 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 Agency or the Commission will insert the following information:

“© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the Consumers, Health, Agriculture and Food Executive Agency (CHAFFEA) and the European Union (EU) under conditions.”

22.3 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

¹⁰ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

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

ARTICLE 23 — PROCESSING OF PERSONAL DATA

23.1 Processing of personal data by the Agency and the Commission

Any personal data under the Agreement will be processed by the Agency or the Commission under Regulation No 23/2001¹¹ and according to the ‘notifications of the processing operations’ to the Data Protection Officer (DPO) of the Agency or the Commission (publicly accessible in the DPO register).

Such data will be processed by the ‘**data controller**’ of the Agency or 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 17).

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) on the Agency and Commission websites.

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

23.2 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 Agency or the Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the Agency or the Commission.

23.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 23.2, the Agency may apply any of the measures described in Chapter 6.

ARTICLE 24 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE AGENCY

The beneficiaries may not assign any of their claims for payment against the Agency to any third party, except if approved by the Agency on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

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

¹¹ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

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

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES

ARTICLE 25 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES

25.1 Roles and responsibilities towards the Agency

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 Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 28, 29 and 30.

25.2 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 12);
- (ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 12);
- (iii) submit to the coordinator in good time:
 - individual financial statements for itself and its affiliated entities and, if required, certificates on the financial statements (see Article 15);
 - the data needed to draw up the technical reports (see Article 15);
 - any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly.

(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 Agency (in particular, providing the Agency with the information described in Article 12), unless the Agreement specifies otherwise;
- (iii) provide a pre-financing guarantee if requested by the Agency (see Article 16.2);

- (iv) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;
- (v) submit the deliverables and reports to the Agency (see Articles 14 and 15);
- (vi) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 16).

The coordinator may not subcontract the above-mentioned tasks.

25.3 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 pre-existing rights and results (see Article 19);
- settlement of internal disputes;
- liability, indemnification and confidentiality arrangements between the beneficiaries.

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

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 26 — REJECTION OF INELIGIBLE COSTS

26.1 Conditions

The Agency will — 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 17).

The rejection may also be based on the **extension of findings from other grants to this grant** (see Article 17.5.2).

26.2 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 28), the Agency 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 16.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the rejection of costs leads to a recovery, the Agency will follow the contradictory procedure with pre-information letter set out in Article 28.

26.3 Effects

If the Agency 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 Article 15.3 and 15.4). It will then calculate the interim payment or payment of the balance as set out in Article 16.3 or 16.4.

If the Agency — **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 costs declared in the next periodic summary financial statement or final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Article 16.3 or 16.4.

If the Agency 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. If the revised final grant amount is lower than the final grant amount, the Agency will recover the difference (see Article 28).

ARTICLE 27 — REDUCTION OF THE GRANT

27.1 Conditions

The Agency may — **at the payment of the balance or afterwards** — reduce the grant, 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) 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 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 17.5.2).

27.2 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 Agency 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 Agency 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 16).

27.3 Effects

If the Agency reduces the grant **at the time of 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 Article 5.3.4 and 16.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the action or for the beneficiary concerned (see Article 5.4). If the revised final grant amount is lower than the final grant amount, the Agency will recover the difference (see Article 28).

ARTICLE 28 — RECOVERY OF UNDUE AMOUNTS

28.1 Amount to be recovered — Calculation — Procedure

The Agency will — **at the payment of the balance** or **afterwards** — claim back any amount that was paid but is not due under the Agreement.

The coordinator is fully liable for repaying debts of the consortium (under the Agreement) even if it has not been the final recipient of those amounts.

In addition, the beneficiaries (including the coordinator) are jointly and severally liable for repaying any unpaid debts under the Agreement (due by the consortium or any beneficiary, including late-payment interest) — up to the maximum EU contribution indicated, for each beneficiary, in the estimated budget (as last amended; see Annex 2).

Undue amounts paid by the Agency for costs declared by an affiliated entity will be considered as amounts unduly paid to the beneficiary.

28.1.1 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 16.4), the Agency 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 and

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

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note** with the terms and the date for payment (together with the notification of amounts due; see Article 16.5).

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

- (a) by ‘**offsetting**’ it — without the coordinator’s consent — against any amounts owed to the coordinator by the Agency, Commission or another executive agency (from the EU or Euratom budget).

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

- (b) not applicable;
- (c) by **holding** the other beneficiaries jointly and severally **liable** — up to the maximum EU contribution indicated, for each beneficiary, in the estimated budget (as last amended; see Annex 2)
- (d) by **taking legal action** (see Article 41) 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 16.11, from the day following the payment date in the debit note, up to and including the date the Agency or 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.

28.1.2 Recovery of amounts after payment of the balance

If — after the payment of the balance — the Agency revised the final grant amount for the action or for the beneficiary concerned (see Article 5.4), due to a rejection of costs or reduction of the grant, and the revised final grant amount is lower than the final grant amount (see Article 5.3), the Agency will:

- if the rejection or reduction does *not* concern a specific beneficiary or its affiliated entities: claim back the difference from the coordinator (even if it has not been the final recipient of the amount in question)

or

- otherwise: claim back the difference from the beneficiary concerned.

The Agency will formally notify a **pre-information letter** to the coordinator or beneficiary concerned:

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

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator or 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 Agency or the Commission will **recover** the amount:

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

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

- (b) by **holding** the other beneficiaries jointly and severally **liable**, up to the maximum EU contribution indicated, for each beneficiary, in the estimated budget (as last amended; see Annex 2)
- (c) by **taking legal action** (see Article 41) 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 16.11, from the day following the date for payment in the debit note, up to and including the date the Agency or 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 29 — ADMINISTRATIVE SANCTIONS

In addition to contractual measures, the Agency or 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 and expert contracts and/or financial penalties).

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 30 — LIABILITY FOR DAMAGES

30.1 Liability of the Agency

The Agency 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 Agency 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.

30.2 Liability of the beneficiaries

Except in case of force majeure (see Article 35), the beneficiaries must compensate the Agency 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 31 — SUSPENSION OF PAYMENT DEADLINE

31.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 16.2 to 16.4) if a request for payment (see Article 15) cannot be approved because:

- (a) it does not comply with the provisions of the Agreement (see Article 15);
- (b) the technical or financial report(s) 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.

31.2 Procedure

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

The suspension will **take effect** the day notification is sent by the Agency (see Article 36).

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 Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial report(s) (see Article 15) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 34.3.1(i)).

ARTICLE 32 — SUSPENSION OF PAYMENTS

32.1 Conditions

The Agency may — at any moment — suspend payments, in whole or in part 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 this 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 17.5.2).

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

32.2 Procedure

Before suspending payments, the Agency 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 Agency 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 Agency.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Agency 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 15.3) must not contain any individual financial statement(s) from the beneficiary concerned and its affiliated entities. 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 33.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 34.1 and 34.2).

ARTICLE 33 — SUSPENSION OF THE ACTION IMPLEMENTATION

33.1 Suspension of the action implementation, by the beneficiaries

33.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 35) — make implementation impossible or excessively difficult.

33.1.2 Procedure

The coordinator must immediately formally notify to the Agency the suspension (see Article 36), stating:

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

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

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the Agency 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 39) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 34).

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).

33.2 Suspension of the action implementation, by the Agency

33.2.1 Conditions

The Agency 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 this Agreement or during the award procedure (including improper implementation of the action, submission of false declaration, 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 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 17.5.2).

33.2.2 Procedure

Before suspending implementation of the action, the Agency 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 Agency 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 39) — unless the Agreement has already been terminated (see Article 34).

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 Agency (see Article 30).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement or participation of a beneficiary (see Article 34), reduce the grant or recover amounts unduly paid (see Articles 27 and 28).

ARTICLE 34 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

34.1 Termination of the Agreement, by the beneficiaries

34.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 36), 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 Agency 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.

34.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit a periodic report (for the open reporting period until termination; see Article 15.3) and the final report (see Article 15.4).

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

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 16.4) on the basis of the report(s) 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 27).

After termination, the beneficiaries' obligations (in particular, Articles 15, 17, 18, 19, 20, 21, 22, 24, 26, 27 and 28) continue to apply.

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

34.2.1 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 Agency (see Article 36) 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 39), 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 40). 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 Agency 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.

34.2.2 Effects

The beneficiary concerned must submit to the coordinator:

- (i) a technical report and

- (ii) a financial statement covering the period from the end of the last reporting period to the date when termination takes effect.

This information must be included by the coordinator in the periodic report for the next reporting period (see Article 15.3).

If the request for amendment is rejected by the Agency (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 34.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 39).

Improper termination may lead to a reduction of the grant (see Article 27) or termination of the Agreement (see Article 34).

After termination, the concerned beneficiary's obligations (in particular Articles 15, 17, 18, 19, 21, 22, 24, 26, 27 and 28) continue to apply.

34.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

34.3.1 Conditions

The Agency 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 40);
- (b) a change to their legal, financial, technical, organisational or ownership situation (or those of its affiliated entities) 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 39);
- (d) implementation of the action is prevented by force majeure (see Article 35) or suspended by the coordinator (see Article 33.1) 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) 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;
- (i) 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) 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);
- (j) 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 17.5.2);
- (k) despite a specific request by the Agency, a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its affiliated entities that is in one of the situations under points (e), (f), (g), (h), (i) or (j) and to reallocate its tasks

34.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency 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 Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency 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), (i.ii) and (k) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (h), (i.i) and (j) above: on the day after the notification of the confirmation is received.

34.3.3 Effects

- (a) for **termination of the Agreement**:

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

report (for the last open reporting period until termination; see Article 15.3) and a final report (see Article 15.4).

If the Agreement is terminated for breach of the obligation to submit reports (see Articles 15.8 and 34.3.1(i)), the coordinator may not submit any reports after termination.

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

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 16.4) on the basis of the report(s) 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 Agency's right to reduce the grant (see Article 27) or to impose administrative sanctions (Article 29).

The beneficiaries may not claim damages due to termination by the Agency (see Article 30).

After termination, the beneficiaries' obligations (in particular Articles 15, 17, 18, 19, 21, 22, 24, 26, 27 and 28) 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 a request for amendment (see Article 39), 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 40). 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.

The beneficiary concerned must submit to the coordinator:

- (i) a technical report and
- (ii) a financial statement covering the period from the end of the last reporting period to the date when termination takes effect.

This information must be included by the coordinator in periodic report for the next reporting period (see Article 15.3).

If the request for amendment is rejected by the Agency (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 34.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 39).

After termination, the concerned beneficiary's obligations (in particular Articles 15, 17, 18, 19, 20, 21, 22, 24, 26, 27 and 28) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 35 — 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 36 — COMMUNICATION BETWEEN THE PARTIES

36.1 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.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery (‘formal notification on paper’).

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 Agency and Commission websites.

36.2 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.

36.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/myarea/projects>

The Agency 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 Agency** must be sent to the following address:

European Health and Digital Executive Agency (HADEA)
Health and Food EU4Health/SMP Food
B-1049 Belgium

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 37 — INTERPRETATION OF THE AGREEMENT

37.1 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.

37.2 Privileges and immunities

Not applicable

ARTICLE 38 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71¹², 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 39 — AMENDMENTS TO THE AGREEMENT

39.1 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.

39.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 36).

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, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The Agency 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 Agency 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.

¹² Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8/6/1971, p. 1).

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 40 — ACCESSION TO THE AGREEMENT

40.1 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 36) within 30 days after its entry into force (see Article 42).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 42).

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 Agency's right to terminate the Agreement (see Article 34).

40.2 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 39. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 36).

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 41 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

41.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

41.2 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).

As an exception, if such a dispute is between the Agency and ‘AGENTIA DE TRANSPLANT’, ‘THE NORWEGIAN MINISTRY OF HEALTH AND CARE SERVICES’, ‘INSTITUT ZA ZASTITU ZDRAVLJA SRBIJEDR MILAN JOVANOVIC BATUT’, the competent Belgian courts have sole jurisdiction.

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under

Article 79(2) of the Financial Regulation No 966/2012 and Article 299 TFEU (see Articles 28, 29 and 30), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against enforceable decisions must be brought against the Commission (not against the Agency).

ARTICLE 42 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Agency or the coordinator, depending on which is later.

SIGNATURES

For the coordinator

Heidi Saario with ECAS id n0043014 signed in the Participant Portal on 14/07/2021 at 08:59:24 (transaction id SigId-65545-TfkfZ FJROLRcwE7r7xjNiRcSeXwSntzMlpkzaXKlvppuWZxWTZqOaDsIDth nn7rJYzt2pi5TzXNRwVkjnP6laoa-yntOf97TTHqL2QVETsEsmO-VwP e3BiWtLBEMd4MtilQeZzFZ87zjSltcC0xQF9Es8kiU3wgbRfWqzIXbf6 dlcnzV8gUYZZcQWcjEmpflm4dVJC). Timestamp by third party at 2021.07.14 09:59:29 CEST

For the Agency

Signed by Nicolas KRIEGER with ECAS id kriegni as an authorised representative on 15-07-2021 18:30:55 (transaction id SigId-85875-8 rIN7OVPwf5avzwrMp9r65U5MQE6Hzlt3JutzMkGGYXM8lwFIQnxvfnU P58xxGFzxdokXgtHNHOazfdJKvtdg5zm-yntOf97TTHqL2QVETsEsmO-BmwSloFCdPSKo8v1O8Ag9zpGR3J5qUbt9zocTNb0PbzyyVMmAOVE8 HvbqY9p89qtvDawmb2zZkqNI7Dr750pj6G) 2021.07.15 18:30:59 CEST