



DELIBERA DEL DIRETTORE GENERALE

432 / 2020 del 31/12/2020

Oggetto: PARTECIPAZIONE DI AREU AL FINANZIAMENTO EUROPEO DI INCREMENTO DELLA RACCOLTA DI CCP NEI CENTRI EMATOLOGICI DELL'UE PER SUPPORTARE LA RACCOLTA DI CCP DURANTE LA PANDEMIA DA DIFFUSIONE DEL VIRUS COVID-19- PROVVEDIMENTI



OGGETTO: PARTECIPAZIONE DI AREU AL FINANZIAMENTO EUROPEO DI INCREMENTO DELLA RACCOLTA DI CCP NEI CENTRI EMATOLOGICI DELL'UE PER SUPPORTARE LA RACCOLTA DI CCP DURANTE LA PANDEMIA DA DIFFUSIONE DEL VIRUS COVID-19- PROVVEDIMENTI

vista la seguente proposta di deliberazione n. 663/2020, avanzata dal Direttore della Struttura Complessa Affari Generali e Legali

IL DIRETTORE GENERALE

PREMESSO che l'Azienda Regionale Emergenza Urgenza, nell'ambito dei LEA, garantisce su tutto il territorio regionale, tra le altre funzioni, lo svolgimento e il coordinamento intra regionale e interregionale delle funzioni a rete relative all'indirizzo, al coordinamento e al monitoraggio dell'attività di emergenza urgenza extra ospedaliera e, inoltre, assicura il coordinamento delle attività trasfusionali dei flussi di scambio e compensazione di sangue, emocomponenti ed emoderivati attraverso la propria articolazione organizzativa definita Struttura Regionale di Coordinamento (SRC), la quale rappresenta anche il riferimento istituzionale per il Centro Nazionale Sangue e coordina la Conferenza Scientifica dei Dipartimenti di Medicina Trasfusionale e Ematologia (DMTE) regionali (rif. Art.16 L.33/2009 così come modificato dalla L.R. n. 23 dell'11 agosto 2015, art.1 co.1 let.v L.R. 11 agosto 2015 n.23 e dalla L.R. n. 22 del 10.12.2019 "Seconda legge di semplificazione 2019" la DGR 2701 del 23.12.2019 "Costituzione Agenzia Regionale Emergenza Urgenza (AREU));

DATO ATTO che l'Unione Europea ha messo a disposizione finanziamenti fino a 40 milioni di euro per sostenere l'aumento della capacità di raccolta del plasma convalescente da parte di centri di sangue pubblici e ONG, con attuazione delle sovvenzioni ad opera della DG Salute e sicurezza alimentare (SANTE) della Commissione Europea nel quadro dello strumento di sostegno alle emergenze dell'UE e in linea con la decisione della Commissione Europea del 23.7.2020, che modifica la decisione C (2020) 2794;

VALUTATA l'opportunità per AREU, quale sede della Struttura Regionale di Coordinamento (SRC) per il coordinamento intra regionale e interregionale delle attività trasfusionali, di scambio e compensazione di sangue, emocomponenti ed emoderivati, nel rispetto degli indirizzi di programmazione strategica assegnati dalla Direzione Generale Welfare di Regione Lombardia, di partecipare al progetto come capofila operando nell'ambito del progetto in collaborazione con altre 13 Aziende affiliate;

EVIDENZIATO che AREU, per il tramite della propria Struttura Regionale di Coordinamento (SRC) ha avanzato, entro il termine previsto del 27.08.2020, apposita domanda di sovvenzione, presentando alla Commissione un progetto di azione congiunta volta a consentire l'incremento della raccolta di CCP nei centri ematologici dell'UE per supportare la raccolta di CCP durante la pandemia da diffusione del virus covid-19, ed i relativi costi;

RILEVATO che la domanda di sovvenzione è stata presentata dalla SRC in collaborazione con i centri ematologici afferenti alle seguenti realtà: Azienda Sanitaria Dell'alto Adisudtiroler Sanitatbetribetrieb Di Bolzano, Azienda Provinciale Per I Servizi Sanitari Della Provincia Autonoma Di Trento, Azienda Ospedaliero Universitaria Città Della Salute E Della Scienza Di Torino, Azienda Ospedale Università Padova, Azienda Sanitaria Locale Frosinone, Azienda Ospedaliera Di Rilievo Nazionale Cardarelli Di Napoli, Grande

Ospedale Metropolitano "Bianchi Melacrino Morelli", Azienda Ospedaliera Papardo Della Sicilia, Azienda Usl Bologna, Ospedale Policlinico San Martino Di Genova, Servizio Ematologia E Medicina Trasfusionale-Azienda Ospedaliero Universitaria Policlinico Bari, Azienda Usl Valle D'Aosta, Azienda Sanitaria Universitaria Friuli Venezia Giulia (C.D. "Entità Affiliate");

DATO ATTO che il contratto, in ottemperanza a quanto richiesto con comunicazioni e-mail (agli atti presso i competenti uffici) dalla Commissione Europea, tra AREU capofila e la Commissione Europea è stato trasmesso alla stessa in data 11.12.2020, termine ultimo per il perfezionamento del progetto, e prende atto del fatto che il progetto stesso ha durata di 10 mesi a partire dal 01.09.2020;

TENUTO CONTO che la partecipazione al progetto garantirà ai partecipanti una quota parte del finanziamento complessivo disposto dalla Commissione Europea, pari ad un importo massimo di € 7.124.297,27 (sette milioni centoventiquattromiladuecentonovantasette euro e ventisette centesimi), come riconosciuta con nota della Commissione del 29.10.2020 (rif. SANTE DDG1 B.4/MA(2020) 6702426), agli atti presso la Direzione SRC;

DATO ATTO che:

- la Commissione Europea effettua a favore del beneficiario AREU, quale capofila, un prefinanziamento pari al 50% dell'importo massimo della sovvenzione e un pagamento del saldo quale rimborso o copertura della parte restante dei costi ammissibili e dei contributi per l'attuazione del progetto presentato;
- la citata somma viene versata interamente ad AREU che si impegna a distribuire la stessa alle proprie "entità affiliate" secondo le proposte di budget che sono state presentate in allegato al "PPPA-ECI-CCP-2020 –Capacity building for collection of COVID-19 convalescent plasma under the Emergency Support Instrument" (Proposal Number: 101024047- Proposal acronym PPPA-ECI-CCP-2020" e da rimodulare nei limiti della somma di € € 7.124.297,27 riconosciuta dalla Commissione per la realizzazione del citato progetto;
- la Commissione Europea riconosce a favore di AREU, nella propria qualità di Ente di riferimento per il progetto anche una quota pari al 7% del totale complessivo dei costi ammessi per l'attività di coordinamento del progetto;

DATO ULTERIORMENTE ATTO che:

- in ottemperanza a quanto richiesto dalla Comunità Europea, sono state acquisite agli atti le procure delle 13 affiliate per la firma del citato accordo (note prot. AREU 2020/14758, prot. AREU 2020/15314 e prot. AREU 15441);
- i rapporti tra AREU e le affiliate verranno disciplinati con apposito atto di convenzione separato e nel rispetto dei progetti e degli impegni assunti dalle Parti con la sottoscrizione dell'Accordo con la Comunità Europea finalizzato al finanziamento del progetto "PPPA-ECI-CCP-2020 –Capacity building for collection of COVID-19 convalescent plasma under the Emergency Support Instrument" (Proposal Number: 101024047- Proposal acronym PPPA-ECI-CCP-2020" con particolare riferimento alle modalità di distribuzione e di rendicontazione del finanziamento;

PRESO ATTO che il Proponente del procedimento attesta la completezza, la regolarità tecnica e la legittimità del presente provvedimento;

ACQUISITI i pareri favorevoli del Direttore Amministrativo e del Direttore Sanitario, resi per quanto di specifica competenza ai sensi dell'art. 3 del D.Lgs. n. 502/1992 e s.m.i.;

DELIBERA

Per tutti i motivi in premessa indicati e integralmente richiamati:

1. di prendere atto dell'approvazione del progetto "PPPA-ECI-CCP-2020 –Capacity building for collection of COVID-19 convalescent plasma under the Emergency Support Instrument" (Proposal Number: 101024047- Proposal acronym PPPA-ECI-CCP-2020" e del conseguente finanziamento individuando quale Responsabile del progetto la dott.ssa Rosa Chianese della Struttura Regionale di Coordinamento (SRC) di AREU;
2. di dare atto che, in ottemperanza a quanto richiesto dalla Commissione Europea, il contratto tra AREU capofila e la Commissione Europea è stato trasmesso alla stessa in data 11.12.2020, termine ultimo per il perfezionamento del progetto, e prende atto del fatto che il progetto stesso ha durata di 10 mesi a partire dal 01.09.2020;
3. di disporre che il contributo riconosciuto dalla Commissione Europea nell'importo massimo finanziabile di € 7.124.297,27 (sette milioni centoventiquattromiladuecentonovantasette euro e ventisette centesimi) a fronte del grant presentato da AREU in qualità di ente capofila del progetto avente valenza nazionale sarà contabilizzato al conto 30101220 CONTRIBUTI IN C/ESERCIZIO DA U.E. (EXTRA FSR INDISTINTO), vincolando lo stesso al finanziamento di AREU e di tutti gli enti partners nella misura strettamente correlata alla puntuale rendicontazione dei costi ammissibili secondo i criteri declinati dalla stessa Commissione Europea ed al finanziamento della quota pari al 7% del totale complessivo dei costi ammessi per l'attività di coordinamento del progetto da parte di AREU;
4. di prevedere che con provvedimento successivo saranno recepiti gli atti convenzionali tra AREE e le Affiliate, sotto indicate, nel rispetto dei progetti e degli impegni assunti dalle Parti con la sottoscrizione dell'Accordo con la Comunità Europea finalizzato al finanziamento del progetto "PPPA-ECI-CCP-2020 –Capacity building for collection of COVID-19 convalescent plasma under the Emergency Support Instrument" (Proposal Number: 101024047- Proposal acronym PPPA-ECI-CCP-2020" con particolare riferimento alle modalità di distribuzione e di rendicontazione del finanziamento da parte delle c.d. "entità affiliate", centri ematologici di Azienda Sanitaria Dell'alto Adisudtiroler Sanitatbetrieb Di Bolzano, Azienda Provinciale Per I Servizi Sanitari Della Provincia Autonoma Di Trento, Azienda Ospedaliero Universitaria Citta' Della Salute E Della Scienza Di Torino, Azienda Ospedale Universita' Padova, Azienda Sanitaria Locale Frosinone, Azienda Ospedaliera Di Rilievo Nazionale Cardarelli Di Napoli, Grande Ospedale Metropolitano "Bianchi Melacrino Morelli", Azienda Ospedaliera Papardo Della Sicilia, Azienda Usl Bologna, Ospedale Policlinico San Martino Di Genova, Servizio Ematologia E Medicina Trasfusionale-Azienda Ospedaliero Universitaria Policlinico Bari, Azienda Usl Valle D'Aosta, Azienda Sanitaria Universitaria Friuli Venezia Giulia;
5. di dare atto che il responsabile dell'esecuzione del progetto "PPPA-ECI-CCP-2020 – Capacity building for collection of COVID-19 convalescent plasma under the Emergency Support Instrument" (Proposal Number: 101024047- Proposal acronym

PPPA-ECI-CCP-2020" è la Dott.ssa Rosa Chianese, Responsabile della Struttura Regionale Coordinamento (SRC) di AREU;

6. di dare atto che, ai sensi della L. n. 241/1990, responsabile del presente procedimento è per gli aspetti amministrativi connessi alla convenzione la Dott.ssa Domenica De Giorgio, Dirigente SC Affari Generali e Legali;
7. di disporre che vengano rispettate tutte le prescrizioni inerenti alla pubblicazione sul portale web aziendale di tutte le informazioni e i documenti richiesti e necessari ai sensi del D.Lgs. n. 33/2013 e s.m.i., c.d. Amministrazione Trasparente;
8. di disporre la pubblicazione del presente provvedimento all'Albo Pretorio on line dell'Azienda, dando atto che lo stesso è immediatamente esecutivo (ex art. 32 comma 5 L. n. 69/2009 s.m.i. e art. 17 comma 6 L.R. n. 33/2009).



La presente delibera è sottoscritta digitalmente, ai sensi dell'art. 21 D.Lgs. n. 82/2005 e s.m.i., da:

Il Direttore Amministrativo Luca Filippo Maria Stucchi

Per il Direttore Sanitario Giuseppe Maria Sechi come da delega acquisita agli atti dell'Azienda Mare Claudio

Il Direttore Generale Alberto Zoli



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Health Systems, medical products and innovation

GRANT AGREEMENT FOR AN ACTION

UNDER EMERGENCY SUPPORT INSTRUMENT (ESI)

AGREEMENT NUMBER — PPPA-ECI-CCP-2020 – SI2.839208

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

on the one part,

The European Union ('the Union'), represented by the European Commission ('the Commission'), represented for the purposes of signature of the Agreement by A. Rys, Director for Health systems, medical products and innovation of the Directorate-General for Health and Food Safety,

and

on the other part,

'the beneficiary'

Azienda Regionale Emergenza Urgenza AREU
Public Institution
Statutory registration number: N/A ¹
Via Alfredo Campanini 6, 20124 Milano, Italy
VAT registration number: 03128170135,

represented for the purposes of signature of the Agreement by ~~Rosa CHIANESE, Director of Regional Blood Center AREU and Blood Establishment ASST Settelaghi,~~
Alberto Zoli - General Director of Azienda Regionale Emergenza Urgenza (AREU)

The parties referred to above

HAVE AGREED

to the Special Conditions ("the Special Conditions") and the following Annexes:

Annex I Invitation to submit applications

¹ To be deleted or filled in according to the "Legal Entity" form

Annex II General Conditions (“the General Conditions”)

Annex III Description of the action and requested budget by the applicant in the attached proposal

Annex IV Model technical report to be sent later by separate e-mail

Annex V Model financial statement to be sent later by separate e-mail

which form an integral part of the Agreement.

The provisions in the Special Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex II "General Conditions" take precedence over the other Annexes.

SPECIAL CONDITIONS

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ARTICLE I.1 – SUBJECT MATTER OF THE AGREEMENT

The Commission has decided to award a grant under the terms and conditions set out in the Special Conditions, the General Conditions and the other Annexes to the Agreement, for the *action* entitled **Increasing EU capacity for Covid-19 Convalescent Plasma Collection** as described in Annex I.

By signing the Agreement the beneficiary accepts the grant and agrees to implement the action, acting on its own responsibility.

Article II.13.4 and point ii) of Article II.25.3(a) do not apply

ARTICLE I.2 – ENTRY INTO FORCE AND IMPLEMENTATION PERIOD OF THE AGREEMENT

I.2.1 The Agreement enters into force on the date on which the last party signs it.

I.2.2 The *action* runs for **10 months** starting on 1st September 2020

ARTICLE I.3 – MAXIMUM AMOUNT AND FORM OF GRANT

I.3.1 *The maximum amount of the grant* is EUR 7.124.297,27 (seven million one hundred twenty four thousand two hundred ninety seven EUR and twenty seven cents).

I.3.2 The grant takes the form of:

- (a) reimbursement of 100% of the eligible costs of the *action* ("reimbursement of eligible costs"), which are estimated at EUR 7.800.365,27 (seven million eight hundred thousand three hundred sixty five EUR and twenty seven cents) and which are:
 - (i) actually incurred ("reimbursement of actual costs") for the categories of costs as described in Annexe I

ARTICLE I.4 – REPORTING, REQUESTS FOR PAYMENTS AND SUPPORTING DOCUMENTS

I.4.1 Reporting periods

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

- Reporting period 1: from month September 2020 to 30 June 2021

I.4.2 Request for payment of the balance and supporting documents

The beneficiary must submit a request for payment of the balance within 60 calendar days following the end of the last reporting period.

This request must be accompanied by the following documents:

- (a) a final report on implementation of the *action* ('final technical report'), drawn up in accordance with Annex IV, containing:
 - (i) the information needed to justify the eligible costs declared or the contribution requested on the basis of financing not linked to costs, unit costs and lump sums (where the grant takes the form of the reimbursement of unit or lump sum costs, of financing not linked to costs or of a unit or lump sum contribution, as provided for in Article I.3.2(a)(ii) and (iii), (b),(c) or (e));
 - (ii) information on subcontracting as referred to in Article II.11.1(d);
- (b) a final financial statement ('final financial statement'). The final financial statement must include a consolidated statement and a breakdown of the amounts claimed by the beneficiary and its affiliated entities.

The final financial statement must be drawn up in accordance with the structure of the estimated budget set out in Annex II and in accordance with Annex V and detail the amounts for each of the forms of grant set out in Article I.3.2 for the last reporting period;

- (c) a summary financial statement ('summary financial statement').

This statement must include a consolidated financial statement and a breakdown of the amounts declared or requested by the beneficiary and its affiliated entities, aggregating the financial statements already submitted previously and indicating the revenue generated by the *action* referred to in Article II.25.3 for the beneficiary and its affiliated entities other than non-profit organisations.

The summary financial statement must be drawn up in accordance with Annex V;

The beneficiary must certify that the information provided in the request for payment of the balance is full, reliable and true.

The beneficiary must also certify that the costs incurred can be considered eligible in accordance with the Agreement and that the request for payment is substantiated by adequate supporting documents that can be produced in the context of the checks or audits described in Article II.27.

In addition, the beneficiary must certify that all the revenues generated by the *action* referred to in Article II.25.3 have been declared for the beneficiary and its affiliated entities other than non-profit organisations.

I.4.3 Information on cumulative expenditure incurred

Not applicable

I.4.4 Currency for requests for payment and financial statements and conversion into euro²

Requests for payment and financial statements must be drafted in euros.

The beneficiary and affiliated entities with general accounts in a currency other than the euro must convert costs incurred in another currency into euros at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union* (available at <http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html>), determined over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, conversion must be made at the average of the monthly accounting rates established by the Commission and published on its website (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), determined over the corresponding reporting period.

The beneficiary and affiliated entities with general accounts in euros must convert costs incurred in another currency into euros in accordance with their usual accounting practices.]

I.4.5 Language of requests for payments, technical reports and financial statements

All requests for payments, technical reports and financial statements must be submitted in English

ARTICLE I.5 — PAYMENTS AND PAYMENT ARRANGEMENTS

I.5.1 Payments to be made

The Commission must make the following payments to the beneficiary:

- one pre-financing payment;
- one payment of the balance, on the basis of the request for payment of the balance referred to in Article I.4.4.

I.5.2 Pre-financing payment

The aim of the pre-financing is to provide the beneficiary with a float. The pre-financing remains the property of the Union until it is cleared against interim payments or, if it is not cleared against interim payments, until the payment of the balance.

² For simplified costs options based on usual cost accounting practices in another currency, the provisions may need to be adapted. Please contact the Central Financial Service for support (unit D02).

The Commission must make the pre-financing payment of 50% of the maximum amount of the grant as specified in Article I.3.1 to the beneficiary within 30 calendar days from the entry into force of the Agreement except if Article II.24.1 applies.

I.5.3 Interim payment

Not applicable

I.5.4 Payment of the balance

The payment of the balance reimburses or covers the remaining part of the eligible costs and contributions for the implementation of the *action*.

If the total amount of earlier payments is greater than the final amount of the grant determined in accordance with Article II.25, the payment of the balance takes the form of a recovery as provided for by Article II.26.

If the total amount of earlier payments is lower than the final amount of the grant determined in accordance with Article II.25, the Commission must pay the balance within 60 calendar days from when it receives the documents referred to in Article I.4.4, except if Article II.24.1 or II.24.2 apply.

Payment is subject to the approval of the request for payment of the balance and of the accompanying documents. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The Commission determines the amount due as the balance by deducting the total amount of pre-financing and interim payments (if any) already made from the final amount of the grant determined in accordance with Article II.25.

The amount to be paid may, however, be offset, without the beneficiary's consent, against any other amount owed by the beneficiary to the Commission or to an executive agency (under the EU or Euratom budget), up to the *maximum amount of the grant*.

I.5.5 Notification of amounts due

The Commission must send a *formal notification* to the beneficiary:

- (a) informing it of the amount due; and
- (b) specifying whether the notification concerns a further pre-financing payment, an interim payment or the payment of the balance.

For the payment of the balance, the Commission must also specify the final amount of the grant determined in accordance with Article II.25.

I.5.6 Interest on late payment

If the Commission does not pay within the time limits for payment, the beneficiary is entitled to late-payment interest at the rate applied by the European Central Bank for its main refinancing operations in euros ('the 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 time limit for payment expires, as published in the C series of the *Official Journal of the European Union*.

Late-payment interest is not due if the beneficiary is a Member State of the Union (including regional and local government authorities and other public bodies acting in the name of and on behalf of the Member State for the purpose of the Agreement).

If the Commission suspends the time limit for payment as provided for in Article II.24.2 or if it suspends an actual payment as provided for in Article II.24.1, these actions may not be considered as cases of late payment.

Late-payment interest covers the period running from the day following the due date for payment, up to and including the date of actual payment as established in Article I.5.8. The Commission does not consider payable interest when determining the final amount of grant within the meaning of Article II.25.

As an exception to the first subparagraph, if the calculated interest is lower than or equal to EUR 200, it must be paid to the beneficiary only if the beneficiary requests it within two months of receiving late payment.

I.5.7 Currency for payments

The Commission must make payments in euros.

I.5.8 Date of payment

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

I.5.9 Costs of payment transfers

Costs of the payment transfers are borne as follows:

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

I.5.10 Payments to the beneficiary

The Commission must make payments to the beneficiary.

Payments to the beneficiary discharge the Commission from its payment obligation.

ARTICLE I.6 — BANK ACCOUNT FOR PAYMENTS

All payments must be made to the beneficiary's bank account as indicated below:

Name of bank: Intesa San Paolo Filiale 01874

Precise denomination of the account holder: azienda regional emergenza urgenza (AREU)

IBAN code: IT55 S030 6909 7901 0000 0300 004

ARTICLE I.7 — DATA CONTROLLER, COMMUNICATION DETAILS OF THE PARTIES

I.7.1 Data controller

The entity acting as a data controller as provided for in Article II.7 is : the Head of Unit of unit B4: Medical products: quality, safety, innovation.

I.7.2 Communication details of the Commission

Any communication addressed to the Commission must be sent to the following address:

European Commission
Directorate-General Health and Food Safety
Directorate B - Health systems, medical products and innovation
Unit B4 - Medical products: quality, safety, innovation
BE 1049 Brussels
Email address: SANTE-SOHO@ec.europa.eu

I.7.3 Communication details of the beneficiary

Any communication from the Commission to the beneficiary must be sent to the following address:

Rosa CHIANESE
Director of Regional Blood Center - AREU and Blood Establishment - ASST Settelaghi
Azienda Regionale Emergenza Urgenza
Via Alfredo Campanini 6, Milano 20124, Italy
Email address: direzione.src@areu.lombardia.it

ARTICLE I.XX — ENTITIES AFFILIATED TO THE BENEFICIARY

The following entities are considered as affiliated entities to the beneficiary for the purpose of the Agreement:

- Azienda Sanitaria Dell'Alto AdiSudtiroler Sanitatbetrieb, Bolzano,
- Azienda Provinciale per i Servizi Sanitari della provincia Autonoma di Trento, Trento,
- Azienda Ospedaliero Universitaria Citta della Salute e delle Scienza di Torino, Torino,
- Azienda Ospedale Universita Padova, Padova,
- Azienda Sanitaria Locale Frosimonte, Lazio, Frosinone
- Azienda Ospedaliera di Rilievo Nazional Antonio Cardarelli, Napoli,
- Grande Ospedale Metropolitano”Bianchi Malacrino Morelli – Regione Calabria,
- Azienda Ospodaliere Papardo, Papardo,
- Azienda USL di Bologna, Bologna,
- Ospedale Policlinico San Martino, Genova
- Blood Establishment and Transfusion Medicine Service, Azienda Ospedale Universitaria Policlinico Bari, Bari,
- Azienda USL Valle d'Aosta, Aosta

- Azienda Sanitaria Universitaria Friuli Venezia Giulia – Udine

ARTICLE I.XX — ADDITIONAL PROVISIONS ON THE REIMBURSEMENT OF COSTS DECLARED ON THE BASIS OF THE BENEFICIARY’S USUAL COST ACCOUNTING PRACTICES

Not applicable

ARTICLE I.XX — ADDITIONAL PROVISIONS ON USE OF THE RESULTS (INCLUDING INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS)

Not applicable

ARTICLE I.XX — INAPPLICABILITY OF THE NO-PROFIT PRINCIPLE

Not applicable

ARTICLE I.XX — ELIGIBILITY OF EQUIPMENT COSTS

As an exception to Article II.19.2(c), the full cost of purchase of equipment is eligible

ARTICLE I.XX — INELIGIBILITY OF VALUE ADDED TAX

As an exception to Article II.19.2(h), paid value added tax (VAT) is not eligible under the Agreement if VAT can be reclaimed by the applicant or affiliated entity.

ARTICLE I.XX — SPECIAL PROVISIONS ON BUDGET TRANSFERS

- As an exception to the first subparagraph of Article II.22, budget transfers between budget categories are limited to 20% of the estimated eligible costs of the *action* specified in Article I.3.2 and upon approval of the Commission for amounts above 10.000 €.

ARTICLE I.XX — SPECIAL PROVISIONS ON BUDGET TRANSFERS INVOLVING USE OF PROVISIONS FOR [CONTINGENCIES] [AND] [FOREIGN EXCHANGE LOSSES]

Not applicable

ARTICLE I.XX — SETTLEMENT OF DISPUTES WITH THE NON-EU BENEFICIARY

This provision applies where the beneficiary is legally established in a country other than a Member State of the European Union (the ‘non-EU beneficiary’).

As an exception to Article II.18.2, any of the parties (the Commission or the non-EU beneficiary) may bring before the Belgian Courts any dispute between them concerning the interpretation, application or validity of the Agreement, if such dispute cannot be settled amicably.

Where one party has brought proceedings before the Belgian Courts, the other party may not bring a claim arising from the interpretation, application or validity of the Agreement in any other court than the Belgian Courts before which the proceedings have already been brought.]

ARTICLE I.XX — THE BENEFICIARY WHICH IS AN INTERNATIONAL ORGANISATION

Not applicable

SIGNATURES

For the beneficiary

~~Rosa CHIANESE~~
Alberto ZOLI

~~Director of Regional Blood Center~~
General Director of AREU

For the Commission

Andrzej RYS

Director of Directorate B

[signature]

Done at [place], [date]

In duplicate in English

[signature]

Done at Brussels, [date]

ANNEX II — GENERAL CONDITIONS

PART A — LEGAL AND ADMINISTRATIVE PROVISIONS

ARTICLE II.1 - DEFINITIONS

The following definitions apply for the purpose of the Agreement:

‘Action’: the set of activities or the project for which the grant is awarded, to be implemented by the beneficiary as described in Annex I;

‘Breach of obligations’: failure by the beneficiary to fulfil one or more of its contractual obligations;

‘Confidential information or document’: any information or document (in any format) received by either party from the other or accessed by either party in the context of the implementation of the Agreement that any of the parties has identified in writing as confidential. It does not include information that is publicly available;

‘Conflict of interests’: a situation where the impartial and objective implementation of the Agreement by the beneficiary is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest or any other shared interest with the Commission or any third party related to the subject matter of the Agreement;

‘Direct costs’: those specific costs which are directly linked to the implementation of the *action* and can therefore be attributed directly to it. They may not include any *indirect costs*;

‘Force majeure’: any unforeseeable, exceptional situation or event beyond the control of the parties that prevents either of them from fulfilling any of their obligations under the Agreement, which is not attributable to error or negligence on their part or on the part of the subcontractors affiliated entities or third parties in receipt of financial support and which proves to be inevitable despite their exercising due diligence. The following cannot be invoked as *force majeure*: labour disputes, strikes, financial difficulties or any default of a service, defect in equipment or materials or delays in making them available, unless they stem directly from a relevant case of *force majeure*;

‘Formal notification’: form of communication between the parties made in writing, by mail or electronic mail which provides the sender with compelling evidence that the message was delivered to the specified recipient;

‘Fraud’: any act or omission relating to the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, the non-disclosure of information in violation of a specific obligation, with the same effect or the misapplication of such funds or assets for purposes other than those for which they were originally granted;

‘Grave professional misconduct’: a violation of applicable laws or regulations or ethical standards of the profession to which a person or entity belongs, or any wrongful conduct of a person or entity which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence;

‘Implementation period’: the period of implementation of the activities forming part of the *action*, as specified in Article I.2.2;

‘Indirect costs’: those costs which are not specific costs directly linked to the implementation of the *action* and which therefore cannot be attributed directly to it. They may not include any costs identifiable or declared as eligible *direct costs*;

‘Irregularity’: any infringement of a provision of Union law resulting from an act or omission by the beneficiary, which has or would have the effect of prejudicing the Union’s budget;

‘Maximum amount of the grant’: the maximum EU contribution to the *action*, as defined in Article I.3.1;

‘Pre-existing material’: any materials, document, technology or know-how which exists prior to the beneficiary using it for the production of a result in the implementation of the *action*;

‘Pre-existing right’: any industrial and intellectual property right on *pre-existing material*; it may consist in a right of ownership, a licence right and/or a right of use belonging to the beneficiary or any other third parties;

‘Related person’: any natural or legal person who is a member of the administrative, management or supervisory body of the beneficiary or who has the powers of representation, decision or control with regard to the beneficiary;

‘Starting date’: the date on which the implementation of the *action* starts as provided for in Article I.2.2;

‘Subcontract’: a procurement contract within the meaning of Article II.10, which covers the implementation by a third party of tasks forming part of the *action* as described in Annex I;

ARTICLE II.2 – GENERAL OBLIGATIONS OF THE BENEFICIARY

The beneficiary:

- (a) is liable for carrying out the *action* in accordance with the Agreement;
- (b) must comply with any legal obligations it is bound by under applicable EU, international and national law;
- (c) must inform the Commission immediately of any events or circumstances of which the beneficiary is aware, that are likely to affect or delay the implementation of the *action*;
- (d) must inform the Commission immediately:
 - (i) of any change in its legal, financial, technical, organisational or ownership situation and of any change in its name, address or legal representative;
 - (ii) of any change in the legal, financial, technical, organisational or ownership situation of its affiliated entities and of any change in their name, address or legal representative;
 - (iii) of any change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046, including for its affiliated entities.

ARTICLE II.3 – COMMUNICATION BETWEEN PARTIES

II.3.1 Form and means of communication

Any communication relating to the Agreement or to its implementation must:

- (a) be made in writing (in paper or electronic form) in the language of the Agreement;
- (b) bear the number of the Agreement; and
- (c) be made using the communication details identified in Article I.7.

If a party requests written confirmation of an electronic communication within a reasonable time, the sender must provide an original signed paper version of the communication as soon as possible.

II.3.2 Date of communications

Any communication is considered to have been made when the receiving party receives it, unless the Agreement states that communication is considered to have been made on the date when the communication was sent.

Email is considered to have been received by the receiving party on the day of dispatch of that email, provided that it is sent to the email address indicated in Article I.7. The sending party must be able to prove the date of dispatch. If the sending party receives a non-delivery report, it must make every effort to ensure that the other party actually receives the communication by email or mail. In such a case, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the Commission using the postal or courier services is considered to have been received by the Commission on the date on which it is registered by the department identified in Article I.7.2.

Formal notifications are considered to have been received by the receiving party on the date of receipt indicated in the proof received by the sending party that the message was delivered to the specified recipient.

ARTICLE II.4 – LIABILITY FOR DAMAGES

II.4.1 The Commission may not be held liable for any damage caused or sustained by the beneficiary, including any damage caused to third parties as a consequence of or during the implementation of the *action*.

II.4.2 Except in cases of *force majeure*, the beneficiary must compensate the Commission for any damage it sustains as a result of the implementation of the *action* or because the *action* was not implemented in full compliance with the Agreement.

ARTICLE II.5 – CONFLICT OF INTEREST

II.5.1 The beneficiary must take all necessary measures to prevent any situation of *conflict of interests*.

II.5.2 The beneficiary must inform the Commission without delay of any situation constituting or likely to lead to a *conflict of interests*. It must take immediately all the necessary steps to rectify this situation.

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

ARTICLE II.6 - CONFIDENTIALITY

II.6.1 During implementation of the *action* and for five years after the payment of the balance, the parties must treat with confidentiality any *confidential information and documents*.

II.6.2 The parties may only use *confidential information and documents* for a reason other than to fulfil their obligations under the Agreement if they have first obtained the prior written agreement of the other party.

II.6.3 The confidentiality obligations do not apply if:

- (a) the disclosing party agrees to release the other party from those obligations;
- (b) the *confidential information or documents* become public through other means than a breach of the confidentiality obligations;
- (c) the disclosure of the *confidential information or documents* is required by law.

ARTICLE II.7 – PROCESSING OF PERSONAL DATA

II.7.1 Processing of personal data by the Commission

Any personal data included in the Agreement must be processed by the Commission in accordance with Regulation (EU) No 2018/1725.³

Such data must be processed by the data controller identified in Article I.7.1 solely for implementing, managing and monitoring the Agreement or to protect the financial interests of the EU, including checks, audits and investigations in accordance with Article II.27.

The beneficiary has the right to access, rectify or erase its own personal data and the right to restrict or, where applicable, the right to data portability or the right to object to data processing in accordance with Regulation (EU) No 2018/1725. For this purpose, it must send any queries about the processing of its personal data to the data controller identified in Article I.7.1.

The beneficiary may have recourse at any time to the European Data Protection Supervisor.

II.7.2 Processing of personal data by the beneficiary

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

³ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC

The beneficiary may grant its personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement. The beneficiary must ensure that the personnel authorised to process personal data has committed itself to confidentiality or is under appropriate statutory obligation of confidentiality.

The beneficiary must adopt appropriate technical and organisational security measures having regard to the risks inherent in the processing and to the nature, scope, context and purposes of processing of the personal data concerned. This is in order to ensure, as appropriate:

- (a) the pseudonymisation and encryption of personal data;
- (b) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;
- (c) the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;
- (d) a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing;
- (e) measures to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to personal data transmitted, stored or otherwise processed.

ARTICLE II.8 – VISIBILITY OF UNION FUNDING

II.8.1 Information on Union funding and use of the European Union emblem

Unless the Commission requests or agrees otherwise, any communication or publication made by the beneficiary that relates to the *action*, including at conferences, seminars or in any information or promotional materials (such as brochures, leaflets, posters, presentations, in electronic form, etc.), must:

- (a) indicate that the *action* has received funding from the Union; and
- (b) display the European Union emblem.

When displayed in association with another logo, the European Union emblem must have appropriate prominence.

The obligation to display the European Union emblem does not confer on the beneficiary a right of exclusive use. The beneficiary may not appropriate the European Union emblem or any similar trademark or logo, either by registration or by any other means.

For the purposes of the first, second and third subparagraphs and under the conditions specified therein, the beneficiary may use the European Union emblem without first obtaining permission from the Commission.

II.8.2 Disclaimers excluding Commission responsibility

Any communication or publication that relates to the *action*, made by the beneficiary in any form and using any means, must indicate:

- (a) that it reflects only the author's view; and
- (b) that the Commission is not responsible for any use that may be made of the information it contains.

ARTICLE II.9 – PRE-EXISTING RIGHTS AND OWNERSHIP AND USE OF THE RESULTS (INCLUDING INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS)

II.9.1 Ownership of the results by the beneficiary

The beneficiary retains ownership of the results of the *action*, including industrial and intellectual property rights, and of the reports and other documents relating to it, unless stipulated otherwise in the Agreement.

II.9.2 Pre-existing rights

If the Commission sends the beneficiary a written request specifying which of the results it intends to use, the beneficiary must:

- (a) establish a list specifying all *pre-existing rights* included in those results; and
- (b) provide this list to the Commission at the latest with the request for payment of the balance.

The beneficiary must ensure that it or its affiliated entities have all the rights to use any *pre-existing rights* during the implementation of the Agreement.

II.9.3 Rights of use of the results and of pre-existing rights by the Union

The beneficiary grants the Union the following rights to use the results of the *action*:

- (a) for its own purposes and in particular to make available to persons working for the Commission, other Union institutions, agencies and bodies and to Member States' institutions, as well as to copy and reproduce in whole or in part and in an unlimited number of copies;
- (b) reproduction: the right to authorise direct or indirect, temporary or permanent reproduction of the results by any means (mechanical, digital or other) and in any form, in whole or in part;
- (c) communication to the public: the right to authorise any display performance or communication to the public, by wire or wireless means, including making the results available to the public in such a way that members of the public may access them from a place and at a time individually chosen by them; this right also includes communication and broadcasting by cable or by satellite;
- (d) distribution: the right to authorise any form of distribution of results or copies of the results to the public;
- (e) adaptation: the right to modify the results;
- (f) translation;
- (g) the right to store and archive the results in line with the document management rules applicable to the Commission, including digitisation or converting the format for preservation or new use purposes;
- (h) where the results are documents, the right to authorise the reuse of the documents in conformity with Commission Decision 2011/833/EU of 12 December 2011 on the reuse of Commission documents if that Decision is applicable and if the documents fall within its scope and are not excluded by any of its provisions. For the sake of this

provision, the terms 'reuse' and 'document' have the meanings given to them by Decision 2011/833/EU.

The above rights of use may be further specified in the Special Conditions.

Additional rights of use for the Union may be provided for in the Special Conditions.

The beneficiary must ensure that the Union has the right to use any *pre-existing rights* included in the results of the *action*. The *pre-existing rights* must be used for the same purposes and under the same conditions as applicable to the rights of use of the results of the *action*, unless specified otherwise in the Special Conditions.

Information about the copyright owner must be inserted in cases where the result is divulged by the Union. The copyright information must read: '© — year — name of the copyright owner. All rights reserved. Licenced to the European Union under conditions.'

If the beneficiary grants rights of use to the Commission, this does not affect its confidentiality obligations under Article II.6 or the beneficiary's obligation under Article II.2.

ARTICLE II.10 – AWARD OF CONTRACTS NECESSARY FOR THE IMPLEMENTATION OF THE ACTION

II.10.1 If the implementation of the *action* requires the beneficiary to procure goods, works or services, it may award the contract in accordance with their usual purchasing practices provided that the contract is awarded to the tender offering best value for money or, as appropriate, to the tender offering the lowest price. In doing so, it must avoid any *conflict of interests*.

The beneficiary must ensure that the Commission, the European Court of Auditors and the European Anti-Fraud Office (OLAF) can exercise their rights under Article II.27 also towards the beneficiary' contractors.

II.10.2 The beneficiary that is a 'contracting authority' within the meaning of Directive 2014/24/EU⁴ or 'contracting entity' within the meaning of Directive 2014/25/EU⁵ must comply with the applicable national public procurement rules.

The beneficiary must ensure that the conditions applicable to it under Articles II.4, II.5, II.6 and II.9 are also applicable to the contractors.

II.10.3 The beneficiary remains solely responsible for carrying out the *action* and for compliance with the Agreement.

II.10.4. If the beneficiary breaches its obligations under Article II.10.1 the costs related to the contract concerned are considered ineligible in accordance with Article II.19.2 (c), (d) and (e).

⁴ 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

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

If the beneficiary breaches its obligations under Article II.10.2 the grant may be reduced in accordance with Article II.25.4.

ARTICLE II.11 – SUBCONTRACTING OF TASKS FORMING PART OF THE ACTION

II.11.1 The beneficiary may subcontract tasks forming part of the *action*. If it does so, it must ensure that, in addition to the conditions specified in Article II.10, the following conditions are also complied with:

- (a) subcontracting does not cover core tasks of the *action*;
- (b) recourse to subcontracting is justified because of the nature of the *action* and what is necessary for its implementation;
- (c) the estimated costs of the subcontracting are clearly identifiable in the estimated budget set out in Annex III;
- (d) any recourse to subcontracting, if not provided for in Annex I, is communicated by the beneficiary and approved by the Commission. The Commission may grant approval:
 - (i) before any recourse to subcontracting, if the beneficiary requests an amendment as provided for in Article II.13; or
 - (ii) after recourse to subcontracting if the subcontracting:
 - is specifically justified in the interim, or final technical report referred to in Articles I.4.3 and I.4.4; and
 - does not entail changes to the Agreement which would call into question the decision awarding the grant or be contrary to the equal treatment of applicants;
- (e) the beneficiary ensures that the conditions applicable to it under Article II.8 are also applicable to the subcontractors.

II.11.2 If the beneficiary breaches its obligations under Article II.11.1 (a), (b), (c) or (d), the costs related to the contract concerned are considered ineligible in accordance with Article II.19.2 (f).

If the beneficiary breaches its obligation under Article II.11.1 (e) the grant may be reduced in accordance with Article II.25.4.

ARTICLE II.12 – FINANCIAL SUPPORT TO THIRD PARTIES

II.12.1 If, while implementing the *action*, the beneficiary has to give financial support to third parties, the beneficiary must give such financial support in accordance with the conditions specified in Annex I. Under those conditions, the following information must be stated at least:

- (a) the maximum amount of financial support. This amount may not exceed EUR 60000 for each third party except if achieving the objective of the *action* as specified in Annex I would otherwise be impossible or overly difficult ;
- (b) the criteria for determining the exact amount of the financial support;
- (c) the different types of activity that may receive financial support, on the basis of a fixed list;
- (d) the persons or categories of persons which may receive financial support;
- (e) the criteria for giving the financial support.

II.12.2 As an exception to Article II.12.1, if the financial support takes the form of a prize, the beneficiary must give such financial support in accordance with the conditions specified in Annex I. Under those conditions, the following information must at least be stated:

- (a) the eligibility and award criteria;
- (b) the amount of the prize;
- (c) the payment arrangements.

II.12.3 The beneficiary must ensure that the conditions applicable to it under Articles II.4, II.5, II.6, II.8, II.9 and II.27 are also applicable to the third parties receiving financial support.

ARTICLE II.13 – AMENDMENTS TO THE AGREEMENT

II.13.1 Any amendment to the Agreement must be made in writing.

II.13.2 An amendment may not have the purpose or the effect of making changes to the Agreement which would call into question the decision awarding the grant or be contrary to the equal treatment of applicants.

II.13.3 Any request for amendment must:

- (a) be duly justified;
- (b) be accompanied by appropriate supporting documents; and
- (c) be sent to the other party in due time before it is due to take effect, and in any case one month before the end of the *implementation period*.

Point (c) does not apply in cases duly substantiated by the party requesting the amendment if the other party agrees.

II.13.4 In case of an operating grant the period set out in Article I.2.2 may not be extended via amendments.

II.13.5 Amendments enter into force on the date on which the last party signs or on the date of approval of the request for amendment.

Amendments take effect on a date agreed by the parties or, in the absence of such an agreed date, on the date on which the amendment enters into force.

ARTICLE II.14 – ASSIGNMENT OF CLAIMS FOR PAYMENTS TO THIRD PARTIES

II.14.1 The beneficiary may not assign any of its claims for payment against the Commission to any third party, except if approved by the Commission on the basis of a reasoned, written request by the beneficiary.

If the Commission does not accept the assignment or the terms of it are not complied with, the assignment has no effect on it.

II.14.2 In no circumstances may an assignment release the beneficiary from its obligations towards the Commission.

ARTICLE II.15 – FORCE MAJEURE

II.15.1 A party faced with *force majeure* must send a *formal notification* to the other party without delay, stating the nature of the situation or of the event, its likely duration and foreseeable effects.

II.15.2 The parties must take the necessary measures to limit any damage due to *force majeure*. They must do their best to resume the implementation of the *action* as soon as possible.

II.15.3 The party faced with *force majeure* may not be considered in breach of its obligations under the Agreement if it has been prevented from fulfilling them by *force majeure*.

ARTICLE II.16 – SUSPENSION OF THE IMPLEMENTATION OF THE ACTION

II.16.1 Suspension of implementation by the beneficiary

The beneficiary may suspend the implementation of the *action* or any part of it, if exceptional circumstances make such implementation impossible or excessively difficult, in particular in the event of *force majeure*.

The beneficiary must immediately inform the Commission, stating:

- (a) the reasons for suspension, including details about the date or period when the exceptional circumstances occurred; and
- (b) the expected date of resumption.

Once the circumstances allow the beneficiary to resume implementing the *action*, the beneficiary must inform the Commission immediately and present a request for amendment of the Agreement as provided for in Article II.16.3. This obligation does not apply if the Agreement is terminated in accordance with Articles II.17.1 or points (b) or (c) of Article II.17.2.1.

II.16.2 Suspension of implementation by the Commission

II.16.2.1 Grounds for suspension

The Commission may suspend the implementation of the *action* or any part thereof:

- (a) if the Commission has evidence that the beneficiary has committed *irregularities, fraud or breach of obligations* in the award procedure or while implementing the Agreement;
- (b) if the Commission has evidence that the beneficiary has committed systemic or recurrent *irregularities, fraud* or serious *breach of obligations* in other grants funded by the Union or the European Atomic Energy Community ('Euratom') awarded to the beneficiary under similar conditions and the *irregularities, fraud or breach of obligations* have a material impact on this grant; or
- (c) if the Commission suspects *irregularities, fraud or breach of obligations* committed by the beneficiary in the award procedure or while implementing the Agreement and needs to verify whether they have actually occurred.

II.16.2.2 Procedure for suspension

Step 1 Before suspending implementation of the *action*, the Commission must send a *formal notification* to the beneficiary:

- (a) informing it of:
 - (i) its intention to suspend the implementation;
 - (ii) the reasons for suspension;
 - (iii) the necessary conditions for resuming the implementation in the cases referred to in points (a) and (b) of Article II.16.2.1; and
- (b) inviting it to submit observations within 30 calendar days of receiving the *formal notification*.

Step 2 If the Commission does not receive observations or decides to pursue the procedure despite the observations it has received, it must send a *formal notification* to the beneficiary informing it of:

- (a) the suspension of the implementation;
- (b) the reasons for suspension; and
- (c) the final conditions for resuming the implementation in the cases referred to in points (a) and (b) of Article II.16.2.1; or
- (d) the indicative date of completion of the necessary verification in the case referred to in point (c) of Article II.16.2.1.

The suspension takes effect on the day the *formal notification* is received by the beneficiary or on a later date specified in the *formal notification*.

Otherwise, the Commission must send a *formal notification* to the beneficiary informing it that it is not continuing the suspension procedure.

II.16.2.3 Resuming implementation

In order to resume the implementation, the beneficiary must meet the notified conditions as soon as possible and must inform the Commission of any progress made.

If the conditions for resuming the implementation are met or the necessary verifications are carried out, the Commission must send a *formal notification* to the beneficiary:

- (a) informing it that the conditions for lifting the suspension are met; and
- (b) requiring it to present a request for amendment of the Agreement as provided for in Article II.16.3. This obligation does not apply if the Agreement is terminated in accordance with Articles II.17.1 or points (b), (f) or (g) of Article II.17.2.1.

II.16.3 Effects of the suspension

If the implementation of the *action* can be resumed and the Agreement has not been terminated, an amendment to the Agreement must be made in accordance with Article II.13 in order to:

- (a) set the date on which the *action* is to be resumed;
- (b) extend the duration of the *action*; and
- (c) make other changes necessary to adapt the *action* to the new situation.

The suspension is 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 the period of suspension that relate to the implementation of the suspended *action* or the suspended part of it may not be reimbursed or covered by the grant.

Suspending implementation of the *action* does not affect the Commission's right to terminate the Agreement in accordance with Article II.17.2, reduce the grant or recover amounts unduly paid in accordance with Articles II.25.4 and II.26.

Neither party may claim damages due to suspension by the other party.

ARTICLE II.17 – TERMINATION OF THE AGREEMENT

II.17.1 Termination of the Agreement by the beneficiary

The beneficiary may terminate the Agreement.

The beneficiary must send a *formal notification* of termination to the Commission, stating:

- (a) the reasons for termination; and
- (b) the date on which the termination takes effect. This date must be set after the *formal notification*.

If the beneficiary does not state the reasons for the termination or if the Commission considers that the reasons do not justify termination, the Agreement is considered to have been terminated improperly.

The termination takes effect on the day specified in the *formal notification*.

II.17.2 Termination of the Agreement by the Commission

II.17.2.1 Grounds for termination

The Commission may terminate the Agreement, if:

- (a) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to affect the implementation of the Agreement substantially or calls into question the decision to award the grant, or a change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046, that calls into question the decision to award the grant;
- (b) the beneficiary, any *related person* or any natural person who is essential for the award or for the implementation of the Agreement have committed serious *breach of obligations*, including improper implementation of the *action* as described in Annex I;
- (c) the implementation of the *action* is prevented or suspended due to *force majeure* or exceptional circumstances and either:
 - (i) resumption is impossible; or
 - (ii) the necessary changes to the Agreement would call into question the decision awarding the grant or be contrary to the equal treatment of applicants;
- (d) the beneficiary or a natural or legal person that assumes unlimited liability for the debts of the beneficiary:
 - (i) is declared bankrupt, is subject to insolvency or winding up procedures, its assets are being administered by a liquidator or by a Court, has entered into an

- agreement with creditors, has suspended business activities or is in any analogous situation arising from a similar procedure provided for under the Union or national law;
- (ii) is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the applicable law;
- (e) the beneficiary or any *related person* or any natural person who is essential for the award or for the implementation of the Agreement has committed:
- (i) *grave professional misconduct* proven by any means;
- (ii) *fraud*;
- (iii) corruption;
- (iv) conduct related to criminal organisations;
- (v) money laundering;
- (vi) terrorism-related crimes (including terrorism financing);
- (vii) child labour or other offences concerning trafficking of human beings;
- (f) the Commission has evidence that the beneficiary or any *related person* or any natural person who is essential for the award or for the implementation of the Agreement has committed *irregularities, fraud* or *breach of obligations* in the award procedure or while implementing the Agreement, including if the beneficiary or *related person* or natural person has submitted false information or failed to provide required information;
- (g) the Commission has evidence that the beneficiary has committed systemic or recurrent *irregularities, fraud* or serious *breach of obligations* in other Union or Euratom grants awarded to it under similar conditions and such *irregularities, fraud* or *breach of obligations* have a material impact on this grant;
- (h) a beneficiary or any *related person* or any natural person who is essential for the award or for the implementation of the Agreement has created an entity under a different jurisdiction with the intend to circumvent fiscal, social or any other legal obligations in the jurisdiction of its registered office, central administration or principal place of business;
- (i) a beneficiary or any *related person* has been created with the intend referred to in point (h) or
- (j) the Commission has sent the beneficiary a *formal notification* asking it to end the participation of its affiliated entity because that entity is in a situation provided for in points (d) to (i) and the beneficiary has failed to request an amendment ending the participation of the entity and reallocating its tasks.

II.17.2.2 Procedure for termination

Step 1- Before terminating the Agreement, the Commission must send a *formal notification* to the beneficiary:

- (a) informing it of:
- (i) its intention to terminate;
- (ii) the reasons for termination; and
- (b) requiring it, within 45 calendar days of receiving the *formal notification*:
- (i) to submit observations; and
- (ii) in the case of point (b) of Article II.17.2.1, to inform the Commission of the measures to ensure compliance with the obligations under the Agreement.

Step 2 — If the Commission does not receive observations or decides to pursue the procedure despite the observations it has received, it will send a *formal notification* to the beneficiary informing it of the termination and the date on which it takes effect.

Otherwise, the Commission must send a *formal notification* to the beneficiary informing it that the termination procedure is not continued.

The termination takes effect:

- (a) for terminations under points (a), (b) and (d) of Article II.17.2.1: on the day specified in the *formal notification* of termination referred to in the second subparagraph (i.e. in Step 2 above);
- (b) for terminations under points (c), (e) to (j) of Article II.17.2.1: on the day after the beneficiary receives the *formal notification* of termination referred to in the second subparagraph (i.e. in Step 2 above).

II.17.3 Effects of termination

Within 60 calendar days from the day on which the termination takes effect, the beneficiary must submit a request for payment of the balance as provided for in Article I.4.4.

If the Commission does not receive the request for payment of the balance by the above deadline, only costs or contributions which are included in an approved technical report and, where relevant, in an approved financial statement, are reimbursed or covered by the grant.

If the Agreement is terminated by the Commission because the beneficiary has breached its obligation to submit the request for payment, the beneficiary may not submit any request for payment after termination. In that case the second subparagraph applies.

The Commission calculates the final grant amount as referred to in Article II.25 and the balance as referred to in Article I.5.4 on the basis of the reports submitted. Only activities undertaken before the date when the termination takes effect or the end date of the *implementation period* as specified in Article I.2.2, whichever is the earliest, must be taken into account. Where the grant takes the form of reimbursement of costs actually incurred as provided for in Article I.3.2(a)(i), only costs incurred before termination takes effect are reimbursed or covered by the grant. Costs relating to contracts due for execution only after termination are not taken into account and are not reimbursed or covered by the grant.

The Commission may reduce the grant in accordance with Article II.25.4 in case of:

- (a) improper termination of the Agreement by the beneficiary within the meaning of Article II.17.1; or
- (b) termination of the Agreement by the Commission on any of the grounds set out in points (b) to (j) of Article II.17.2.1.

Neither party may claim damages on the grounds that the other party terminated the Agreement.

After termination, the beneficiary's obligations continue to apply, in particular those under Articles I.4, II.6, II.8, II.9, II.14, II.27 and any additional provisions on the use of the results, as set out in the Special Conditions.

ARTICLE II.18 – APPLICABLE LAW, SETTLEMENT OF DISPUTES AND ENFORCEABLE DECISIONS

II.18.1 The Agreement is governed by the applicable Union law, complemented, where necessary, by the law of Belgium.

II.18.2 In accordance with Article 272 TFEU, the General Court or, on appeal, the Court of Justice of the European Union, has sole jurisdiction to hear any dispute between the Union and any beneficiary concerning the interpretation, application or validity of the Agreement, if such dispute cannot be settled amicably.

II.18.3 In accordance with Article 299 TFEU, for the purposes of recovery within the meaning of Article II.26, the Commission may adopt an enforceable decision to impose pecuniary obligations on persons other than States.

An *action* may be brought against such decision before the General Court of the European Union in accordance with Article 263 TFEU.

PART B — FINANCIAL PROVISIONS

ARTICLE II.19 – ELIGIBLE COSTS

II.19.1 Conditions for the eligibility of costs

Eligible costs of the *action* are costs actually incurred by the beneficiary and which meet the following criteria:

- (a) they are incurred within the *implementation period*, with the exception of costs relating to the request for payment of the balance and the corresponding supporting documents referred to in Article I.4.4;
- (b) they are indicated in the estimated budget. The estimated budget is set out in Annex III;
- (c) they are incurred in connection with the *action* as described in Annex I and are necessary for its implementation;
- (d) they are identifiable and verifiable, in particular they are recorded in the beneficiary's accounting records and determined according to the applicable accounting standards of the country where the beneficiary is established and according to the beneficiary's usual cost accounting practices;
- (e) they comply with the requirements of applicable tax and social legislation; and
- (f) they are reasonable, justified and comply with the principle of sound financial management, in particular regarding economy and efficiency.

II.19.2 Eligible direct costs

To be eligible, the *direct costs* of the *action* must comply with the eligibility conditions set out in Article II.19.1.

In particular, the following categories of costs are eligible *direct costs*, provided that they satisfy the eligibility conditions set out in Article II.19.1 as well as the following conditions:

- (a) the costs of personnel working under an employment contract with the beneficiary or an equivalent appointing act and assigned to the *action*, provided that these costs are in line with the beneficiary's usual policy on remuneration.

Those costs include actual salaries plus social security contributions and other statutory costs included in the remuneration. They may also comprise additional remunerations, including payments on the basis of supplementary contracts regardless of the nature of those contracts, provided that they are paid in a consistent manner whenever the same kind of work or expertise is required, independently from the source of funding used.

The costs of natural persons working under a contract with the beneficiary other than an employment contract or who are seconded to the beneficiary by a third party against payment may also be included under such personnel costs, provided that the following conditions are fulfilled:

- (i) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);
 - (ii) the result of the work belongs to the beneficiary (unless exceptionally agreed otherwise); and
 - (iii) the costs are not significantly different from the costs of staff performing similar tasks under an employment contract with the beneficiary;
- (b) costs of travel and related subsistence allowances, provided that these costs are in line with the beneficiary's usual practices on travel;
 - (c) the depreciation costs of equipment or other assets (new or second-hand) as recorded in the beneficiary's accounting statements, provided that the asset:
 - (i) is written off in accordance with the international accounting standards and the beneficiary's usual accounting practices; and
 - (ii) has been purchased in accordance with Article II.10.1 if the purchase occurred within the *implementation period*;

The costs of renting or leasing equipment or other assets are also eligible, provided that these costs do not exceed the depreciation costs of similar equipment or assets and are exclusive of any finance fee;

Only the portion of the equipment's depreciation, rental or lease costs corresponding to the *implementation period* and the rate of actual use for the purposes of the *action* may be taken into account when determining the eligible costs. By way of exception, the full cost of purchase of equipment may be eligible under the Special Conditions, if this is justified by the nature of the *action* and the context of the use of the equipment or assets;

- (d) costs of consumables and supplies, provided that they:
 - (i) are purchased in accordance with Article II.10.1; and
 - (ii) are directly assigned to the *action*;
- (e) costs arising directly from requirements imposed by the Agreement (dissemination of information, specific evaluation of the *action*, audits, translations, reproduction), including the costs of requested financial guarantees, provided that the corresponding services are purchased in accordance with Article II.10.1;
- (f) costs entailed by *subcontracts* within the meaning of Article II.11, provided that the conditions laid down in Article II.11.1 (a), (b), (c) and (d) are met;
- (g) costs of financial support to third parties within the meaning of Article II.12, provided that the conditions laid down in that Article are met;
- (h) duties, taxes and charges paid by the beneficiary, notably value added tax (VAT), provided that they are included in eligible *direct costs*, and unless specified otherwise in the Agreement.

II.19.3 Eligible indirect costs

To be eligible, *indirect costs* of the *action* must represent a fair apportionment of the overall overheads of the beneficiary and must comply with the conditions of eligibility set out in Article II.19.1.

Eligible *indirect costs* must be declared on the basis of a flat rate of 7 % of the total eligible *direct costs* unless otherwise specified in Article I.3.2.

II.19.4 Ineligible costs

In addition to any other costs which do not fulfil the conditions set out in Article II.19.1, the following costs may not be considered eligible:

- (a) return on capital and dividends paid by the beneficiary;
- (b) debt and debt service charges;
- (c) provisions for losses or debts;
- (d) interest owed;
- (e) doubtful debts;
- (f) exchange losses;
- (g) costs of transfers from the Commission charged by the bank of the beneficiary;
- (h) costs declared by the beneficiary under another *action* receiving a grant financed from the Union budget. Such grants include grants awarded by a Member State and financed from the Union budget and grants awarded by bodies other than the Commission for the purpose of implementing the Union budget. In particular, if the beneficiary receives an operating grant financed by the EU or Euratom budget, it may not declare *indirect costs* for the period(s) covered by the operating grant, unless it can demonstrate that the operating grant does not cover any costs of the *action*;
- (i) contributions in kind from third parties;
- (j) excessive or reckless expenditure;
- (k) deductible VAT.

ARTICLE II.20 – IDENTIFIABILITY AND VERIFIABILITY OF THE AMOUNTS DECLARED

II.20.1 Declaring costs and contributions

The beneficiary must declare as eligible costs or as a requested contribution:

- (a) for actual costs: the costs it actually incurred for the *action*;
- (b) for unit costs or unit contributions: the amount obtained by multiplying the amount per unit specified in Article I.3.2(a)(ii) or (b) by the actual number of units used or produced;
- (c) for lump sum costs or lump sum contributions: the global amount specified in Article I.3.2(a)(iii) or (c), if the corresponding tasks or part of the *action* as described in Annex I have been implemented properly;
- (d) for flat-rate costs or flat-rate contributions: the amount obtained by applying the flat rate specified in Article I.3.2(a)(iv) or (d);

- (e) for financing not linked to costs: the global amount specified in Article I.3.2(e), if the corresponding results or conditions as described in Annex I have been properly achieved or fulfilled;
- (f) for unit costs declared on the basis of the beneficiary's usual cost accounting practices: the amount obtained by multiplying the amount per unit calculated in accordance with the beneficiary's usual cost accounting practices by the actual number of units used or produced;
- (g) for lump sum costs declared on the basis of the beneficiary's usual cost accounting practices: the global amount calculated in accordance with its usual cost accounting practices, if the corresponding tasks or part of the *action* have been implemented properly;
- (h) for flat-rate costs declared on the basis of the beneficiary's usual cost accounting practices: the amount obtained by applying the flat rate calculated in accordance with the beneficiary's usual cost accounting practices.

For the forms of grant referred to in points (b), (c), (d), (f), (g) and (h), the amounts declared must comply with the conditions specified in points (a) and (b) of Article II.19.1.

II.20.2 Records and other documentation to support the costs and contributions declared

The beneficiary must provide the following if requested to do so in the context of the checks or audits described in Article II.27:

- (a) for actual costs: adequate supporting documents to prove the costs declared, such as contracts, invoices and accounting records.
In addition, the beneficiary's usual accounting and internal control procedures must permit direct reconciliation of the amounts declared with the amounts recorded in its accounting statements and with the amounts indicated in the supporting documents;
- (b) for unit costs or unit contributions: adequate supporting documents to prove the number of units declared.
The beneficiary does not need to identify the actual eligible costs covered or to provide supporting documents, such as accounting statements, to prove the amount declared per unit;
- (c) for lump sum costs or lump sum contributions: adequate supporting documents to prove that the *action* has been properly implemented.
The beneficiary does not need to identify the actual eligible costs covered or to provide supporting documents, such as accounting statements, to prove the amount declared as a lump sum;
- (d) for flat-rate costs or flat-rate contributions: adequate supporting documents to prove the eligible costs or requested contribution to which the flat rate applies.

The beneficiary does not need to identify the actual eligible costs covered or to provide supporting documents, such as accounting statements, for the flat rate applied;

- (e) for financing not linked to costs: adequate supporting documents to prove that the *action* has been properly implemented;
The beneficiary does not need to identify the actual eligible costs covered or to provide supporting documents, such as accounting statements, to prove the amount declared as a financing not linked to costs;
- (f) for unit costs declared on the basis of the beneficiary's usual cost accounting practices: adequate supporting documents to prove the number of units declared;
- (g) for lump sum costs declared on the basis of the beneficiary's usual cost accounting practices: adequate supporting documents to prove that the *action* has been properly implemented;
- (h) for flat-rate costs declared on the basis of the beneficiary's usual cost accounting practices: adequate supporting documents to prove the eligible costs to which the flat rate applies.

II.20.3 Conditions to determine the compliance of cost accounting practices

II.20.3.1 In the case of points (f), (g) and (h) of Article II.20.2, the beneficiary does not need to identify the actual eligible costs covered, but it must ensure that the cost accounting practices used for the purpose of declaring eligible costs are in compliance with the following conditions:

- (a) the cost accounting practices used constitute its usual cost accounting practices and are applied in a consistent manner, based on objective criteria independent from the source of funding;
- (b) the costs declared can be directly reconciled with the amounts recorded in its general accounts; and
- (c) the categories of costs used for the purpose of determining the costs declared are exclusive of any ineligible cost or costs covered by other forms of grant as provided for in Article I.3.2.

II.20.3.2 If the Special Conditions so provide, the beneficiary may submit to the Commission a request asking it to assess the compliance of its usual cost accounting practices. If required by the Special Conditions, the request must be accompanied by a certificate on the compliance of the cost accounting practices ('certificate on the compliance of the cost accounting practices').

The certificate on the compliance of the cost accounting practices must be:

- (a) produced by an approved auditor or, if the beneficiary is a public body, by a competent and independent public officer; and
- (b) drawn up in accordance with Annex VII.

The certificate must certify that the beneficiary's cost accounting practices used for the purpose of declaring eligible costs comply with the conditions laid down in

Article II.20.3.1 and with the additional conditions that may be laid down in the Special Conditions.

II.20.3.3 If the Commission has confirmed that the beneficiary's usual cost accounting practices are in compliance, costs declared in application of these practices may not be challenged *ex post*, if:

- (a) the practices actually used comply with those approved by the Commission; and
- (b) the beneficiary did not conceal any information for the purpose of the approval of its cost accounting practices.

ARTICLE II.21 – ELIGIBILITY OF COSTS OF ENTITIES AFFILIATED TO THE BENEFICIARY

If the Special Conditions contain a provision on entities affiliated to the beneficiary, costs incurred by such an entity are eligible, if:

- (a) they satisfy the same conditions under Articles II.19 and II.20 as apply to the beneficiary; and
- (b) the beneficiary ensures that the conditions applicable to it under Articles II.4, II.5, II.6, II.8, II.10, II.11 and II.27 are also applicable to the entity.

ARTICLE II.22 – BUDGET TRANSFERS

The beneficiary is allowed to adjust the estimated budget set out in Annex III by transfers between the different budget categories, if the *action* is implemented as described in Annex I. This adjustment does not require an amendment of the Agreement as provided for in Article II.13.

However, the beneficiary may not add costs relating to *subcontracts* not provided for in Annex 1, unless such additional *subcontracts* are approved by the Commission in accordance with Article II.11.1(d).

The first two subparagraphs do not apply to amounts which, as provided for in Article I.3.2(a)(iii) or (c), take the form of lump sums or which, as provided for in Article I.3.2(e), take the form of financing not linked to cost.

ARTICLE II.23 – NON-COMPLIANCE WITH THE REPORTING OBLIGATIONS

The Commission may terminate the Agreement as provided for in Article II.17.2.1(b) and may reduce the grant as provided for in Article II.25.4 if the beneficiary:

- (a) did not submit a request for interim payment or payment of the balance accompanied by the documents referred to in Articles I.4.3 or I.4.4 within 60 calendar days following the end of the corresponding reporting period; and
- (b) still fails to submit such a request within further 60 calendar days following a written reminder sent by the Commission.

ARTICLE II.24 – SUSPENSION OF PAYMENTS AND TIME LINE FOR PAYMENT

II.24.1 Suspension of payments

II.24.1.1 Grounds for suspension

The Commission may, at any time during the implementation of the Agreement, suspend the pre-financing payments, interim payments or payment of the balance:

- (a) if the Commission has evidence that the beneficiary has committed *irregularities, fraud or breach of obligations* in the award procedure or while implementing the Agreement;
- (b) if the Commission has evidence that the beneficiary has committed systemic or recurrent *irregularities, fraud* or serious *breach of obligations* in other grants funded by the Union or the European Atomic Energy Community ('Euratom') awarded to the beneficiary under similar conditions and such *irregularities, fraud or breach of obligations* have a material impact on this grant; or
- (c) if the Commission suspects *substantial irregularities, fraud or breach of obligations* committed by the beneficiary in the award procedure or while implementing the Agreement and needs to verify whether they have actually occurred.

II.24.1.2 Procedure for suspension

Step 1 — Before suspending payments, the Commission must send a *formal notification* to the beneficiary:

- (a) informing it of:
 - (i) its intention to suspend payments;
 - (ii) the reasons for suspension;
 - (iii) in the cases referred to in points (a) and (b) of Article II.24.1.1, the conditions that need to be met for payments to resume; and
- (b) inviting it to submit observations within 30 calendar days of receiving the *formal notification*.

Step 2 — If the Commission does not receive observations or decides to pursue the procedure despite the observations it has received, it must send a *formal notification* to the beneficiary informing it of:

- (a) the suspension of payments;
- (b) the reasons for suspension;
- (c) the final conditions under which payments may resume in the cases referred to in points (a) and (b) of Article II.24.1.1;
- (d) the indicative date of completion of the necessary verification in the case referred to in point (c) of Article II.24.1.1.

The suspension takes effect on the day the Commission sends *formal notification* of suspension (Step 2).

Otherwise, the Commission must send a *formal notification* to the beneficiary informing it that it is not continuing with the suspension procedure.

II.24.1.3 Effects of suspension

During the period of suspension of payments the beneficiary is not entitled to submit any requests for payments and supporting documents referred to in Articles I.4.2, I.4.3 and I.4.4.

The corresponding requests for payments and supporting documents may be submitted as soon as possible after resumption of payments or may be included in the first request for payment due following resumption of payments in accordance with the schedule laid down in Article I.4.1.

The suspension of payments does not affect the right of the beneficiary to suspend the implementation of the *action* as provided for in Article II.16.1 or to terminate the Agreement as provided for in Article II.17.1.

II.24.1.4 Resuming payments

In order for the Commission to resume payments, the beneficiary must meet the notified conditions as soon as possible and must inform the Commission of any progress made.

If the conditions for resuming payments are met, the suspension will be lifted. The Commission will send a *formal notification* to the beneficiary informing it of this.

II.24.2 Suspension of the time limit for payments

II.24.2.1 The Commission may at any moment suspend the time limit for payment specified in Articles I.5.2, I.5.3 and I.5.4 if a request for payment cannot be approved because:

- (a) it does not comply with the Agreement;
- (b) the appropriate supporting documents have not been produced; or
- (c) there is a doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

II.24.2.2 The Commission must send a *formal notification* to the beneficiary informing it of:

- (a) the suspension; and
- (b) the reasons for the suspension.

The suspension takes effect on the day the Commission sends the *formal notification*.

II.24.2.3 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 beneficiary may request the Commission if the suspension will continue.

If the payment deadline has been suspended because the technical reports or financial statements do not comply with the Agreement and the revised report or statement is not submitted or was submitted but is also rejected, the Commission may terminate the Agreement as provided for in Article II.17.2.1(b) and reduce the grant as provided for in Article II.25.4.

ARTICLE II.25 – CALCULATION OF THE FINAL AMOUNT OF THE GRANT

The final amount of the grant depends on the extent to which the *action* has been implemented in accordance with the terms of the Agreement.

The final amount of the grant is calculated by the Commission at the time of the payment of the balance. The calculation involves the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs and addition of the financing not linked to costs, unit, flat-rate and lump sum contributions

Step 2 — Limit to the *maximum amount of the grant*

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation, irregularities, fraud or breach of obligations.

II.25.1 Step 1 — Application of the reimbursement rate to the eligible costs and addition of the financing not linked to costs, unit, flat-rate and lump sum contributions

This step is applied as follows:

- (a) If, as provided for in Article I.3.2(a)(i), the grant takes the form of the reimbursement of eligible costs actually incurred, the reimbursement rate specified in that Article is applied to those eligible costs as approved by the Commission for the corresponding categories of costs, for the beneficiary and its affiliated entities
- (b) If, as provided for in Article I.3.2(a) (ii) to (v), the grant takes the form of the reimbursement of eligible unit costs, , lump sum costs or flat rate costs, the reimbursement rate specified in that Article is applied to the those eligible costs as approved by the Commission for the corresponding categories of costs, for the beneficiary and its affiliated entities;

The accepted amount of volunteers' work for the beneficiary and its affiliated entities must be limited to the following amount, whichever is the lowest:

- (i) the total sources of financing as indicated in the estimated budget set out in Annex III and as accepted by the Commission multiplied by fifty per cent; or
- (ii) the amount of volunteers' work as indicated in the final financial statement .
- (c) If, as provided for in Article I.3.2(b), the grant takes the form of a unit contribution, the unit contribution specified in that Article is multiplied by the actual number of units approved by the Commission for the beneficiary and its affiliated entities;
- (d) If, as provided for in Article I.3.2(c), the grant takes the form of a lump sum contribution, the Commission applies the lump sum specified in that Article for the beneficiary and its affiliated entities if it finds that the corresponding tasks or part of the *action* were implemented properly in accordance with Annex I;

- (e) If, as provided for in Article I.3.2(d), the grant takes the form of a flat-rate contribution, the flat rate referred to in that Article is applied to the eligible costs or to the contribution approved by the Commission for the beneficiary and its affiliated entities;
- (f) If, as provided for in Article I.3.2(e), the grant takes the form of financing not linked to costs, the Commission applies the amount specified in that Article for the beneficiary and its affiliated entities if it finds that [the conditions specified in Annex I were fulfilled][and][the results specified in Annex I were achieved].

If Article I.3.2 provides for a combination of different forms of grant, the amounts obtained must be added together.

II.25.2 Step 2 — Limit to maximum amount of the grant

The total amount paid to the beneficiary by the Commission may in no circumstances exceed the *maximum amount of the grant*.

If the amount obtained following Step 1 is higher than this maximum amount, the final amount of the grant is limited to the latter.

If volunteers' work is declared as part of direct eligible costs, the final amount of the grant is limited to the amount of total eligible costs and contributions approved by the Commission minus the amount of volunteers' work approved by the Commission.

II.25.3 Step 3 — Reduction due to the no-profit rule

The grant may not produce a profit for the beneficiary, unless specified otherwise in the Special Conditions.

The profit must be calculated as follows:

- (a) calculate the surplus of the total receipts of the action, over the total eligible costs of the action, as follows:

{ receipts of the action

minus

the consolidated total eligible costs and contributions approved by the Commission corresponding to the amounts determined in accordance with Step 1 }

The receipts of the action are calculated as follows:

{ the revenue generated by the *action* for the beneficiary and its affiliated entities other than non-profit organisations

plus

the amount obtained following Steps 1 and 2 }

The revenue generated by the *action* is the consolidated revenue established, generated or confirmed for the beneficiary and its affiliated entities other than non-profit organisations on the date on which the request for payment of the balance is drawn up by the beneficiary.

The following are not considered receipts:

- (i) in kind and financial contributions made by third parties,
 - (ii) in case of an operating grant, amounts dedicated to the building up of reserves.
- (b) If the amount calculated under (a) is positive, this amount will be deducted from the amount calculated following Steps 1 and 2 in proportion to the final rate of reimbursement of the actual eligible costs of the *action* approved by the Commission for the categories of costs referred to in Article I.3.2(a)(i).

II.25.4 Step 4 — Reduction due to improper implementation, irregularities, fraud or breach of obligations

The Commission may reduce the *maximum amount of the grant* if the *action* has not been implemented properly as described in Annex I (i.e. if it has not been implemented or has been implemented poorly, partially or late), or in case of *irregularity, fraud* or breach of an obligation under the Agreement.

The amount of the reduction will be proportionate to the degree to which the *action* has been implemented improperly or to the seriousness of the *irregularity, fraud* or *breach of obligation*.

Before the Commission reduces the grant, it must send a *formal notification* to the beneficiary:

- (a) informing it of:
 - (i) its intention to reduce the *maximum amount of the grant*;
 - (ii) the amount by which it intends to reduce the grant;
 - (iii) the reasons for reduction; and
- (b) inviting it to submit observations within 30 calendar days of receiving the *formal notification*.

If the Commission does not receive any observations or decides to pursue reduction despite the observations it has received, it will send a *formal notification* informing the beneficiary of its decision.

If the grant is reduced, the Commission must calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the *action* or to the seriousness of the *irregularity, fraud* or *breach of obligations*) from the *maximum amount of the grant*.

The final amount of the grant will be the lower of the following two:

- (a) the amount obtained following Steps 1 to 3; or
- (b) the reduced grant amount following Step 4.

ARTICLE II.26 - RECOVERY

II.26.1 Recovery

Where an amount is to be recovered under the terms of the Agreement, the beneficiary must repay the Commission the amount in question.

The beneficiary is responsible for the repayment of any amount unduly paid by the Commission as a contribution towards the costs incurred by its affiliated entities.

II.26.2 Recovery procedure

Before recovery, the Commission must send a *formal notification* to the beneficiary:

- (a) informing it of its intention to recover the amount unduly paid;
- (b) specifying the amount due and the reasons for recovery; and
- (c) inviting the beneficiary to make any observations within a specified period.

If no observations have been submitted or if, despite the observations submitted by the beneficiary, the Commission decides to pursue the recovery procedure, the Commission may confirm recovery by sending a *formal notification* to the beneficiary consisting of a debit note, specifying the terms and the date for payment.

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

- (a) by offsetting it, without the beneficiary's prior consent, against any amounts owed to the beneficiary by the Commission or an executive agency (from the Union or the European Atomic Energy Community (Euratom) budget) ('offsetting');

In exceptional circumstances, to safeguard the financial interests of the Union, the Commission may offset before the due date.

An *action* may be brought against such offsetting before the General Court of the European Union in accordance with Article 263 TFEU;

- (b) by drawing on the financial guarantee where provided for in accordance with Article I.5.2 ('drawing on the financial guarantee');
- (c) by taking legal action as provided for in Article II.18.2 or in the Special Conditions or by adopting an enforceable decision as provided for in Article II.18.3.

II.26.3 Interest on late payment

If payment is not made by the date in the debit note, the amount to be recovered will be increased by late-payment interest at the rate set out in Article I.5.6 from the day following the date for payment in the debit note up to and including the date the Commission receives full payment of the amount.

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

II.26.4 Bank charges

Bank charges incurred in the recovery process must be borne by the beneficiary, unless Directive 2007/64/EC⁶ applies.

ARTICLE II.27 – CHECKS, AUDITS AND EVALUATIONS

II.27.1 Technical and financial checks, audits, interim and final evaluations

The Commission may, during the implementation of the *action* or afterwards, carry out technical and financial checks and audits to determine that the beneficiary is implementing the *action* properly and is complying with the obligations under the Agreement. It may also check the beneficiary's statutory records for the purpose of periodic assessments of lump sum, unit cost or flat-rate amounts.

Information and documents provided as part of checks or audits must be treated on a confidential basis.

In addition, the Commission may carry out an interim or final evaluation of the impact of the *action*, measured against the objective of the Union programme concerned.

Commission checks, audits or evaluations may be carried out either directly by the Commission's own staff or by any other outside body authorised to do so on its behalf.

The Commission may initiate such checks, audits or evaluations during the implementation of the Agreement and during a period of five years starting from the date of payment of the balance. This period is limited to three years if the *maximum amount of the grant* is not more than EUR 60 000.

The check, audit or evaluation procedures are considered to be initiated on the date of receipt of the letter of the Commission announcing it.

If the audit is carried out on an affiliated entity, the beneficiary must inform that affiliated entity.

II.27.2 Duty to keep documents

⁶ Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC.

The beneficiary must keep all original documents, especially accounting and tax records, stored on any appropriate medium, including digitalised originals when they are authorised by their respective national law and under the conditions laid down therein, during a period of five years starting from the date of payment of the balance.

The period during which documents must be kept is limited to three years if the *maximum amount of the grant* is not more than EUR 60 000.

The periods set out in the first and second subparagraphs are longer if there are ongoing audits, appeals, litigation or pursuit of claims concerning the grant, including in the cases referred to in Article II.27.7. In such cases, the beneficiary must keep the documents until such audits, appeals, litigation or pursuit of claims have been closed.

II.27.3 Obligation to provide information

The beneficiary must provide any information, including information in electronic format, requested by the Commission or by any other outside body authorised by the Commission.

If the beneficiary does not comply with the obligation set out in the first subparagraph, the Commission may consider:

- (a) any cost insufficiently substantiated by information provided by the beneficiary as ineligible;
- (b) any financing not linked to costs, unit, lump sum or flat-rate contribution insufficiently substantiated by information provided by the beneficiary as undue.

II.27.4 On-the-spot visits

During an on-the-spot visit, the beneficiary must allow Commission staff and outside personnel authorised by the Commission to have access to the sites and premises where the *action* is or was carried out, and to all the necessary information, including information in electronic format.

The beneficiary must ensure that the information is readily available at the moment of the on-the-spot visit and that information requested is handed over in an appropriate form.

If the beneficiary refuses to provide access to the sites, premises and information as required in the first and second subparagraphs, the Commission may consider:

- (a) any cost insufficiently substantiated by information provided by the beneficiary as ineligible;
- (b) any financing not linked to costs, unit, lump sum or flat-rate contribution insufficiently substantiated by information provided by the beneficiary as undue.

II.27.5 Contradictory audit procedure

On the basis of the findings made during the audit, a provisional report ('draft audit report') must be drawn up. It must be sent by the Commission or its authorised representative to the beneficiary, which must have 30 calendar days from the date of receipt to submit observations. The final report ('final audit report') must be sent to the beneficiary within 60 calendar days of expiry of the time limit for submission of observations.

II.27.6 Effects of audit findings

On the basis of the final audit findings, the Commission may take the measures it considers necessary, including recovery of all or part of the payments made by it, as provided for in Article II.26.

In the case of final audit findings after the payment of the balance, the amount to be recovered corresponds to the difference between the revised final amount of the grant, determined in accordance with Article II.25, and the total amount paid to the beneficiary under the Agreement for the implementation of the *action*.

II.27.7 Correction of systemic or recurrent irregularities, fraud or breach of obligations

II.27.7.1 The Commission may extend audit findings from other grants to this grant if:

- (a) the beneficiary is found to have committed systemic or recurrent *irregularities, fraud or breach of obligations* in other EU or Euratom grants awarded under similar conditions and such *irregularities, fraud or breach of obligations* have a material impact on this grant; and
- (b) the final audit findings are sent to the beneficiary through a *formal notification*, together with the list of grants affected by the findings within the period referred to in Article II.27.1

The extension of findings may lead to:

- (a) the rejection of costs as ineligible;
- (b) reduction of the grant as provided for in Article II.25.4;
- (c) recovery of undue amounts as provided for in Article II.26;
- (d) suspension of payments as provided for in Article II.24.1;
- (e) suspension of the *action* implementation as provided for in Article II.16.2;
- (f) termination as provided for in Article II.17.2.

II.27.7.2 The Commission must send a *formal notification* to the beneficiary informing it of the systemic or recurrent irregularities, *fraud or breach of obligations* and of its intention to extend the audit findings, together with the list of grants affected.

- (a) If the findings concern eligibility of costs the procedure is as follows:

Step 1 — The *formal notification* must include:

- (i) an invitation to submit observations on the list of grants affected by the findings;
- (ii) a request to submit revised financial statements for all grants affected;
- (iii) where possible, the correction rate for extrapolation established by the Commission to calculate the amounts to be rejected on the basis of the systemic or recurrent *irregularities, fraud or breach of obligations*, if the beneficiary:
 - considers that the submission of revised financial statements is not possible or practicable; or
 - will not submit revised financial statements.

Step 2 — The beneficiary has 60 calendar days from when it receives the *formal notification* to submit observations and revised financial statements or to propose a duly substantiated alternative correction method. This period may be extended by the Commission in justified cases.

Step 3 — If the beneficiary submits revised financial statements that take account of the findings the Commission will determine the amount to be corrected on the basis of those revised statements.

If the beneficiary proposes an alternative correction method and the Commission accepts it, the Commission must send a *formal notification* to the beneficiary informing it:

- (i) that it accepts the alternative method;
- (ii) of the revised eligible costs determined by applying this method.

Otherwise the Commission must send a *formal notification* to the beneficiary informing it:

- (i) that it does not accept the observations or the alternative method proposed;
- (ii) of the revised eligible costs determined by applying the extrapolation method initially notified to the beneficiary.

If the systemic or recurrent *irregularities, fraud or breach of obligations* are found after the payment of the balance, the amount to be recovered corresponds to the difference between:

- (i) the revised final amount of the grant, determined in accordance with Article II.25 on the basis of the revised eligible costs declared by the beneficiary and approved by the Commission or on the basis of the revised eligible costs after extrapolation; and
- (ii) the total amount paid to the beneficiary under the Agreement for the implementation of the *action*;

- (b) If the findings concern improper implementation or a breach of another obligation the procedure is as follows:

Step 1 — The *formal notification* must include:

- (i) an invitation to the beneficiary to submit observations on the list of grants affected by the findings and
- (ii) the correction flat rate the Commission intends to apply to the *maximum amount of the grant* or to part of it, according to the principle of proportionality.

Step 2 — The beneficiary has 60 calendar days from receiving the *formal notification* to submit observations or to propose a duly substantiated alternative flat-rate.

Step 3 — If the Commission accepts the alternative flat rate proposed by the beneficiary, it must send a *formal notification* to the beneficiary informing it:

- (i) that it accepts the alternative flat-rate;

- (ii) of the corrected grant amount by applying this flat rate.

Otherwise the Commission must send a *formal notification* to the beneficiary informing it:

- (i) that it does not accept the observations or the alternative flat rate proposed;
- (ii) of the corrected grant amount by applying the flat rate initially notified to the beneficiary.

If the systemic or recurrent *irregularities, fraud or breach of obligations* are found after the payment of the balance, the amount to be recovered corresponds to the difference between:

- (i) the revised final amount of the grant after flat-rate correction; and
- (ii) the total amount paid to the beneficiary under the Agreement for the implementation of the *action*.

II.27.8 Rights of OLAF

The European Anti-Fraud Office (OLAF) has the same rights as the Commission, particularly the right of access, for the purpose of checks and investigations.

Under Council Regulation (Euratom, EC) No 2185/96⁷ and Regulation (EU, Euratom) No 883/2013⁸ OLAF may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by Union law for the protection of the financial interests of the Union against *fraud* and other *irregularities*.

Where appropriate, OLAF findings may lead to the Commission recovering amounts from the beneficiary.

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

II.27.9 Rights of the European Court of Auditors and EPPO

The European Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939 ('the EPPO') have the same rights as the Commission, particularly the right of access, for the purpose of checks, audits and investigations.

⁷ Council Regulation (Euratom, EC) No 2185/96 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.

⁸ 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).