

**DELIBERAZIONE DEL DIRETTORE GENERALE**

*(Nominato con D.P.G.R.T. n. 72 del 29/04/2022)*

N° 8 del 17/01/2023

Oggetto: Progetto “ <b>PartnERship to Contrast HPV</b> ” – PERCH, finanziato da European Health and Digital Executive Agency, nell’ambito del Programma “EU4Health 2021-2027”, coordinato dall’ Istituto Superiore di Sanità. Approvazione del Grant Agreement, della relazione progettuale, del piano economico finanziario e recepimento del finanziamento. CUP I83C22002140005		
Struttura Proponente	S.S. Programmazione e Gestione Risorse economiche	Cristina Gheri
	Responsabile del procedimento	Manola Turci
	Estensore	Manola Turci
ALLEGATI N.	3	

**IMMEDIATAMENTE ESEGUIBILE**

Conti Economici			
Spesa	Descrizione Conto	Codice Conto	Anno Bilancio

Eseguibile a norma di Legge dal 01/02/2023

Pubblicato a norma di Legge il 17/01/2023

Inviato al Collegio Sindacale il 17/01/2023

**IL DIRETTORE GENERALE**

di questo Istituto per lo studio, la prevenzione e la rete oncologica, con sede in Via Cosimo il Vecchio 2 - 50139 Firenze, in forza del Decreto del Presidente della Giunta Regionale Toscana n. 72 del 29.04.2022

**Visti:**

- il Decreto Legislativo 30 dicembre 1992, n. 502 e successive modifiche ed integrazioni;
- la Legge Regionale Toscana 24 febbraio 2005, n. 40 di disciplina del Servizio Sanitario Regionale e successive modifiche ed integrazioni;
- la Legge Regionale Toscana 14 dicembre 2017, n. 74 recante “Disciplina dell’Istituto per lo studio, la prevenzione e la rete oncologica (ISPRO)”;
- la Delibera GRT n. 490 del 7 maggio 2018 di parere favorevole sullo statuto e regolamento dell’ISPRO;
- la Delibera DG ISPRO n. 150 del 31 maggio 2018 di presa d’atto della Delibera GRT n. 490 del 7 maggio 2018 sopra menzionata;
- la Delibera DG ISPRO n. 277 del 11 ottobre 2021 con la quale è stato modificato lo Statuto Aziendale, il Regolamento di organizzazione e funzionamento e l’organigramma dell’Istituto adottati con delibera del Direttore Generale n. 150 del 31/05/2018 e già modificati con Delibera del Direttore Generale n. 11 del 13/01/2020;

**Vista** la Delibera del Direttore Generale n.72 del 29.03.2022 con la quale è stato approvato il regolamento dei progetti finalizzati;

**Premesso che:**

- La **European Health and Digital Executive Agency ( di seguito HADEA)**, nell’ambito del programma **“EU4Health”** volto a garantire un livello elevato di protezione della salute umana in tutte le politiche e le attività dell’Unione, in linea con l’approccio "One Health", ha finanziato, per complessivi € 3.800.000,00, il progetto di ricerca **“PartnERship to Contrast HPV” PERCH** della durata di 30 mesi, individuando come Coordinatore del medesimo l’Istituto Superiore di Sanità che riceverà l’intero finanziamento e provvederà a distribuirlo ai beneficiari;
- In data 16/09/2022 è stato firmato il Grant Agreement n. 101075314 tra HaDEA, rappresentata dal Direttore della Direzione Generale per l’Informatica, il Coordinatore del progetto Istituto Superiore di Sanità e le 17 Istituzioni di ricerca individuate come beneficiari, allegato alla presente sotto lettera “A” quale parte integrante e sostanziale;
- L’Istituto per lo studio, la prevenzione e la rete oncologica partecipa al progetto in qualità di “Affiliated Entity” e, come previsto al punto 2.4 dell’Application form del Grant Agreement, sottoscriverà, assieme alle Autorità competenti e agli altri Enti affiliati, il Consortium Agreement;
- Il progetto sopra indicato terminerà il 30/04/2025 prevedendo un contributo a favore di ISPRO pari ad € 23.687,88;
- Responsabile del progetto per ISPRO è la Dr.ssa Paola Mantellini, Dirigente Medico – Direttore della SC Screening e Prevenzione Secondaria;

**Preso atto** che, il Responsabile del progetto, ha presentato una relazione progettuale per la realizzazione degli obiettivi previsti dal progetto stesso, allegata alla presente sotto lettera “B” quale parte integrante e sostanziale;

**Ritenuto**, pertanto, opportuno approvare il progetto recependo il finanziamento di Euro 23.687,88 (ventitremila seicentottantasette/88) che avendo natura contributiva è fuori dal campo di applicazione dell’Imposta sul Valore Aggiunto (IVA) ai sensi dell’art. 4 del D.P.R. 26 gennaio 1972 n. 633, e il relativo piano economico finanziario, allegato alla presente sotto lettera “C” quale parte integrante e sostanziale;

**Rilevata** la legittimità e la congruenza dell'atto con le finalità istituzionali di questo Ente, stante l'istruttoria effettuata a cura del Responsabile del procedimento;

**Preso atto** della sottoscrizione del Direttore Amministrativo e del Direttore Sanitario, ciascuno per quanto di competenza, ai sensi dell'art. 3 del Decreto Legislativo n. 502/1992 e ss.mm.ii.;

## D E L I B E R A

Per quanto esposto in narrativa che espressamente si richiama:

1. di prendere atto che in data 16/09/2022 è stato firmato il Grant Agreement tra la European Health and Digital Executive Agency, il Coordinatore Istituto Superiore di Sanità ed i beneficiari del progetto "PERCH", allegato di lettera "A" quale parte integrante e sostanziale;
2. di prendere atto che, come previsto al punto 2.4 dell'Application form del Grant Agreement ISPRO sottoscriverà, assieme alle Autorità competenti e agli altri Enti affiliati, il Consortium Agreement;
3. di approvare la Relazione progettuale relativa al progetto di ricerca "**PartnERship to Contrast HPV**" **PERCH** finanziato da European Health and Digital Executive Agency, Allegato di lettera "B" alla presente quale parte integrante e sostanziale, recependone il relativo finanziamento;
4. di approvare il relativo piano economico finanziario, redatto dal Responsabile del progetto per ISPRO, documento allegato sotto lettera "C" quale parte integrante e sostanziale;
5. di prendere atto che ISPRO, per l'effettuazione delle attività connesse al progetto, riceverà la somma di 23.687,88 (ventitremila seicentottantasette/88), a valere dei ricavi registrati nel bilancio d'esercizio dell'Istituto per il periodo di competenza relativo, aut n. 107/2022, conto economico n. 3A01020305 (contributi in conto esercizio per ricerca finalizzata);
6. Di trasmettere il presente atto al Collegio Sindacale ai sensi dell'art. 42, comma 2, della L.R. Toscana n. 40/2005 contemporaneamente all'inoltro all'albo di pubblicità degli atti di questo Istituto.

IL DIRETTORE SANITARIO

*Dott. Roberto Gusinu*

IL DIRETTORE AMMINISTRATIVO

*Dott. Enrico Volpe*

IL DIRETTORE GENERALE

*Avv. Katia Belvedere*

**STRUTTURE AZIENDALI DA PARTECIPARE:**

S.C. Screening e Prevenzione Secondaria ISPRO;

S.S. Programmazione e Gestione Risorse Economiche ISPRO;

Settore Supporto alla Ricerca ISPRO;

Dipartimento Amministrazione e Finanza USL Toscana Centro.

## Elenco degli allegati

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## EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)

HADEA.A – Health and Food  
A.1 – EU4Health

### GRANT AGREEMENT

#### **Project 101075314 — PERCH**

#### **PREAMBLE**

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

**on the one part,**

the **European Health and Digital Executive Agency (HADEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

**and**

**on the other part,**

1. 'the coordinator':

**ISTITUTO SUPERIORE DI SANITA (ISS)**, PIC 999978821, established in Viale Regina Elena 299, ROMA 00161, Italy,

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

2. **SCIENSANO (Sciensano)**, PIC 906160809, established in JULIETTE WYTSMANSTRAAT 14, ELSENE 1050, Belgium,

3. **HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO (CIPH)**, PIC 998128255, established in ROCKEFELLEROVA 7, ZAGREB 10000, Croatia,

4. **USTAV ZDRAVOTNICKYCH INFORMACI A STATISTIKY CESKE REPUBLIKY (UZIS)**, PIC 920415929, established in PALACKEHO NAMESTI 4, PRAHA 12801, Czechia,

5. **TERVISE ARENGU INSTITUUT (TAI)**, PIC 997543539, established in Hiiu 42, TALLINN 11619, Estonia,

6. **INSTITUT NATIONAL DU CANCER GIP (INCA)**, PIC 999953892, established in AVENUE ANDRE MORIZET 52, BOULOGNE BILLANCOURT 92513, France,

7. **BUNDESZENTRALE FÜR GESUNDHEITLICHE AUFKLÄRUNG (BZgA)**, PIC 998190723, established in MAARWEG 149-161, KOLN 50825, Germany,

8. **1ST YGEIONOMIKI PERIFEREIA DYPE ATTIKIS (1ST YPE)**, PIC 998963910, established in ODOS ZACHAROF 3, ATHINA 11521, Greece,

9. **NEMZETI NEPEGESZSEGUGYI KOZPONT (NNK)**, PIC 998706957, established in ALBERT FLORIAN UT 2-6, BUDAPEST 1097, Hungary,
10. **NACIONALINIS VISUOMENES SVEIKATOS CENTRAS PRIE SVEIKATOS APSAUGOS MINISTERIJOS (NVSC)**, PIC 918030796, established in KALVARIJU 153, VILNIUS LT-08221, Lithuania,
11. **FOLKEHELSEINSTITUTTET (NIPH)**, PIC 999478883, established in LOVISENBERGGATA 8, OSLO 0456, Norway,
12. **NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO PZH - PANSTWOWY INSTYTUT BADAWCZY (NIZP-PZH)**, PIC 998403735, established in CHOCIMSKA 24, WARSZAWA 00791, Poland,
13. **INSTITUTUL NATIONAL DE SANATATE PUBLICA (INSP)**, PIC 985926237, established in STR DR LEONTE 1-3 SECTOR 5, BUCURESTI 050463, Romania,
14. **MINISTERSTVO ZDRAVOTNICTVA SLOVENSKEJ REPUBLIKY (SK MoH)**, PIC 999825173, established in LIMBOVA 2, BRATISLAVA 83752, Slovakia,
15. **ONKOLOSKI INSTITUT LJUBLJANA (IOL)**, PIC 986222475, established in ZALOSKA CESTA 2, LJUBLJANA 1000, Slovenia,
16. **INSTITUT CATALA D'ONCOLOGIA (ICO)**, PIC 998420031, established in AV GRAN VIA DE L'HOSPITALET 199-203, L'HOSPITALET DEL LLOBREGAT 08908, Spain,
17. **FOLKHALSOMYNDIGHETEN (FOHM)**, PIC 949789954, established in NOBELS VAG 18, SOLNA 171 82, Sweden,

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator and affiliated entities (if any).

If only one beneficiary signs the grant agreement ('mono-beneficiary grant'), all provisions referring to the 'coordinator' or the 'beneficiaries' will be considered — mutatis mutandis — as referring to the beneficiary.

The parties referred to above have agreed to enter into the Agreement.

By signing the Agreement and the accession forms, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

The Agreement is composed of:

Preamble

Terms and Conditions (including Data Sheet)

- Annex 1 Description of the action<sup>1</sup>
- Annex 2 Estimated budget for the action
- Annex 2a Additional information on unit costs and contributions (if applicable)
- Annex 3 Accession forms (if applicable)<sup>2</sup>
- Annex 3a Declaration on joint and several liability of affiliated entities (if applicable)<sup>3</sup>
- Annex 4 Model for the financial statements
- Annex 5 Specific rules (if applicable)

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<sup>1</sup> Template published on [Portal Reference Documents](#).

<sup>2</sup> Template published on [Portal Reference Documents](#).

<sup>3</sup> Template published on [Portal Reference Documents](#).



## **TERMS AND CONDITIONS**

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## DATA SHEET

### 1. General data

Project summary:

Project summary
<p>Human papillomavirus (HPV) is a DNA virus that consists of more than 100 subtypes, of which more than 40 are sexually transmitted and can infect anogenital and oropharyngeal mucosa. At least 14 HPV types classified as ‘high risk’ can cause cervical cancer in women, and a fraction of other anogenital cancers and head and neck cancers in both genders. In 2020, according to data from the Global Cancer Observatory (CGO), cervical cancer was the 4th most common cancer among women worldwide. Cervical cancer is a highly preventable disease through HPV vaccination (primary prevention) and cervical cancer screening (secondary prevention), and is a treatable disease if detected promptly and properly treated. However, it still represents an important public health problem in Europe and worldwide, especially in poor countries, including several Eastern Europe countries, where access to public health services is limited and screening and treatment for the disease have not been widely implemented. Although vaccines have been available since 2006 and have been progressively introduced into national immunization plans, both introduction and coverage still do not reach optimal levels in Europe and globally. In 2020, according to the WHO/UNICEF Joint Reporting Form on Immunization (JRF), the European Region reported a program coverage of the 27%. In order to achieve the 90% HPV vaccination coverage goal set up by the WHO, many countries require actions to improve their specific vaccination coverages. Moreover, the variation observed in the vaccination coverage between and within countries, indicates the presence of inequalities in access to and information on vaccines. The General Objective of PERCH (PartNERship to Contrast HPV) is to contribute to the implementation of Europe’s Beating Cancer Plan, which aims to support Member States’ efforts to extend the roll-out of routine HPV vaccination to eliminate cervical cancer and other cancers caused by HPV in the coming decade. To this aim, determinants of vaccination hesitancy will be analyzed in order to increase knowledge and awareness among the target population, and training activities will be set up for healthcare personnel on vaccination communication. Transferability of good practices will be promoted and facilitated among participating countries. And finally Member States will be supported to launch large-scale human papillomavirus vaccination campaigns.</p>

Keywords: not defined

Project number: 101075314

Project name: PartNERship to Contrast HPV

Project acronym: PERCH

Call: EU4H-2021-JA-IBA

Topic: EU4H-2021-JA-02

Type of action: EU4H Project Grants

Granting authority: European Health and Digital Executive Agency

Grant managed through EU Funding & Tenders Portal: Yes (eGrants)

Project starting date: fixed date: 1 November 2022

Project end date: 30 April 2025

Project duration: 30 months

Consortium agreement: Yes

### 2. Participants

List of participants:

N°	Role	Short name	Legal name	Ctry	PIC	Total eligible costs (BEN and AE)	Max grant amount
1	COO	ISS	ISTITUTO SUPERIORE DI SANITA	IT	999978821	550 404.01	440 323.21
1.1	AE	UCSC	UNIVERSITA CATTOLICA DEL SACRO CUORE	IT	999915771	39 993.93	31 995.14
1.2	AE	UNIPD	UNIVERSITA DEGLI STUDI DI PADOVA	IT	999995602	32 314.00	25 851.20

N°	Role	Short name	Legal name	Ctry	PIC	Total eligible costs (BEN and AE)	Max grant amount
1.3	AE	CRO AVIANO	CENTRO DI RIFERIMENTO ONCOLOGICO DI AVIANO	IT	989442002	28 042.03	22 433.62
1.4	AE	AUSL RE	AZIENDA UNITA SANITARIA LOCALE DI REGGIO EMILIA	IT	951345931	30 671.57	24 537.26
1.5	AE	CNR	CONSIGLIO NAZIONALE DELLE RICERCHE	IT	999979500	26 595.15	21 276.12
1.6	AE	ISPRO	ISTITUTO PER LO STUDIO E LA PREVENZIONE E LA RETE ONCOLOGICA	IT	998396945	29 609.85	23 687.88
1.7	AE	UNIFI	UNIVERSITA DEGLI STUDI DI FIRENZE	IT	999895789	25 814.85	20 651.88
1.8	AE	IT MoH	MINISTERO DELLA SALUTE	IT	999531942	17 120.00	13 696.00
2	BEN	Sciensano	SCIENSANO	BE	906160809	983 033.13	786 426.50
3	BEN	CIPH	HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO	HR	998128255	79 527.31	63 621.85
4	BEN	UZIS	USTAV ZDRAVOTNICKYCH INFORMACI A STATISTIKY CESKE REPUBLIKY	CZ	920415929	60 631.55	48 505.24
5	BEN	TAI	TERVISE ARENGU INSTITUUT	EE	997543539	65 008.92	52 007.14
5.1	AE	HB	TERVISEAMET	EE	933659727	137 351.09	109 880.87
6	BEN	INCA	INSTITUT NATIONAL DU CANCER GIP	FR	999953892	53 874.50	43 099.60
6.1	AE	EHESP	ECOLE DES HAUTES ETUDES EN SANTE PUBLIQUE	FR	998161429	36 016.20	28 812.96
7	BEN	BZgA	BUNDESZENTRALE FUR GESUNDHEITLICHE AUFKLARUNG	DE	998190723	531 917.06	425 533.65
7.1	AE	RKI	ROBERT KOCH-INSTITUT	DE	999515549	99 465.84	79 572.67
8	BEN	IST YPE	IST YGEIONOMIKI PERIFEREIA DYPE ATTIKIS	EL	998963910	241 980.50	193 584.40
9	BEN	NNK	NEMZETI NEPEGESZSEGUGYI KOZPONT	HU	998706957	146 872.48	117 497.98
10	BEN	NVSC	NACIONALINIS VISUOMENES SVEIKATOS CENTRAS PRIE SVEIKATOS APSAUGOS MINISTERIJS	LT	918030796	85 006.15	68 004.92
11	BEN	NIPH	FOLKEHELSEINSTITUTTET	NO	999478883	99 668.79	79 735.03
12	BEN	NIZP-PZH	NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO PZH - PANSTWOWY INSTYTUT BADAWCZY	PL	998403735	91 642.40	73 313.92
13	BEN	INSP	INSTITUTUL NATIONAL DE SANATATE PUBLICA	RO	985926237	80 427.46	64 341.97
14	BEN	SK MoH	MINISTERSTVO ZDRAVOTNICTVA SLOVENSKEJ REPUBLIKY	SK	999825173	143 594.00	114 875.20
15	BEN	IOL	ONKOLOSKI INSTITUT LJUBLJANA	SI	986222475	324 959.00	259 967.20
15.1	AE	NIJZ	NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	SI	948891346	111 114.15	88 891.32
16	BEN	ICO	INSTITUT CATALA D'ONCOLOGIA	ES	998420031	511 835.04	409 468.03
16.1	AE	IDIBELL	FUNDACIO INSTITUT D'INVESTIGACIO BIOMEDICA DE BELLVITGE	ES	999600618	0.00	0.00
17	BEN	FOHM	FOLKHALSOMYNDIGHETEN	SE	949789954	65 082.75	52 066.20
17.1	AE	KI	KAROLINSKA INSTITUTET	SE	999978530	20 426.30	16 341.04
18	AP	HSE	HEALTH SERVICE EXECUTIVE HSE	IE	993521919	0.00	0.00
19	AP	ASH	ANDREAS SYGGROS HOSPITAL FOR SKIN AND VENEREAL DISEASES	EL	885049632	0.00	0.00
20	AP	AH	ALEXANDRA GENERAL HOSPITAL	EL	894215744	0.00	0.00
<b>Total</b>						4 750 000.01	3 800 000.00

**Coordinator:**

- ISTITUTO SUPERIORE DI SANITA (ISS)

**3. Grant**

**Maximum grant amount, total estimated eligible costs and contributions and funding rate:**

Total eligible costs (BEN and AE)	Funding rate (%)	Maximum grant amount (Annex 2)	Maximum grant amount (award decision)
4 750 000.01	80	3 800 000.00	3 800 000.00

**Grant form:** Budget-based

**Grant mode:** Action grant

**Budget categories/activity types:**

- A. Personnel costs
  - A.1 Employees, A.2 Natural persons under direct contract, A.3 Seconded persons
  - A.4 SME owners and natural person beneficiaries
- B. Subcontracting costs
- C. Purchase costs
  - C.1 Travel and subsistence
  - C.2 Equipment
  - C.3 Other goods, works and services
- D. Other cost categories
  - D.1 Financial support to third parties
- E. Indirect costs

**Cost eligibility options:**

- Standard supplementary payments
- Limitation for subcontracting
- Travel and subsistence:
  - Travel: Unit or Actual costs
  - Accommodation: Unit or Actual costs
  - Subsistence: Unit or Actual costs
- Equipment: depreciation only
- Costs for providing financial support to third parties (actual cost; max amount for each recipient: EUR 0.00)
- Indirect cost flat-rate: 7% of the eligible direct costs (categories A-D, except volunteers costs and exempted specific cost categories, if any)
- VAT: Yes
- Other ineligible costs

**Budget flexibility:** Yes (no flexibility cap)

**4. Reporting, payments and recoveries**

**4.1 Continuous reporting** (art 21)

**Deliverables:** see Funding & Tenders Portal Continuous Reporting tool

**4.2 Periodic reporting and payments**

**Reporting and payment schedule** (art 21, 22):



Reporting					Payments	
Reporting periods			Type	Deadline	Type	Deadline (time to pay)
RP No	Month from	Month to				
					Initial prefinancing	30 days from entry into force/10 days before starting date/ financial guarantee (if required) – whichever is the latest
1	1	15	Periodic report	60 days after end of reporting period	Interim payment	90 days from receiving periodic report
2	16	30	Periodic report	60 days after end of reporting period	Final payment	90 days from receiving periodic report

### Prefinancing payments and guarantees:

Prefinancing payment		Prefinancing guarantee		
Type	Amount	Guarantee amount	Division per participant	
Prefinancing 1 (initial)	2 660 000.00	n/a	1 - ISS	n/a
			1.1 - UCSC	n/a
			1.2 - UNIPD	n/a
			1.3 - CRO AVIANO	n/a
			1.4 - AUSL RE	n/a
			1.5 - CNR	n/a
			1.6 - ISPRO	n/a
			1.7 - UNIFI	n/a
			1.8 - IT MoH	n/a
			2 - Sciensano	n/a
			3 - CIPH	n/a
			4 - UZIS	n/a
			5 - TAI	n/a
			5.1 - HB	n/a
			6 - INCA	n/a
			6.1 - EHESP	n/a
7 - BZgA	n/a			
7.1 - RKI	n/a			
8 - 1ST YPE	n/a			
9 - NNK	n/a			
10 - NVSC	n/a			
11 - NIPH	n/a			
12 - NIZP-PZH	n/a			
13 - INSP	n/a			
14 - SK MoH	n/a			
15 - IOL	n/a			
15.1 - NIJZ	n/a			
16 - ICO	n/a			

Prefinancing payment		Prefinancing guarantee	
Type	Amount	Guarantee amount	Division per participant
			16.1 - IDIBELL
			17 - FOHM
			17.1 - KI

**Reporting and payment modalities** (art 21, 22):

Mutual Insurance Mechanism (MIM): No

Restrictions on distribution of initial prefinancing: The prefinancing may be distributed only if the minimum number of beneficiaries set out in the call conditions (if any) have acceded to the Agreement and only to beneficiaries that have acceded.

Interim payment ceiling (if any): 90% of the maximum grant amount

No-profit rule: Yes

Late payment interest: ECB + 3.5%

Bank account for payments:

IT65U0100003245350200022349

Conversion into euros: Double conversion

Reporting language: Language of the Agreement

**4.3 Certificates** (art 24):

Certificates on the financial statements (CFS):

Conditions:

Schedule: interim/final payment, if threshold is reached

Standard threshold (beneficiary-level):

- financial statement: requested EU contribution to costs  $\geq$  EUR 325 000.00

**4.4 Recoveries** (art 22)**First-line liability for recoveries:**

Beneficiary termination: Beneficiary concerned

Final payment: Coordinator

After final payment: Beneficiary concerned

**Joint and several liability for enforced recoveries (in case of non-payment):**

Limited joint and several liability of other beneficiaries — up to the maximum grant amount of the beneficiary

Joint and several liability of affiliated entities — n/a

**5. Consequences of non-compliance, applicable law & dispute settlement forum**

**Applicable law** (art 43):

Standard applicable law regime: EU law + law of Belgium

**Dispute settlement forum** (art 43):

Standard dispute settlement forum:

EU beneficiaries: EU General Court + EU Court of Justice (on appeal)

Non-EU beneficiaries: Courts of Brussels, Belgium (unless an international agreement provides for the enforceability of EU court judgements)

**6. Other**

**Specific rules (Annex 5):** Yes

**Standard time-limits after project end:**

Confidentiality (for X years after final payment): 5

Record-keeping (for X years after final payment): 5 (or 3 for grants of not more than EUR 60 000)

Reviews (up to X years after final payment): 5 (or 3 for grants of not more than EUR 60 000)

Audits (up to X years after final payment): 5 (or 3 for grants of not more than EUR 60 000)

Extension of findings from other grants to this grant (no later than X years after final payment): 5 (or 3 for grants of not more than EUR 60 000)

Impact evaluation (up to X years after final payment): 5 (or 3 for grants of not more than EUR 60 000)

## **CHAPTER 1 GENERAL**

### **ARTICLE 1 — SUBJECT OF THE AGREEMENT**

This Agreement sets out the rights and obligations and terms and conditions applicable to the grant awarded for the implementation of the action set out in Chapter 2.

### **ARTICLE 2 — DEFINITIONS**

For the purpose of this Agreement, the following definitions apply:

**Actions** — The project which is being funded in the context of this Agreement.

**Grant** — The grant awarded in the context of this Agreement.

**EU grants** — Grants awarded by EU institutions, bodies, offices or agencies (including EU executive agencies, EU regulatory agencies, EDA, joint undertakings, etc.).

**Participants** — Entities participating in the action as beneficiaries, affiliated entities, associated partners, third parties giving in-kind contributions, subcontractors or recipients of financial support to third parties.

**Beneficiaries (BEN)** — The signatories of this Agreement (either directly or through an accession form).

**Affiliated entities (AE)** — Entities affiliated to a beneficiary within the meaning of Article 187 of EU Financial Regulation 2018/1046<sup>4</sup> which participate in the action with similar rights and obligations as the beneficiaries (obligation to implement action tasks and right to charge costs and claim contributions).

**Associated partners (AP)** — Entities which participate in the action, but without the right to charge costs or claim contributions.

**Purchases** — Contracts for goods, works or services needed to carry out the action (e.g. equipment, consumables and supplies) but which are not part of the action tasks (see Annex 1).

**Subcontracting** — Contracts for goods, works or services that are part of the action tasks (see Annex 1).

**In-kind contributions** — In-kind contributions within the meaning of Article 2(36) of EU Financial

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<sup>4</sup> For the definition, see Article 187 Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 ('EU Financial Regulation') (OJ L 193, 30.7.2018, p. 1): "**affiliated entities** [are]:

- (a) entities that form a sole beneficiary [(i.e. where an entity is formed of several entities that satisfy the criteria for being awarded a grant, including where the entity is specifically established for the purpose of implementing an action to be financed by a grant)];
- (b) entities that satisfy the eligibility criteria and that do not fall within one of the situations referred to in Article 136(1) and 141(1) and that have a link with the beneficiary, in particular a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation".

Regulation 2018/1046, i.e. non-financial resources made available free of charge by third parties.

**Fraud** — Fraud within the meaning of Article 3 of EU Directive 2017/1371<sup>5</sup> and Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995<sup>6</sup>, as well as any other wrongful or criminal deception intended to result in financial or personal gain.

**Irregularities** — Any type of breach (regulatory or contractual) which could impact the EU financial interests, including irregularities within the meaning of Article 1(2) of EU Regulation 2988/95<sup>7</sup>.

**Grave professional misconduct** — Any type of unacceptable or improper behaviour in exercising one's profession, especially by employees, including grave professional misconduct within the meaning of Article 136(1)(c) of EU Financial Regulation 2018/1046.

**Applicable EU, international and national law** — Any legal acts or other (binding or non-binding) rules and guidance in the area concerned.

**Portal** — EU Funding & Tenders Portal; electronic portal and exchange system managed by the European Commission and used by itself and other EU institutions, bodies, offices or agencies for the management of their funding programmes (grants, procurements, prizes, etc.).

## **CHAPTER 2 ACTION**

### **ARTICLE 3 — ACTION**

The grant is awarded for the action **101075314 — PERCH** ('action'), as described in Annex 1.

### **ARTICLE 4 — DURATION AND STARTING DATE**

The duration and the starting date of the action are set out in the Data Sheet (see Point 1).

## **CHAPTER 3 GRANT**

### **ARTICLE 5 — GRANT**

#### **5.1 Form of grant**

The grant is an action grant<sup>8</sup> which takes the form of a budget-based mixed actual cost grant (i.e. a

<sup>5</sup> Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law (OJ L 198, 28.7.2017, p. 29).

<sup>6</sup> OJ C 316, 27.11.1995, p. 48.

<sup>7</sup> Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (OJ L 312, 23.12.1995, p. 1).

<sup>8</sup> For the definition, see Article 180(2)(a) EU Financial Regulation 2018/1046: '**action grant**' means an EU grant to finance "an action intended to help achieve a Union policy objective".

grant based on actual costs incurred, but which may also include other forms of funding, such as unit costs or contributions, flat-rate costs or contributions, lump sum costs or contributions or financing not linked to costs).

## **5.2 Maximum grant amount**

The maximum grant amount is set out in the Data Sheet (see Point 3) and in the estimated budget (Annex 2).

## **5.3 Funding rate**

The funding rate for costs is 80% of the action's eligible costs.

Contributions are not subject to any funding rate.

## **5.4 Estimated budget, budget categories and forms of funding**

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

It contains the estimated eligible costs and contributions for the action, broken down by participant and budget category.

Annex 2 also shows the types of costs and contributions (forms of funding)<sup>9</sup> to be used for each budget category.

If unit costs or contributions are used, the details on the calculation will be explained in Annex 2a.

## **5.5 Budget flexibility**

The budget breakdown may be adjusted — without an amendment (see Article 39) — by transfers (between participants and budget categories), as long as this does not imply any substantive or important change to the description of the action in Annex 1.

However:

- changes to the budget category for volunteers (if used) always require an amendment
- changes to budget categories with lump sums costs or contributions (if used; including financing not linked to costs) always require an amendment
- changes to budget categories with higher funding rates or budget ceilings (if used) always require an amendment
- addition of amounts for subcontracts not provided for in Annex 1 either require an amendment or simplified approval in accordance with Article 6.2
- other changes require an amendment or simplified approval, if specifically provided for in Article 6.2
- flexibility caps: not applicable.

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<sup>9</sup> See Article 125 EU Financial Regulation 2018/1046.

## ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS AND CONTRIBUTIONS

In order to be eligible, costs and contributions must meet the **eligibility** conditions set out in this Article.

### 6.1 General eligibility conditions

The **general eligibility conditions** are the following:

- (a) for actual costs:
  - (i) they must be actually incurred by the beneficiary
  - (ii) they must be incurred in the period set out in Article 4 (with the exception of costs relating to the submission of the final periodic report, which may be incurred afterwards; see Article 21)
  - (iii) they must be declared under one of the budget categories set out in Article 6.2 and Annex 2
  - (iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation
  - (v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices
  - (vi) they must comply with the applicable national law on taxes, labour and social security and
  - (vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency
- (b) for unit costs or contributions (if any):
  - (i) they must be declared under one of the budget categories set out in Article 6.2 and Annex 2
  - (ii) the units must:
    - be actually used or produced by the beneficiary in the period set out in Article 4 (with the exception of units relating to the submission of the final periodic report, which may be used or produced afterwards; see Article 21)
    - be necessary for the implementation of the action and
  - (iii) the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 20)
- (c) for flat-rate costs or contributions (if any):
  - (i) they must be declared under one of the budget categories set out in Article 6.2 and Annex 2

- (ii) the costs or contributions to which the flat-rate is applied must:
  - be eligible
  - relate to the period set out in Article 4 (with the exception of costs or contributions relating to the submission of the final periodic report, which may be incurred afterwards; see Article 21)
- (d) for lump sum costs or contributions (if any):
  - (i) they must be declared under one of the budget categories set out in Article 6.2 and Annex 2
  - (ii) the work must be properly implemented by the beneficiary in accordance with Annex 1
  - (iii) the deliverables/outputs must be achieved in the period set out in Article 4 (with the exception of deliverables/outputs relating to the submission of the final periodic report, which may be achieved afterwards; see Article 21)
- (e) for unit, flat-rate or lump sum costs or contributions according to usual cost accounting practices (if any):
  - (i) they must fulfil the general eligibility conditions for the type of cost concerned
  - (ii) the cost accounting practices must be applied in a consistent manner, based on objective criteria, regardless of the source of funding
- (f) for financing not linked to costs (if any): the results must be achieved or the conditions must be fulfilled as described in Annex 1.

In addition, for direct cost categories (e.g. personnel, travel & subsistence, subcontracting and other direct costs) only costs that are directly linked to the action implementation and can therefore be attributed to it directly are eligible. They must not include any indirect costs (i.e. costs that are only indirectly linked to the action, e.g. via cost drivers).

## 6.2 Specific eligibility conditions for each budget category

For each budget category, the **specific eligibility conditions** are as follows:

### **Direct costs**

#### **A. Personnel costs**

**A.1 Costs for employees (or equivalent)** are eligible as personnel costs if they fulfil the general eligibility conditions and are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action.

They must be limited to salaries, social security contributions, taxes and other costs linked to the remuneration, if they arise from national law or the employment contract (or equivalent appointing act) and be calculated on the basis of the costs actually incurred, in accordance with the following method:



{daily rate for the person  
multiplied by  
number of day-equivalents worked on the action (rounded up or down to the nearest half-day)}.

The daily rate must be calculated as:

{annual personnel costs for the person  
divided by  
215}.

The number of day-equivalents declared for a person must be identifiable and verifiable (see Article 20).

The total number of day-equivalents declared in EU grants, for a person for a year, cannot be higher than 215.

The personnel costs may also include supplementary payments for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

- it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required
- the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

**A.2 and A.3 Costs for natural persons working under a direct contract** other than an employment contract and costs for **seconded persons by a third party against payment** are also eligible as personnel costs, if they are assigned to the action, fulfil the general eligibility conditions and:

- (a) work 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) and
- (b) the result of the work belongs to the beneficiary (unless agreed otherwise).

They must be calculated on the basis of a rate which corresponds to the costs actually incurred for the direct contract or secondment and must not be significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

**A.4** The work of **SME owners** for the action (i.e. owners of beneficiaries that are small and medium-sized enterprises<sup>10</sup> not receiving a salary) or **natural person beneficiaries** (i.e. beneficiaries that are natural persons not receiving a salary) may be declared as personnel costs, if they fulfil the general

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<sup>10</sup> For the definition, see Commission Recommendation 2003/361/EC: micro, small or medium-sized enterprise (SME) are enterprises

- engaged in an economic activity, irrespective of their legal form (including, in particular, self-employed persons and family businesses engaged in craft or other activities, and partnerships or associations regularly engaged in an economic activity) and
- employing fewer than 250 persons (expressed in 'annual working units' as defined in Article 5 of the Recommendation) and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.

eligibility conditions and are calculated as unit costs in accordance with the method set out in Annex 2a.

## B. Subcontracting costs

**Subcontracting costs** for the action (including related duties, taxes and charges, such as non-deductible or non-refundable value added tax (VAT)) are eligible, if they are calculated on the basis of the costs actually incurred, fulfil the general eligibility conditions and are awarded using the beneficiary's usual purchasing practices — provided these ensure subcontracts with best value for money (or if appropriate the lowest price) and that there is no conflict of interests (see Article 12).

Beneficiaries that are 'contracting authorities/entities' within the meaning of the EU Directives on public procurement must also comply with the applicable national law on public procurement.

Subcontracting may cover only a limited part of the action.

The tasks to be subcontracted and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2 (or may be approved ex post in the periodic report, if the use of subcontracting does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants; 'simplified approval procedure').

## C. Purchase costs

**Purchase costs** for the action (including related duties, taxes and charges, such as non-deductible or non-refundable value added tax (VAT)) are eligible if they fulfil the general eligibility conditions and are bought using the beneficiary's usual purchasing practices — provided these ensure purchases with best value for money (or if appropriate the lowest price) and that there is no conflict of interests (see Article 12).

Beneficiaries that are 'contracting authorities/entities' within the meaning of the EU Directives on public procurement must also comply with the applicable national law on public procurement.

### C.1 Travel and subsistence

Purchases for **travel, accommodation and subsistence** must be calculated as follows:

- travel: as unit costs in accordance with the method set out in Annex 2a if covered by Decision C(2021)35<sup>11</sup> or otherwise as costs actually incurred and in line with the beneficiary's usual practices on travel
- accommodation: as unit costs in accordance with the method set out in Annex 2a if covered by Decision C(2021)35<sup>12</sup> or otherwise as costs actually incurred and in line with the beneficiary's usual practices on travel
- subsistence: as unit costs in accordance with the method set out in Annex 2a if covered by

<sup>11</sup> Commission Decision of 12 January 2021 authorising the use of unit costs for travel, accommodation and subsistence costs under an action or work programme under the 2021-2027 multi-annual financial framework (C(2021)35).

<sup>12</sup> Commission Decision of 12 January 2021 authorising the use of unit costs for travel, accommodation and subsistence costs under an action or work programme under the 2021-2027 multi-annual financial framework (C(2021)35).

Decision C(2021)35<sup>13</sup> or otherwise as costs actually incurred and in line with the beneficiary's usual practices on travel.

## C.2 Equipment

Purchases of **equipment, infrastructure or other assets** used for the action must be declared as depreciation costs, calculated on the basis of the costs actually incurred and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

Only the portion of the costs that corresponds to the rate of actual use for the action during the action duration can be taken into account.

Costs for **renting or leasing** equipment, infrastructure or other assets are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

## C.3 Other goods, works and services

Purchases of **other goods, works and services** must be calculated on the basis of the costs actually incurred.

Such goods, works and services include, for instance, consumables and supplies, promotion, dissemination, protection of results, translations, publications, certificates and financial guarantees, if required under the Agreement.

## D. Other cost categories

### D.1 Financial support to third parties

**Costs for providing financial support to third parties** (in the form of **grants, prizes** or similar forms of support; if any) are eligible, if and as declared eligible in the call conditions, if they fulfil the general eligibility conditions, are calculated on the basis of the costs actually incurred and the support is implemented in accordance with the conditions set out in Annex 1.

These conditions must ensure objective and transparent selection procedures and include at least the following:

(a) for grants (or similar):

- (i) the maximum amount of financial support for each third party ('recipient'); this amount may not exceed the amount set out in the Data Sheet (see Point 3) or otherwise agreed with the granting authority
- (ii) the criteria for calculating the exact amount of the financial support
- (iii) the different types of activity that qualify for financial support, on the basis of a closed list
- (iv) the persons or categories of persons that will be supported and
- (v) the criteria and procedures for giving financial support

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<sup>13</sup> Commission Decision of 12 January 2021 authorising the use of unit costs for travel, accommodation and subsistence costs under an action or work programme under the 2021-2027 multi-annual financial framework (C(2021)35).

- (b) for prizes (or similar):
  - (i) the eligibility and award criteria
  - (ii) the amount of the prize and
  - (iii) the payment arrangements.

### **Indirect costs**

#### **E. Indirect costs**

**Indirect costs** will be reimbursed at the flat-rate of 7% of the eligible direct costs (categories A-D, except volunteers costs and exempted specific cost categories, if any).

### **Contributions**

Not applicable

### **6.3 Ineligible costs and contributions**

The following costs or contributions are **ineligible**:

- (a) costs or contributions that do not comply with the conditions set out above (Article 6.1 and 6.2), in particular:
  - (i) costs related to return on capital and dividends paid by a beneficiary
  - (ii) debt and debt service charges
  - (iii) provisions for future losses or debts
  - (iv) interest owed
  - (v) currency exchange losses
  - (vi) bank costs charged by the beneficiary's bank for transfers from the granting authority
  - (vii) excessive or reckless expenditure
  - (viii) deductible or refundable VAT (including VAT paid by public bodies acting as public authority)
  - (ix) costs incurred or contributions for activities implemented during grant agreement suspension (see Article 31)
  - (x) in-kind contributions by third parties
- (b) costs or contributions declared under other EU grants (or grants awarded by an EU Member State, non-EU country or other body implementing the EU budget), except for the following cases:
  - (i) Synergy actions: not applicable

- (ii) if the action grant is combined with an operating grant<sup>14</sup> running during the same period and the beneficiary can demonstrate that the operating grant does not cover any (direct or indirect) costs of the action grant
- (c) costs or contributions for staff of a national (or regional/local) administration, for activities that are part of the administration’s normal activities (i.e. not undertaken only because of the grant)
- (d) costs or contributions (especially travel and subsistence) for staff or representatives of EU institutions, bodies or agencies
- (e) other :
  - (i) country restrictions for eligible costs: not applicable
  - (ii) costs or contributions declared specifically ineligible in the call conditions.

## 6.4 Consequences of non-compliance

If a beneficiary declares costs or contributions that are ineligible, they will be rejected (see Article 27).

This may also lead to other measures described in Chapter 5.

## CHAPTER 4 GRANT IMPLEMENTATION

### SECTION 1 CONSORTIUM: BENEFICIARIES, AFFILIATED ENTITIES AND OTHER PARTICIPANTS

#### **ARTICLE 7 — BENEFICIARIES**

The beneficiaries, as signatories of the Agreement, are fully responsible towards the granting authority for implementing it and for complying with all its obligations.

They must implement the Agreement to their best abilities, in good faith and in accordance with all the obligations and terms and conditions it sets out.

They must have the appropriate resources to implement the action and implement the action under their own responsibility and in accordance with Article 11. If they rely on affiliated entities or other participants (see Articles 8 and 9), they retain sole responsibility towards the granting authority and the other beneficiaries.

They are jointly responsible for the *technical* implementation of the action. If one of the beneficiaries fails to implement their part of the action, the other beneficiaries must ensure that this part is implemented by someone else (without being entitled to an increase of the maximum grant amount and subject to an amendment; see Article 39). The *financial* responsibility of each beneficiary in case of recoveries is governed by Article 22.

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<sup>14</sup> For the definition, see Article 180(2)(b) of EU Financial Regulation 2018/1046: ‘**operating grant**’ means an EU grant to finance “the functioning of a body which has an objective forming part of and supporting an EU policy”.

The beneficiaries (and their action) must remain eligible under the EU programme funding the grant for the entire duration of the action. Costs and contributions will be eligible only as long as the beneficiary and the action are eligible.

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

(a) Each beneficiary must:

- (i) keep information stored in the Portal Participant Register up to date (see Article 19)
- (ii) inform the granting authority (and the other beneficiaries) immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 19)
- (iii) submit to the coordinator in good time:
  - the prefinancing guarantees (if required; see Article 23)
  - the financial statements and certificates on the financial statements (CFS) (if required; see Articles 21 and 24.2 and Data Sheet, Point 4.3)
  - the contribution to the deliverables and technical reports (see Article 21)
  - any other documents or information required by the granting authority under the Agreement
- (iv) submit via the Portal data and information related to the participation of their affiliated entities.

(b) The coordinator must:

- (i) monitor that the action is implemented properly (see Article 11)
- (ii) act as the intermediary for all communications between the consortium and the granting authority, unless the Agreement or granting authority specifies otherwise, and in particular:
  - submit the prefinancing guarantees to the granting authority (if any)
  - request and review any documents or information required and verify their quality and completeness before passing them on to the granting authority
  - submit the deliverables and reports to the granting authority
  - inform the granting authority about the payments made to the other beneficiaries (report on the distribution of payments; if required, see Articles 22 and 32)
- (iii) distribute the payments received from the granting authority to the other beneficiaries without unjustified delay (see Article 22).

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

However, coordinators which are public bodies may delegate the tasks set out in Point (b)(ii) last indent and (iii) above to entities with ‘authorisation to administer’ which they have created or which are controlled by or affiliated to them. In this case, the coordinator retains sole responsibility for the payments and for compliance with the obligations under the Agreement.

Moreover, coordinators which are ‘sole beneficiaries’<sup>15</sup> (or similar, such as European research infrastructure consortia (ERICs)) may delegate the tasks set out in Point (b)(i) to (iii) above to one of their members. The coordinator retains sole responsibility for compliance with the obligations under the Agreement.

The beneficiaries must have **internal arrangements** regarding their operation and co-ordination, to ensure that the action is implemented properly.

If required by the granting authority (see Data Sheet, Point 1), these arrangements must be set out in a written **consortium agreement** between the beneficiaries, covering for instance:

- the internal organisation of the consortium
- the management of access to the Portal
- different distribution keys for the payments and financial responsibilities in case of recoveries (if any)
- additional rules on rights and obligations related to background and results (see Article 16)
- settlement of internal disputes
- liability, indemnification and confidentiality arrangements between the beneficiaries.

The internal arrangements must not contain any provision contrary to this Agreement.

## ARTICLE 8 — AFFILIATED ENTITIES

The following entities which are linked to a beneficiary will participate in the action as ‘affiliated entities’:

- **UNIVERSITA CATTOLICA DEL SACRO CUORE (UCSC)**, PIC 999915771, linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **UNIVERSITA DEGLI STUDI DI PADOVA (UNIPD)**, PIC 999995602, linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **CENTRO DI RIFERIMENTO ONCOLOGICO DI AVIANO (CRO AVIANO)**, PIC 989442002, linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **AZIENDA UNITA SANITARIA LOCALE DI REGGIO EMILIA (AUSL RE)**, PIC 951345931, linked to ISTITUTO SUPERIORE DI SANITA (ISS)

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<sup>15</sup> For the definition, see Article 187(2) EU Financial Regulation 2018/1046: “Where several entities satisfy the criteria for being awarded a grant and together form one entity, that entity may be treated as the **sole beneficiary**, including where it is specifically established for the purpose of implementing the action financed by the grant.”

- **CONSIGLIO NAZIONALE DELLE RICERCHE (CNR)**, PIC 999979500, linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **ISTITUTO PER LO STUDIO E LA PREVENZIONE E LA RETE ONCOLOGICA (ISPRO)**, PIC 998396945, linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **UNIVERSITA DEGLI STUDI DI FIRENZE (UNIFI)**, PIC 999895789, linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **MINISTERO DELLA SALUTE (IT MoH)**, PIC 999531942, linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **TERVISEAMET (HB)**, PIC 933659727, linked to TERVISE ARENGU INSTITUUT (TAI)
- **ECOLE DES HAUTES ETUDES EN SANTE PUBLIQUE (EHESP)**, PIC 998161429, linked to INSTITUT NATIONAL DU CANCER GIP (INCA)
- **ROBERT KOCH-INSTITUT (RKI)**, PIC 999515549, linked to BUNDESZENTRALE FUR GESUNDHEITLICHE AUFKLARUNG (BZgA)
- **NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ)**, PIC 948891346, linked to ONKOLOSKI INSTITUT LJUBLJANA (IOL)
- **FUNDACIO INSTITUT D'INVESTIGACIO BIOMEDICA DE BELLVITGE (IDIBELL)**, PIC 999600618, linked to INSTITUT CATALA D'ONCOLOGIA (ICO)
- **KAROLINSKA INSTITUTET (KI)**, PIC 999978530, linked to FOLKHALSOMYNDIGHETEN (FOHM)

Affiliated entities can charge costs and contributions to the action under the same conditions as the beneficiaries and must implement the action tasks attributed to them in Annex 1 in accordance with Article 11.

Their costs and contributions will be included in Annex 2 and will be taken into account for the calculation of the grant.

The beneficiaries must ensure that all their obligations under this Agreement also apply to their affiliated entities.

The beneficiaries must ensure that the bodies mentioned in Article 25 (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.) can exercise their rights also towards the affiliated entities.

Breaches by affiliated entities will be handled in the same manner as breaches by beneficiaries. Recovery of undue amounts will be handled through the beneficiaries.

If the granting authority requires joint and several liability of affiliated entities (see Data Sheet, Point 4.4), they must sign the declaration set out in Annex 3a and may be held liable in case of enforced recoveries against their beneficiaries (see Article 22.2 and 22.4).

## **ARTICLE 9 — OTHER PARTICIPANTS INVOLVED IN THE ACTION**

### **9.1 Associated partners**



The following entities which cooperate with a beneficiary will participate in the action as ‘associated partners’:

- **HEALTH SERVICE EXECUTIVE HSE (HSE)**, PIC 993521919
- **ANDREAS SYGGROS HOSPITAL FOR SKIN AND VENEREAL DISEASES (ASH)**, PIC 885049632
- **ALEXANDRA GENERAL HOSPITAL (AH)**, PIC 894215744

Associated partners must implement the action tasks attributed to them in Annex 1 in accordance with Article 11. They may not charge costs or contributions to the action and the costs for their tasks are not eligible.

The tasks must be set out in Annex 1.

The beneficiaries must ensure that their contractual obligations under Articles 11 (proper implementation), 12 (conflict of interests), 13 (confidentiality and security), 14 (ethics), 17.2 (visibility), 18 (specific rules for carrying out action), 19 (information) and 20 (record-keeping) also apply to the associated partners.

The beneficiaries must ensure that the bodies mentioned in Article 25 (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.) can exercise their rights also towards the associated partners.

## **9.2 Third parties giving in-kind contributions to the action**

Other third parties may give in-kind contributions to the action (i.e. personnel, equipment, other goods, works and services, etc. which are free-of-charge), if necessary for the implementation.

Third parties giving in-kind contributions do not implement any action tasks. They may not charge costs or contributions to the action and the costs for the in-kind contributions are not eligible.

The third parties and their in-kind contributions should be set out in Annex 1.

## **9.3 Subcontractors**

Subcontractors may participate in the action, if necessary for the implementation.

Subcontractors must implement their action tasks in accordance with Article 11. The costs for the subcontracted tasks (invoiced price from the subcontractor) are eligible and may be charged by the beneficiaries, under the conditions set out in Article 6. The costs will be included in Annex 2 as part of the beneficiaries’ costs.

The beneficiaries must ensure that their contractual obligations under Articles 11 (proper implementation), 12 (conflict of interest), 13 (confidentiality and security), 14 (ethics), 17.2 (visibility), 18 (specific rules for carrying out action), 19 (information) and 20 (record-keeping) also apply to the subcontractors.

The beneficiaries must ensure that the bodies mentioned in Article 25 (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.) can exercise their rights also towards the subcontractors.

## **9.4 Recipients of financial support to third parties**

If the action includes providing financial support to third parties (e.g. grants, prizes or similar forms of support), the beneficiaries must ensure that their contractual obligations under Articles 12 (conflict of interest), 13 (confidentiality and security), 14 (ethics), 17.2 (visibility), 18 (specific rules for carrying out action), 19 (information) and 20 (record-keeping) also apply to the third parties receiving the support (recipients).

The beneficiaries must also ensure that the bodies mentioned in Article 25 (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.) can exercise their rights also towards the recipients.

## **ARTICLE 10 — PARTICIPANTS WITH SPECIAL STATUS**

### **10.1 Non-EU participants**

Participants which are established in a non-EU country (if any) undertake to comply with their obligations under the Agreement and:

- to respect general principles (including fundamental rights, values and ethical principles, environmental and labour standards, rules on classified information, intellectual property rights, visibility of funding and protection of personal data)
- for the submission of certificates under Article 24: to use qualified external auditors which are independent and comply with comparable standards as those set out in EU Directive 2006/43/EC<sup>16</sup>
- for the controls under Article 25: to allow for checks, reviews, audits and investigations (including on-the-spot checks, visits and inspections) by the bodies mentioned in that Article (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.).

Special rules on dispute settlement apply (see Data Sheet, Point 5).

### **10.2 Participants which are international organisations**

Participants which are international organisations (IOs; if any) undertake to comply with their obligations under the Agreement and:

- to respect general principles (including fundamental rights, values and ethical principles, environmental and labour standards, rules on classified information, intellectual property rights, visibility of funding and protection of personal data)
- for the submission of certificates under Article 24: to use either independent public officers or external auditors which comply with comparable standards as those set out in EU Directive 2006/43/EC
- for the controls under Article 25: to allow for the checks, reviews, audits and investigations by the bodies mentioned in that Article, taking into account the specific agreements concluded by them and the EU (if any).

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<sup>16</sup> Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts or similar national regulations (OJ L 157, 9.6.2006, p. 87).

For such participants, nothing in the Agreement will be interpreted as a waiver of their privileges or immunities, as accorded by their constituent documents or international law.

Special rules on applicable law and dispute settlement apply (see Article 43 and Data Sheet, Point 5).

### 10.3 Pillar-assessed participants

Pillar-assessed participants (if any) may rely on their own systems, rules and procedures, in so far as they have been positively assessed and do not call into question the decision awarding the grant or breach the principle of equal treatment of applicants or beneficiaries.

‘Pillar-assessment’ means a review by the European Commission on the systems, rules and procedures which participants use for managing EU grants (in particular internal control system, accounting system, external audits, financing of third parties, rules on recovery and exclusion, information on recipients and protection of personal data; see Article 154 EU Financial Regulation 2018/1046).

Participants with a positive pillar assessment may rely on their own systems, rules and procedures, in particular for:

- record-keeping (Article 20): may be done in accordance with internal standards, rules and procedures
- currency conversion for financial statements (Article 21): may be done in accordance with usual accounting practices
- guarantees (Article 23): for public law bodies, prefinancing guarantees are not needed
- certificates (Article 24):
  - certificates on the financial statements (CFS): may be provided by their regular internal or external auditors and in accordance with their internal financial regulations and procedures
  - certificates on usual accounting practices (CoMUC): are not needed if those practices are covered by an ex-ante assessment

and use the following specific rules, for:

- recoveries (Article 22): in case of financial support to third parties, there will be no recovery if the participant has done everything possible to retrieve the undue amounts from the third party receiving the support (including legal proceedings) and non-recovery is not due to an error or negligence on its part
- checks, reviews, audits and investigations by the EU (Article 25): will be conducted taking into account the rules and procedures specifically agreed between them and the framework agreement (if any)
- impact evaluation (Article 26): will be conducted in accordance with the participant’s internal rules and procedures and the framework agreement (if any)
- grant agreement suspension (Article 31): certain costs incurred during grant suspension are eligible (notably, minimum costs necessary for a possible resumption of the action and costs

relating to contracts which were entered into before the pre-information letter was received and which could not reasonably be suspended, reallocated or terminated on legal grounds)

- grant agreement termination (Article 32): the final grant amount and final payment will be calculated taking into account also costs relating to contracts due for execution only after termination takes effect, if the contract was entered into before the pre-information letter was received and could not reasonably be terminated on legal grounds
- liability for damages (Article 33.2): the granting authority must be compensated for 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 only if the damage is due to an infringement of the participant's internal rules and procedures or due to a violation of third parties' rights by the participant or one of its employees or individual for whom the employees are responsible.

Participants whose pillar assessment covers procurement and granting procedures may also do purchases, subcontracting and financial support to third parties (Article 6.2) in accordance with their internal rules and procedures for purchases, subcontracting and financial support.

Participants whose pillar assessment covers data protection rules may rely on their internal standards, rules and procedures for data protection (Article 15).

The participants may however not rely on provisions which would breach the principle of equal treatment of applicants or beneficiaries or call into question the decision awarding the grant, such as in particular:

- eligibility (Article 6)
- consortium roles and set-up (Articles 7-9)
- security and ethics (Articles 13, 14)
- IPR (including background and results, access rights and rights of use), communication, dissemination and visibility (Articles 16 and 17)
- information obligation (Article 19)
- payment, reporting and amendments (Articles 21, 22 and 39)
- rejections, reductions, suspensions and terminations (Articles 27, 28, 29-32)

If the pillar assessment was subject to remedial measures, reliance on the internal systems, rules and procedures is subject to compliance with those remedial measures.

Participants whose assessment has not yet been updated to cover (the new rules on) data protection may rely on their internal systems, rules and procedures, provided that they ensure that personal data is:

- processed lawfully, fairly and in a transparent manner in relation to the data subject
- collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes

- adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed
- accurate and, where necessary, kept up to date
- kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data is processed and
- processed in a manner that ensures appropriate security of the personal data.

Participants must inform the coordinator without delay of any changes to the systems, rules and procedures that were part of the pillar assessment. The coordinator must immediately inform the granting authority.

Pillar-assessed participants that have also concluded a framework agreement with the EU, may moreover — under the same conditions as those above (i.e. not call into question the decision awarding the grant or breach the principle of equal treatment of applicants or beneficiaries) — rely on the provisions set out in that framework agreement.

## **SECTION 2 RULES FOR CARRYING OUT THE ACTION**

### **ARTICLE 11 — PROPER IMPLEMENTATION OF THE ACTION**

#### **11.1 Obligation to properly implement the action**

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

#### **11.2 Consequences of non-compliance**

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

### **ARTICLE 12 — CONFLICT OF INTERESTS**

#### **12.1 Conflict of interests**

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the Agreement could be compromised for reasons involving family, emotional life, political or national affinity, economic interest or any other direct or indirect interest ('conflict of interests').

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

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

## 12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28) and the grant or the beneficiary may be terminated (see Article 32).

Such breaches may also lead to other measures described in Chapter 5.

## ARTICLE 13 — CONFIDENTIALITY AND SECURITY

### 13.1 Sensitive information

The parties must keep confidential any data, documents or other material (in any form) that is identified as sensitive in writing ('sensitive information') — during the implementation of the action and for at least until the time-limit set out in the Data Sheet (see Point 6).

If a beneficiary requests, the granting authority may agree to keep such information confidential for a longer period.

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

The beneficiaries may disclose sensitive information to their personnel or other participants involved in the action only if they:

- (a) need to know it in order to implement the Agreement and
- (b) are bound by an obligation of confidentiality.

The granting authority may disclose sensitive information to its staff and to other EU institutions and bodies.

It may moreover disclose sensitive information to third parties, if:

- (a) this is necessary to implement the Agreement or safeguard the EU financial interests and
- (b) the recipients of the information are bound by an obligation of confidentiality.

The confidentiality obligations no longer apply if:

- (a) the disclosing party agrees to release the other party
- (b) the information becomes publicly available, without breaching any confidentiality obligation
- (c) the disclosure of the sensitive information is required by EU, international or national law.

Specific confidentiality rules (if any) are set out in Annex 5.

### 13.2 Classified information

The parties must handle classified information in accordance with the applicable EU, international or national law on classified information (in particular, Decision 2015/444<sup>17</sup> and its implementing rules).

Deliverables which contain classified information must be submitted according to special procedures agreed with the granting authority.

Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the granting authority.

Classified information may not be disclosed to any third party (including participants involved in the action implementation) without prior explicit written approval from the granting authority.

Specific security rules (if any) are set out in Annex 5.

### **13.3 Consequences of non-compliance**

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

## **ARTICLE 14 — ETHICS AND VALUES**

### **14.1 Ethics**

The action must be carried out in line with the highest ethical standards and the applicable EU, international and national law on ethical principles.

Specific ethics rules (if any) are set out in Annex 5.

### **14.2 Values**

The beneficiaries must commit to and ensure the respect of basic EU values (such as respect for human dignity, freedom, democracy, equality, the rule of law and human rights, including the rights of minorities).

Specific rules on values (if any) are set out in Annex 5.

### **14.3 Consequences of non-compliance**

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

## **ARTICLE 15 — DATA PROTECTION**

### **15.1 Data processing by the granting authority**

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<sup>17</sup> Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

Any personal data under the Agreement will be processed under the responsibility of the data controller of the granting authority in accordance with and for the purposes set out in the Portal Privacy Statement.

For grants where the granting authority is the European Commission, an EU regulatory or executive agency, joint undertaking or other EU body, the processing will be subject to Regulation 2018/1725<sup>18</sup>.

## **15.2 Data processing by the beneficiaries**

The beneficiaries must process personal data under the Agreement in compliance with the applicable EU, international and national law on data protection (in particular, Regulation 2016/679<sup>19</sup>).

They must ensure that personal data is:

- processed lawfully, fairly and in a transparent manner in relation to the data subjects
- collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes
- adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed
- accurate and, where necessary, kept up to date
- kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data is processed and
- processed in a manner that ensures appropriate security of the data.

The beneficiaries may grant their personnel access to personal data only if it is strictly necessary for implementing, managing and monitoring the Agreement. The beneficiaries must ensure that the personnel is under a confidentiality obligation.

The beneficiaries must inform the persons whose data are transferred to the granting authority and provide them with the Portal Privacy Statement.

## **15.3 Consequences of non-compliance**

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

## **ARTICLE 16 — INTELLECTUAL PROPERTY RIGHTS (IPR) — BACKGROUND AND RESULTS — ACCESS RIGHTS AND RIGHTS OF USE**

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<sup>18</sup> 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 (OJ L 295, 21.11.2018, p. 39).

<sup>19</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC ('GDPR') (OJ L 119, 4.5.2016, p. 1).



## 16.1 Background and access rights to background

The beneficiaries must give each other and the other participants access to the background identified as needed for implementing the action, subject to any specific rules in Annex 5.

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

- (a) held by the beneficiaries before they acceded to the Agreement and
- (b) needed to implement the action or exploit the results.

If background is subject to rights of a third party, the beneficiary concerned must ensure that it is able to comply with its obligations under the Agreement.

## 16.2 Ownership of results

The granting authority does not obtain ownership of the results produced under the action.

‘Results’ means any tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights.

## 16.3 Rights of use of the granting authority on materials, documents and information received for policy, information, communication, dissemination and publicity purposes

The granting authority has the right to use non-sensitive information relating to the action and materials and documents received from the beneficiaries (notably summaries for publication, deliverables, as well as any other material, such as pictures or audio-visual material, in paper or electronic form) for policy, information, communication, dissemination and publicity purposes — during the action or afterwards.

The right to use the beneficiaries’ materials, documents and information is granted in the form of a royalty-free, non-exclusive and irrevocable licence, which includes the following rights:

- (a) **use for its own purposes** (in particular, making them available to persons working for the granting authority or any other EU service (including institutions, bodies, offices, agencies, etc.) or EU Member State institution or body; copying or reproducing them in whole or in part, in unlimited numbers; and communication through press information services)
- (b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes)
- (c) **editing or redrafting** (including shortening, summarising, inserting other elements (e.g. meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation)
- (d) **translation**
- (e) **storage** in paper, electronic or other form

- (f) **archiving**, in line with applicable document-management rules
- (g) the right to authorise **third parties** to act on its behalf or sub-license to third parties the modes of use set out in Points (b), (c), (d) and (f), if needed for the information, communication and publicity activity of the granting authority
- (h) **processing**, analysing, aggregating the materials, documents and information received and **producing derivative works**.

The rights of use are granted for the whole duration of the industrial or intellectual property rights concerned.

If materials or documents are subject to moral rights or third party rights (including intellectual property rights or rights of natural persons on their image and voice), the beneficiaries must ensure that they comply with their obligations under this Agreement (in particular, by obtaining the necessary licences and authorisations from the rights holders concerned).

Where applicable, the granting authority will insert the following information:

“© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the [name of granting authority] under conditions.”

#### **16.4 Specific rules on IPR, results and background**

Specific rules regarding intellectual property rights, results and background (if any) are set out in Annex 5.

#### **16.5 Consequences of non-compliance**

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such a breach may also lead to other measures described in Chapter 5.

### **ARTICLE 17 — COMMUNICATION, DISSEMINATION AND VISIBILITY**

#### **17.1 Communication — Dissemination — Promoting the action**

Unless otherwise agreed with the granting authority, the beneficiaries must promote the action and its results by providing targeted information to multiple audiences (including the media and the public), in accordance with Annex 1 and in a strategic, coherent and effective manner.

Before engaging in a communication or dissemination activity expected to have a major media impact, the beneficiaries must inform the granting authority.

#### **17.2 Visibility — European flag and funding statement**

Unless otherwise agreed with the granting authority, communication activities of the beneficiaries related to the action (including media relations, conferences, seminars, information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via traditional or social media, etc.), dissemination activities and any infrastructure, equipment, vehicles, supplies or major result funded

by the grant must acknowledge EU support and display the European flag (emblem) and funding statement (translated into local languages, where appropriate):



Funded by the  
European Union



Co-funded by the  
European Union



Funded by the  
European Union



Co-funded by the  
European Union

The emblem must remain distinct and separate and cannot be modified by adding other visual marks, brands or text.

Apart from the emblem, no other visual identity or logo may be used to highlight the EU support.

When displayed in association with other logos (e.g. of beneficiaries or sponsors), the emblem must be displayed at least as prominently and visibly as the other logos.

For the purposes of their obligations under this Article, the beneficiaries may use the emblem without first obtaining approval from the granting authority. This does not, however, give them the right to exclusive use. Moreover, they may not appropriate the emblem or any similar trademark or logo, either by registration or by any other means.

### 17.3 Quality of information — Disclaimer

Any communication or dissemination activity related to the action must use factually accurate information.

Moreover, it must indicate the following disclaimer (translated into local languages where appropriate):

“Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or [name of the granting authority]. Neither the European Union nor the granting authority can be held responsible for them.”

### 17.4 Specific communication, dissemination and visibility rules

Specific communication, dissemination and visibility rules (if any) are set out in Annex 5.

## **17.5 Consequences of non-compliance**

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

## **ARTICLE 18 — SPECIFIC RULES FOR CARRYING OUT THE ACTION**

### **18.1 Specific rules for carrying out the action**

Specific rules for implementing the action (if any) are set out in Annex 5.

### **18.2 Consequences of non-compliance**

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such a breach may also lead to other measures described in Chapter 5.

## **SECTION 3 GRANT ADMINISTRATION**

## **ARTICLE 19 — GENERAL INFORMATION OBLIGATIONS**

### **19.1 Information requests**

The beneficiaries must provide — during the action or afterwards and in accordance with Article 7 — any information requested in order to verify eligibility of the costs or contributions declared, proper implementation of the action and compliance with the other obligations under the Agreement.

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

### **19.2 Participant Register data updates**

The beneficiaries must keep — at all times, during the action or afterwards — their information stored in the Portal Participant Register up to date, in particular, their name, address, legal representatives, legal form and organisation type.

### **19.3 Information about events and circumstances which impact the action**

The beneficiaries must immediately inform the granting authority (and the other beneficiaries) of any of the following:

- (a) **events** which are likely to affect or delay the implementation of the action or affect the EU's financial interests, in particular:
  - (i) changes in their legal, financial, technical, organisational or ownership situation (including changes linked to one of the exclusion grounds listed in the declaration of honour signed before grant signature)

(ii) linked action information: not applicable

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

#### **19.4 Consequences of non-compliance**

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

### **ARTICLE 20 — RECORD-KEEPING**

#### **20.1 Keeping records and supporting documents**

The beneficiaries must — at least until the time-limit set out in the Data Sheet (see Point 6) — keep records and other supporting documents to prove the proper implementation of the action in line with the accepted standards in the respective field (if any).

In addition, the beneficiaries must — for the same period — keep the following to justify the amounts declared:

- (a) for actual costs: adequate records and supporting documents to prove the costs declared (such as contracts, subcontracts, invoices and accounting records); in addition, the beneficiaries' usual accounting and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documents
- (b) for flat-rate costs and contributions (if any): adequate records and supporting documents to prove the eligibility of the costs or contributions to which the flat-rate is applied
- (c) for the following simplified costs and contributions: the beneficiaries do not need to keep specific records on the actual costs incurred, but must keep:
  - (i) for unit costs and contributions (if any): adequate records and supporting documents to prove the number of units declared
  - (ii) for lump sum costs and contributions (if any): adequate records and supporting documents to prove proper implementation of the work as described in Annex 1
  - (iii) for financing not linked to costs (if any): adequate records and supporting documents to prove the achievement of the results or the fulfilment of the conditions as described in Annex 1
- (d) for unit, flat-rate and lump sum costs and contributions according to usual cost accounting practices (if any): the beneficiaries must keep any adequate records and supporting documents to prove that their cost accounting practices have been applied in a consistent manner, based on

objective criteria, regardless of the source of funding, and that they comply with the eligibility conditions set out in Articles 6.1 and 6.2.

Moreover, the following is needed for specific budget categories:

- (e) for personnel costs: time worked for the beneficiary under the action must be supported by declarations signed monthly by the person and their supervisor, unless another reliable time-record system is in place; the granting authority may accept alternative evidence supporting the time worked for the action declared, if it considers that it offers an adequate level of assurance
- (f) additional record-keeping rules: not applicable

The records and supporting documents must be made available upon request (see Article 19) or in the context of checks, reviews, audits or investigations (see Article 25).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 25), the beneficiaries must keep these records and other supporting documentation until the end of these procedures.

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

## 20.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs or contributions insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 27), and the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

## ARTICLE 21 — REPORTING

### 21.1 Continuous reporting

The beneficiaries must continuously report on the progress of the action (e.g. **deliverables, milestones, outputs/outcomes, critical risks, indicators**, etc; if any), in the Portal Continuous Reporting tool and in accordance with the timing and conditions it sets out (as agreed with the granting authority).

Standardised deliverables (e.g. progress reports not linked to payments, reports on cumulative expenditure, special reports, etc; if any) must be submitted using the templates published on the Portal.

### 21.2 Periodic reporting: Technical reports and financial statements

In addition, the beneficiaries must provide reports to request payments, in accordance with the schedule and modalities set out in the Data Sheet (see Point 4.2):

- for additional prefinancings (if any): an **additional prefinancing report**
- for interim payments (if any) and the final payment: a **periodic report**.

The prefinancing and periodic reports include a technical and financial part.

The technical part includes an overview of the action implementation. It must be prepared using the template available in the Portal Periodic Reporting tool.

The financial part of the additional prefinancing report includes a statement on the use of the previous prefinancing payment.

The financial part of the periodic report includes:

- the financial statements (individual and consolidated; for all beneficiaries/affiliated entities)
- the explanation on the use of resources (or detailed cost reporting table, if required)
- the certificates on the financial statements (CFS) (if required; see Article 24.2 and Data Sheet, Point 4.3).

The **financial statements** must detail the eligible costs and contributions for each budget category and, for the final payment, also the revenues for the action (see Articles 6 and 22).

All eligible costs and contributions incurred should be declared, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts that are not declared in the individual financial statements will not be taken into account by the granting authority.

By signing the financial statements (directly in the Portal Periodic Reporting tool), the beneficiaries confirm that:

- the information provided is complete, reliable and true
- the costs and contributions declared are eligible (see Article 6)
- the costs and contributions can be substantiated by adequate records and supporting documents (see Article 20) that will be produced upon request (see Article 19) or in the context of checks, reviews, audits and investigations (see Article 25)
- for the final periodic report: all the revenues have been declared (if required; see Article 22).

Beneficiaries will have to submit also the financial statements of their affiliated entities (if any). In case of recoveries (see Article 22), beneficiaries will be held responsible also for the financial statements of their affiliated entities.

### **21.3 Currency for financial statements and conversion into euros**

The financial statements must be drafted in euro.

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

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

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

#### **21.4 Reporting language**

The reporting must be in the language of the Agreement, unless otherwise agreed with the granting authority (see Data Sheet, Point 4.2).

#### **21.5 Consequences of non-compliance**

If a report submitted does not comply with this Article, the granting authority may suspend the payment deadline (see Article 29) and apply other measures described in Chapter 5.

If the coordinator breaches its reporting obligations, the granting authority may terminate the grant or the coordinator's participation (see Article 32) or apply other measures described in Chapter 5.

### **ARTICLE 22 — PAYMENTS AND RECOVERIES — CALCULATION OF AMOUNTS DUE**

#### **22.1 Payments and payment arrangements**

Payments will be made in accordance with the schedule and modalities set out in the Data Sheet (see Point 4.2).

They will be made in euro to the bank account indicated by the coordinator (see Data Sheet, Point 4.2) and must be distributed without unjustified delay (restrictions may apply to distribution of the initial prefinancing payment; see Data Sheet, Point 4.2).

Payments to this bank account will discharge the granting authority from its payment obligation.

The cost of payment transfers will be borne as follows:

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

Payments by the granting authority will be considered to have been carried out on the date when they are debited to its account.

#### **22.2 Recoveries**

Recoveries will be made, if — at beneficiary termination, final payment or afterwards — it turns out that the granting authority has paid too much and needs to recover the amounts undue.

The general liability regime for recoveries (first-line liability) is as follows: At final payment, the coordinator will be fully liable for recoveries, even if it has not been the final recipient of the undue amounts. At beneficiary termination or after final payment, recoveries will be made directly against the beneficiaries concerned.

Beneficiaries will be fully liable for repaying the debts of their affiliated entities.



In case of enforced recoveries (see Article 22.4):

- the beneficiaries will be jointly and severally liable for repaying debts of another beneficiary under the Agreement (including late-payment interest), if required by the granting authority (see Data Sheet, Point 4.4)
- affiliated entities will be held liable for repaying debts of their beneficiaries under the Agreement (including late-payment interest), if required by the granting authority (see Data Sheet, Point 4.4).

## 22.3 Amounts due

### 22.3.1 Prefinancing payments

The aim of the prefinancing is to provide the beneficiaries with a float.

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

For **initial prefinancings** (if any), the amount due, schedule and modalities are set out in the Data Sheet (see Point 4.2).

For **additional prefinancings** (if any), the amount due, schedule and modalities are also set out in the Data Sheet (see Point 4.2). However, if the statement on the use of the previous prefinancing payment shows that less than 70% was used, the amount set out in the Data Sheet will be reduced by the difference between the 70% threshold and the amount used.

Prefinancing payments (or parts of them) may be offset (without the beneficiaries' consent) against amounts owed by a beneficiary to the granting authority — up to the amount due to that beneficiary.

For grants where the granting authority is the European Commission or an EU executive agency, offsetting may also be done against amounts owed to other Commission services or executive agencies.

Payments will not be made if the payment deadline or payments are suspended (see Articles 29 and 30).

### 22.3.2 Amount due at beneficiary termination — Recovery

In case of beneficiary termination, the granting authority will determine the provisional amount due for the beneficiary concerned. Payments (if any) will be made with the next interim or final payment.

The **amount due** will be calculated in the following step:

Step 1 — Calculation of the total accepted EU contribution

#### Step 1 — Calculation of the total accepted EU contribution

The granting authority will first calculate the 'accepted EU contribution' for the beneficiary for all reporting periods, by calculating the 'maximum EU contribution to costs' (applying the funding rate to the accepted costs of the beneficiary), taking into account requests for a lower contribution to costs and CFS threshold cappings (if any; see Article 24.5) and adding the contributions (accepted unit, flat-rate or lump sum contributions and financing not linked to costs, if any).

After that, the granting authority will take into account grant reductions (if any). The resulting amount is the ‘total accepted EU contribution’ for the beneficiary.

The **balance** is then calculated by deducting the payments received (if any; see report on the distribution of payments in Article 32), from the total accepted EU contribution:

$$\begin{aligned} & \{ \text{total accepted EU contribution for the beneficiary} \\ & \text{minus} \\ & \{ \text{prefinancing and interim payments received (if any)} \} \}. \end{aligned}$$

If the balance is **positive**, the amount will be included in the next interim or final payment to the consortium.

If the balance is **negative**, it will be **recovered** in accordance with the following procedure:

The granting authority will send a **pre-information letter** to the beneficiary concerned:

- formally notifying the intention to recover, the amount due, the amount to be recovered and the reasons why and
- requesting observations within 30 days of receiving notification.

If no observations are submitted (or the granting authority decides to pursue recovery despite the observations it has received), it will confirm the amount to be recovered and ask this amount to be paid to the coordinator (**confirmation letter**).

The amounts will later on also be taken into account for the next interim or final payment.

### 22.3.3 Interim payments

Interim payments reimburse the eligible costs and contributions claimed for the implementation of the action during the reporting periods (if any).

Interim payments (if any) will be made in accordance with the schedule and modalities set out the Data Sheet (see Point 4.2).

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

The **interim payment** will be calculated by the granting authority in the following steps:

Step 1 — Calculation of the total accepted EU contribution

Step 2 — Limit to the interim payment ceiling

#### Step 1 — Calculation of the total accepted EU contribution

The granting authority will calculate the ‘accepted EU contribution’ for the action for the reporting period, by first calculating the ‘maximum EU contribution to costs’ (applying the funding rate to the accepted costs of each beneficiary), taking into account requests for a lower contribution to costs, and CFS threshold cappings (if any; see Article 24.5) and adding the contributions (accepted unit, flat-rate or lump sum contributions and financing not linked to costs, if any).

After that, the granting authority will take into account grant reductions from beneficiary termination (if any). The resulting amount is the ‘total accepted EU contribution’.

#### Step 2 — Limit to the interim payment ceiling

The resulting amount is then capped to ensure that the total amount of prefinancing and interim payments (if any) does not exceed the interim payment ceiling set out in the Data Sheet (see Point 4.2).

Interim payments (or parts of them) may be offset (without the beneficiaries’ consent) against amounts owed by a beneficiary to the granting authority — up to the amount due to that beneficiary.

For grants where the granting authority is the European Commission or an EU executive agency, offsetting may also be done against amounts owed to other Commission services or executive agencies.

Payments will not be made if the payment deadline or payments are suspended (see Articles 29 and 30).

### **22.3.4 Final payment — Final grant amount — Revenues and Profit — Recovery**

The final payment (payment of the balance) reimburses the remaining part of the eligible costs and contributions claimed for the implementation of the action (if any).

The final payment will be made in accordance with the schedule and modalities set out in the Data Sheet (see Point 4.2).

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

The **final grant amount for the action** will be calculated in the following steps:

Step 1 — Calculation of the total accepted EU contribution

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

#### Step 1 — Calculation of the total accepted EU contribution

The granting authority will first calculate the ‘accepted EU contribution’ for the action for all reporting periods, by calculating the ‘maximum EU contribution to costs’ (applying the funding rate to the total accepted costs of each beneficiary), taking into account requests for a lower contribution to costs, CFS threshold cappings (if any; see Article 24.5) and adding the contributions (accepted unit, flat-rate or lump sum contributions and financing not linked to costs, if any).

After that, the granting authority will take into account grant reductions (if any). The resulting amount is the ‘total accepted EU contribution’.

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

If the resulting amount is higher than the maximum grant amount set out in Article 5.2, it will be limited to the latter.

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

If the no-profit rule is provided for in the Data Sheet (see Point 4.2), the grant must not produce a profit (i.e. surplus of the amount obtained following Step 2 plus the action's revenues, over the eligible costs and contributions approved by the granting authority).

'Revenue' is all income generated by the action, during its duration (see Article 4), for beneficiaries that are profit legal entities.

If there is a profit, it will be deducted in proportion to the final rate of reimbursement of the eligible costs approved by the granting authority (as compared to the amount calculated following Steps 1 and 2 minus the contributions).

The **balance** (final payment) is then calculated by deducting the total amount of prefinancing and interim payments already made (if any), from the final grant amount:

$$\left. \begin{array}{l} \{\text{final grant amount} \\ \text{minus} \\ \{\text{prefinancing and interim payments made (if any)}\} \} \end{array} \right\}$$

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

The final payment (or part of it) may be offset (without the beneficiaries' consent) against amounts owed by a beneficiary to the granting authority — up to the amount due to that beneficiary.

For grants where the granting authority is the European Commission or an EU executive agency, offsetting may also be done against amounts owed to other Commission services or executive agencies.

Payments will not be made if the payment deadline or payments are suspended (see Articles 29 and 30).

If the balance is **negative**, it will be **recovered** in accordance with the following procedure:

The granting authority will send a **pre-information letter** to the coordinator:

- formally notifying the intention to recover, the final grant amount, the amount to be recovered and the reasons why
- requesting observations within 30 days of receiving notification.

If no observations are submitted (or the granting authority decides to pursue recovery despite the observations it has received), it will confirm the amount to be recovered (**confirmation letter**), together with a **debit note** with the terms and date for payment.

If payment is not made by the date specified in the debit note, the granting authority will **enforce recovery** in accordance with Article 22.4.

#### **22.3.5 Audit implementation after final payment — Revised final grant amount — Recovery**

If — after the final payment (in particular, after checks, reviews, audits or investigations; see

Article 25) — the granting authority rejects costs or contributions (see Article 27) or reduces the grant (see Article 28), it will calculate the **revised final grant amount** for the beneficiary concerned.

The **beneficiary revised final grant amount** will be calculated in the following step:

Step 1 — Calculation of the revised total accepted EU contribution

#### Step 1 — Calculation of the revised total accepted EU contribution

The granting authority will first calculate the ‘revised accepted EU contribution’ for the beneficiary, by calculating the ‘revised accepted costs’ and ‘revised accepted contributions’.

After that, it will take into account grant reductions (if any). The resulting ‘revised total accepted EU contribution’ is the beneficiary revised final grant amount.

If the revised final grant amount is lower than the beneficiary’s final grant amount (i.e. its share in the final grant amount for the action), it will be **recovered** in accordance with the following procedure:

The **beneficiary final grant amount** (i.e. share in the final grant amount for the action) is calculated as follows:

$$\left\{ \begin{array}{l} \text{\{total accepted EU contribution for the beneficiary} \\ \text{divided by} \\ \text{total accepted EU contribution for the action\}} \\ \text{multiplied by} \\ \text{final grant amount for the action\}}. \end{array} \right.$$

The granting authority will send a **pre-information letter** to the beneficiary concerned:

- formally notifying the intention to recover, the amount to be recovered and the reasons why and
- requesting observations within 30 days of receiving notification.

If no observations are submitted (or the granting authority decides to pursue recovery despite the observations it has received), it will confirm the amount to be recovered (**confirmation letter**), together with a **debit note** with the terms and the date for payment.

Recoveries against affiliated entities (if any) will be handled through their beneficiaries.

If payment is not made by the date specified in the debit note, the granting authority will **enforce recovery** in accordance with Article 22.4.

## 22.4 Enforced recovery

If payment is not made by the date specified in the debit note, the amount due will be recovered:

- (a) by offsetting the amount — without the coordinator or beneficiary’s consent — against any amounts owed to the coordinator or beneficiary by the granting authority.

In exceptional circumstances, to safeguard the EU financial interests, the amount may be offset before the payment date specified in the debit note.

For grants where the granting authority is the European Commission or an EU executive agency, debts may also be offset against amounts owed by other Commission services or executive agencies.

- (b) by drawing on the financial guarantee(s) (if any)
- (c) by holding other beneficiaries jointly and severally liable (if any; see Data Sheet, Point 4.4)
- (d) by holding affiliated entities jointly and severally liable (if any, see Data Sheet, Point 4.4)
- (e) by taking legal action (see Article 43) or, provided that the granting authority is the European Commission or an EU executive agency, by adopting an enforceable decision under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 100(2) of EU Financial Regulation 2018/1046.

The amount to be recovered will be increased by **late-payment interest** at the rate set out in Article 22.5, from the day following the payment date in the debit note, up to and including the date the full payment is received.

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

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2015/2366<sup>20</sup> applies.

For grants where the granting authority is an EU executive agency, enforced recovery by offsetting or enforceable decision will be done by the services of the European Commission (see also Article 43).

## 22.5 Consequences of non-compliance

**22.5.1** If the granting authority does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus the rate specified in the Data Sheet (Point 4.2). The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

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

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

If payments or the payment deadline are suspended (see Articles 29 and 30), payment will not be considered as late.

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<sup>20</sup> Directive (EU) 2015/2366 of the European Parliament and of the Council of 25 November 2015 on payment services in the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) No 1093/2010, and repealing Directive 2007/64/EC (OJ L 337, 23.12.2015, p. 35).

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

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

**22.5.2** If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 29) and the grant or the coordinator may be terminated (see Article 32).

Such breaches may also lead to other measures described in Chapter 5.

## **ARTICLE 23 — GUARANTEES**

### **23.1 Prefinancing guarantee**

If required by the granting authority (see Data Sheet, Point 4.2), the beneficiaries must provide (one or more) prefinancing guarantee(s) in accordance with the timing and the amounts set out in the Data Sheet.

The coordinator must submit them to the granting authority in due time before the prefinancing they are linked to.

The guarantees must be drawn up using the template published on the Portal and fulfil the following conditions:

- (a) be provided by a bank or approved financial institution established in the EU or — if requested by the coordinator and accepted by the granting authority — by a third party or a bank or financial institution established outside the EU offering equivalent security
- (b) the guarantor stands as first-call guarantor and does not require the granting authority to first have recourse against the principal debtor (i.e. the beneficiary concerned) and
- (c) remain explicitly in force until the final payment and, if the final payment takes the form of a recovery, until five months after the debit note is notified to a beneficiary.

They will be released within the following month.

### **23.2 Consequences of non-compliance**

If the beneficiaries breach their obligation to provide the prefinancing guarantee, the prefinancing will not be paid.

Such breaches may also lead to other measures described in Chapter 5.

## **ARTICLE 24 — CERTIFICATES**

### **24.1 Operational verification report (OVR)**

Not applicable

### **24.2 Certificate on the financial statements (CFS)**

If required by the granting authority (see Data Sheet, Point 4.3), the beneficiaries must provide

certificates on their financial statements (CFS), in accordance with the schedule, threshold and conditions set out in the Data Sheet.

The coordinator must submit them as part of the periodic report (see Article 21).

The certificates must be drawn up using the template published on the Portal, cover the costs declared on the basis of actual costs and costs according to usual cost accounting practices (if any), and fulfil the following conditions:

- (a) be provided by a qualified approved external auditor which is independent and complies with Directive 2006/43/EC<sup>21</sup> (or for public bodies: by a competent independent public officer)
- (b) the verification must be carried out according to the highest professional standards to ensure that the financial statements comply with the provisions under the Agreement and that the costs declared are eligible.

The certificates will not affect the granting authority's right to carry out its own checks, reviews or audits, nor preclude the European Court of Auditors (ECA), the European Public Prosecutor's Office (EPPO) or the European Anti-Fraud Office (OLAF) from using their prerogatives for audits and investigations under the Agreement (see Article 25).

If the costs (or a part of them) were already audited by the granting authority, these costs do not need to be covered by the certificate and will not be counted for calculating the threshold (if any).

### **24.3 Certificate on the compliance of usual cost accounting practices (CoMUC)**

Not applicable

### **24.4 Systems and process audit (SPA)**

Not applicable

### **24.5 Consequences of non-compliance**

If a beneficiary does not submit a certificate on the financial statements (CFS) or the certificate is rejected, the accepted EU contribution to costs will be capped to reflect the CFS threshold.

If a beneficiary breaches any of its other obligations under this Article, the granting authority may apply the measures described in Chapter 5.

## **ARTICLE 25 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS**

### **25.1 Granting authority checks, reviews and audits**

#### **25.1.1 Internal checks**

The granting authority may — during the action or afterwards — check the proper implementation of

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<sup>21</sup> Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts or similar national regulations (OJ L 157, 9.6.2006, p. 87).



the action and compliance with the obligations under the Agreement, including assessing costs and contributions, deliverables and reports.

### 25.1.2 Project reviews

The granting authority may carry out reviews on the proper implementation of the action and compliance with the obligations under the Agreement (general project reviews or specific issues reviews).

Such project reviews may be started during the implementation of the action and until the time-limit set out in the Data Sheet (see Point 6). They will be formally notified to the coordinator or beneficiary concerned and will be considered to start on the date of the notification.

If needed, the granting authority may be assisted by independent, outside experts. If it uses outside experts, the coordinator or beneficiary concerned will be informed and have the right to object on grounds of commercial confidentiality or conflict of interest.

The coordinator or beneficiary concerned must cooperate diligently and provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The granting authority may request beneficiaries to provide such information to it directly. Sensitive information and documents will be treated in accordance with Article 13.

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

For **on-the-spot visits**, the beneficiary concerned must allow access to sites and premises (including to the outside experts) and must ensure that information requested is readily available.

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

On the basis of the review findings, a **project review report** will be drawn up.

The granting authority will formally notify the project review report to the coordinator or beneficiary concerned, which has 30 days from receiving notification to make observations.

Project reviews (including project review reports) will be in the language of the Agreement.

### 25.1.3 Audits

The granting authority may carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Such audits may be started during the implementation of the action and until the time-limit set out in the Data Sheet (see Point 6). They will be formally notified to the beneficiary concerned and will be considered to start on the date of the notification.

The granting authority may use its own audit service, delegate audits to a centralised service or use external audit firms. If it uses an external firm, the beneficiary concerned will be informed and have the right to object on grounds of commercial confidentiality or conflict of interest.

The beneficiary concerned must cooperate diligently and provide — within the deadline requested —

any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. Sensitive information and documents will be treated in accordance with Article 13.

For **on-the-spot** visits, the beneficiary concerned must allow access to sites and premises (including for the external audit firm) and must ensure that information requested is readily available.

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

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

The auditors will formally notify the draft audit report to the beneficiary concerned, which has 30 days from receiving notification to make observations (contradictory audit procedure).

The **final audit report** will take into account observations by the beneficiary concerned and will be formally notified to them.

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

## **25.2 European Commission checks, reviews and audits in grants of other granting authorities**

Where the granting authority is not the European Commission, the latter has the same rights of checks, reviews and audits as the granting authority.

## **25.3 Access to records for assessing simplified forms of funding**

The beneficiaries must give the European Commission access to their statutory records for the periodic assessment of simplified forms of funding which are used in EU programmes.

## **25.4 OLAF, EPPO and ECA audits and investigations**

The following bodies may also carry out checks, reviews, audits and investigations — during the action or afterwards:

- the European Anti-Fraud Office (OLAF) under Regulations No 883/2013<sup>22</sup> and No 2185/96<sup>23</sup>
- the European Public Prosecutor's Office (EPPO) under Regulation 2017/1939
- the European Court of Auditors (ECA) under Article 287 of the Treaty on the Functioning of the EU (TFEU) and Article 257 of EU Financial Regulation 2018/1046.

If requested by these bodies, the beneficiary concerned must provide full, accurate and complete information in the format requested (including complete accounts, individual salary statements or

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<sup>22</sup> Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18/09/2013, p. 1).

<sup>23</sup> Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15/11/1996, p. 2).

other personal data, including in electronic format) and allow access to sites and premises for on-the-spot visits or inspections — as provided for under these Regulations.

To this end, the beneficiary concerned must keep all relevant information relating to the action, at least until the time-limit set out in the Data Sheet (Point 6) and, in any case, until any ongoing checks, reviews, audits, investigations, litigation or other pursuits of claims have been concluded.

## **25.5 Consequences of checks, reviews, audits and investigations — Extension of results of reviews, audits or investigations**

### **25.5.1 Consequences of checks, reviews, audits and investigations in this grant**

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to rejections (see Article 27), grant reduction (see Article 28) or other measures described in Chapter 5.

Rejections or grant reductions after the final payment will lead to a revised final grant amount (see Article 22).

Findings in checks, reviews, audits or investigations during the action implementation may lead to a request for amendment (see Article 39), to change the description of the action set out in Annex 1.

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

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

### **25.5.2 Extension from other grants**

Results of checks, reviews, audits or investigations in other grants may be extended to this grant, if:

- (a) the beneficiary concerned is found, in other EU grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and
- (b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — within the time-limit for audits set out in the Data Sheet (see Point 6).

The granting authority will formally notify the beneficiary concerned of the intention to extend the findings and the list of grants affected.

If the extension concerns **rejections of costs or contributions**: the notification will include:

- (a) an invitation to submit observations on the list of grants affected by the findings
- (b) the request to submit revised financial statements for all grants affected
- (c) the correction rate for extrapolation, established on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected, if the beneficiary concerned:

- (i) considers that the submission of revised financial statements is not possible or practicable or
- (ii) does not submit revised financial statements.

If the extension concerns **grant reductions**: the notification will include:

- (a) an invitation to submit observations on the list of grants affected by the findings and
- (b) the **correction rate for extrapolation**, established on the basis of the systemic or recurrent errors and the principle of proportionality.

The beneficiary concerned has **60 days** from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method/rate**.

On the basis of this, the granting authority will analyse the impact and decide on the implementation (i.e. start rejection or grant reduction procedures, either on the basis of the revised financial statements or the announced/alternative method/rate or a mix of those; see Articles 27 and 28).

## 25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs or contributions insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 27), and the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

## ARTICLE 26 — IMPACT EVALUATIONS

### 26.1 Impact evaluation

The granting authority may carry out impact evaluations of the action, measured against the objectives and indicators of the EU programme funding the grant.

Such evaluations may be started during implementation of the action and until the time-limit set out in the Data Sheet (see Point 6). They will be formally notified to the coordinator or beneficiaries and will be considered to start on the date of the notification.

If needed, the granting authority may be assisted by independent outside experts.

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

### 26.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the granting authority may apply the measures described in Chapter 5.

## CHAPTER 5 CONSEQUENCES OF NON-COMPLIANCE

## **SECTION 1 REJECTIONS AND GRANT REDUCTION**

### **ARTICLE 27 — REJECTION OF COSTS AND CONTRIBUTIONS**

#### **27.1 Conditions**

The granting authority will — at beneficiary termination, interim payment, final payment or afterwards — reject any costs or contributions which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 25).

The rejection may also be based on the extension of findings from other grants to this grant (see Article 25).

Ineligible costs or contributions will be rejected.

#### **27.2 Procedure**

If the rejection does not lead to a recovery, the granting authority will formally notify the coordinator or beneficiary concerned of the rejection, the amounts and the reasons why. The coordinator or beneficiary concerned may — within 30 days of receiving notification — submit observations if it disagrees with the rejection (payment review procedure).

If the rejection leads to a recovery, the granting authority will follow the contradictory procedure with pre-information letter set out in Article 22.

#### **27.3 Effects**

If the granting authority rejects costs or contributions, it will deduct them from the costs or contributions declared and then calculate the amount due (and, if needed, make a recovery; see Article 22).

### **ARTICLE 28 — GRANT REDUCTION**

#### **28.1 Conditions**

The granting authority may — at beneficiary termination, final payment or afterwards — reduce the grant for a beneficiary, if:

- (a) the beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed:
  - (i) substantial errors, irregularities or fraud or
  - (ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions, submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.), or
- (b) the beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants

awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (see Article 25).

The amount of the reduction will be calculated for each beneficiary concerned and proportionate to the seriousness and the duration of the errors, irregularities or fraud or breach of obligations, by applying an individual reduction rate to their accepted EU contribution.

## 28.2 Procedure

If the grant reduction does not lead to a recovery, the granting authority will formally notify the coordinator or beneficiary concerned of the reduction, the amount to be reduced and the reasons why. The coordinator or beneficiary concerned may — within 30 days of receiving notification — submit observations if it disagrees with the reduction (payment review procedure).

If the grant reduction leads to a recovery, the granting authority will follow the contradictory procedure with pre-information letter set out in Article 22.

## 28.3 Effects

If the granting authority reduces the grant, it will deduct the reduction and then calculate the amount due (and, if needed, make a recovery; see Article 22).

## SECTION 2 — SUSPENSION AND TERMINATION

### ARTICLE 29 — PAYMENT DEADLINE SUSPENSION

#### 29.1 Conditions

The granting authority may — at any moment — suspend the payment deadline if a payment cannot be processed because:

- (a) the required report (see Article 21) has not been submitted or is not complete or additional information is needed
- (b) there are doubts about the amount to be paid (e.g. ongoing audit extension procedure, queries about eligibility, need for a grant reduction, etc.) and additional checks, reviews, audits or investigations are necessary, or
- (c) there are other issues affecting the EU financial interests.

#### 29.2 Procedure

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

The suspension will **take effect** the day the notification is sent.

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining time to pay (see Data Sheet, Point 4.2) will resume.

If the suspension exceeds two months, the coordinator may request the granting authority to confirm if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the report and the revised report is not submitted (or was submitted but is also rejected), the granting authority may also terminate the grant or the participation of the coordinator (see Article 32).

## ARTICLE 30 — PAYMENT SUSPENSION

### 30.1 Conditions

The granting authority may — at any moment — suspend payments, in whole or in part for one or more beneficiaries, if:

- (a) a beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed or is suspected of having committed:
  - (i) substantial errors, irregularities or fraud or
  - (ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions, submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.), or
- (b) a beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant.

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

### 30.2 Procedure

Before suspending payments, the granting authority will send a **pre-information letter** to the beneficiary concerned:

- formally notifying the intention to suspend payments and the reasons why and
- requesting observations within 30 days of receiving notification.

If the granting authority does not receive observations or decides to pursue the procedure despite the observations it has received, it will confirm the suspension (**confirmation letter**). Otherwise, it will formally notify that the procedure is discontinued.

At the end of the suspension procedure, the granting authority will also inform the coordinator.

The suspension will **take effect** the day after the confirmation notification is sent.

If the conditions for resuming payments are met, the suspension will be **lifted**. The granting authority will formally notify the beneficiary concerned (and the coordinator) and set the suspension end date.

During the suspension, no prefinancing will be paid to the beneficiaries concerned. For interim payments, the periodic reports for all reporting periods except the last one (see Article 21) must not contain any financial statements from the beneficiary concerned (or its affiliated entities). The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

## ARTICLE 31 — GRANT AGREEMENT SUSPENSION

### 31.1 Consortium-requested GA suspension

#### 31.1.1 Conditions and procedure

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

The coordinator must submit a request for **amendment** (see Article 39), with:

- the reasons why
- the date the suspension takes effect; this date may be before the date of the submission of the amendment request and
- the expected date of resumption.

The suspension will **take effect** on the day specified in the amendment.

Once circumstances allow for implementation to resume, the coordinator must immediately request another **amendment** of the Agreement to set the suspension end date, the resumption date (one day after suspension end date), extend the duration and make other changes necessary to adapt the action to the new situation (see Article 39) — unless the grant has been terminated (see Article 32). The suspension will be **lifted** with effect from the suspension end date set out in the amendment. This date may be before the date of the submission of the amendment request.

During the suspension, no prefinancing will be paid. Costs incurred or contributions for activities implemented during grant suspension are not eligible (see Article 6.3).

### 31.2 EU-initiated GA suspension

#### 31.2.1 Conditions

The granting authority may suspend the grant or any part of it, if:

- (a) a beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed or is suspected of having committed:
  - (i) substantial errors, irregularities or fraud or
  - (ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions,



submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.), or

(b) a beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant

(c) other:

(i) linked action issues: not applicable

(ii) additional GA suspension grounds: not applicable.

### 31.2.2 Procedure

Before suspending the grant, the granting authority will send a **pre-information letter** to the coordinator:

- formally notifying the intention to suspend the grant and the reasons why and
- requesting observations within 30 days of receiving notification.

If the granting authority does not receive observations or decides to pursue the procedure despite the observations it has received, it will confirm the suspension (**confirmation letter**). Otherwise, it will formally notify that the procedure is discontinued.

The suspension will **take effect** the day after the confirmation notification is sent (or on a later date specified in the notification).

Once the conditions for resuming implementation of the action are met, the granting authority will formally notify the coordinator a **lifting of suspension letter**, in which it will set the suspension end date and invite the coordinator to request an amendment of the Agreement to set the resumption date (one day after suspension end date), extend the duration and make other changes necessary to adapt the action to the new situation (see Article 39) — unless the grant has been terminated (see Article 32). The suspension will be **lifted** with effect from the suspension end date set out in the lifting of suspension letter. This date may be before the date on which the letter is sent.

During the suspension, no prefinancing will be paid. Costs incurred or contributions for activities implemented during suspension are not eligible (see Article 6.3).

The beneficiaries may not claim damages due to suspension by the granting authority (see Article 33).

Grant suspension does not affect the granting authority's right to terminate the grant or a beneficiary (see Article 32) or reduce the grant (see Article 28).

## ARTICLE 32 — GRANT AGREEMENT OR BENEFICIARY TERMINATION

### 32.1 Consortium-requested GA termination

#### 32.1.1 Conditions and procedure

The beneficiaries may request the termination of the grant.

The coordinator must submit a request for **amendment** (see Article 39), with:

- the reasons why
- the date the consortium ends work on the action ('end of work date') and
- the date the termination takes effect ('termination date'); this date must be after the date of the submission of the amendment request.

The termination will **take effect** on the termination date specified in the amendment.

If no reasons are given or if the granting authority considers the reasons do not justify termination, it may consider the grant terminated improperly.

### 32.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit a **periodic report** (for the open reporting period until termination).

The granting authority will calculate the final grant amount and final payment on the basis of the report submitted and taking into account the costs incurred and contributions for activities implemented before the end of work date (see Article 22). Costs relating to contracts due for execution only after the end of work are not eligible.

If the granting authority does not receive the report within the deadline, only costs and contributions which are included in an approved periodic report will be taken into account (no costs/contributions if no periodic report was ever approved).

Improper termination may lead to a grant reduction (see Article 28).

After termination, the beneficiaries' obligations (in particular Articles 13 (confidentiality and security), 16 (IPR), 17 (communication, dissemination and visibility), 21 (reporting), 25 (checks, reviews, audits and investigations), 26 (impact evaluation), 27 (rejections), 28 (grant reduction) and 42 (assignment of claims)) continue to apply.

## 32.2 Consortium-requested beneficiary termination

### 32.2.1 Conditions and procedure

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

The coordinator must submit a request for **amendment** (see Article 39), with:

- the reasons why
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing)
- the date the beneficiary ends work on the action ('end of work date')

- the date the termination takes effect ('termination date'); this date must be after the date of the submission of the amendment request.

If the termination concerns the coordinator and is done without its agreement, the amendment request must be submitted by another beneficiary (acting on behalf of the consortium).

The termination will **take effect** on the termination date specified in the amendment.

If no information is given or if the granting authority considers that the reasons do not justify termination, it may consider the beneficiary to have been terminated improperly.

### 32.2.2 Effects

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

- (i) a **report on the distribution of payments** to the beneficiary concerned
- (ii) a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, the financial statement, the explanation on the use of resources, and, if applicable, the certificate on the financial statement (CFS; see Articles 21 and 24.2 and Data Sheet, Point 4.3)
- (iii) a second **request for amendment** (see Article 39) with other amendments needed (e.g. reallocation of the tasks and the estimated budget of the terminated beneficiary; addition of a new beneficiary to replace the terminated beneficiary; change of coordinator, etc.).

The granting authority will calculate the amount due to the beneficiary on the basis of the report submitted and taking into account the costs incurred and contributions for activities implemented before the end of work date (see Article 22). Costs relating to contracts due for execution only after the end of work are not eligible.

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 21).

If the granting authority does not receive the termination report within the deadline, only costs and contributions which are included in an approved periodic report will be taken into account (no costs/contributions if no periodic report was ever approved).

If the granting authority does not receive the report on the distribution of payments within the deadline, it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

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

If the second request for amendment is rejected by the granting authority (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the grant may be terminated (see Article 32).

Improper termination may lead to a reduction of the grant (see Article 31) or grant termination (see Article 32).

After termination, the concerned beneficiary's obligations (in particular Articles 13 (confidentiality and security), 16 (IPR), 17 (communication, dissemination and visibility), 21 (reporting), 25 (checks, reviews, audits and investigations), 26 (impact evaluation), 27 (rejections), 28 (grant reduction) and 42 (assignment of claims)) continue to apply.

### **32.3 EU-initiated GA or beneficiary termination**

#### **32.3.1 Conditions**

The granting authority may terminate the grant or the participation of one or more beneficiaries, if:

- (a) one or more beneficiaries do not accede to the Agreement (see Article 40)
- (b) a change to the action or the legal, financial, technical, organisational or ownership situation of a beneficiary is likely to substantially affect the implementation of the action or calls into question the decision to award the grant (including changes linked to one of the exclusion grounds listed in the declaration of honour)
- (c) following termination of one or more beneficiaries, the necessary changes to the Agreement (and their impact on the action) would call into question the decision awarding the grant or breach the principle of equal treatment of applicants
- (d) implementation of the action has become impossible or the changes necessary for its continuation would call into question the decision awarding the grant or breach the principle of equal treatment of applicants
- (e) a beneficiary (or person with unlimited liability for its debts) is subject to bankruptcy proceedings or similar (including insolvency, winding-up, administration by a liquidator or court, arrangement with creditors, suspension of business activities, etc.)
- (f) a beneficiary (or person with unlimited liability for its debts) is in breach of social security or tax obligations
- (g) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has been found guilty of grave professional misconduct
- (h) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed fraud, corruption, or is involved in a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking
- (i) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) was created under a different jurisdiction with the intent to circumvent fiscal, social or other legal obligations in the country of origin (or created another entity with this purpose)
- (j) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed:

- (i) substantial errors, irregularities or fraud or
- (ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions, submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.)
- (k) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings from other grants to this grant; see Article 25)
- (l) despite a specific request by the granting authority, a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its affiliated entities or associated partners that is in one of the situations under points (d), (f), (e), (g), (h), (i) or (j) and to reallocate its tasks, or
- (m) other:
  - (i) linked action issues: not applicable
  - (ii) additional GA termination grounds: not applicable.

### 32.3.2 Procedure

Before terminating the grant or participation of one or more beneficiaries, the granting authority will send a **pre-information letter** to the coordinator or beneficiary concerned:

- formally notifying the intention to terminate and the reasons why and
- requesting observations within 30 days of receiving notification.

If the granting authority does not receive observations or decides to pursue the procedure despite the observations it has received, it will confirm the termination and the date it will take effect (**confirmation letter**). Otherwise, it will formally notify that the procedure is discontinued.

For beneficiary terminations, the granting authority will — at the end of the procedure — also inform the coordinator.

The termination will **take effect** the day after the confirmation notification is sent (or on a later date specified in the notification; ‘termination date’).

### 32.3.3 Effects

- (a) for **GA termination**:

The coordinator must — within 60 days from when termination takes effect — submit a **periodic report** (for the last open reporting period until termination).

The granting authority will calculate the final grant amount and final payment on the basis of the report submitted and taking into account the costs incurred and contributions for activities

implemented before termination takes effect (see Article 22). Costs relating to contracts due for execution only after termination are not eligible.

If the grant is terminated for breach of the obligation to submit reports, the coordinator may not submit any report after termination.

If the granting authority does not receive the report within the deadline, only costs and contributions which are included in an approved periodic report will be taken into account (no costs/contributions if no periodic report was ever approved).

Termination does not affect the granting authority's right to reduce the grant (see Article 28) or to impose administrative sanctions (see Article 34).

The beneficiaries may not claim damages due to termination by the granting authority (see Article 33).

After termination, the beneficiaries' obligations (in particular Articles 13 (confidentiality and security), 16 (IPR), 17 (communication, dissemination and visibility), 21 (reporting), 25 (checks, reviews, audits and investigations), 26 (impact evaluation), 27 (rejections), 28 (grant reduction) and 42 (assignment of claims)) continue to apply.

**(b) for beneficiary termination:**

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

- (i) a **report on the distribution of payments** to the beneficiary concerned
- (ii) a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, the financial statement, the explanation on the use of resources, and, if applicable, the certificate on the financial statement (CFS; see Articles 21 and 24.2 and Data Sheet, Point 4.3)
- (iii) a **request for amendment** (see Article 39) with any amendments needed (e.g. reallocation of the tasks and the estimated budget of the terminated beneficiary; addition of a new beneficiary to replace the terminated beneficiary; change of coordinator, etc.).

The granting authority will calculate the amount due to the beneficiary on the basis of the report submitted and taking into account the costs incurred and contributions for activities implemented before termination takes effect (see Article 22). Costs relating to contracts due for execution only after termination are not eligible.

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 21).

If the granting authority does not receive the termination report within the deadline, only costs and contributions included in an approved periodic report will be taken into account (no costs/contributions if no periodic report was ever approved).

If the granting authority does not receive the report on the distribution of payments within the deadline, it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

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

If the request for amendment is rejected by the granting authority (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the grant may be terminated (see Article 32).

After termination, the concerned beneficiary's obligations (in particular Articles 13 (confidentiality and security), 16 (IPR), 17 (communication, dissemination and visibility), 21 (reporting), 25 (checks, reviews, audits and investigations), 26 (impact evaluation), 27 (rejections), 28 (grant reduction) and 42 (assignment of claims)) continue to apply.

## **SECTION 3 OTHER CONSEQUENCES: DAMAGES AND ADMINISTRATIVE SANCTIONS**

### **ARTICLE 33 — DAMAGES**

#### **33.1 Liability of the granting authority**

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

The granting authority cannot be held liable for any damage caused by any of the beneficiaries or other participants involved in the action, as a consequence of the implementation of the Agreement.

#### **33.2 Liability of the beneficiaries**

The beneficiaries must compensate the granting authority 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, provided that it was caused by gross negligence or wilful act.

The liability does not extend to indirect or consequential losses or similar damage (such as loss of profit, loss of revenue or loss of contracts), provided such damage was not caused by wilful act or by a breach of confidentiality.

### **ARTICLE 34 — ADMINISTRATIVE SANCTIONS AND OTHER MEASURES**

Nothing in this Agreement may be construed as preventing the adoption of administrative sanctions (i.e. exclusion from EU award procedures and/or financial penalties) or other public law measures, in addition or as an alternative to the contractual measures provided under this Agreement (see, for instance, Articles 135 to 145 EU Financial Regulation 2018/1046 and Articles 4 and 7 of Regulation 2988/95<sup>24</sup>).

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<sup>24</sup> Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (OJ L 312, 23.12.1995, p. 1).

## **SECTION 4 FORCE MAJEURE**

### **ARTICLE 35 — FORCE MAJEURE**

A party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

‘Force majeure’ means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties’ control,
- was not due to error or negligence on their part (or on the part of other participants involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

## **CHAPTER 6 FINAL PROVISIONS**

### **ARTICLE 36 — COMMUNICATION BETWEEN THE PARTIES**

#### **36.1 Forms and means of communication — Electronic management**

EU grants are managed fully electronically through the EU Funding & Tenders Portal (‘Portal’).

All communications must be made electronically through the Portal, in accordance with the Portal Terms and Conditions and using the forms and templates provided there (except if explicitly instructed otherwise by the granting authority).

Communications must be made in writing and clearly identify the grant agreement (project number and acronym).

Communications must be made by persons authorised according to the Portal Terms and Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a ‘legal entity appointed representative (LEAR)’. The role and tasks of the LEAR are stipulated in their appointment letter (see Portal Terms and Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Portal.

#### **36.2 Date of communication**

The sending date for communications made through the Portal will be the date and time of sending, as indicated by the time logs.



The receiving date for communications made through the Portal will be the date and time the communication is accessed, as indicated by the time logs. Formal notifications that have not been accessed within 10 days after sending, will be considered to have been accessed (see Portal Terms and Conditions).

If a communication is exceptionally made on paper (by e-mail or postal service), general principles apply (i.e. date of sending/receipt). Formal notifications by registered post with proof of delivery will be considered to have been received either on the delivery date registered by the postal service or the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

### **36.3 Addresses for communication**

The Portal can be accessed via the Europa website.

The address for paper communications to the granting authority (if exceptionally allowed) is the official mailing address indicated on its website.

For beneficiaries, it is the legal address specified in the Portal Participant Register.

## **ARTICLE 37 — INTERPRETATION OF THE AGREEMENT**

The provisions in the Data Sheet take precedence over the rest of the Terms and Conditions of the Agreement.

Annex 5 takes precedence over the Terms and Conditions; the Terms and Conditions take precedence over the Annexes other than Annex 5.

Annex 2 takes precedence over Annex 1.

## **ARTICLE 38 — CALCULATION OF PERIODS AND DEADLINES**

In accordance with Regulation No 1182/71<sup>25</sup>, periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

‘Days’ means calendar days, not working days.

## **ARTICLE 39 — AMENDMENTS**

### **39.1 Conditions**

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

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<sup>25</sup> Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8/6/1971, p. 1).

Amendments may be requested by any of the parties.

## 39.2 Procedure

The party requesting an amendment must submit a request for amendment signed directly in the Portal Amendment tool.

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3). If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

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

The granting authority may request additional information.

If the party receiving the request agrees, it must sign the amendment in the tool within 45 days of receiving notification (or any additional information the granting authority has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date of entry into force or other date specified in the amendment.

## ARTICLE 40 — ACCESSION AND ADDITION OF NEW BENEFICIARIES

### 40.1 Accession of the beneficiaries mentioned in the Preamble

The beneficiaries which are not coordinator must accede to the grant by signing the accession form (see Annex 3) directly in the Portal Grant Preparation tool, within 30 days after the entry into force of the Agreement (see Article 44).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 44).

If a beneficiary does not accede to the grant within the above deadline, the coordinator must — within 30 days — request an amendment (see Article 39) to terminate the beneficiary and make any changes necessary to ensure proper implementation of the action. This does not affect the granting authority's right to terminate the grant (see Article 32).

### 40.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 39. It must include an accession form (see Annex 3) signed by the new beneficiary directly in the Portal Amendment tool.

New beneficiaries will assume the rights and obligations under the Agreement with effect from the date of their accession specified in the accession form (see Annex 3).

Additions are also possible in mono-beneficiary grants.

## **ARTICLE 41 — TRANSFER OF THE AGREEMENT**

In justified cases, the beneficiary of a mono-beneficiary grant may request the transfer of the grant to a new beneficiary, provided that this would not call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiary must submit a request for **amendment** (see Article 39), with

- the reasons why
- the accession form (see Annex 3) signed by the new beneficiary directly in the Portal Amendment tool and
- additional supporting documents (if required by the granting authority).

The new beneficiary will assume the rights and obligations under the Agreement with effect from the date of accession specified in the accession form (see Annex 3).

## **ARTICLE 42 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE GRANTING AUTHORITY**

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

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

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

## **ARTICLE 43 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES**

### **43.1 Applicable law**

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

Special rules may apply for beneficiaries which are international organisations (if any; see Data Sheet, Point 5).

### **43.2 Dispute settlement**

If a dispute concerns the interpretation, application or validity of the Agreement, the parties must bring action before the EU General Court — or, on appeal, the EU Court of Justice — under Article 272 of the Treaty on the Functioning of the EU (TFEU).

For non-EU beneficiaries (if any), such disputes must be brought before the courts of Brussels, Belgium — unless an international agreement provides for the enforceability of EU court judgements.

For beneficiaries with arbitration as special dispute settlement forum (if any; see Data Sheet, Point 5), the dispute will — in the absence of an amicable settlement — be settled in accordance with the Rules for Arbitration published on the Portal.

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 22 and 34), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice — under Article 263 TFEU.

For grants where the granting authority is an EU executive agency (see Preamble), actions against offsetting and enforceable decisions must be brought against the European Commission (not against the granting authority; see also Article 22).

#### **ARTICLE 44 — ENTRY INTO FORCE**

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

#### **SIGNATURES**

For the coordinator

For the granting authority



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Istituto per lo studio, la prevenzione  
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## S.C. Screening e Prevenzione Secondaria

Firenze, 09.01.2023

Prot. n. 152

Alla c.a  
Direttore Generale ISPRO  
Avv. Katia Belvedere

Direttore Sanitario ISPRO  
Dott. Roberto Gusinu

Direttore Amministrativo ISPRO  
Dott. Enrico Volpe

Oggetto: Relazione progettuale del progetto finanziato dalla Comunità Europea nell'ambito del programma "EU4Health" – Grant Agreement number: 101075314 – progetto "PartnERship to Contrast HPV" – PERCH

Il progetto PERCH della durata di 30 mesi è stato finanziato dalla Comunità Europea nell'ambito del programma "EU4Health" – tema "Attivazione di strategie e modalità atte ad aumentare la copertura vaccinale contro l'HPV in tutti i paesi membri". Il progetto si sviluppa attraverso una serie di sottoprogetti (da ora in poi workpackages), alcuni dei quali con caratteristiche prioritarie di coordinamento, altri con caratteristiche maggiormente operative. I vari workpackages saranno sviluppati da un team multidisciplinare di esperti di sanità pubblica, epidemiologi, ginecologi, patologi, genetisti, esperti di economia e di politiche sanitarie che lavoreranno insieme con l'obiettivo di contribuire all'attuazione dell'Europa Beating Cancer Plan, che mira a sostenere gli sforzi degli Stati membri per estendere l'introduzione della vaccinazione HPV di routine per eliminare il cancro cervicale e altri tumori causati dall'HPV nel prossimo decennio.

A tal fine, verranno analizzati i determinanti dell'esitazione vaccinale per aumentare la conoscenza e la consapevolezza tra la popolazione target e saranno predisposte attività di formazione del personale sanitario sulla comunicazione vaccinale.

La trasferibilità delle buone pratiche sarà promossa e facilitata tra i paesi partecipanti. Infine gli Stati membri saranno supportati per lanciare campagne di vaccinazione contro il papillomavirus umano su larga scala.

ISPRO collabora ai seguenti sottoprogetti:

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Insieme in Toscana per capire, evitare e curare il cancro.



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## S.C. Screening e Prevenzione Secondaria

### **WP4 Integrazione nelle politiche nazionali e sostenibilità**

#### Obiettivi generali

Inquadrare le condizioni da soddisfare per raggiungere e mantenere un'elevata copertura vaccinale contro l'HPV (obiettivo 90% entro il 2030), tra le ragazze, e se possibile anche i ragazzi, prima che raggiungano l'età di 15 anni come definito nell'iniziativa OMS per l'eliminazione del cancro cervicale. Promuovere l'integrazione della vaccinazione contro l'HPV nelle politiche nazionali di vaccinazione, aumentare l'empowerment e l'engagement del cittadino relativamente alla fiducia nei vaccini, assicurare scorte sufficienti di vaccini a costi ragionevoli e facilitare l'accesso ai servizi di vaccinazione.

#### Obiettivi specifici

Indagare su come la vaccinazione contro l'HPV è attualmente attuata nei paesi dell'UE, inclusa l'identificazione di barriere e fattori di facilitazione che influenzano l'implementazione di successo delle politiche di vaccinazione contro l'HPV.

Promuovere l'integrazione delle attività di vaccinazione contro l'HPV nel calendario vaccinale di routine dei vari paesi membri.

### **WP5 Monitoraggio**

#### Obiettivi generali

Descrivere come la vaccinazione contro l'HPV è attualmente monitorata nella UE e proporre sistemi comuni di raccolta dei dati per migliorare il monitoraggio della copertura della popolazione, la valutazione di processo e di impatto della vaccinazione contro l'HPV.

#### Obiettivi specifici

Monitorare la copertura vaccinale contro l'HPV, utilizzando i sistemi di raccolta dati disponibili.

Sostenere i paesi partecipanti per migliorare la futura raccolta di dati sulla vaccinazione contro l'HPV permettendo a livello internazionale l'assistenza e il collegamento in rete con i servizi di screening oncologico ai fini delle valutazioni di processo e di impatto.

Presentare dati completi ed esaustivi sulla vaccinazione contro l'HPV in tutti gli Stati membri utilizzando moduli strutturati per la raccolta dei dati.

### **WP6 Migliorare la conoscenza e la consapevolezza per aumentare la diffusione del vaccino in specifiche comunità target**

#### Obiettivo generale

Sostenere gli Stati membri nell'aumentare la conoscenza e la consapevolezza sulle malattie correlate all'HPV e prevenzione nelle ragazze e nei ragazzi adolescenti.

#### Obiettivi specifici

Comprendere le dinamiche che impediscono l'accesso al vaccino contro l'HPV.

Migliorare l'accesso e l'uso di informazioni affidabili sulla vaccinazione contro l'HPV per aumentare la fiducia dei cittadini dei vari paesi membri.

### **WP7 Formazione e supporto nella comunicazione sui vaccini**

#### Obiettivo generale

Fornire supporto agli operatori sanitari (medici di medicina generale, infermieri, specialisti, care givers) in termini di formazione per facilitare, da una parte, la comunicazione con gli adolescenti e i loro genitori e

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Insieme in Toscana per capire, evitare e curare il cancro.



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## S.C. Screening e Prevenzione Secondaria

fornire, dall'altra, agli operatori sanitari strumenti adeguati per promuovere la fiducia nel vaccino anti HPV.

### Obiettivi specifici

Comprendere lo stato di avanzamento sulla formazione alla comunicazione sul vaccino anti HPV e sullo screening oncologico nei vari paesi membri.

Individuare i fabbisogni formativi.

Migliorare la consapevolezza tra gli operatori sanitari dell'importanza del controllo e della eradicazione del cancro della cervice uterina.

### **Finanziamento**

Il finanziamento previsto per ISPRO, al netto del cofinanziamento, è pari ad € 23.687,88 per 30 mesi (dal 1 novembre 2022 al 30 aprile 2025).

Le voci di spesa sono suddivise nelle seguenti voci:

€ 16,950,79 rimborso personale dipendente

€ 4.800,00 per missioni

€ 1.937,09 di overhead

ISPRO contribuirà con un cofinanziamento di € 5.921,97, per l'impegno lavorativo del personale.

Per la realizzazione delle attività dei WP 4,5,6,7 è previsto un'impegno di circa 3 PM

Il Personale di ISPRO che collaborerà alle attività del progetto è:

Paola Mantellini, svolgerà attività di coordinamento del progetto a livello locale e sarà coinvolta in tutti i workpackages sopra indicati (impegno presunto PM 0,7)

Anna Iossa collaborerà ai WP5, 6 e 7 (impegno presunto PM 0,4)

Carmen Beatriz Visioli collaborerà al WP4 e WP5 (impegno presunto PM 0,6)

Giuseppe Gorini collaborerà al WP4 e WP5 (impegno presunto PM 0,3)

Lisa Lelli collaborerà al WP6 e WP7 (impegno presunto PM 0,3)

Noemi Auzzi collaborerà al WP6 e WP7 (impegno presunto PM 0,3)

Responsabile del progetto

Dr.ssa Paola Mantellini

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Insieme in Toscana per capire, evitare e curare il cancro.



**PIANO ECONOMICO-FINANZIARIO  
PROGETTI FINALIZZATI**

Struttura organizzativa proponente:

Responsabile del progetto: Paola Mantellini  
 Titolo del progetto: PartNERship to Contrast HPV™ – PERCH  
 Ente finanziatore: European Health and Digital Executive Agency Coordinatore Istituto Superiore di Sanità  
 Importo finanziamento: € 3.800.000,00  
 Importo destinato a ISPRO: € 23.687,88  
 Delibera numero:  
 Codice Autorizzazione: AUT  
 Centro di Costo:  
 Data inizio progetto: Grant Agreement n. 101075314  
 Data conclusione progetto: 01/11/2022-30/04/2025  
 Modalità di pagamento:

	2022/2023	2024	2025	Totale	Voce di spesa corrispondente Ente erogatore
<b>Beni di consumo:</b>	0,00	0,00	0,00	0,00	
- cancelleria ed altri beni economici (es. stampati, mouse, ...)	0,00	0,00	0,00	0,00	
- farmaci	0,00	0,00	0,00	0,00	
- presidi (es. guanti, sonde, ...)	0,00	0,00	0,00	0,00	
- diagnostici (reagenti per biologia molecolare, biologia cellulare, immunofluorescenza ecc.)	0,00	0,00	0,00	0,00	
- acquisto libri e riviste (anche su supporto informatico; riviste on line)				0,00	
- altro (specificare)					
<b>Beni di tipo strumentale:</b>	0,00	0,00	0,00	0,00	
- attrezzature sanitarie	0,00	0,00	0,00	0,00	
- attrezzature informatiche, e altro non sanitario (es. computer, stampanti, ... importi > 516,00 euro; Per importi < 516,00 euro riferirsi a beni di consumo)					
<b>Beni immateriali:</b>	0,00	0,00	0,00	0,00	
- software, opere di ingegno, brevetti; acquisto software per gestione sistema informativo e immagini radiologiche per archiviazione e valutazione quantitativa della densità	0,00	0,00	0,00	0,00	
<b>Servizi:</b>	0,00	0,00	0,00	0,00	
- Acquisto prestazioni sanitarie	0,00	0,00	0,00	0,00	
- Acquisto prestazioni non sanitarie	0,00	0,00	0,00	0,00	
- Spese per pubblicazioni	0,00	0,00	0,00	0,00	
- Spese per organizzazione convegni e congressi	0,00	0,00	0,00	0,00	
- Spese postali	0,00	0,00	0,00	0,00	
- Assicurazione	0,00	0,00	0,00	0,00	
- Spese telefoniche	0,00	0,00	0,00	0,00	
<b>Personale</b>	7.910,37	6.780,32	2.260,11	16.950,79	Personnel costs
- collaborazioni, consulenze ed incarichi professionali	0,00	0,00	0,00	0,00	
- personale dipendente, tempo determinato	0,00	0,00	0,00	0,00	
- personale dipendente, tempo indeterminato	7.910,37	6.780,32	2.260,11	16.950,79	
<b>Rimborsi</b>	1.000,00	2.000,00	1.800,00	4.800,00	Meeting and travel cost
- rimborsi spese collaborazioni, consulenze ed incarichi professionali	0,00	0,00	0,00	0,00	
- missioni/rimborsi spese dipendenti, tempo determinato	0,00	0,00	0,00	0,00	
- missioni/rimborsi degli OR partecipanti	0,00	0,00	0,00	0,00	
- missioni/rimborso spese tempo indeterminato (incluso PI)	1.000,00	2.000,00	1.800,00	4.800,00	
<b>Spese generali di gestione (overheads)</b>	700,00	537,09	700,00	1.937,09	Overheads
<b>Totale (A)</b>	9.610,37	9.317,41	4.760,11	23.687,88	
<b>Trasferimenti</b>	0,00	0,00	0,00	0,00	
<b>COSTI ALTRE RISORSE UTILIZZATE</b>					
<b>Personale</b>	2.763,59	2.368,79	789,60	5.921,97	
<b>Beni di consumo</b>					
<b>Beni strumentali o immateriali</b>					
<b>Altro (specificare)</b>					
<b>TOTALE (B)</b>	2.763,59	2.368,79	789,60	5.921,97	
<b>COSTO COMPLESSIVO PER ISPO DEL PROGETTO (A+B)</b>					
<b>% copertura costi complessivi con finanziamento esterno (A/(A+B))*100</b>	77,67	79,73	85,77	80,00	
data 30.12.22	Firma del Responsabile del progetto		Paola Mantellini		
	Firma del Direttore S.O.				