EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)

HADEA.A – Health and Food
A.3 – Health research

GRANT AGREEMENT

Project 101095594 — XpanDH

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':

ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte), PIC 894471533, established in AVENIDA DAS FORCAS ARMADAS, EDIFICIO ISCTE-IUL, LISBOA 1649-026, Portugal,

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

2. **ECHALLIANCE COMPANY LIMITED BY GUARANTEE (ECHA)**, PIC 907578852, established in 13A BALLYHOY AVENUE RAHENY, DUBLIN DUBLIN 5, Ireland,

3. **FEDERATION EUROPEENNE DES HOPITAUX ET DES SOINS DE SANTE (HOPE)**, PIC 994557879, established in AVENUE MARNIX 30/17, BRUXELLES 1000, Belgium,

4. **HL7 INTERNATIONAL FONDATION (HL7)**, PIC 974224448, established in SQUARE DE MEEUS 38-40, BRUSSELS 1000, Belgium,

5. **GNOMON PLIROPHORIKIS AE (Gnomon)**, PIC 991636433, established in ANTONI TRITSI 21, PYLAIA THESSALONIKI 570 01, Greece,

6. **EMPIRICA GESELLSCHAFT FUR KOMMUNIKATIONS UND TECHNOLOGIEFORSCHUNG MBH (EMPIRICA)**, PIC 999801990, established in OXFORDSTRASSE 2, BONN 53111, Germany,

7. **CENTRO HOSPITALAR UNIVERSITARIO DO PORTO EPE (CHUPorto)**, PIC 950258852, established in LARGO PROFESSOR ABEL SALAZAR, PORTO 4099 001, Portugal,

8. **THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH DATA (I~HD)**, PIC 923112723, established in OUDE MECHELSESTRAAT 165, STROMBEEK-BEVER 1853, Belgium,

9. **KENTRO TEKMIRIOSIS KAI KOSTOLOGISIS NOSOKOMEIAKON YPIRESION ANONYMI ETAIREIA (KETEKNY)**, PIC 889986641, established in VERANZEROU 13, ATHENS 10438, Greece,

10. **UNINOVA-INSTITUTO DE DESENVOLVIMENTO DE NOVAS TECNOLOGIAS-ASSOCIACAO (UNINOVA)**, PIC 999633889, established in CAMPUS DA CAPARICA QUINTA DA TORRE, CAPARICA 2829-516, Portugal,

11. **NARODNE CENTRUM ZDRAVOTNICKYCH INFORMACII (NCZI)**, PIC 998884370, established in LAZARETSKA 26, BRATISLAVA 811 09, Slovakia,

12. **INTEGRATING THE HEALTHCARE ENTERPRISE-EUROPE AISBL (IHE-EUR)**, PIC 998727133, established in BOULEVARD AUGUSTE REYERS 80, BRUXELLES 1030, Belgium,

13. **EUROPEAN HEALTH MANAGEMENT ASSOCIATION (EHMA)**, PIC 912703944, established in RUE BELLIARD 15-17, BRUXELLES 1040, Belgium,

14. **UNIVERSITETET I OSLO (UiO)**, PIC 999975814, established in PROBLEMVEIEN 5-7, OSLO 0313, Norway,

15. **SPITALUL CLINIC DE URGENTA BAGDASAR-ARSENI (SCUBA)**, PIC 952500522, established in SOSEAUA BERCENI 10-12, BUCURESTI 041915, Romania,

16. **AZIENDA REGIONALE PER L'INNOVAZIONEE GLI ACQUISTI S.P.A. (ARIA)**, PIC 985380127, established in VIA TORQUATO TARAMELLI 26, MILANO 20124, Italy,

17. **DIGITALEUROPE AISBL* (Digital Europe)**, PIC 952919756, established in RUE DE LA SCIENCE 14, BRUXELLES 1040, Belgium,

18. **ORSZAGOS KORHAZI FOIGAZGATOSAG (OKFO)**, PIC 891516331, established in DIOS AROK 3, BUDAPEST 1125, Hungary,

19. **FONDAZIONE CLUSTER REGIONALE LOMBARDO DELLE TECNOLOGIE PER GLI AMBIENTI DI VITA (TechForLife)**, PIC 919670096, established in VIA TONALE 28 30, LECCO 23900, Italy,

20. **STICHTING NATIONAAL ICT INSTITUUT IN DE ZORG (Nictiz)**, PIC 998830147, established in Oude Middenweg 55, Den Haag 2491AC, Netherlands,

21. **EUROPEAN DIGITAL HEALTH ACADEMY GGMBH (EDHA)**, PIC 886608907, established in MOHNBLUMENWEG 1, ABENSBERG 93326, Germany,

22. **STEGWEE ROBERT (CEN/TH)**, PIC 900965392, established in SPOORSTRAAT 31, GOOR 7471 BV, Netherlands,

23. **AZIENDA SANITARIA UNIVERSITARIA FRIULI CENTRALE (ASUFC)**, PIC 894464355, established in VIA POZZUOLO 330, UDINE 33100, Italy,

24. **EUROPEAN CANCER PATIENT COALITION (ECPC)**, PIC 984108263, established in AVENUE DES ARTS 6, BRUXELLES 1210, Belgium,

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[1]

Annex 2 Estimated budget for the action

Annex 2a Additional information on unit costs and contributions (if applicable)

Annex 3 Accession forms (if applicable)[2]

Annex 3a Declaration on joint and several liability of affiliated entities (if applicable)[3]

Annex 4 Model for the financial statements

Annex 5 Specific rules (if applicable)

[1] Template published on Portal Reference Documents.
[2] Template published on Portal Reference Documents.
[3] Template published on Portal Reference Documents.

TERMS AND CONDITIONS

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DATA SHEET

1. General data

Project summary:

Project summary
XpanDH is a CSA aimed at mobilizing and building capacity in individuals and organisations to create, adapt and explore purposeful use of interoperable digital health solutions based on a shared adoption of the European Electronic Health Records Exchange format (EEHRxF) across Europe. This pan-European effort will use a "network-of-networks" approach ensuring that digital health actors are motivated and supported by tailored guidance and real examples to help early adopters to advance to the concrete use of EEHRxF-embedded digital health solutions to add value to health and care and promote Personal and European Health Data Spaces. XpanDH pursues the main goal of maturing and accelerating a sustainable and scalable interoperability environment for digital health innovations based on the EEHRxF, around 5 Goals: 1) To develop robust technical specifications and resources for the EEHRxF building; 2) To establish the X-Bundle Readiness model; 3) To verify the usefulness of the X-Bundle in real-world with a set of early adopters grouped under selected adoption domains; 4) To mature a pan-European digital health ecosystem of solution providers and end-users, 5) To develop a framework for sustainable ecosystem. The consortium will thrive on past and ongoing eHealth interoperability projects and services, and particularly on the X-eHealth and DigitalHealthEurope projects recommendations, through digital health data activism and strong patient engagement. It brings together 26 Digital Health Actors under a co-creation and co-implementation concept, supported by a Policy Board (linking to Governments and the eHealth Network). To expand its impact, 10 XpandDH networks of hundreds of health stakeholders will be nurtured to form a vibrant pan-European (Digital) Health space converging on common, usable, and reliable tools for real interoperable services that adoption of the EEHRxF and enhance healthcare cooperation for better health towards a European Health Union.

Keywords: not defined

Project number: 101095594

Project name: Expanding Digital Health through a pan-European EHRxF-based Ecosystem

Project acronym: XpanDH

Call: HORIZON-HLTH-2022-IND-13

Topic: HORIZON-HLTH-2022-IND-13-05

Type of action: HORIZON Coordination and Support Actions

Granting authority: European Health and Digital Executive Agency

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

Project starting date: fixed date: 1 January 2023

Project end date: 31 December 2024

Project duration: 24 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	Iscte	ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS	PT	894471533	193 176.25	193 176.25
2	BEN	ECHA	ECHALLIANCE COMPANY LIMITED BY GUARANTEE	IE	907578852	145 415.00	145 415.00
3	BEN	HOPE	FEDERATION EUROPEENNE DES HOPITAUX ET DES SOINS DE SANTE	BE	994557879	14 250.00	14 250.00
4	BEN	HL7	HL7 INTERNATIONAL FONDATION	BE	974224448	197 793.75	197 793.75

N°	Role	Short name	Legal name	Ctry	PIC	Total eligible costs (BEN and AE)	Max grant amount
5	BEN	Gnomon	GNOMON PLIROPHORIKIS AE	EL	991636433	71 875.00	71 875.00
6	BEN	EMPIRICA	EMPIRICA GESELLSCHAFT FUR KOMMUNIKATIONS UND TECHNOLOGIEFORSCHUNG MBH	DE	999801990	177 675.00	177 675.00
7	BEN	CHUPorto	CENTRO HOSPITALAR UNIVERSITARIO DO PORTO EPE	PT	950258852	59 781.25	59 781.00
8	BEN	I~HD	THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH DATA	BE	923112723	134 033.75	134 033.75
9	BEN	KETEKNY	KENTRO TEKMIRIOSIS KAI KOSTOLOGISIS NOSOKOMEIAKON YPIRESION ANONYMI ETAIREIA	EL	889986641	55 806.25	55 806.00
10	BEN	UNINOVA	UNINOVA-INSTITUTO DE DESENVOLVIMENTO DE NOVAS TECNOLOGIAS-ASSOCIACAO	PT	999633889	227 571.25	227 571.25
11	BEN	NCZI	NARODNE CENTRUM ZDRAVOTNICKYCH INFORMACII	SK	998884370	45 808.75	45 808.75
12	BEN	IHE-EUR	INTEGRATING THE HEALTHCARE ENTERPRISE-EUROPE AISBL	BE	998727133	170 233.75	170 233.75
13	BEN	EHMA	EUROPEAN HEALTH MANAGEMENT ASSOCIATION	BE	912703944	29 690.00	29 690.00
14	BEN	UiO	UNIVERSITETET I OSLO	NO	999975814	62 987.50	62 987.50
15	BEN	SCUBA	SPITALUL CLINIC DE URGENTA BAGDASAR-ARSENI	RO	952500522	17 677.50	17 677.50
16	BEN	ARIA	AZIENDA REGIONALE PER L'INNOVAZIONEE GLI ACQUISTI S.P.A.	IT	985380127	56 743.75	56 743.75
17	BEN	Digital Europe	DIGITALEUROPE AISBL*	BE	952919756	33 993.75	33 993.75
18	BEN	OKFO	ORSZAGOS KORHAZI FOIGAZGATOSAG	HU	891516331	52 187.50	52 187.50
19	BEN	TechForLife	FONDAZIONE CLUSTER REGIONALE LOMBARDO DELLE TECNOLOGIE PER GLI AMBIENTI DI VITA	IT	919670096	23 125.00	23 125.00
20	BEN	Nictiz	STICHTING NATIONAAL ICT INSTITUUT IN DE ZORG	NL	998830147	35 550.00	35 500.00
21	BEN	EDHA	EUROPEAN DIGITAL HEALTH ACADEMY GGMBH	DE	886608907	38 687.50	38 687.50
22	BEN	CEN/TH	STEGWEE ROBERT	NL	900965392	59 390.00	59 390.00
23	BEN	ASUFC	AZIENDA SANITARIA UNIVERSITARIA FRIULI CENTRALE	IT	894464355	46 733.75	46 733.75
24	BEN	ECPC	EUROPEAN CANCER PATIENT COALITION	BE	984108263	22 125.00	22 125.00
25	AP	SU	SEMMELWEIS EGYETEM	HU	999860675	0.00	0.00
26	AP	UNEW	UNIVERSITY OF NEWCASTLE UPON TYNE	UK	999985417	0.00	0.00
Total						1 972 311.25	1 972 260.75

Coordinator:

– ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte)

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)
1 972 311.25	100	1 972 260.75	1 972 260.75

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.2 Internally invoiced goods and services

- E. Indirect costs

Cost eligibility options:

- In-kind contributions eligible costs

- Parental leave

- Project-based supplementary payments

- Average personnel costs (unit cost according to usual cost accounting practices)

- Limitation for subcontracting

- Travel and subsistence:
  - Travel: Actual costs
  - Accommodation: Actual costs
  - Subsistence: Actual costs

- Equipment: depreciation only

- Indirect cost flat-rate: 25% of the eligible direct costs (categories A-D, except volunteers costs, subcontracting costs, financial support to third parties 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 – whichever is the latest
1	1	12	Periodic report	60 days after end of reporting period	Interim payment	90 days from receiving periodic report
2	13	24	Periodic report	60 days after end of reporting period	Final payment	90 days from receiving periodic report

Prefinancing payments and guarantees:

Prefinancing payment	
Type	Amount
Prefinancing 1 (initial)	1 577 808.40

Reporting and payment modalities (art 21, 22):

Mutual Insurance Mechanism (MIM): Yes

MIM contribution: 5% of the maximum grant amount (98 613.04), retained from the initial prefinancing

Restrictions on distribution of initial prefinancing: The prefinancing may be distributed only if the minimum number of beneficiaries set out in the call condititions (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

Exception for revenues: Yes

No-profit rule: Yes

Late payment interest: ECB + 3.5%

Bank account for payments:

PT50003501970005603163080

Conversion into euros: Double conversion

Reporting language: Language of the Agreement

4.3 Certificates (art 24):

Certificates on the financial statements (CFS):

Conditions:

Schedule: only at final payment, if threshold is reached

Standard threshold (beneficiary-level):

- financial statement: requested EU contribution to costs ≥ EUR 430 000.00

Special threshold for beneficiaries with a systems and process audit(see Article 24): financial statement: requested EU contribution to costs ≥ EUR 725 000.00

4.4 Recoveries (art 22)

First-line liability for recoveries:

Beneficiary termination: Beneficiary concerned

Final payment: Each beneficiary for their own debt

After final payment: Beneficiary concerned

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

Individual financial responsibility: Each beneficiary is liable only for its own debts (and those of its affiliated entities, if any)

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

Suspension and termination:

Additional suspension grounds (art 31)

Additional termination grounds (art 32)

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): 2

Audits (up to X years after final payment): 2

Extension of findings from other grants to this grant (no later than X years after final payment): 2

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[4] 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

[4] 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[5] 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[6], 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[7].

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 **101095594 — XpanDH** ('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[8] which takes the form of a budget-based mixed actual cost grant (i.e. a

[5] 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).
[6] OJ C 316, 27.11.1995, p. 48.
[7] 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).
[8] 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 100% 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)[9] 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.

[9] 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).

In-kind contributions provided by third parties free of charge may be declared as eligible direct costs by the beneficiaries which use them (under the same conditions as if they were their own, provided that they concern only direct costs and that the third parties and their in-kind contributions are set out in Annex 1 (or approved ex post in the periodic report, if their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants; 'simplified approval procedure').

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 (including net payments during parental leave), 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 actual time spent on parental leave by a person assigned to the action may be deducted from the 215 days indicated in the above formula.

The total number of day-equivalents declared in EU grants, for a person for a year, cannot be higher than 215, minus time spent on parental leave (if any).

For personnel which receives supplementary payments for work in projects (project-based remuneration), the personnel costs must be calculated at a rate which:

- corresponds to the actual remuneration costs paid by the beneficiary for the time worked by the person in the action over the reporting period
- does not exceed the remuneration costs paid by the beneficiary for work in similar projects funded by national schemes (‘national projects reference’)
- is defined based on objective criteria allowing to determine the amount to which the person is entitled

and

- reflects the usual practice of the beneficiary to pay consistently bonuses or supplementary payments for work in projects funded by national schemes.

The national projects reference is the remuneration defined in national law, collective labour agreement or written internal rules of the beneficiary applicable to work in projects funded by national schemes.

If there is no such national law, collective labour agreement or written internal rules or if the project-based remuneration is not based on objective criteria, the national project reference will be the average

remuneration of the person in the last full calendar year covered by the reporting period, excluding remuneration paid for work in EU actions.

If the beneficiary uses average personnel costs (unit cost according to usual cost accounting practices), the personnel costs must fulfil the general eligibility conditions for such unit costs and the daily rate must be calculated:

- using the actual personnel costs recorded in the beneficiary's accounts and excluding any costs which are ineligible or already included in other budget categories; the actual personnel costs may be adjusted on the basis of budgeted or estimated elements, if they are relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information

and

- according to usual cost accounting practices which are applied in a consistent manner, based on objective criteria, regardless of the source of funding.

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[10] 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 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

[10] 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.

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: on the basis of the costs actually incurred and in line with the beneficiary's usual practices on travel
- accommodation: on the basis of the costs actually incurred and in line with the beneficiary's usual practices on travel
- subsistence: on the basis of the 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.2 Internally invoiced goods and services

Costs for internally invoiced goods and services directly used for the action may be declared as unit cost according to usual cost accounting practices, if and as declared eligible in the call conditions, if they fulfil the general eligibility conditions for such unit costs and the amount per unit is calculated:

- using the actual costs for the good or service recorded in the beneficiary's accounts, attributed either by direct measurement or on the basis of cost drivers, and excluding any cost which are ineligible or already included in other budget categories; the actual costs may be adjusted on the basis of budgeted or estimated elements, if they are relevant for calculating the costs, reasonable and correspond to objective and verifiable information

and

- according to usual cost accounting practices which are applied in a consistent manner, based on objective criteria, regardless of the source of funding.

'Internally invoiced goods and services' means goods or services which are provided within the beneficiary's organisation directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

This cost will not be taken into account for the indirect cost flat-rate.

Indirect costs

E. Indirect costs

Indirect costs will be reimbursed at the flat-rate of 25% of the eligible direct costs (categories A-D, except volunteers costs, subcontracting costs, financial support to third parties 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: not applicable

(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[11] 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.

[11] 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".

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.

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'[12] (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)

[12] 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."

- 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

Not applicable

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':

- **SEMMELWEIS EGYETEM (SU)**, PIC 999860675, associated partner of ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte)
- **UNIVERSITY OF NEWCASTLE UPON TYNE (UNEW)**, PIC 999985417, associated partner of ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte)

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, but the costs for the in-kind contributions are eligible and may be charged by the beneficiaries which use them, under the conditions set out in Article 6. The costs will be included in Annex 2 as part of the beneficiaries' costs.

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

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 third parties giving in-kind contributions.

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[13]

- for the controls under Article 25: to allow for checks, reviews, audits and investigations

[13] 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).

(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).

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[14] 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

[14] 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).

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

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[15].

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[16]).

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.

[15] 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).

[16] 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).

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

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):

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.

Each beneficiary's financial responsibility in case of recovery is in principle limited to their own debt and undue amounts of their affiliated entities.

In case of enforced recoveries (see Article 22.4), affiliated entities will be held liable for repaying debts of their beneficiaries, 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.

The contribution to the Mutual Insurance Mechanism will be retained from the prefinancing payments (at the rate and in accordance with the modalities set out in the Data Sheet, see Point 4.2) and transferred to the Mechanism.

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:

{total accepted EU contribution for the beneficiary

minus

{prefinancing and interim payments received (if any)}}.

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**).

If payment is not made to the coordinator by the date specified in the confirmation letter, the granting authority may call on the Mutual Insurance Mechanism to intervene, if continuation of the action is guaranteed and the conditions set out in the rules governing the Mechanism are met.

In this case, it will send a **beneficiary recovery letter**, together with a **debit note** with the terms and date for payment.

The debit note for the beneficiary will include the amount calculated for the affiliated entities which also had to end their participation (if any).

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.

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 (— with the exception of income generated by the exploitation of results, which are not considered as revenues).

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:

{final grant amount

minus

{prefinancing and interim payments made (if any)}}.

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

The amount retained for the Mutual Insurance Mechanism (see above) will be released and **paid** to the coordinator (in accordance with the rules governing the Mechanism).

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 — despite the release of the Mutual Insurance Mechanism contribution — 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 a report on the distribution of payments to the beneficiaries within 30 days of receiving notification 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) and the coordinator has submitted the report on the distribution of payments, it will calculate the **share of the debt per beneficiary**, by:

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

{{{total accepted EU contribution for the beneficiary

divided by

total accepted EU contribution for the action}

multiplied by

final grant amount for the action},

minus

{prefinancing and interim payments received by the beneficiary (if any)}}

and

(b) dividing the debt:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount to be recovered}.

and confirm the amount to be recovered from each beneficiary concerned (**confirmation letter**), together with **debit notes** with the terms and date for payment.

The debit notes for beneficiaries will include the amounts calculated for their affiliated entities (if any).

If the coordinator has not submitted the report on the distribution of payments, the granting authority will **recover** the full amount from the coordinator (**confirmation letter** and **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:

{{total accepted EU contribution for the beneficiary

divided by

total accepted EU contribution for the action}

multiplied by

final grant amount for the action}.

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) financial guarantee(s): not applicable

(c) joint and several liability of beneficiaries: not applicable

(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.

If the Mutual Insurance Mechanism was called on by the granting authority to intervene, recovery will be continued in the name of the Mutual Insurance Mechanism. If two debit notes were sent, the second one (in the name of the Mutual Insurance Mechanism) will be considered to replace the first one (in the name of the granting authority). Where the MIM intervened, offsetting, enforceable decisions or any other of the above-mentioned forms of enforced recovery may be used mutatis mutandis.

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[17] 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

[17] 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).

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.

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

Not applicable

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[18] (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)

Beneficiaries which:

- use unit, flat rate or lump sum costs or contributions according to documented (i.e. formally approved and in writing) usual costs accounting practices (if any) or

- have formalised documentation on the systems and processes for calculating their costs and contributions (i.e. formally approved and in writing), have participated in at least 150 actions under Horizon 2020 or the Euratom Research and Training Programme (2014-2018 or 2019-2020) and participate in at least 3 ongoing actions under Horizon Europe or the Euratom Research and Training Programme (2021-2025 or 2026-2027)

may apply to the granting authority for a systems and process audit (SPA).

This audit will be carried out as follows:

Step 1 – Application by the beneficiary.

Step 2 – If the application is accepted, the granting authority will carry out the systems and process audit, complemented by an audit of transactions (on a sample of the beneficiary's Horizon Europe or the Euratom Research and Training Programme financial statements).

Step 3 – The audit result will take the form of a risk assessment classification for the beneficiary: low, medium or high.

Low-risk beneficiaries will benefit from less (or less in-depth) ex-post audits (see Article 25) and a higher threshold for submitting certificates on the financial statements (CFS; see Articles 21 and 24.2 and Data Sheet, Point 4.3).

[18] 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).

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 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[19] and No 2185/96[20]

- 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 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

[19] 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).

[20] 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).

(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) the action has lost its scientific or technological relevance, for EIC Accelerator actions: the action has lost its economic relevance, for challenge-based EIC Pathfinder actions and Horizon Europe Missions: the action has lost its relevance as part of the Portfolio for which it has been initially selected

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) the action has lost its scientific or technological relevance, for EIC Accelerator actions: the action has lost its economic relevance, for challenge-based EIC Pathfinder actions and Horizon Europe Missions: the action has lost its relevance as part of the Portfolio for which it has been initially selected

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[21]).

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

[21] 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).

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[22], 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.

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.

[22] 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).

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

ANNEX 1

Horizon Europe (HORIZON)

Description of the action (DoA)

Part A

Part B

DESCRIPTION OF THE ACTION (PART A)

COVER PAGE

Part A of the Description of the Action (DoA) must be completed directly on the Portal Grant Preparation screens.

PROJECT *Grant Preparation (General Information screen) — Enter the info.*	
Project number:	101095594
Project name:	Expanding Digital Health through a pan-European EHRxF-based Ecosystem
Project acronym:	XpanDH
Call:	HORIZON-HLTH-2022-IND-13
Topic:	HORIZON-HLTH-2022-IND-13-05
Type of action:	HORIZON-CSA
Service:	HADEA/A/03
Project starting date:	fixed date: 1 January 2023
Project duration:	24 months

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List of participants 3
List of work packages 5
Staff effort 15
List of deliverables 17
List of milestones (outputs/outcomes) 29
List of critical risks 30

Associated with document Ref. Ares(2022)7907384 - 16/11/2022

PROJECT SUMMARY

Project summary

Grant Preparation (General Information screen) — Provide an overall description of your project (including context and overall objectives, planned activities and main achievements, and expected results and impacts (on target groups, change procedures, capacities, innovation etc)). This summary should give readers a clear idea of what your project is about.

Use the project summary from your proposal.

XpanDH is a CSA aimed at mobilizing and building capacity in individuals and organisations to create, adapt and explore purposeful use of interoperable digital health solutions based on a shared adoption of the European Electronic Health Records Exchange format (EEHRxF) across Europe. This pan-European effort will use a “network-of-networks” approach ensuring that digital health actors are motivated and supported by tailored guidance and real examples to help early adopters to advance to the concrete use of EEHRxF-embedded digital health solutions to add value to health and care and promote Personal and European Health Data Spaces.
XpanDH pursues the main goal of maturing and accelerating a sustainable and scalable interoperability environment for digital health innovations based on the EEHRxF, around 5 Goals: 1) To develop robust technical specifications and resources for the EEHRxF building; 2) To establish the X-Bundle Readiness model; 3) To verify the usefulness of the X-Bundle in real-world with a set of early adopters grouped under selected adoption domains; 4) To mature a pan-European digital health ecosystem of solution providers and end-users, 5) To develop a framework for sustainable ecosystem.
The consortium will thrive on past and ongoing eHealth interoperability projects and services, and particularly on the X-eHealth and DigitalHealthEurope projects recommendations, through digital health data activism and strong patient engagement.

It brings together 26 Digital Health Actors under a co-creation and co-implementation concept, supported by a Policy Board (linking to Governments and the eHealth Network). To expand its impact, 10 XpandDH networks of hundreds of health stakeholders will be nurtured to form a vibrant pan-European (Digital) Health space converging on common, usable, and reliable tools for real interoperable services that adoption of the EEHRxF and enhance healthcare cooperation for better health towards a European Health Union.

LIST OF PARTICIPANTS

PARTICIPANTS

Grant Preparation (Beneficiaries screen) — Enter the info.

Number	Role	Short name	Legal name	Country	PIC
1	COO	Iscte	ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS	PT	894471533
2	BEN	ECHA	ECHALLIANCE COMPANY LIMITED BY GUARANTEE	IE	907578852
3	BEN	HOPE	FEDERATION EUROPEENNE DES HOPITAUX ET DES SOINS DE SANTE	BE	994557879
4	BEN	HL7	HL7 INTERNATIONAL FONDATION	BE	974224448
5	BEN	Gnomon	GNOMON PLIROPHORIKIS AE	EL	991636433
6	BEN	EMPIRICA	EMPIRICA GESELLSCHAFT FUR KOMMUNIKATIONS UND TECHNOLOGIEFORSCHUNG MBH	DE	999801990
7	BEN	CHUPorto	CENTRO HOSPITALAR UNIVERSITARIO DO PORTO EPE	PT	950258852

PARTICIPANTS

Grant Preparation (Beneficiaries screen) — Enter the info.

Number	Role	Short name	Legal name	Country	PIC
8	BEN	I~HD	THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH DATA	BE	923112723
9	BEN	KETEKNY	KENTRO TEKMIRIOSIS KAI KOSTOLOGISIS NOSOKOMEIAKON YPIRESION ANONYMI ETAIREIA	EL	889986641
10	BEN	UNINOVA	UNINOVA-INSTITUTO DE DESENVOLVIMENTO DE NOVAS TECNOLOGIAS-ASSOCIACAO	PT	999633889
11	BEN	NCZI	NARODNE CENTRUM ZDRAVOTNICKYCH INFORMACII	SK	998884370
12	BEN	IHE-EUR	INTEGRATING THE HEALTHCARE ENTERPRISE-EUROPE AISBL	BE	998727133
13	BEN	EHMA	EUROPEAN HEALTH MANAGEMENT ASSOCIATION	BE	912703944
14	BEN	UiO	UNIVERSITETET I OSLO	NO	999975814
15	BEN	SCUBA	SPITALUL CLINIC DE URGENTA BAGDASAR-ARSENI	RO	952500522
16	BEN	ARIA	AZIENDA REGIONALE PER L'INNOVAZIONEE GLI ACQUISTI S.P.A.	IT	985380127
17	BEN	Digital Europe	DIGITALEUROPE AISBL*	BE	952919756
18	BEN	OKFO	ORSZAGOS KORHAZI FOIGAZGATOSAG	HU	891516331
19	BEN	TechForLife	FONDAZIONE CLUSTER REGIONALE LOMBARDO DELLE TECNOLOGIE PER GLI AMBIENTI DI VITA	IT	919670096
20	BEN	Nictiz	STICHTING NATIONAAL ICT INSTITUUT IN DE ZORG	NL	998830147
21	BEN	EDHA	EUROPEAN DIGITAL HEALTH ACADEMY GGMBH	DE	886608907
22	BEN	CEN/TH	STEGWEE ROBERT	NL	900965392
23	BEN	ASUFC	AZIENDA SANITARIA UNIVERSITARIA FRIULI CENTRALE	IT	894464355
24	BEN	ECPC	EUROPEAN CANCER PATIENT COALITION	BE	984108263
25	AP	SU	SEMMELWEIS EGYETEM	HU	999860675
26	AP	UNEW	UNIVERSITY OF NEWCASTLE UPON TYNE	UK	999985417

LIST OF WORK PACKAGES

Work packages

Grant Preparation (Work Packages screen) — Enter the info.

Work Package No	Work Package name	Lead Beneficiary	Effort (Person-Months)	Start Month	End Month	Deliverables
WP1	Coordination	1 - Iscte	36.10	1	24	D1.1 – D1.1.1-XpanDH project Handbook D1.2 – D1.1.2-Technical and Financial Reports D1.3 – D1.2-QRC Plan D1.4 – D1.3-Evaluation and Impact Assessment D1.5 – D1.4-Definition of the EEHRxF adoption domains Report D1.6 – D1.5.1-Ethics and Data Management Plan D1.7 – D1.5.2-EEHRxF legal, cybersecurity & trust issues Report D1.8 – D1.6 - Report on Policy Dialogue activities and achievements D1.9 – D1.5.3- Updated Ethics and Data Management Plan
WP2	Standards & Technical artefacts	4 - HL7	26.70	1	24	D2.1 – D2.1-Digital health compass for the application of EHRxF D2.2 – D2.2-EHRxF FHIR IG and repository of supporting materials D2.3 – D2.3-Report on for quality labelling of EHRs
WP3	Organisational Readiness	12 - IHE-EUR	40.70	1	24	D3.1 – D3.1.1-First version of the X-Bundle Readiness model D3.2 – D3.1.2 - Final version of the X-Bundle Readiness model

Work packages

Grant Preparation (Work Packages screen) — Enter the info.

Work Package No	Work Package name	Lead Beneficiary	Effort (Person-Months)	Start Month	End Month	Deliverables
						D3.3 – D3.2.1 - Intermediate readiness model evaluation process D3.4 – D3.2.2 - Readiness model evaluation process Report D3.5 – D3.3 - X-Bundle Readiness steppingstone guides
WP4	Feasibility & Experimentation	10 - UNINOVA	58.20	1	24	D4.1 – D4.1.1-XpanDH Adoption Domains D4.2 – D4.1.2 - Adoption opportunities, challenges and barrier D4.3 – D4.2 - XpanDH feasibility demonstrators D4.4 – D4.3 - X-Bundle refinement Report
WP5	Growing Digital Health ecosystems	6 - EMPIRICA	39.60	1	24	D5.1 – D5.1 - XpanDH Ecosystem Report D5.2 – D5.2 - Interoperability Enabler Report D5.3 – D5.3 - X-Bundle open-source community of the doers
WP6	Sustainability and Future Action	8 - I~HD	17.30	1	24	D6.1 – D6.1.1-Governance & operating model for asset bundles & Exploitation PLan D6.2 – D6.1.2 - Published library of documented asset bundle D6.3 – D6.2 - Report on EEHRxF new adoption domains D6.4 – D6.3 - Recommendation for MS & EC
WP7	Dissemination and Outreach	2 - ECHA	16.30	1	24	D7.1 – D7.1 - XpanDH DC,Outreach and Exploitation Plan

Work packages

Grant Preparation (Work Packages screen) — Enter the info.

Work Package No	Work Package name	Lead Beneficiary	Effort (Person-Months)	Start Month	End Month	Deliverables
						D7.2 – D7.2 - XpanDH DC and Outreach Report D7.3 – D7.3 - Concertation Activities Report D7.4 – D7.4-X-panDH website

Associated with document Ref. Ares(2022)7907384 - 16/11/2022

Work package WP1 – Coordination

Work Package Number	WP1	Lead Beneficiary	1. Iscte
Work Package Name	Coordination		
Start Month	1	End Month	24

Objectives

WP1 has the overall aim of efficiently managing the XpanDH project for the delivery of its settled objectives, according to committed resources, within the time and budget limits, and following all the European Commission contractual obligations. Project management is organised around 4 management bodies, integrated into a clear governance structure: Project Coordinator (PC, formal intermediary between the EC and the Partners); Project Management Board [PMB, composed of the PC, the Project Manager (PM) and 1 representative from each Partner]; the Executive Board (EB, composed of the WP Leaders) and external Advisory (including an ethics subgroup) and Policy Boards. This structure will be refined and a schemata will be included in the project handbook. WP1 will also ensure the definition of EEHRxF adoption domains, the compliance with all ethical, legal and cyber security issues, as well as liaise with the Policy Board. All 27 XpanDH partners will be committed with the necessary dedication to the project management, even without allocated PM. Synergies with other WP and Tasks (T): T1.1 to 1.3 are horizontal to the remaining WP and tasks; T1.4 is will be connected with T2.1, 4.1 and 4.2, 5.1 and 6.1; T1.5 will contribute decisively to T3.1 and it will provide important updated input to T6.1; T1.6 will be based on outputs from WP2/WP3/WP4. We will include a more detailed impact-oriented strategy as a subtask of T1.3, and particularly in T1.6 by creating a sub-task dedicated to concrete commitments by MS authorities/relevant large healthcare providers regarding their formal commitments towards the EHRxF.

Description

Task 1.1 - Administrative and operational management (M1-M24) | Lead: Iscte | Partners: HL-7, EMP, IHE- EUR, UNINOVA, ECHA, I~HD - The consortium will follow the XpanDH Management Handbook (D1.1), to ensure project's activities and results are delivered in a transparent, effective and efficient manner, according to the highest quality standards, with a lean decision-making process. The PC (Iscte, Henrique Martins) and the PM (to be designated) will ensure at least a monthly communication with WP leaders, within each WP and also inter WP for a close and straight-forward articulation, and the communication with the EC. Communication with external stakeholders is covered in WP7. T1.1 will also perform the monitoring and reporting on the overall project execution. An annual internal assessment of the implementation will be performed together with the XpanDH external Advisory Board to identify, anticipate and correct any possible deviations.

Task 1.2 - Quality Assurance, Risk management and Contingency (M1-M24) | Lead: Iscte| Partners: HL-7, EMP, IHE-EUR, UNINOVA, ECHA, I~HD - T1.2 will define and implement a set of standard and systematic procedures, including a Quality and Risk Management Plan (QRC Plan, D1.2) for continuous risk monitoring and assessment. This will ensure the compliance with external and internal standards in force, as well as the assessment and monitoring of the project's progress, together with Task 1.3.

Task 1.3 – Project evaluation and Impact Assessment (M1-M24) | Lead: Iscte | Partners: ECHA, I~HD

T1.3 will conduct an evaluation and impact assessment of the project and provide evidence-based recommendations to ensure the project meets and goes beyond its settled goals. It will be built on evidence and lessons learned from the interim evaluation carried out every semester that will provide recommendations for the 2nd year of implementation. The evaluation and impact assessment will also take into consideration recommendations from the Policy and other external boards consulted on this matter. The set of KPI will be closed during the Kick-off meeting (KOM), based on the preliminary assessment made in the proposal stage (Sections 1.2 and 2.1). Two impact assessment reports will be produced (D1.3).

Task 1.4 – Definition of EEHRxF adoption domains (M1 - M4) | Lead: Iscte | Partners: HL7, EMPIRICA, ARIA, IHE-EUR, UNINOVA, I~HD, SCUBA, UNEW - T1.4 will identify and refine 3-4 adoption domains, for different EuropeanEHRxF domains and contexts of purposeful use. These are to be citizen-centred scenarios/Use cases, the criteria will namely include: Market relevance (link with WP2, HL7); Feasibility/experimentation possibilities (link with WP4); High societal relevance and high prevalence - Data collection/sharing; Range of beneficiaries: between patient, HCP, researcher, policy/health management; Link to experimentation possibilities and success
stories from other initiatives (Big bubbles topic); and Articulation with WP2/WP3 needs, and ensuring solid definitions for WP4/WP5 activities.

Task 1.5 – Legal, Ethical, Cyber Security Issues (M4 - M24) | Lead: Iscte | Partners: ARIA, IHE-EUR, I~HD, SU - This task will deliver the Ethics and Data Management Plan that will be taken over by other WP during the lifecycle

of the project. The task will contribute via SU to supporting the secure cooperation and development of cross-border health data exchange by utilising results of ECHO (H2020 project for the European network of Cybersecurity centres and competence Hub for innovation and Operations). This task will provide Reports on the legal, ethical and cyber security aspects of cross-border healthcare data exchange within the project's scope and address the legal and ethical challenges that will arise during the project, in the form of continuous guidance to project partners, and eventually contributing to future scenarios worked in T6.1.
Task 1.6 – Policy Dialogue (M4 - M24) | Lead: NCZI | Partners: Iscte, Nictiz, SCUBA - This Task will be focused on Policy Dialogues with different policy spaces, especially the eHealth Network and the MoH Representatives (as detailed in section 1.2), but not excluding WHO Europe, WHO or the Global Digital Health Partnership (GDHP). T1.6 will coordinate and interact with Policy Makers, such as Ministries of Health and of Social Affairs, and Digital Health Authorities, and this will be mainly achieved through the creation and engagement with the Policy Board. Task 1.6 will also prepare and deliver proposals on guidelines for adoption at the eHealth Network
if asked to do so, or information and updates, as needed.

Work package WP2 – Standards & Technical artefacts

Work Package Number	WP2	**Lead Beneficiary**	4. HL7
Work Package Name	Standards & Technical artefacts		
Start Month	1	**End Month**	24

Objectives

Description
T2.1. X-Bundle technical specs based on HL7 FHIR REST API for EHRxF (M1-M24) | Lead: HL7| Partners: ARIA, Gnomon, IHE-EUR, CEN/TH, UniNova, ASUFC, Digital Europe - Following the methodology developed in eStandards, this task aims to elaborate standards and technical artefacts for use cases and application domains selected in T6.1, using the specifications and technical assets developed in previous or ongoing projects such as X-eHealth as building blocks. In this way, and in collaboration with other tasks, we will support and strengthen the EEHRxF open community of practice with an Inventory of available EEHRxF specifications and their implementations. T2.1 will engage in developing and experimenting with FHIR-based rest API specs and value sets in alignment with the European Semantic Strategy. To support the open EEHRxF community, we will coordinate with other initiatives with the ultimate aim of creating synthetic data for the selected EHRxF domains and use cases. Besides supporting technical and semantic interoperability, T2.1 will also maintain the maturity levels for EHRxF implementations to further support organisational interoperability (WP3). T2.2. Creation of an only resource to harbour X-Bundle assets, success stories, and online EEHRxF co-creation and support communities (M1-M24) | Lead: HL7 | Partners: Iscte, Gnomon, IHE-EUR, CEN/TH, UniNova, TechForlife, ASUFC, Digital Europe - It aims to create an open repository to maintain the artefacts for the EEHRxF specifications and their implementation instructions organised per adoption domain. The artefacts maintained in the repository will be linked to deliverables of WP2, WP3, and offer instructions on how to use them for WP4. This open repository will serve as a catalyst to accelerate the contributions of the EEHRxF community including the outputs, lessons learned, and success stories of WP4 experimentation outputs. Thus, it will be a meeting point for the online EEHRxF communities as it will point to resources used by WP5 and WP7 to simulate ecosystem maturation and engagement of X-Net members (e.g., Hospitals-on-FHIR). T2.3. Technical requirements for quality labelling of consumer health products and EHR systems (M1-M18)| Lead: CEN/TH| Partners: Iscte, HL7, IHE, ASUFC, Digital Europe - T2.3 will associate the "consumer health products category" with the identification of the requirements behind the main initiatives, frameworks, and stanards at the EU level and in the MS relevant to the quality labelling of consumer health products, digital tools and EHR systems supporting EEHRxF and FAIR data. In this effort, it will incorporate input from XpanDH tasks and activities particularly WP5 and WP6. It will identify the technical requirements for quality labelling of consumer health products, built on and/or extending the identified initiatives, frameworks, and standards.

Work package WP3 – Organisational Readiness

Work Package Number	WP3	Lead Beneficiary	12. IHE-EUR
Work Package Name	Organisational Readiness		
Start Month	1	End Month	24

Objectives
Objectives: WP3 has the overall aim(s) of: i) defining the X-Bundle Readiness model, ii) developing the readiness model evaluation processes; and iii) educating the relevant parties (User/Hospital organisations, Vendors and Patient Organisations) on the steps to take to reach their next level in the readiness models. Synergies with other WP: share inputs and coordinate with WP2, align with WP4 Bubbles, WP5 community of doers and WP6 primary drafts developed for the feasibility check for WP4 and feedback will be taken into consideration in T3.1.

Description
Task 3.1: Define the X-Bundle Readiness model (M1-M20) | Lead: IHE| Partners: Iscte, HL-7,OKFO, ARIA, CHUP, UNINOVA, ECHA, CEN, ECPC, EDHA - This task will assess MS' accreditation models by identifying the legal and organisational (objectives, business case, strategy, structure, capacities, abilities, motivations, etc...) readiness prerequisites that can be fused with technical specifications , and, on that basis, develop a set of integrated practical requirements for interoperability. To achieve this goal, the team will reuse artefacts from relevant eHDSI documents, IHE Interoperability framework, the Refined eHealth Interoperability Framework (ReEIF) and mobile application accreditation framework. This task will deliver 2 versions of the readiness models: the first version will be used to gather feedback from other WPs (especially WP2) on the accreditation models and the second will be the final one. Task 3.2: Develop the readiness model evaluation process feedback loop (M6-M13) | Lead: OKFO| Partners: HL-7, Gnomon, IHE-EUR, UiO, UNINOVA, Nictiz, CEN, NCZI - This task has for goal to describe the process definition for assessing the X-Bundle specifications relying on the ISO Conformance assessment of the X-Bundle, reusing artefacts from maturity level of Hospital on FHIR, Antilope and Euro-CAS and considering HIMSS maturity models especially CCMM and EMRAM, based on T3.1. This task will also explain how individual organisations can use the model (from T4.1) and evaluate themselves against this model (with the help of the readiness level for legal, organisational, technical, and care delivery settings). Task 3.3: X-Bundle Readiness steppingstone guides and capacitation (M11-M24) | Lead: CHUP | Partners: EHMA, Gnomon, IHE-EUR, ECPC, EDHA, UiO, OKFO - T3.3 will create easy to use (online durable guides and paper based) guides for key constituencies (User, Healthcare Management, Health Professionals, Patients, Health Systems, Vendors). T3.3 also has the goal to educate the relevant parties on the next steps to take to reach their next level in the readiness model by creating materials/curricula and choosing methods for effective education, providing what they need to advocate for and to obtain the EEHRxF gains.

Work package WP4 – Feasibility & Experimentation

Work Package Number	WP4	Lead Beneficiary	10. UNINOVA
Work Package Name	Feasibility & Experimentation		
Start Month	1	End Month	24

Objectives
WP4 has the overall aim of assessing the feasibility/validity of available solutions in real-case scenarios – experimentation of the EEHRxF, around 3 dimensions: i) Adoption domains: situations/context under which interoperability is required; ii) Use cases: specifying the purpose and data required, data sources, actors and context; iii) National/regional legal and ethical aspects: considering also differences in language terminologies, etc. Focusing on early adopters, platforms, and solutions for EEHRxF will be selected and engaged with (e.g., Smart4Health), to understand how the guidance produced by WP2/WP3 is useful, how to create conditions for purposeful use of the EEHRxF and how to improve the guidance. Synergies: WP1 (Adoption domains), WP2 (Standards/technical specifications), WP3 (model),

WP5 (gaps/opportunities for expanding the ecosystem, community of co-creators) WP6 (feedback from bubbles), WP7 (dissemination).

Description
Task 4.1 - Preparing the experimentation bubbles (M01 – M20) | Lead: UNINOVA | Partners: Iscte, OKFO, Gnomon, HPI, KETEKNY, UiO, NCZI- Task 4.1 will set the scene for experimentation working in tight connection with WP1 (T1.4). Bubbles of experimentations will be defined around the identified adoption domains and the associated bubbles of experimentation will be evaluated taking into consideration their maturity/readiness levels in alignment with WP3. Aspects such as ethics and legal issues, differences in languages and terminologies will be considered as well as in international/national/regional contexts. In T4.1, the criteria for the selection of bubble sites will be finalised and the concrete experimentation bubbles and use cases will be selected. Also, T4.1 will promote workshops with internal and external stakeholders, including policy makers, around the 3 dimensions of implementation not only to provide guidance for adoption to (potential) adopters but also to identify and raise awareness on challenges and barriers that may compromise the adoption. Task 4.2 - EHRxF-based infrastructure (X-Bundle) feasibility demonstration (M06-M21) | Lead: HPI | Partners: EHMA, OKFO, ARIA, Gnomon, IHE-EUR, CHUP, UNINOVA, I~HD, CEN, HPI, KETEKNY, SCUBA, UiO, ASUFC, UNEW, NCZI, SU - will demonstrate the feasibility of using EEHRxF-based infrastructure within the experimentation bubbles. 4 bubbles are foreseen around the following situations: supporting clinical workflows and primary use of health data, both domestic and cross-border (reusing existing eHDSI connectors and APIs); supporting individuals' access to and exchange of health data, via mobile apps/portals, focusing on the role of citizen as active partner/co-producer; supporting healthcare providers to collect Discharge letters for reporting and public health data to authorities for effective planning, evidence-based decision making and coverage of the real needs; and engage with data exchange for research or ERN collaboration, considering aspects such as de-identification and transformation into research-related data formats such as OMOP or openEHR . Experimentation cases will be selected, identifying the most promising and with greater impact scenarios, and taking into consideration the most mature/feasible in each bubble. Smart4Health platform and apps such as CHUP App, eHealthPass and MHealth, will be used as reference specially in individual centred access and exchange. T4.2 will also assist adopters to identify obstacles to moving from the current level to the next by organising and conducting trainings necessary to prepare them to change, monitor, evaluate and assist actions of the adopters, and measure if they manage to eliminate obstacles and reach the next readiness level. Task 4.3 - Integrate lessons learnt from feasibility and experimentation (M18-M24) | Lead: EMP | Partners: IHE-EUR, UiO, UNINOVA, HPI, OKFO - T4.3 will be responsible for analysing the results from T4.2 and translate it into concrete lessons learnt for the validation and improvement of the X-Bundle. The task will rely also on the knowledge gained from the many interactions between the early adopters and other stakeholders to pave the way for extending the lessons to other potential adoption domains and adopters.

Work package WP5 – Growing Digital Health ecosystems

Work Package Number	WP5	**Lead Beneficiary**	6. EMPIRICA
Work Package Name	Growing Digital Health ecosystems		
Start Month	1	**End Month**	24

Objectives
WP5 aims to engage and activate the XpanDH ecosystem. It will create networks that cover and go beyond the adoption domains and respective bubbles in WP4, linking to relevant XpanDH X-Nets and external networks. It will demonstrate the business case of EEHRxF interoperability, explore factors for value capturing and outline investment and change needed. A community of doers will co-create assets to support the adoption of the X-Bundle. Synergies with other WP: Strong links with WPs 1 (D1.1, D1.7), WP3 (readiness), WP4 (domains and bubbles), WP6 (sustainable exploitation) and WP7 (dissemination).

Description
Task 5.1 - Expanding the networks around XpanDH adoption domains and beyond (M4-M24) | Lead: EMP | Partners: HOPE, HL-7, EHMA, OKFO, ECHA, EDHA, UNEW, Digital Europe - This task will create stakeholder networks around the adoption domains and beyond. Firstly, it will create networks to exchange knowledge and experiences specific

to the adoption domains, focused on two main stakeholders: patients/citizens and healthcare providers. Supported by the Patient association and the Citizens and Society X-Nets the task will focus on access to data from healthcare professionals - specifically mobile access to hospital information (by engaging with the mHealthHub community), telemonitoring and teleconsultation. The healthcare provider network will focus on continuity of care and clinical workflows through streamlining primary use of data across health systems, as well as hospital reporting. Supported by the Health Management & Regulators X-Net, it will focus on how to motivate adoption in the different domains, considering demand and supply stakeholders. A multi-stakeholder focus group will offer a more general perspective on the EEHRxF, sharing experiences across different actors, paying particular attention to the interdependencies of action between stakeholders. It will be staffed with representatives of all X-Nets and linked to already existing networks and projects to ensure that XpanDH builds on previous work. These will include ERNs, ECHA ecosystems, European Partnership on Transforming Health and Care Systems, synergy projects like X-eHealth, Smart4Health, DARWIN, InteropEHRate, GravitateHealth, Procure4Health, EHDEN, EUCanImagine). XpanDH Bubble exchange space will enable dialogue on lessons learnt during experimentations (from T4.3). It will elicit preliminary good practices and develop a concept to transfer it to other adopters (e.g., other ERNs) incl. measures for scaling up to other adoption domains.
Task 5.2 - Sharing drivers and benefits of interoperability (M1-M24) | Lead: IHD | Partners: Iscte, HL-7, EMP, ARIA, IHE-EUR, EDHA, ASUFC - This task will strengthen the interoperability business case, as demonstrated in the XpanDH adoption domains and bubbles. It will analyse drivers of interoperability success and elicit related requirements for HCP and ISP providers. It will also demonstrate the market needs to achieve interoperability in each adoption domain, building on the experiences from T 5.1. In addition, the task will join evidence of the value added through interoperable EHR data exchange and promote interoperability benefits in the domains: patient and societal benefit; health system efficiency; cost and savings implication and influence on health strategy. Also, it will analyse how to best capture innovation value from interoperability. Based on the enablers elicited before, T5.2 will explore the investment and change needed to enhance adoption and reap these benefits. These investments relate to education and literacy; organisational change; procurement and reimbursement; citizen and vendor support. Will also develop resources to promote importance and support these measures adoption.
Task 5.3 - Setting up a community of doers and co-creators (M3-M24) | Lead: GNOMON | Partners: Iscte, EMP, CHUP, KETEKNY, TechForLife, EDHA, ECPC, UiO - The scope of this task is to bring together implementers and end-users of new and existing solutions: IT developers and vendors/suppliers on one hand; patients and healthcare professionals on the other, under the concept of the 3C-3P community (Co-creation Community of Patients, Professionals and Programmers). The community will follow an open-source community and collaborative approach inviting end-users to participate and support IT developers. It will reuse assets from WP2 (i.e., the implementation guides) and from WP3 (i.e., the steppingstone guides). It will establish a transparent and open process governance model based on co-creating IT assets for the X-Bundle infrastructure. This X-Bundle community will embody the vibrant quality and governance models, as openNCP and openHIE. It will use a wiki and collaborative tools (provided by WP1, WP2 and WP7). It will organise support documentation, helpdesk processes so that early adopters or innovators can be supported to adopt the EEHRxF specifications by proposing ready to use tools. The community will involve patients (namely through ECPC and EDHA and professionals with a high interest in ICT who together with ISPs will ensure in a co-creation mode continuous input/feedback to WP4 and WP6. Task 5.3 results will feed T6.1 (Asset Bundles).

Work package WP6 – Sustainability and Future Action

Work Package Number	WP6	**Lead Beneficiary**	8. I~HD
Work Package Name	Sustainability and Future Action		
Start Month	1	**End Month**	24

Objectives
1) To package and promote, per adoption scenario, the relevant standards, resources, profiles value sets as “interoperability asset bundles" along with their corresponding interoperability testing and certification processes, procurement organisational change guidance; 2) To develop and publish a governance and an operating model for the maintenance of these bundles and a formal plan for the development of new bundles for the next priority of adoption scenarios; 3) To collate recommendations from WP that target desired action by MS & EC to accelerate the adoption of, and benefits realisation from, the asset bundles. Synergies with all tasks.

Description

Task 6.1 - Promoting and sustaining the XpanDH Asset Bundles (M1 - M24) | Lead: I~HD | Partners: Iscte, EMPIRICA, ECHA, TechForLife, EDHA, UNEW, SU – T6.1 will focus on packaging the asset bundles for each adoption scenario, so that any adopting community knows what assets it requires, how they fit together for achieving that interoperability. Asset bundles will include the standards, profiles, the available product/service testing and certification mechanisms, how to obtain any required licences or agreements, procurement and organisational change guidance, the fit with the eHDSI, ERNs, EHDS, DARWIN EU etc. These bundles will primarily use the outputs of WP 2,3,4,5. T6.1 will develop a governance and an operating model for the maintenance of these bundles. Because the asset bundles will need to be held, maintained and promoted by an entity, identify the most suitable partner to undertake this role and develop a business model for the bundle sustainability activity.
Task 6.2 - EEHRxF new adoption domains: consumer use cases for remote visit, telehealth, and telemonitoring (M6-M24) | Lead: Iscte| Partners: HL7, EMPIRICA, ARIA, Gnomon, CHUP, ECHA, I~HD, UNEW, Digital Europe, OKFO - This task will develop a formal methodology for the development of new asset bundles for the next priority of adoption scenarios, through an interoperability needs assessment, multi-stakeholder engagement for prioritisation, a health outcomes benefits case and a health economic assessment that can be used to construct business cases. A core area already identified by XpanDH is to focus on the upscale of interoperable telehealth solutions and services and existing frameworks: 1) Study and identify new assets, context cases, personas and existing interoperability frameworks related to the identified areas; 2) Create and define a formal methodology for the development of the new assets; 3) Propose an interoperability framework that focuses on the upscaling of specific area of work (e.g., telemonitoring solutions). T6.2 will articulate with WP2 and will start from the work of X-eHealth specifications. It will: 1. Help identify consumer use cases in articulation with WP1 (T1.4) and WP2, 2. Apply the eStandards digital compass framework analysis, and 3. address health services for citizens offered by digital health innovators, health systems, and insurance companies, particularly telehealth services.
Task 6.3 Recommendations to Member States and the European Commission (M6 - M24) | Lead: Iscte| Partners: Nictiz, ECHA, I~HD, UNEW - The EEHRxF is for the most part a local and organisational challenge, recommending its use is easy, recommending how it can be used and how MS can prepare and facilitate is more difficult and that is the purpose of this task. T6.3 will work with different WPs to produce a set of final project recommendations targeted at MS and the EC. These are generic, and future looking suggestions to be aligned with messages, guidelines and information notes developed and consolidated under T1.6 to ensure coherence.

Work package WP7 – Dissemination and Outreach

Work Package Number	WP7	**Lead Beneficiary**	2. ECHA
Work Package Name	Dissemination and Outreach		
Start Month	1	**End Month**	24

Objectives
1) To raise awareness about the project and its results among the key stakeholder groups, 2) To fast-track the transfer of knowledge between XpanDH and its target stakeholders, and unveiling the inwards-outwards value streams of the project and capitalising on the results obtained, 3) To facilitate sharing the knowledge inside the consortium and collaboration with the related European initiatives, incl. the European Health Data Space and Data Spaces Support Centre, 4) To support project implementation and sustainability (WP6), as well as ecosystem expansion towards the relevant user groups (WP5), 5) To create a platform for showcasing and exchanging knowledge and know-how of XpanDH. Synergies: Collecting knowledge from all WPs and supporting WP5 and WP6.

Description
Task 7.1 - Communication and Dissemination (M1-M24)	Lead: ECHA	Partners: Iscte, HOPE, HL7, EMPIRICA, EHMA, IHE, UNINOVA, NICTIZ, Digital Europe - This task will undertake all the activities relevant to communication, dissemination and promotional activities of the project, which are continuously synchronised with the different tasks of the project and described in detail in Section 2.2.2. It will design and run the communication campaigns to efficiently build traction among a broad audience, mobilise stakeholders, deploy a series of mechanisms including the XpanDH website, regular social media communication, diverse publications, and one-to-one messaging etc. It will also include the Communication and Dissemination Plan (C&DP, D7.1) and reporting (D7.1). The project results will be disseminated via the Digital Health Observatory. In close collaboration with other WPs, this task addresses the production of relevant

scientific articles developed as outcomes of the project outputs, as well as the definition and coordination of non-scientific activities to distribute technical and public policy and practice information (D7.4).

Task 7.2 - Outreach and Stakeholder Engagement (M1-M24) | Lead: ECHA | Partners: Iscte, EHMA, I~HD, TechForLife - After launching the project, XpanDH will proactively stimulate several highly committed stakeholders from each country, experimentation bubbles (feasibility activities) and ECHA ecosystems and generate high attention towards their initiatives. By ensuring high levels of visibility through dedicated stories and interviews, we will stimulate other stakeholders to join the community. As the numbers grow, we will continue the dissemination of the project and the key results of the engagement process, to maintain the visibility and keep stakeholders involved (Snowball approach). Within this task, 2 workshops/sessions and one final conference will be organised, leveraging on ECHA's work on the TIE on Health Data and Digital Health Society, to enable a direct communication between the XpanDH partners and the key stakeholders. Feedback from attendees will be sought and will be used to refine and fine-tune the strategy for the experimentation bubbles and acquire relevant insight for the sustainability plan (WP6). ECHA oversee the organisation of the workshops and the final conference, together with Iscte. The ECHA pan-European and multi-stakeholder network will play a strong role in enabling the CD strategy to operate as an impact multiplier.

Task 7.3 - Concertation Activities (M1-M24) | Lead: EMPIRICA | Partners: HL-7, ECHA, I~HD - will continuously monitor the relevant developments to amplify the work of the project, its consortium and ecosystem, and to enable knowledge exchange, collaboration and exchange of research results. It will also gather outputs from the system validation to assess XpanDH relevance for the EHDS, interoperability, data intermediaries and similar on the European and national levels, to establish links and synergies and its market impact. This information will lead to the development of a Book of Recommendations for future implementation of XpanDH and results will directly feed the sustainability plan and serve potential uptake and dissemination of relevant policy instruments

Associated with document Ref. Ares(2022)7907384 - 16/11/2022

STAFF EFFORT

Staff effort per participant

Grant Preparation (Work packages - Effort screen) — Enter the info.

Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	Total Person-Months
1 - Iscte	18.30	1.20	2.70	0.90	1.30	3.70	2.10	30.20
2 - ECHA	1.30		0.70		1.20	1.00	6.00	10.20
3 - HOPE					0.70		0.50	1.20
4 - HL7	1.50	8.50	1.80		1.40	0.50	1.10	14.80
5 - Gnomon		2.70	1.50	2.50	5.40	0.20		12.30
6 - EMPIRICA	1.70			1.40	9.50	1.30	1.00	14.90
7 - CHUPorto			10.40	4.50	1.50	0.20		16.60
8 - I~HD	2.70			0.30	1.70	3.90	0.60	9.20
9 - KETEKNY				12.00	2.00			14.00
10 - UNINOVA	1.90	1.50	2.40	15.80			0.50	22.10
11 - NCZI	2.10		1.40	6.00				9.50
12 - IHE-EUR	2.10	4.70	7.20	0.80	0.30		0.50	15.60
13 - EHMA			1.40	1.00	1.30		1.40	5.10
14 - UiO			2.00	1.00	1.00			4.00
15 - SCUBA	1.50			2.40				3.90
16 - ARIA	1.40	2.00	0.90	0.90	0.60	0.60		6.40
17 - Digital Europe		1.50			0.70	0.50	0.50	3.20
18 - OKFO			5.60	4.10	1.50			11.20
19 - TechForLife		1.10			2.50	1.30	1.50	6.40

Staff effort per participant

Grant Preparation (Work packages - Effort screen) — Enter the info.

Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	Total Person-Months
20 - Nictiz	0.30		0.10			1.00	0.60	2.00
21 - EDHA					2.20	1.90		4.10
22 - CEN/TH		2.10	1.10	0.20				3.40
23 - ASUFC		1.40		1.90	1.80			5.10
24 - ECPC			1.50		2.00			3.50
25 - SU	1.00			2.00		0.50		3.50
26 - UNEW	0.30			0.50	1.00	0.70		2.50
Total Person-Months	36.10	26.70	40.70	58.20	39.60	17.30	16.30	234.90

LIST OF DELIVERABLES

Deliverables

Grant Preparation (Deliverables screen) — Enter the info.

The labels used mean:

Public — fully open (⚠ automatically posted online)
Sensitive — limited under the conditions of the Grant Agreement
EU classified —RESTREINT-UE/EU-RESTRICTED, CONFIDENTIEL-UE/EU-CONFIDENTIAL, SECRET-UE/EU-SECRET under Decision 2015/444

Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D1.1	D1.1.1-XpanDH project Handbook	WP1	1 - Iscte	R — Document, report	PU - Public	4
D1.2	D1.1.2-Technical and Financial Reports	WP1	1 - Iscte	R — Document, report	SEN - Sensitive	12
D1.3	D1.2-QRC Plan	WP1	1 - Iscte	R — Document, report	PU - Public	4
D1.4	D1.3-Evaluation and Impact Assessment	WP1	1 - Iscte	R — Document, report	SEN - Sensitive	13
D1.5	D1.4-Definition of the EEHRxF adoption domains Report	WP1	1 - Iscte	R — Document, report	PU - Public	4
D1.6	D1.5.1-Ethics and Data Management Plan	WP1	1 - Iscte	R — Document, report	PU - Public	6
D1.7	D1.5.2-EEHRxF legal, cybersecurity & trust issues Report	WP1	1 - Iscte	R — Document, report	PU - Public	6
D1.8	D1.6 - Report on Policy Dialogue activities and achievements	WP1	11 - NCZI	R — Document, report	PU - Public	23
D1.9	D1.5.3- Updated Ethics and Data Management Plan	WP1	1 - Iscte	R — Document, report	PU - Public	18
D2.1	D2.1-Digital health compass for the application of EHRxF	WP2	4 - HL7	R — Document, report	PU - Public	9
D2.2	D2.2-EHRxF FHIR IG and repository of supporting materials	WP2	4 - HL7	OTHER	PU - Public	12

Deliverables

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D2.3	D2.3-Report on for quality labelling of EHRs	WP2	22 - CEN/TH	R — Document, report	PU - Public	10
D3.1	D3.1.1-First version of the X-Bundle Readiness model	WP3	12 - IHE-EUR	R — Document, report	PU - Public	9
D3.2	D3.1.2 - Final version of the X-Bundle Readiness model	WP3	12 - IHE-EUR	R — Document, report	PU - Public	18
D3.3	D3.2.1 - Intermediate readiness model evaluation process	WP3	18 - OKFO	R — Document, report	PU - Public	12
D3.4	D3.2.2 - Readiness model evaluation process Report	WP3	18 - OKFO	R — Document, report	PU - Public	13
D3.5	D3.3 - X-Bundle Readiness steppingstone guides	WP3	7 - CHUPorto	R — Document, report	PU - Public	12
D4.1	D4.1.1-XpanDH Adoption Domains	WP4	10 - UNINOVA	R — Document, report	PU - Public	6
D4.2	D4.1.2 - Adoption opportunities, challenges and barrier	WP4	10 - UNINOVA	R — Document, report	PU - Public	21
D4.3	D4.2 - XpanDH feasibility demonstrators	WP4	10 - UNINOVA	R — Document, report	PU - Public	12
D4.4	D4.3 - X-Bundle refinement Report	WP4	6 - EMPIRICA	R — Document, report	PU - Public	24
D5.1	D5.1 - XpanDH Ecosystem Report	WP5	6 - EMPIRICA	R — Document, report	SEN - Sensitive	22
D5.2	D5.2 - Interoperability Enabler Report	WP5	8 - I~HD	R — Document, report	PU - Public	18

Deliverables

Grant Preparation (Deliverables screen) — Enter the info.

The labels used mean:

Public — fully open (automatically posted online)
Sensitive — limited under the conditions of the Grant Agreement
EU classified —RESTREINT-UE/EU-RESTRICTED, CONFIDENTIEL-UE/EU-CONFIDENTIAL, SECRET-UE/EU-SECRET under Decision 2015/444

Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D5.3	D5.3 - X-Bundle open-source community of the doers	WP5	5 - Gnomon	R — Document, report	PU - Public	24
D6.1	D6.1.1-Governance & operating model for asset bundles & Exploitation PLan	WP6	8 - I~HD	R — Document, report	PU - Public	18
D6.2	D6.1.2 - Published library of documented asset bundle	WP6	8 - I~HD	R — Document, report	PU - Public	24
D6.3	D6.2 - Report on EEHRxF new adoption domains	WP6	1 - Iscte	R — Document, report	PU - Public	24
D6.4	D6.3 - Recommendation for MS & EC	WP6	1 - Iscte	R — Document, report	PU - Public	24
D7.1	D7.1 - XpanDH DC,Outreach and Exploitation Plan	WP7	2 - ECHA	R — Document, report	PU - Public	6
D7.2	D7.2 - XpanDH DC and Outreach Report	WP7	2 - ECHA	R — Document, report	PU - Public	12
D7.3	D7.3 - Concertation Activities Report	WP7	6 - EMPIRICA	R — Document, report	PU - Public	12
D7.4	D7.4-X-panDH website	WP7	2 - ECHA	DEC —Websites, patent filings, videos, etc	PU - Public	6

Associated with document Ref. Ares(2022)7907384 - 16/11/2022

Deliverable D1.1 – D1.1.1-XpanDH project Handbook

Deliverable Number	D1.1	Lead Beneficiary	1. Iscte
Deliverable Name	D1.1.1-XpanDH project Handbook		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	4	Work Package No	WP1

Description
XpanDH project Handbook (M4) | Lead: Iscte (R, PU) will cover guidance on how to identify and mitigate gender bias, or on how to solve any conflict resulting from differences in partners or coordinator's GEPs, and monitor progress towards achieving a greater gender balance in all project activities (e.g., experimentation bubbles, X-Nets dynamics, invitations for events and workshops, as well as in decision making processes). Gender diversity was sought in the leading figure of the main partners of the consortium.

Deliverable D1.2 – D1.1.2-Technical and Financial Reports

Deliverable Number	D1.2	Lead Beneficiary	1. Iscte
Deliverable Name	D1.1.2-Technical and Financial Reports		
Type	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	12	Work Package No	WP1

Description
Technical and Financial Reports (M12, M24) | Lead: Iscte (R, CSEN)

Deliverable D1.3 – D1.2-QRC Plan

Deliverable Number	D1.3	Lead Beneficiary	1. Iscte
Deliverable Name	D1.2-QRC Plan		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	4	Work Package No	WP1

Description
Quality and Risk Management Plan (QRC Plan, D1.2) for continuous risk monitoring and assessment. This will ensure the compliance with external and internal standards in force, as well as the assessment and monitoring of the project's progress.

Deliverable D1.4 – D1.3-Evaluation and Impact Assessment

Deliverable Number	D1.4	Lead Beneficiary	1. Iscte
Deliverable Name	D1.3-Evaluation and Impact Assessment		
Type	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	13	Work Package No	WP1

Description
Evaluation and Impact Assessment Reports (M13, M24) | Lead: Iscte (R, SEN)

Deliverable D1.5 – D1.4-Definition of the EEHRxF adoption domains Report

Deliverable Number	D1.5	**Lead Beneficiary**	1. Iscte
Deliverable Name	D1.4-Definition of the EEHRxF adoption domains Report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	4	**Work Package No**	WP1

Description
Definition of the EEHRxF adoption domains Report (M4,18)| Lead: Iscte (R, PU)

Deliverable D1.6 – D1.5.1-Ethics and Data Management Plan

Deliverable Number	D1.6	**Lead Beneficiary**	1. Iscte
Deliverable Name	D1.5.1-Ethics and Data Management Plan		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	6	**Work Package No**	WP1

Description
D1.5.1-Ethics and Data Management Plan 1 Iscte R PU M6, 24 Ethics and Data Management Plan will be taken over by other WP during the lifecycle of the project.

Deliverable D1.7 – D1.5.2-EEHRxF legal, cybersecurity & trust issues Report

Deliverable Number	D1.7	**Lead Beneficiary**	1. Iscte
Deliverable Name	D1.5.2-EEHRxF legal, cybersecurity & trust issues Report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	6	**Work Package No**	WP1

Description
D1.5.2 - EEHRxF related legal, cybersecurity & trust issues report (M6, M20) – Overview of legal, cybersecurity and trust related issues relevant for the X-Bundle creation and sustainability | Lead: Iscte (R, PU)

Deliverable D1.8 – D1.6 - Report on Policy Dialogue activities and achievements

Deliverable Number	D1.8	**Lead Beneficiary**	11. NCZI
Deliverable Name	D1.6 - Report on Policy Dialogue activities and achievements		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	23	**Work Package No**	WP1

Description
D1.6 – Report on Policy Dialogue activities and achievements (M23) – Summary of policy dialogue efforts, policy board constitution, engagement and achievements| Lead: NCZI (R, PU)

Deliverable D1.9 – D1.5.3- Updated Ethics and Data Management Plan

Deliverable Number	D1.9	**Lead Beneficiary**	1. Iscte
Deliverable Name	D1.5.3- Updated Ethics and Data Management Plan		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	18	**Work Package No**	WP1

Description
D1.5.3- Updated Ethics and Data Management Plan (M18); Lead: Iscte (R, PU) Updated data management plan, as the DMP will be updated subsequently during the course of the project

Deliverable D2.1 – D2.1-Digital health compass for the application of EHRxF

Deliverable Number	D2.1	**Lead Beneficiary**	4. HL7
Deliverable Name	D2.1-Digital health compass for the application of EHRxF		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	9	**Work Package No**	WP2

Description
D2.1 - Digital health compass for the application of EHRxF (M9) | Lead: HL7 (R, PU): Sets up the framework for the WP6 work, linking to previous and parallel efforts

Deliverable D2.2 – D2.2-EHRxF FHIR IG and repository of supporting materials

Deliverable Number	D2.2	**Lead Beneficiary**	4. HL7
Deliverable Name	D2.2-EHRxF FHIR IG and repository of supporting materials		
Type	OTHER	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP2

Description
D2.2 - EHRxF FHIR IG and repository of supporting materials (M12, M24) | Lead: HL7 (Other, PU): Website repository to collect artefacts used to accelerate the contributions of the EEHRxF community. Results build incrementally, continuously updated, intermediate snapshot on M12, final release on M24

Deliverable D2.3 – D2.3-Report on for quality labelling of EHRs

Deliverable Number	D2.3	**Lead Beneficiary**	22. CEN/TH
Deliverable Name	D2.3-Report on for quality labelling of EHRs		

Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	10	**Work Package No**	WP2

Description
D2.3 - Report on quality labelling of EHRs (M10, M15) | Lead: CEN/TH (R, PU): technical contributions in the Quality labelling for EHRs and consumer health products.

Deliverable D3.1 – D3.1.1-First version of the X-Bundle Readiness model

Deliverable Number	D3.1	**Lead Beneficiary**	12. IHE-EUR
Deliverable Name	D3.1.1-First version of the X-Bundle Readiness model		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	9	**Work Package No**	WP3

Description
D3.1.1 - First version of the X-Bundle Readiness model (M9) – Assess member states accreditation model by identifying the legal and organisational readiness prerequisites that can be fused with technical specifications, first loop - link to WP2 | Lead: IHE-EUR (R, PU)

Deliverable D3.2 – D3.1.2 - Final version of the X-Bundle Readiness model

Deliverable Number	D3.2	**Lead Beneficiary**	12. IHE-EUR
Deliverable Name	D3.1.2 - Final version of the X-Bundle Readiness model		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	18	**Work Package No**	WP3

Description
D3.1.2 - Final version of the X-Bundle Readiness model (M18) - Re-evaluate the readiness model based on feedback of WP5-7 | Lead: IHE-EUR (R, PU)

Deliverable D3.3 – D3.2.1 - Intermediate readiness model evaluation process

Deliverable Number	D3.3	**Lead Beneficiary**	18. OKFO
Deliverable Name	D3.2.1 - Intermediate readiness model evaluation process		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP3

Description
D3.2.1 - Intermediate readiness model evaluation process 1.0 (M12) - Intermediate version to be delivered to WP4, WP5 and WP6 - Work in progress verification of the milestone version 1 | Lead: OKFO (R, PU)

Associated with document Ref. Ares(2022)7907384 - 16/11/2022

Deliverable D3.4 – D3.2.2 - Readiness model evaluation process Report

Deliverable Number	D3.4	**Lead Beneficiary**	18. OKFO
Deliverable Name	D3.2.2 - Readiness model evaluation process Report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	13	**Work Package No**	WP3

Description
D3.2.2 - Readiness model evaluation process Report (M13) – Describing the process for assessing the X- Bundle specifications and explain how individual organisations can use the model and evaluate themselves against this model | Lead: OKFO (R, PU)

Deliverable D3.5 – D3.3 - X-Bundle Readiness steppingstone guides

Deliverable Number	D3.5	**Lead Beneficiary**	7. CHUPorto
Deliverable Name	D3.3 - X-Bundle Readiness steppingstone guides		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP3

Description
D3.3 - X-Bundle Readiness steppingstone guides (M12,24) - Easy to use guides for key constituencies and educational material to train the relevant parties on the steps to take to reach their next level in the readiness model | Lead: CHUP (R, PU)

Deliverable D4.1 – D4.1.1-XpanDH Adoption Domains

Deliverable Number	D4.1	**Lead Beneficiary**	10. UNINOVA
Deliverable Name	D4.1.1-XpanDH Adoption Domains		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	6	**Work Package No**	WP4

Description
D4.1.1 - XpanDH Adoption Domains (M6) – Adoption domains defined, associated bubbles of experimentation specified | Lead: UNINOVA (R, PU)

Deliverable D4.2 – D4.1.2 - Adoption opportunities, challenges and barrier

Deliverable Number	D4.2	**Lead Beneficiary**	10. UNINOVA
Deliverable Name	D4.1.2 - Adoption opportunities, challenges and barrier		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	21	**Work Package No**	WP4

Description

D4.1.2 - Adoption opportunities, challenges and barriers (M21) - Adoption workshops organised and executed, interactions with external stakeholders, identification of opportunities, challenges and barriers for adoption |) Lead: UNINOVA (R, PU

Deliverable D4.3 – D4.2 - XpanDH feasibility demonstrators

Deliverable Number	D4.3	**Lead Beneficiary**	10. UNINOVA
Deliverable Name	D4.2 - XpanDH feasibility demonstrators		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP4

Description
D4.2 - XpanDH feasibility demonstrators (M12, M21) – Interim results, experimentation results, if and how selected parties managed to reach the next maturity/readiness level | Lead: UniNova (R, PU)

Deliverable D4.4 – D4.3 - X-Bundle refinement Report

Deliverable Number	D4.4	**Lead Beneficiary**	6. EMPIRICA
Deliverable Name	D4.3 - X-Bundle refinement Report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	24	**Work Package No**	WP4

Description
D4.3 - X-Bundle refinement Report (M24) – Report on the results obtained and their translation into lessons learnt to improve guidance | Lead: EMPIRICA (R, PU)

Deliverable D5.1 – D5.1 - XpanDH Ecosystem Report

Deliverable Number	D5.1	**Lead Beneficiary**	6. EMPIRICA
Deliverable Name	D5.1 - XpanDH Ecosystem Report		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	22	**Work Package No**	WP5

Description
D5.1 - XpanDH Ecosystem Report (M22) - exchange activities and results of the adoption domain networks (patients/ citizens; healthcare providers), multi-stakeholder focus group and bubble exchange space | Lead: EMP (R, SEN)

Deliverable D5.2 – D5.2 - Interoperability Enabler Report

Deliverable Number	D5.2	**Lead Beneficiary**	8. I~HD
Deliverable Name	D5.2 - Interoperability Enabler Report		
Type	R — Document, report	**Dissemination Level**	PU - Public

Due Date (month)	18	Work Package No	WP5

Description
D5.2 - Interoperability Enabler Report (M18) - l factors that drive and help to capture value from interoperability for each of the adoption domains, related benefits, investment and change needed. | Lead: IHD | (R, PU)

Deliverable D5.3 – D5.3 - X-Bundle open-source community of the doers

Deliverable Number	D5.3	Lead Beneficiary	5. Gnomon
Deliverable Name	D5.3 - X-Bundle open-source community of the doers		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	24	Work Package No	WP5

Description
D5.3 - X-Bundle open-source community of the doers (M24) - community governance model and tools, incl. recommendations on the community sustainability | Lead: Gnomon (R, PU)

Deliverable D6.1 – D6.1.1-Governance & operating model for asset bundles & Exploitation PLan

Deliverable Number	D6.1	Lead Beneficiary	8. I~HD
Deliverable Name	D6.1.1-Governance & operating model for asset bundles & Exploitation PLan		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	18	Work Package No	WP6

Description
D6.1.1 - Governance and operating model for XpanDH asset bundles and their exploitation plan (M18) | A comprehensive framework and workflow for the quality assurance, licensing, usage feedback and maintenance of asset bundles. lean Exploitation Plan will be devised under WP6 (T6.1). The main exploitable and sustainable results of the project will be well formulated definitions of interoperability adoption domains, an inventory of the corresponding interoperability assets needed to support the exchange of information, along with the specification of profiles, FHIR resources, value lists, licence requirements and any data protection impact analysis that applies. Lead: I~HD (R, PU)

Deliverable D6.2 – D6.1.2 - Published library of documented asset bundle

Deliverable Number	D6.2	Lead Beneficiary	8. I~HD
Deliverable Name	D6.1.2 - Published library of documented asset bundle		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	24	Work Package No	WP6

Description
D6.1.2 - Published library of documented asset bundles (M24) - Inventory of all XpanDH asset bundles with links to all of their digital content needed for use | Lead: I~HD (R, PU)

Deliverable D6.3 – D6.2 - Report on EEHRxF new adoption domains

Deliverable Number	D6.3	Lead Beneficiary	1. Iscte
Deliverable Name	D6.2 - Report on EEHRxF new adoption domains		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	24	Work Package No	WP6

Description
D6.2 - Report on EEHRxF new adoption domains (updated M24) - Formalised proposal for the next priority of adoption domains, and on how to proceed with the development of asset bundles, with concrete examples in the area of telehealth| Lead: Iscte (R, PU)

Deliverable D6.4 – D6.3 - Recommendation for MS & EC

Deliverable Number	D6.4	Lead Beneficiary	1. Iscte
Deliverable Name	D6.3 - Recommendation for MS & EC		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	24	Work Package No	WP6

Description
D6.3 - Recommendation for MS & EC (M24) - recommendations and calls to action for MS, EC and other stakeholders involved in the EEHRxF | Lead: Iscte (R, PU)

Deliverable D7.1 – D7.1 - XpanDH DC,Outreach and Exploitation Plan

Deliverable Number	D7.1	Lead Beneficiary	2. ECHA
Deliverable Name	D7.1 - XpanDH DC,Outreach and Exploitation Plan		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	6	Work Package No	WP7

Description
D7.1 - XpanDH Dissemination, Communication, Outreach and Exploitation Plan (M6, 12) - outlines the project visual identity and the DC & Outreach activities, revised during the project | Lead: ECHA (R, PU)

Deliverable D7.2 – D7.2 - XpanDH DC and Outreach Report

Deliverable Number	D7.2	Lead Beneficiary	2. ECHA
Deliverable Name	D7.2 - XpanDH DC and Outreach Report		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	12	Work Package No	WP7

Description

D7.2 - XpanDH DC and Outreach Report (M12, M24) - evaluation of the CD and outreach activities| Lead: ECHA (R, PU)

Deliverable D7.3 – D7.3 - Concertation Activities Report

Deliverable Number	D7.3	**Lead Beneficiary**	6. EMPIRICA
Deliverable Name	D7.3 - Concertation Activities Report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP7

Description
D7.3 - Concertation Activities Report (M12, 24) with activities towards other relevant initiatives, projects etc. | Lead: EMPIRICA (R, PU)

Deliverable D7.4 – D7.4-X-panDH website

Deliverable Number	D7.4	**Lead Beneficiary**	2. ECHA
Deliverable Name	D7.4-X-panDH website		
Type	DEC —Websites, patent filings, videos, etc	**Dissemination Level**	PU - Public
Due Date (month)	6	**Work Package No**	WP7

Description
D7.4-X-panDH website Public presence in the web and social media (including a website) where all outputs and activities will be disseminated as described in Task 7.1 (M6), Lead: ECHA (DEC, PU)

Associated with document Ref. Ares(2022)7907384 - 16/11/2022

LIST OF MILESTONES

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
1	Kick-off meeting (KOM)	WP1	1-Iscte	Meeting Report, Operational Plan	2
2	Project Visual identity established	WP7	2-ECHA	Website, social media, logo available	3
3	Interim Implementation	WP1	1-Iscte	XpanDH Handbook, Interim Reports	12
4	Technical artefact repository	WP2	4-HL7	Repository available	6
5	Identification of technical requirements for quality labelling	WP2	4-HL7	First version of D2.3 available	12
6	EEHRxF FHIR IG releases	WP2	4-HL7	EEHRxF FHIR IG first release	12
7	Adoption domains selected	WP4	10-UNINOVA	D4.1 released	6
8	EEHRxF guidance improved	WP4	10-UNINOVA	D4.3 released	24
9	Doers & co-creators community set up	WP5	6-EMPIRICA	Existence of online community space	12
10	X-Bundle Guides wide endorsement	WP3, WP7	12-IHE-EUR	Documental evidence of endorsement	18
11	Release of first XpanDH Asset bundle	WP6	8-I~HD	Initial version of at least 1 X- Bundle with governance model and sustainability plan	18

LIST OF CRITICAL RISKS

Critical risks & risk management strategy

Grant Preparation (Critical Risks screen) — Enter the info.

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
1	Difficulties in implementation within the budget (L, M)	WP1	Continuous interim monitoring to detect at an early stage any unpredicted obstacles and apply proper mitigation measures.
2	Discrepancies between the plan and the implementation, progress (L, M)	WP1	Regular interim WP meetings, progress reports, and internal communication will keep the PC informed to act upon.
3	Disagreements between partners or about the assigned tasks in a large consortium (L, M)	WP2, WP3, WP5, WP1, WP6, WP7, WP4	Work assignment and related questions will be decided in internal meetings. Cases of disagreement will be discussed in internal meetings, with final decision from the Coordinator
4	Proper standards & technical artefacts available in time for all interrelated activities (L, M)	WP2	Regular WP meetings, progress reports, and internal communication will mitigate this risk and the WP will make intermediate data available for the proper needs.
5	Delay in gathering necessary legal and technical requirements (M, M)	WP3	Preliminary content to be shared by M3 and joint meetings of WP1, 2 and 3 will anticipate potential delays and act upon.
6	Low interoperability literacy, difficulty in stakeholders' engagement (H, M)	WP3, WP7	Communication/dissemination and outreach activities with targeted stakeholders will be reinforced with the help of WP5, WP6 and WP7
7	Difficulties in the implementation activities in the experimentation bubbles (L, M)	WP4	Coordination of the actions will be prepared well in advance to ensure all involved stakeholders allocate enough time to contribute to the joint preparation of the different actions
8	Maturity level in the early adopters is insufficient (L, M)	WP4	Support actions will be developed to prepare the bubbles and make sure involved stakeholders fulfil necessary requirements
9	Low engagement in the X-Networks (L, M)	WP5	Early involvement of key stakeholders leveraging of the vast consortium networks; meticulous engagement of X-Nets.
10	Dependency on activities performed by external partners without allocated budget (M, M) 5,6 P	WP5, WP6	Pinpoint win-win situations for external partners to enhance motivation; promote their visibility through dissemination; offer to contribute to partner's endeavours in return

Critical risks & risk management strategy

Grant Preparation (Critical Risks screen) — Enter the info.

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
11	Disagreement between organisations on the sustainability strategy (L, M)	WP6, WP7	Careful stakeholder consultation; investment in early common definitions of sustainability; seeking guidance from the EC

Description of the action (DoA)

Part B

Acronym: XpanDH |
***Title**: E**xpan**ding **D**igital **H**ealth through a **pan**-European EHRxF-based Ecosystem*
Coordinator: Prof. Henrique Martins
|Iscte | henrique.manuel.martins@iscte-iul.pt
***Duration**:* 24 months

TABLE OF HISTORY OF CHANGES

Version (Date)	Changes -Annex 1 -Part A and Part B
V1 12/08/2022	**Annex 1 Part A** 1- The Partner UNEW as a UK participant in our proposal will continue to participate (carrying out the originally foreseen tasks). UNEW was therefore removed from the list of Beneficiaries to the list of Associated partners. UNEW will rely on UK funding, through the financial guarantee delivered by UK Research and Innovation (UKRI) on behalf of the Department for Business, Energy, and Industrial Strategy (BEIS). The UKRI Horizon European Guarantee Guidance currently covers all calls that have an expected deadline for signing of the grant agreement before 31 December 2022. The annex to the guidance lists all the eligible grants – see page 24 for confirmation that grants with the prefix HORIZON-HLTH-IND-13 are indeed covered. The full document is available at:https://www.ukri.org/wp-content/uploads/2021/12/UKRI-180722-HorizonEuropeGuaranteeGuidanceJuly2022.pdf Consequently, and following the financial officer's instruction, the maximum grant amount is set at 1.972.260,50 EUR. 2- Milestone 3 - Due date of 12 months was added, instead of M12-M20 in the original proposal submission (mistake) 3- Milestone 6 - Due date of 12 months was added, instead of M12-M24 in the original proposal submission (mistake) 4- A new deliverable was added to WP1, Task 1.5: D1.5.3- Updated Ethics and Data Management Plan (M18); Lead: Iscte (R, PU) (an oversight) 5- In WP4, Partner Digital Europe was participant with 0PM, by mistake. This was now correctly removed from WP4 6- In WP6, Partner ECPC was participant with 0PM, by mistake. This was now correctly removed from WP6 7- A new deliverable was added to WP7, Task 7.1: Task Description we add (website D7.4). In the General Description of All Deliverables we add: D7.4- Public presence in the web and social media (including a website) where all outputs and activities of XpanDH will be disseminated as described in Task 7.1 (M6) Lead: ECHA (DEC, PU) (an oversight) In Table 3.1c: List of Deliverables (D) in in the original proposal submission: 8- -Deliverable 1.1.1: Due date of 12 months was added, instead of "M12, M24" in the original proposal submission (mistake)

26/07/2022	9- -Deliverable 1.3: Due date of 13 months was added, instead of "M13, M24" in the original proposal submission (mistake) 10- -Deliverable 1.4: Due date of 4 months was added, instead of "M4, M18" in the original proposal submission (mistake) 11- -Deliverable 1.5.1: Due date of 6 months was added, instead of "M6, M24" in the original proposal submission (mistake) 12- -Deliverable 1.5.2: Due date of 6 months was added, instead of "M6, M20" in the original proposal submission (mistake) 13- -Deliverable 2.2: Due date of 12 months was added, instead of "M12, M24" in the original proposal submission (mistake) 14- -Deliverable 2.3: Due date of 10 months was added, instead of "M10, M15" in the original proposal submission (mistake) 15- -Deliverable 3.3: Due date of 12 months was added, instead of "M12, M24" in the original proposal submission (mistake) 16- -Deliverable 4.2: Due date of 12 months was added, instead of "M12, M21" in the original proposal submission (mistake) 17- -Deliverable 7.1: Due date of 4 months was added, instead of "M4, M12" in the original proposal submission (mistake) 18- -Deliverable 7.2: Due date of 12 months was added, instead of "M12, M24" in the original proposal submission (mistake) 19- -Deliverable 7.3: Due date of 12 months was added, instead of "M12, M24" in the original proposal submission (mistake) 20- By mistake in the Table 3.1a: List of work packages (WP) of the original submitted proposal, the sum of PMs was wrongly indicated as 234,3 instead of 234,9 as it should and is now corrected in the dashboard (Part A) 21- By mistake in the Table 3.1f: Summary of XpanDH staff effort of the original submitted proposal, the sum of PMs was wrongly indicated as 234,3 instead of 234,9 as it should and is now corrected in the dashboard (Part A)
V2 21/09/2022	22- Following officer's recommendation and 2.2.3 Exploitation Plan, Sustainability and IPR management in page 16, we renamed D24 (D6.1.1) to "Governance and operating model for XpanDH asset bundles and their exploitation plan" with the following description: A comprehensive framework and workflow for the quality assurance, licensing, usage feedback and maintenance of asset bundles. lean Exploitation Plan will be devised under WP6 (T6.1). The main exploitable and sustainable results of the project will be well formulated definitions of interoperability adoption domains, an inventory of the corresponding interoperability assets needed to support the exchange of information, along with the specification of profiles, FHIR resources, value lists, licence requirements and any data protection impact analysis that applies. Lead: I~HD (R, PU)"
V3 04/10/2022	23- Latest starting date is 2nd January 2023 chosen and justification written in the system >> General information tab: "XpanDH is to follow from the findings and deliverables of X-eHealth project, namely the set of 4 specifications for 4 domains of the EEHRxF, we were informed by X-eHealth project coordinator (SPMS) that the project has been extended from expected end in Oct 31st to Nov 30th, some partners are the same and would like to see one project ending, producing final conclusions and work and then reorganize their teams and start fresh. On the other hand, starting on 1st January reduced administration costs internally as only 2 financial years are involved for all partners. Technically the XpanDH consortium would not be stopped until Jan, we expect to organize an informal open warm-up event in Lisbon on 27th of October back to back with X-eHealth to increase the chances of passing knowledge, but we would like to work with eHealth Network approved EEHRxF (so far only 1 domain has been published in August

	2022) which is likely to occur toward the end of Nov/Dec 2022.
V4 27/10/2022	24- On the 25th of October of 2022, the Partner KV (VYSOCINA KRAJ (Kraj) Vysocina has informed the Coodinator (Iscte) that will no longer be a beneficiary. As a result, the Partner was deleted from the platform. Its total budget (20952€) was added to the budget of BEN 1(Iscte). Furthermore, the WP1, WP7, D7 were corrected with all tasks previously from KV being now attributed to Iscte. The corresponding PMs were also corrected.
V5 09/11/2022	25- On the 9th of November of 2022, the Partner KV (VYSOCINA KRAJ (Kraj) Vysocina has sent the letter of commitment to become Associated Partner. Therefore, they were inserted as Associated Partner in the Platform F&T. 26- On the 8th of November of 2022, the Partner Hasso-Plattner-Institut for Digital Engineering gGmbH (HPI) has informed the Coodinator (Iscte) that will no longer be a beneficiary. As a result, the Beneficiary HPI was deleted from the platform. Its total budget (81750€) was added to the budget of BEN 10(UNINOVA). Furthermore, the WP2, WP2, D20 were corrected with all tasks previously from HPI being now attributed to UniNova. The corresponding PMs were also corrected. 27- In the Abstract, the number of digital health actors was changed from 28 to 27.
V6 10/11/2022	28- Following Project Officer instructions, Partner KV was removed from the platform. 29- In the Abstract, the number of digital health actors was changed from 27 to 26.
V1 12/08/2022	**Annex 1 Part B** 1-Comments from the ESR have been addressed as follows: -**Excellence** criterion: *"Additionally, the proposal does not adequately explain integration with population-based patient registries or consideration of artificial intelligence. These are shortcomings."* Reply: The inclusion of an ERN experienced partner (METAB ERN Coordinator) and partners covering the provision of regional digital services like ARIA will allow the consortium to understand how the EEHRXF can help integrate with population-based patient registries. The project will add considerations on AI based on the EEHRxF exchanged data to its task 1.4. (pages 5, 6, 9 , 10) -**Impact** criterion: "S*ome of the KPIs are formulated too conservatively and are limiting the credibility of project results towards the expected outcomes. Since their baseline is missing, their achievability is unclear. This is a shortcoming.*" Reply: The EHRxF is a very new concept and in practice only last month the first concrete specification came out from X-eHealth/eHealth Network therefore it's not possible to have baseline and a conservative approach was considered to create more credibility then an overrated, likely unachievable, target list (pages: 4, 15,18). "*While the proposal clearly explains the concrete impacts on a societal, economic, and scientific level, it does not adequately elaborate on the scale of such impacts (i.e., it is not clear how many different stakeholders could benefit over time, scale is limited and mostly linked with the outreach efforts), which is a shortcoming.*" Reply: WP1 and WP5 (task 5.1) will work to define more concretely these impacts, the proposed creation of the X-nets with such a variety of stakeholders is a concrete mechanism

	to reach them in an action-oriented manner (e.g. Hospitals-on-FHIR which has already started) so far beyond the usually outreach activities. (pages 3, 6-Table1, 14, 15) "*The proposal does not sufficiently address potential barriers (and their mitigation measures) that hinder the consistent acceptance, exploitation, and use case development harnessing involved standards and technical frameworks in the industrial sector, public procurement, and actual patient-centric approach required by the topic. This is another shortcoming.*" And "*The details on the tangible results, their owners, and appropriate measures for their exploitation are insufficiently described and are not linked with tangible project outcomes. This is a shortcoming.*" Reply: WP1 will further work with the consortium to detail the already presented list of risks and mitigation actions, as well as, on tangible results. It was not possible due to space constraints and the absence of any published EHRxF specifications/guidance to conduct such detailed analysis at the proposal stage, as these are brought to public by X-eHealth project/eHealth Network it is then possible to understand the true dimension of the barriers and plan logical mitigation actions. "*Any concrete IPR management measures are insufficiently described. The proposal merely mentions that the consortium will define IPR management rules in the CA. This is a shortcoming.*" Reply: The EHRxF is not a technology but a set/pack of standards that range from legal, organizational, technical and semantic, and which is by its own nature public open and to be widely available in the EU and beyond, this means IPR management was considered adequately addressed by guaranteeing that these principles are core to the Consortium, and that is achievable at the CA formulation stage (page 16). -**Implementation** criterion: The ESR only identified minor shortcomings in this part, the main one is perhaps: "*The proposal identifies and elaborates on relevant critical risks, but only on a generic level. More project-specific risks related to, e.g., access to specific data sets for the experimentation or ethics and legal aspects, are missing. Additionally, some likelihoods are too optimistic (for example, Difficulties in implementation within the budget and Proper standards & technical artifacts available in time for all interrelated activities). These are minor shortcomings."*
V2 21/09/2022	Reply: To address this one and in relation to others, WP1 task 1.3 and task 1.4 can be reinforced to more precisely address the reviewers concerns. We have included a more detailed impact-oriented strategy as a subtask of 1.3, and particularly in 1.6 by creating a sub-task dedicated to concrete commitments by MS authorities/relevant large healthcare providers regarding their formal commitments towards the EHRxF. This last sentence has been added to the Objectives section of WP1 description in the Grant Management platform System. 2- The prior mistaken inconsistencies from Table 3.1h have been identified and corrected. A new version of the table has been inserted (in page 20), matching the values in the financial information tab in the system. 3 -In Table 3.1j (page 22) we gave more details about the third party giving in-kind contributions: "Iscte-Instituto Universitário de Lisboa is a third party giving in-kind contributions for free to the action (Article 9.2). These contributions will be in the form of human resources (13.40 PM) to the coordinator entity (P1) for the implementation of the project activities. This staff will be involved in all 7 WPs, leading WP1 and Tasks: 1.1, 1.2,1.3, 1.4, 6.2, 6.3"
V3 03/10/2022	4- In Table 3.1 h (page 21) we have added new lines for Partner24-KV, participants 4 and 8 were removed.
V4 28/10/2022	5- - In Table 3.1 h (page 21) Partner24-KV was removed. The value of P1 travel and subsistence was increased to 12350€ and the justification updated to: "- Costs for the participation of 2 Iscte's representatives in 2 consortium meetings (1 per year),

	for 7 participants attending the WP Leaders meetings, 4 participations in WP coordination meetings, and for the participation of the Coordinator in 4 relevant representation events. The average travel cost considered for each trip is 650€ (including subsistence and accommodation)." 6-In page 22, three references to KV have been deleted.
V5 09/11/2022	7- In page 22, section 3.2, the number of partners was changed from 28 to 27. 8- In Table 3.1 h (page 21) due to Partner16-HPI exit, the value of P10's travel and subsistence was increased to 15600€ and the justification updated to: "- Costs associated with in person attendance of 18 participations to the WP4 Workshops - bubbles (11700€).". 9-In page 22, six references to HPI have been deleted. 10-In Figures 1 2 and 5, the text "(HPI was replaced by Uninova)" was inserted 11-In page 22, three references to KV have been recovered.
V6 10/11/2022	12- In page 22, three references to KV have been deleted. 13- In Figures 1, 2 and 5, the text "(KV was replaced by Iscte)" was inserted. 14- In page 22, section 3.2, the number of partners was changed from 27 to 26.

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Abbreviation List

AP - Associated Partner

CA - Consortium Agreement

CD - Communications and disseminations

CSA - Coordination and Support Action

DG - Directorate General

DG CONNECT - DG for Communications Networks, Content and Technology

DG RTD - DG for Research and Innovation

DG SANTE - DG for Health and Food Safety

DGA - Data Governance Act

DMP - Data Management Plan

DSM - Digital Single Market

EC - European Commission

EEHRxF - European EHR Exchange Format

eHDSI - eHealth Digital Service Infrastructure

HER - Electronic Health Records

EU - European Union

HCP - Healthcare Providers

IPR - Intellectual Property Rights

ISP - Information Solutions Providers

KPI - Key Performance Indicators

MoH- Ministries of Health

MS- Member States

PM - Person-Month

RT - Roundtables

SDO - Standards Developing Organisations

SG - Specific Goal

T - Task

WP - Work Packages

WS – Workshop

1. Excellence

Following the success of the **establishment of the eHealth Digital Service Infrastructure (eHDSI)** and its **"MyHealth@EU" services**, and the EU Digital Covid Certificate, **it is now clear that the European Union (EU) can use standards to define interoperable and cross-border services between Member States (MS)**. For the most part, these services have involved national level organisations. On the other hand, while in several MS, definitions for inter-organizational sharing of health data exist, especially for linking each organisation to regional or national Electronic Health Records (EHR), large-scale adoption of interoperable solutions based on a common EU foundation is non-existent. The EU healthcare provider (HCP) organisations, and all other stakeholders including citizens, await agreements on common definitions, reference implementations and common interoperability assets that could allow such solutions to be used across and between organisations, in cross-border and inside-borders settings, in a format that would be flexible to specific contexts but also European in its approach, allowing adaptation efforts in line with the Digital Single Market (DSM) and supporting full EU citizen mobility. In this context, the **European Electronic Health Record Exchange Format (EEHRxF)** was announced in 2018 as part of the Communication on Digital Transformation of Health and Care (DTHC 2018)[1] and later made concrete in the Recommendation on the European Electronic Health Record exchange format (EHRxF, 2019)[2]. As part of the Digital Single Market (DSM) Strategy[3], and particularly following the COVID-19 pandemic, European digital health actors increasingly feel a need to **converge on common, usable, and reliable tools for real interoperable services that enhance healthcare cooperation for better health and European healthcare solidarity, paving the way to the European Health Union**[1]. The DigitalHealthEurope Roundtables (RT) on Interoperability[4], led by the coordinator (2021), demonstrated the

[1] The Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society is available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A233%3AFIN

[2] Commission Recommendation on a European Electronic Health Record exchange format (C(2019)800) of 6 February 2019, COMMISSION RECOMMENDATION (EU) 2019/ 243 - of 6 February 2019 - on a European Electronic Health Record exchange format (europa.eu)

[3] The DSM Strategy is available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52015DC0192; it was revised in 2017 but in essence the pillars are the same.

[4] https://digitalhealtheurope.eu/results-and-publications/expert-roundtables-on-health-data-sharing-and-use-summary-of-discussions/

need for compelling use cases for health data interoperability, showcasing the benefits health data standards bring, and demonstrating how much efficiency and good patient outcomes are lost without interoperability. Such interoperability tools include the EEHRxF. Its wide adoption, however, is not an easy task nor will it happen automatically due to many factors (e.g., legacy systems, non-interoperability supporting systems, local or national specifications, that would need to converge as well). The XpanDH is devoted to facilitating the extensive adoption of the EEHRxF through the maturation of a **pan-European Ecosystem of Early Adopters of new/adapted digital solutions that implement EEHRxF specifications**, within a specific socio-technical ethos of support for trusted, sustainable and resilient solutions.

1.1 Objectives

In 2019, the **eHealth Network**[5] approved important recommendations on Interoperable ecosystem[6] and funding criteria, linking for the first time the funding of projects and structural funds to interoperable solutions and harmonisation efforts such as those inaugurated by the EEHRxF Recommendation[2]. The cross-border eHealth interoperability landscape has changed in the last three years, with more MS sharing cross-border data (e.g., Patient Summary and ePrescription/eDispensation) or preparing to do so, supporting mobility between MS, and establishing new roles and practices in the eHealth Network, particularly now with mature specialised subgroups on technical and semantic issues. On the other hand, cybersecurity has become increasingly important and needs to be balanced with increased data sharing while at the same time telehealth services and mHealth have seen unprecedented increases that call for common, harmonised, and interoperable approaches. At intra-borders, or at an intra- and interorganizational level, however, the challenges of exchanging health data in a European context, have remained the same and await a serious commitment from all actors (e.g., Governments, National Authorities, Healthcare Providers (HCP), Information Solution Providers (ISP), professionals, patients and managers) to collaborate around common ways to exchange health data. **Therefore, an ecosystem of users, developers and adopters is needed in Europe to foster Digital Health innovation that nurtures interoperability (in the form of the EEHRxF) at its core.** This is the spirit with which the **XpanDH** consortium was formed to serve Europe by ***Expan****ding* ***D****igital* ***H****ealth through a* ***pan****-european EHRxF-based ecosystem*.

Cognisant of this policy context and in close alignment with MS, the eHealth Network and the forthcoming European Health Data Space governance structures, the **XpanDH Coordination and Support Action (CSA) will approach the promotion of the adoption of the EEHRxF specifications and recommendations that have been developed in the X-eHealth project**[7]**,** embracing many of the lessons learnt from other past eHealth interoperability projects, particularly the recent DigitalHealthEurope CSA[8], which contributed to all three priorities foreseen in the DTHC [1], by creating a live ecosystem of early EEHRxF users, adopters and promoters.

XpanDH will involve different stakeholders not just as opinion-providers but as active partners engaged in finding resources and with the will to create joint services based on the EEHRxF. This challenge will be addressed by the project through the **XpanDH networks - X-Nets** - networks of organisations directly or indirectly related to health and digital health and that will be involved or need to be involved in an expanding European Digital Health Ecosystem as it matures its use of the European EHRxF (e.g., Networks of Patients and Patient Associations, HCP, ISP, Standards Development Organisations and Industry).

MAIN XpanDH OBJECTIVES: XpanDH is an ambitious project aimed at preparing and building capacity in individuals and organisations to be ready to use the European Electronic Health Records Exchange format (EEHRxF), by establishing a pan-European effort through a Network of Networks approach, that will ensure that the involved and multiple digital health actors are motivated, inspired and supported to advance to concrete adoption of the EEHRxF by guidance and real examples organised as an aggregation of interoperability assets - **the X-bundle** -, around the EEHRxF. The **XpanDH project pursues the main goal of maturing and accelerating a sustainable and scalable interoperability environment** in Europe **for digital health innovations based on the EEHRxF, involving**

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[5] https://ec.europa.eu/health/ehealth-digital-health-and-care/eu-cooperation/ehealth-network_pt

[6] eHealth Network Guidelines on an interoperable eco-system for digital health and investment programmes for a new/updated generation of digital infrastructure in Europe, https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20190611_co922_en.pdf

[7] https://www.x-ehealth.eu

[8] Recommendations on the EHDS 2021 https://digitalhealtheurope.eu/results-and-publications/digitalhealtheurope-recommendations-on-the-european-health-data-space /

both the supply and demand sides of healthcare provision. To attain this main goal, the project activities were planned to allow XpanDH to reach **6 Specific Objectives (SO), through 7 interconnected Work Packages (WP)** with **Key Performance Indicators (KPI)** that were selected to monitor its achievements by the end of the 2-year duration:

Specific Goal (SG) [Related WP(s)] |Expected delivery timeline (M-Month)	Key Performance Indicator (KPI)	Target(s)
SO1 - To develop robust technical specifications and resources for the EEHRxF, building on the results of the X-eHealth project and ensuring smooth transition to HL7 FHIR based REST APIs, paving the way towards quality assurance of EHR systems within the EHDS. [**WP2**] **M21**	**KPI1** - Nº of use cases with complete technical specification package	3-4
	KPI2 – Nº of artefacts accessible at the open repository	10
SO2 - To establish the X-Bundle Readiness model, develop its evaluation processes, and build educational materials (ICT toolkit) for the relevant parties (HCP, ISP and Patient Organisations) on the steps to take to reach their next level in the EEHRxF readiness model. [**WP3**] **M23**	**KPI3** - Nº of organisations assessing their EEHRxF maturity level	20
	KPI4 - Nº of X-Net HCP, ISP and Patient Associations endorsing the educational materials	20 20 5
SO3 - To demonstrate feasibility and verify the usefulness of the X-Bundle in real-world experimentations with a set of EEHRxF early adopters' organisations grouped under selected adoption domains, and thus refine the guidance material and create reference cases for purposeful use to stimulate ecosystem maturation. [**WP4**] **M21**	**KPI5** - Nº of successful feasibility demonstrations (at least 1 use case per experimentation bubble)	4
	KPI6 - Nº of formal collaborations signed and agreed with projects and initiatives	6
SO4 - To mature a pan-European digital health ecosystem that adopts the EEHRxF as a common feature, through networking between solution providers, adopters, and end-users around and beyond the XpanDH adoption domains and bubbles [**WP5, WP7**] **M22**	**KPI7 -** Nº of X-Net members involved in multi-stakeholder focus groups	100
	KPI8- Nº of registered participants in the community of doers and co-creators	50
SO5 - To develop a framework for Sustainable ecosystem maintenance and development that can serve to address each adoption scenario, so that any adopting community knows immediately what assets it may require, while also setting up an operating model for the maintenance of these bundles and foresee the growth of a pan-European digital health ecosystem [**WP6**] **M22**	**KPI9 -** Nº of outreach workshops/ speaking engagements during international events	6
	KPI10 - Nº of new use cases/domains for the EEHRxF described and supported by experts and the ecosystem.	2
	KPI11 - Nº of policy briefs	2
SO6 - To communicate and disseminate the XpanDH achievements broadly, and outreach to other EU-funded projects and initiatives for cooperation in the adoption of the EEHRxF in those contexts whenever possible and help outreach to the XpanDH Networks of stakeholders bringing those organisations together around the adoption domains. [**WP7**] **M24**	**KPI12** - Nº of total quality followers on social media (LinkedIn/Twitter)	900
	KPI13 - Ratio site visits to unique visitors in XpanDH website	2:1
	KPI14 - Nº of XpanDH scientific publications	2:5

1.2 Coordination and/or support measures and methodology

An ecosystem approach to Digital Health Innovation and the creation of conditions for new cross and intra-border interoperable environments around a proposed set of standards – in this case a EEHRxF-based infrastructure – is different from the EU cross-border initiatives so far that have been mostly governmental lead. **Understanding digital health as an ecosystem means accepting some systemic properties: i) Open innovation.** ***ii)*** **Multiple leadership**, iii) **Concepts over action plans,** iv) **Industry involvement and co-creation spaces,** and v) **Government as coordinators.**

Revisiting the EEHRxF: Following from the EEHRxF Recommendation[9], the EEHRxF includes the health

[9] COMMISSION RECOMMENDATION (EU) 2019/ 243 - of 6 February 2019 - on a European Electronic Health Record exchange format

information domains and interoperability specifications including standards, and profiles necessary for representing and exchanging (structured and unstructured) health data. It should be further refined and extended through a joint coordination process (involving the EC and the MS) where additional international standards, specifications and profiles, currently being developed, under revision or in the trial implementation phase should be considered when further developing a EEHRxF. The **XpanDH consortium understands EEHRxF to be a composite of information domains and interoperability specifications necessary to allow two or more parties to exchange a subset of EHR data between themselves, and valuable secondary use of health data, containing a common block of definitions that are data independent and a variable block that adapts to information domain needs.** It is applicable to all EU MS, and is the result of a dynamic, open, and participated evolution process.

One of the main roles of XpanDH is to create, nurture and stimulate an EEHRxf Network of Networks. Only by this process, can significant impact in a EU-wide space be achieved with time and budget constraints. **XpanDH will be both a Network of Capacity and Network of Action**. As a **Network of Capacity**, XpanDH will ensure that Organizations can verify if they are EEHRxF-ready by assessing their level of maturity regarding the different interoperability assets they need to set in place to be able to use the EEHRxF for purposeful data sharing. Such a maturity model requires the consolidation of knowledge from all previous relevant projects (e.g., Antilope, epSOS, Trillium Bridge, Expand, ValueHealth, eAction, and DigitalHealthEurope) and the gained experienced with the setting up and audits for the eHDSI MyHealth@EU services, instantiated to particular adoption domains and three types of actors (HCP, ISP and Patients). As a **Network of Actions,** XpanDH will ensure that the delivery of exchanges actually happens between organisations, or between these and end-users such as patients and professionals. Significant effort will be dedicated to the feasibility activities to support concrete usage. The **"One Digital Health" conceptual framework** ("built around two key ideas (i.e., one Health and digital health), three perspectives (i.e., individual health and well-being, population and society, and ecosystem), and five dimensions (i.e., citizens' engagement, education, environment, human and veterinary health care, and Healthcare Industry 4.0)"[10] will help to inspire the work of evolving the interoperability environment into a fertile ecosystem for purposeful Digital Health innovations that make use of the EEHRxF.

XpanDH was designed and consolidated to contribute to all expected outcomes and impacts set out in the call topic and to contribute to "Maintaining an innovative, sustainable and globally competitive health industry" Destination impacts, as explained in section 2.2. The consortium involves 3 SMEs (Trace Health, Gnomon and EMPIRICA) and organisations such as IHE-EUR that will bring the industry perspective and help identify needs to the scale-up and take-up of digital solutions at national, as well as European level.

The XpanDH core concepts are: X-Bundle, EEHRxF adoption domains, Experimentation Bubbles and the X-Nets. The consortium understands an "infrastructure based on the EHRxF" as a "**publicly driven bundle of interoperability assets that allow the secure and ethical exchange of health data according to the EEHRxF related specification, guidelines and ethos**" that was herewith named as the **X-Bundle,** which is **conceived as a technical, personnel and processes infrastructure**. The X-Bundle does not imply the use of a particular or unique IT infrastructure, or level of interchange. This means its applicability extends from intra-organizational infrastructures and health data exchanges (i.e., inside an HCP using its interoperability infrastructure) to inter-organizational exchanges at local, regional, national or cross-border levels. It can also be supported by existing data sharing infrastructures such as those resulting from the Smart4Health project, the MyHealth@EU, or any other that can comply with its specifications. Because it is not possible to adopt the emerging EEHRxF in all envisioned use-cases and contexts at once, the consortium has introduced the **concept of EEHRxF adoption domains.** These will allow for consolidated efforts to reach the capacity needed to experiment and verify feasibility within the confined domains. **EEHRxF adoption domains** are data and purpose contextualised use-cases that include, but are not limited to, data interoperability situations for supporting clinical workflows, primary use of health data, patient access to his or her health record from healthcare provider organisations, or situations where healthcare providers are asked to report data to authorities or engage with data exchange for research or ERN collaboration. Finally, following a bottom-up approach, we understand the required feasibility verification to mean the capacity to show how organisations were able to get ready to adopt, and hence adapted to, the EEHRxF though different degrees of testing and usage that can be perceived as **intra-organisational experimentation**. "**Experimentation bubbles'' are**

[10] Benis A, Tamburis O, Chronaki C, Moen A, One Digital Health: A Unified Framework for Future Health Ecosystems,J Med Internet Res 2021;23(2):e22189

collections of organisations that agreed to experiment with using the EEHRxF, in a set adoption domain and under the X-Bundle defined conditions, mostly on their own budget, or using other projects budgets, or pro-bono, but in effective articulation with XpanDH. The experimentation bubbles can be further extended to include other third party organisations, and European or EU-funded initiatives and projects through the efforts of the X-Nets.

For the necessary scale and pan-European impact, XpanDH will deploy the aforementioned activities through the **XpanDH X-Nets** - networks of stakeholders (EU or MS organisations) that, linked by similar interests, form the existing pan-European (Digital) Health space and can potentially use or benefit from the widest adoption of the EEHRxF. Ten such networks will be promoted throughout the CSA, inspired by the Hospitals-on-FHIR initiative set out in March 2022 to network all Hospitals and Healthcare Providers (HCP) across Europe[11]. The following 10 XpanDH X-Nets have been established in the proposal stage, engaging already and just in a few days, around 20 organisations (local, regional, or national in nature) in total, out of 461 invited, and will be further enlarged and nurtured by the X-Net Agitators, throughout and beyond the project duration (Table 1).

Table 1: List of XpanDH X-Nets and assigned X-Net agitators (partners from the stakeholders' sector who will engage and activate the organisations of the X-Net in the relevant XpanDH activities).

X-Net Name	X-Net description	Nº of Engaged/Invited Organisations	Agitator(s)
Patient association	Network of patient associations, particularly supported by WP1 and engage particularly with WP3/4/5	3/78	ECPC, Iscte, EDHA
SDOs & Industry Board	Network of Digital Health Industry players (companies, and associations) as well as relevant SDOs (e.g., SNOMED Int)	0/27	IHE-EUR
Hospitals-on-FHIR X-Net	Network of organisations affiliated with the HL7 Europe Hospital-on-FHIR Initiative and interested parties	7/48	HL7
BioMedical Research	Network of Researchers and Research collaboration initiatives in the life sciences and biomedical areas	1/37	I~HD
Professionals Associations	Network of Health professionals' chambers, associations and unions national and European	2/181	CHUP
Citizens and Society	Network of citizen associations, consumer groups, and other representatives of civil society, including media	1/10	EMPIRICA, Iscte
Health Mgt & Regulators	Network of health management professionals and associations, as well as healthcare regulators and financers	1/5	EHMA
Innovation Hubs	Network of partners of the innovation cycle (e.g., venture capital and innovation funds, incubators, innovation hubs)	1/6	TechForLife
ERNs and PerMed	Network of all EU ERNs established and projects/initiatives in personalised medicine (e.g., ICPerMed)	1/11	UNEW
Health Regional Authorities	Network of all health regional authorities responsible for healthcare provision or oversight/planning healthcare	3/58	ARIA

Finding a balance between a bottom-up ecosystem approach and a state drive agenda is essential. Governmental leadership can set general lines and promote these ecosystems to higher levels of maturity while firming political commitments. From its inception XpanDH sought the support and endorsement of MS Ministries of Health (MoH) and received over 8 emails expressing support and conducted an online informal meeting with the participation of 5 other MS. XpanDH envisions a powerful policy dialogue as part of its CSA activities, through the **XpanDH Policy Board,** which will act as the mediator between the project and Ministries of Health and Social Affairs, Digital Health Authorities/Competence centres. The **XpanDH Policy Board** will be a Forum of invited MoH representatives from the 27+3 (Island, Norway, Liechtenstein - observers to the eHealth Network) to mediate fruitful policy dialogues with the EU and other European and International Organisations such as the WHO, GDHP and OECD. This Board will be managed under WP1 (Coordination) to ensure that Policy makers and eHealth Network (DG SANTE) and other policy fora, such as the eHealth Stakeholder Group[12] (DG CONNECT) are informed and advised on potential

11 https://www.hospitalsonfhir.eu/map

12 https://ec.europa.eu/digital-single-market/en/news/call-expression-interest-ehealth-stakeholder-group-members-2019-2022

evolutions of the EEHRxF and its extension to other use cases.

Finally, **XpanDH project's vision entails a true and participatory involvement from all relevant end-users**, such as patients, caregivers and professionals, in the EEHRxF implementation, adoption and dissemination. In this vision, patients, caregivers, citizens and health care professionals are NOT JUST recipients of digital services, or users of digital services for the betterment of their health/healthcare service, NOR JUST requirement holders to be consulted in a unidirectional way. In the project vision, these key stakeholders ARE ALL THIS, AND they can and should be empowered and given access to health data and co-create the **AEIOU (A**ccessible**, E**ngaging**, I**nteroperable**, O**perational and **U**seful) **digital health tools of the future**, that are being proposed by XpanDH. This **Participatory design approach** will have 2 main implications: 1) all key stakeholders will be actively involved in the co-creation of the EEHRxF ecosystem in all project phases, from the beginning, and 2) the consortium will ensure the necessary flexibility and openness to manage potential changes and needs that arise from the co-creation, to ensure real acceptance[13,14,15]. Through the **"3Cs-3Ps community" - Co-creation Community (3Cs) of (3Ps) Patients, Professionals and Programmers (or other ISP developers), implemented in WP5,** we aim to close the secular gap between these 3 Pillars of digital health that has meant significant problems in the creation of meaningful digital health tools and services for both patients and professionals. Having a shared repertoire and language, and creating mutual understanding is essential for an inclusive pan-European ecosystem. While some activities may be more focused on each of the pillars, continuing the work of X-eHealth WP8 on Communities and fostering the links with the 3 relevant X-Nets (Industry and SDOs, Patients and Pat. Associations, and Professionals) will allow this core of co-creation community to eventually serve as a replicable model for inspiring similar co-creation movements in MS. This **community** will follow an open-source community and collaborative approach[16,17] inviting end-users to participate and support IT developers. Starting from, but going beyond, the past OpenNCP community model created in epSOS and continued through Expand, the **"3Cs-3Ps community"** will be deployed with the knowledge and experience of different partners. Iscte will bring patients co-creation engagement methodologies which were matured under the Iscte-health's PatientsUp initiative; EMPIRICA, EDHA and ECPC will ensure stakeholders engagement and communication, taking into consideration their real needs, perspectives, and expectations. This vision will be framed by the patient participation from a Personal Health Data Space perspective (UiO)[18].

[13] Thabrew, H., *et al.* (2018). Co-design of eHealth interventions with children and young people. Frontiers in psychiatry, 481.

[14] Bowen S, et al. Engaging teenagers productively in service design. Int J Child Comp Interact. (2014) 1:71–81.

[15] Boyd H, McKernon S, Mullin B, Old A. Improving healthcare through the use of co-design. N Z Med J. (2010) 125:4–15.

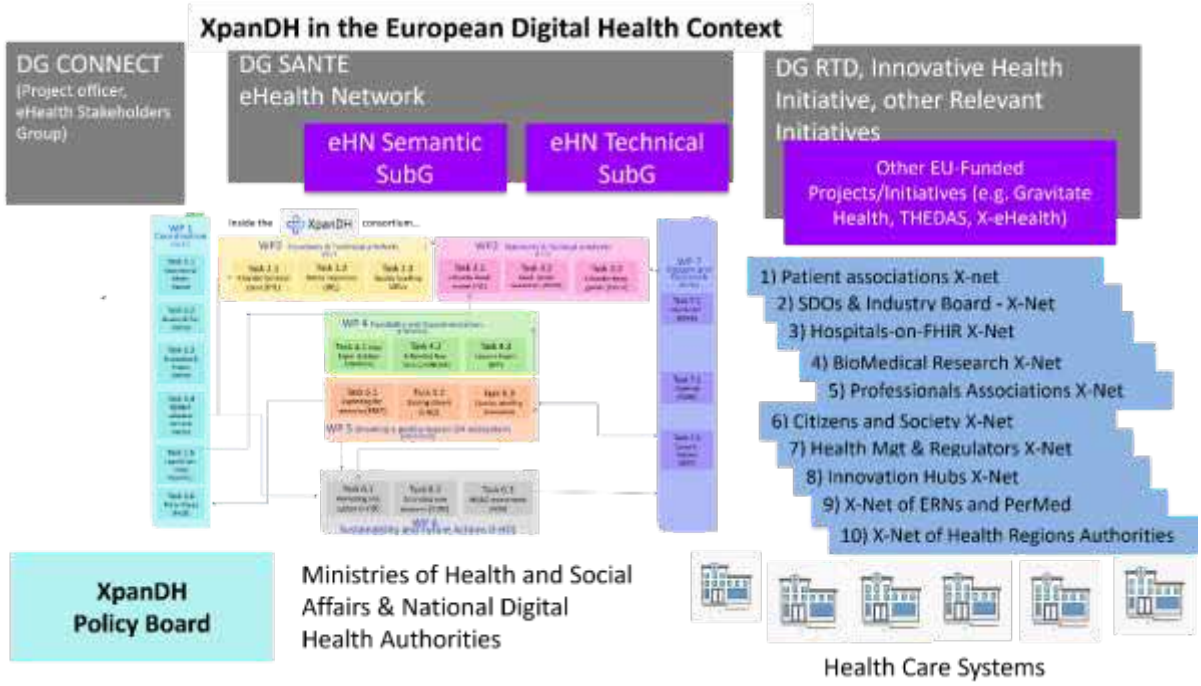
[16] Thabrew, H et al. (2018). Co-design of eHealth interventions with children and young people. Frontiers in psychiatry, 481.,

[17] Boyd H, McKernon S, Mullin B, Old A. Improving healthcare through the use of co-design. N Z Med J. (2010) 125:4–15.

[18] Moen, A., et al. (in press) People centric model to harness user value: reflection on Personal Data Spaces in transformation of health and care. Issue on Healthcare Digitization Pathways, **healthmanagement.org**

The **XpanDH CSA is organised in 7 interconnected Work Packages (WP),** involves past and current coordinators and/or WP leaders of the most relevant EU projects as WP leaders, and is led by a Coordinator (Henrique Martins, Iscte) with a proven and extensive track-record of establishing interorganizational connections and coordinating EU-funded health interoperability projects. Appropriate links will be made with prominent EU large scale projects such as UNICOM[19] (7 XpanDH partners) or the IMI project Gravitate Health[20] (5 partners, including its coordinator - UiO). Synergies will be established with other relevant initiatives on FAIR data, such as EOSC4CANCER co-lead ELIXIR (2 XpanDH partners), IDEA4RC (2 partners), upcoming initiatives on health data. Connections will be also forged with the European Cancer Imaging Initiative, HOSMARTAI, etc.

Figure 1 – XpanDH in a nutshell



(HPI was replaced replaced by Uninova, KV was replaced by Iscte)

WP1 (Coordination, Lead: Iscte) will take care mainly of coordination tasks (T1.1 to T1.3) that will ensure the **proper governance of the consortium efforts**, but also two tasks related to providing the **content and strategic decisions common ground** that allow all other WP to articulate around shared efforts (T1.4, T1.5). A task focusing on **Policy Dialogues with the different policy spaces** and the MoH (via Policy Board) is equally envisioned (T1.6) and articulated with WP7 (T7.1). 2 workshops (WS) are foreseen around Month 3 (to coordinate WP2,3,4) and in Month 10 (for WP5,6,7). Policy Dialogues Forums will be held around M4 and M21.

WP2 (Standards & Technical Artefacts, Lead HL7) will ensure the **maintenance and improvements to the technical artefacts** received from past relevant projects (notably X-eHealth) and **create a core set of specifications relevant for the chosen adoption domains** (see T1.4) but exploring and conceptualising further usages and use cases for the EEHRxF from a standards and technical perspective. It will deliver its outputs to WP3 that will **bundle a six layered** (**X-Bundle**) **readiness verification and upskilling tool** for organisations to be ready for using the EEHRxF for a particular domain of data sharing practices. WP2 will also provide input to the quality assurance and certification of consumer health products and EHR systems contributing to the preparation of healthcare organisations for the EHDS. Specifically, WP2 will elaborate on standards and technical artefacts for use cases and application domains developed in WP6 and specifically consumer health use cases for EEHRxF and will address digital health services for individuals beyond those offered by public health systems. In this process WP2 will facilitate and support the EEHRxF open community and build on X-eHealth specifications and forging links to European semantic strategy. Core element of the approach taken in this WP2 is to develop and experiment with FHIR-based REST API specs

[19] https://unicom-project.eu/

[20] https://www.gravitatehealth.eu/

based on HL7 FHIR for EEHRxF, maintain artefacts and develop resources to accelerate adoption of the REST API, advance data quality with synthetic data, terminology assets and services, as well as refining Maturity levels for Hospitals on FHIR. WP2 will also support maintaining technical requirements for quality labelling of consumer health products and EHR systems by identifying the technical requirements for quality labelling of consumer health products, built on and/or extending identified initiatives, frameworks, and standards. WP2 will cover technical requirements for quality labelling enabling the certification of EHR systems supporting EEHRxF in the context of FAIR data and EHDS.

WP3 (Organisational Readiness Model, Lead: IHE-EUR) will engage hospital, patient and vendor organisations to co-define evolving **X-Bundle organisational and technical readiness models for the use of EEHRxF** for the particular domains defined in WP2. The readiness model will be built on the accumulated experience and assets of **previous European Projects/Initiatives** (see section 3.2) as well as assets related to the eHDSI Cross-border services, and particularly the organisational and audit framework that were adopted by the eHealth Network to better assess the needs. WP3 will also deliver **guides** to educate relevant parties on the next steps they will have to take to reach their next level in the readiness model. WP2 and WP3 will work on a **shared online repository** that will serve as a safe hub for documentation open to the ecosystem of early and later adopters.

WP4 (Feasibility and Experimentation, Lead: UNINOVA) will involve multiple partners, and any other institution participating through any of the ten foreseen XpanDH Networks (the X-Nets), around 3 or 4 pre-selected adoption domains (T1.4), to check for the feasibility and verify in as real as possible scenarios, how the EEHRxF serves concrete integration functions and can be used.

Through this process a validation and improvement of the **X-Bundle** is obtained from the lessons learnt in the **WP4 Experimental Bubbles**. 4 **bubbles of experimentation** are foreseen around EEHRxF adoption domains containing different contextualised use-cases. Bubble 1 will focus on EEHRxF between HCP institutions both in domestic and cross border settings. For this purpose, experimentations will involve Romania (SCUBA), Hungary (OKFO) and Slovakia (NCZI) and will include the reuse of existing eHDSI connectors and APIs based on X-Bundle. Bubble 2 will focus on EEHRxF to facilitate report to national health care regions/Ministry of health organisations, etc. involving Hungary and Greece and will include discharge data collected from the patient's medical and administrative files, from hospitals. Bubble 3 will focus on EEHRxF for secondary data use. Experimentations will involve secondary data use covering the data provision from HCP to ERN (ASUFC) and for the citizen-initiated data provision for research (interlinked with citizen-centered data exchange via the Smart4Health platform). In Bubble 4, the focus is on the individuals and Smart4Health Citizen Health Data Platform will be used as the role model. Experimentations will be around EEHRxF for establishing connections with healthcare providers via the Smart4Health Connector (FHIR R4, IHE, SNOMED, ICD, LOINC, RX-norm, while allowing also custom connections of any Hospital infrastructure realising

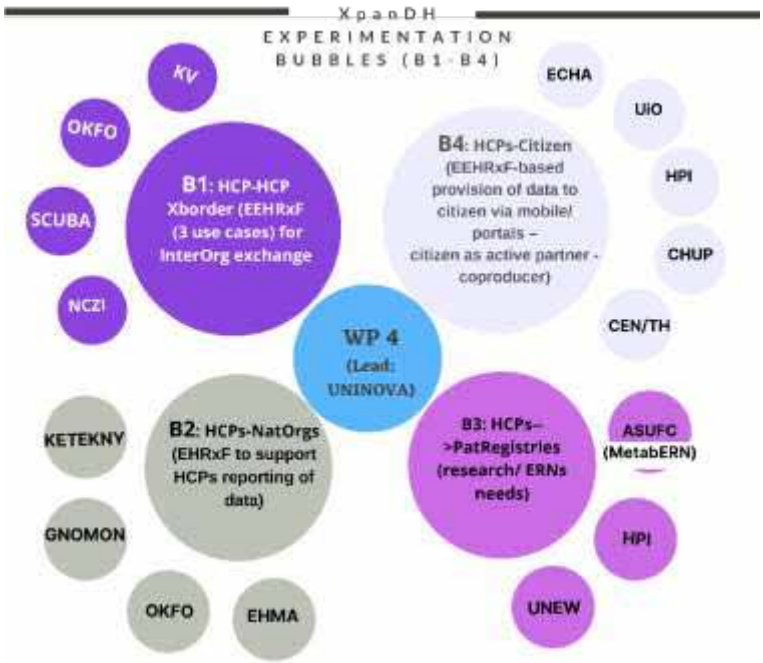


Figure 2 - Preliminary outline of the 4 experimentation bubbles.

unstructured and structured data extraction for citizen-use purpose) as well as on connecting mobile applications (e.g., CHUP App) to add other health-related data with Smart4Health Software Development Kit (SDK) or similar.

XpanDH foresees one adoption domain where data aggregation from multiple HCPs is to be shared with a national level authority, for reporting and health management functions. This can involve the use of AI models in data validation, or even prediction based on large data sets that result from harmonised reporting using the EEHRxF. While it is out of scope and budget to create new AI tools in this CSA, the considerations that data exchanges through the EEHRxF should support such advanced tools will permeate the work in T1.4 as well as T4.1 and in experimentation bubble 2. Likewise, the inclusion of a strong ERN coordinator partner, in metabolic diseases (ASUFC is the coordinator of MetabERN) will allow XpanDH to surface the challenges of integrating Omics type of information with other exchanged datasets, namely in this case, laboratory data and the integration of MetabERN hospital's data into the patient registries is a foreseeing aspect to be covered in WP4.

EEHRxF can enable meaningful engagement with digitally provided information, to build necessary trust and ethical conduct in line with **European Ethical Principles for Digital Health**[21]. Resources and standards facilitating continuity and cross-border care can through experiments co-create and coproduce value that support and offer a good overview of health data that when deployed at scale, come with opportunities and convenience to improve user-experience, engage the person, and transform personal health management[22]. This is a demand-side push for a more interoperable digital health ecosystem that can only be realised with the offering of tailored and patient-friendly digital tools. **To reap full benefit of a EEHRxF, digital health tools and services are urgently needed to equip Citizens as patients, informal caregivers or family members,** in need of digital health data and services for health management activities at their personal convenience, discretion and control. The **Bubbles activities** will focus on how to exchange and use health data for multiple purposes to demonstrate that smart delivery of digital health information can improve access, understanding and adherence, leading to better outcomes and a healthier society[23]. These will capitalise on the recently successful completed DigitalHealthEurope (DHE) project[24], which highlighted the need to empower citizens and foster "health data activism" in patients, and leverage functionalities for curation to contribute quality of data for real world visualisations and analytics.

In **WP4** (**Feasibility and Experimentation)** a small group of early adopters, mostly XpanDH partners and a few other organisations, will prove that guidance produced by WP2/WP3 is useful, **creating conditions for purposeful-use of the EEHRxF in concrete health and care domains**, and have been refined, a **much larger ecosystem engagement and activation is needed**. This will be the core focus of WP5 while exploring new ways to expand the potential ecosystem actors and finding new ways to engage them. One such way will be the **Co-creation Community**, joining up patients, professionals, and programmers, surrounding the EEHRxF with a community of doers ready to help others to use and engage with digital health interoperability.

WP5 (Growing a Pan-European DH ecosystem, Lead: EMPIRICA) will **engage and activate the XpanDH ecosystem**. It will create networks that cover and go beyond adoption domains and bubbles, linking to XpanDH X-Nets and external networks. It will demonstrate the business case of EEHRxF interoperability, explore factors for value capturing and outline investment and change needed. A community of doers will co-create assets that support the adoption of the X-Bundle in real life use cases. The ecosystem will showcase the drivers and benefits of interoperability and demonstrate how to capture value from it while a community of doers will co-create assets for the X-Bundle and foster support to further adopters.

WP6 (Sustainability and Future Actions, Lead: I~HD) will work with lessons and outcomes of the process of creating and engaging sub-ecosystems created around each domain by WP5, alongside WP2 proposed ideas for new use-cases, and the findings from feasibility and experimentation (T4.3) to create the **Framework for Sustainable**

[21] https://presidence-francaise.consilium.europa.eu/en/news/the-european-union-sets-out-a-framework-of-trust-as-a-basis-for-digital-health

[22] Moen. A., Cramer, A., Chronaki, C. (2022) Engage the people – health informatics and personal health management. In Delaney, C.W., Weaver, C.A., Sensmeier, J., Pruinelli, L, Weber, P. (eds) *Realizing Digital Health – Bold Challenges and Opportunities for Nursing - Nursing and Informatics for the 21st Century – Embracing a Digital World*, 3rd Edition, Taylor & Frances ISBN: 9780367516895

[23] Moen, A., Chronaki, C., Martins, H., Ferrari G., (in press) People centric model to harness user value: reflection on Personal Data Spaces in transformation of health and care. Issue on Healthcare Digitization Pathways, **healthmanagement.org**

[24] https://digitalhealtheurope.eu/

ecosystem maintenance and development (T6.1), including quality, governance and operational procedures, that should address how future evolution can be ensured while further exploitation of existing exchange contexts can be diversified. In articulation with WP1, particularly T1.6, WP6 will also produce a set of recommendations and points for future action (T6.2, Iscte, I~HD) and organise small meeting(s) as satellite meetings of relevant events

Finally, **WP7 (Dissemination and Outreach, lead: ECHA)** is a horizontal endeavour, that will ensure the smooth communication and effective dissemination of all WPs relevant activities, in straight linkage with WP1 and the respective WPs leaders, but it will go further by promoting outreach activities, ensuring the expansion and activation of the X-Nets alongside each of the ten **X-Net agitators** and active collaboration with other relevant activities, namely other UE projects and European initiatives within the topic.

All WP will involve the organisation of focus groups, workshops and forums under different tasks. In WP4, Bubbles WS for training/education events/courses will be necessary to prepare the parties to make the change(s).

HORIZONTAL APPROACHES

Gender Dimension: The XpanDH members are committed to follow the Coordinators (Iscte)'s Charter of Principles for Gender Equality and/or their respective Gender Equality Plans (GEP), to ensure awareness on non-discrimination and unconscious gender biases, gender balance in data collection, and gender equality and diversity in all activities, including use case descriptions or examples used in dissemination or education materials. The XpanDH Management Handbook (T1.1) will cover guidance on how to identify and mitigate gender bias, or on how to solve any conflict resulting from differences in partners or coordinator's GEPs, and monitor progress towards achieving a greater gender balance in all project activities (e.g., experimentation bubbles, X-Nets dynamics, invitations for events and workshops, as well as in decision making processes). Gender diversity was sought in the leading figure of the main partners of the consortium.

Open Science: XpanDH will comply with appropriate open science practises, complying with the EC rules in place. It will cooperate to share the outcomes in open access and disseminate them as widely as possible to allow others to use and replicate them. We will deposit, licence, version and give access to the project outcomes by uploading them in the SocioDigital Lab community in Zenodo**.** These outcomes may include research data, roadmaps, reports, case studies, etc. **Scientific peer-reviewed publications** will be deposited in institutional repositories of the consortium under Creative Commons licences. Immediate open access through the repositories should be provided. The authors will retain enough rights to accomplish the immediate open access, or in case the suitable scientific journal does not allow the immediate open access for any type of version, the publishing choice offered by **Open Research Europe** will be considered. The produced data and other results needed for validation of the conclusions of scientific publications will be provided according to the principle "as open as possible as closed as necessary".

Data Management: The consortium will effectively manage all data through the project lifecycle regarding planning, organising, documenting, processing, storing, and protecting the data. A **Data Management Plan (DMP)** will be created in the open and collaborative **ARGOS (OpenAIRE) platform,** under WP1 delivered by M6 and updated at the end of the project. The deposition of data will take place in Zenodo's SocioDigital Lab community, as soon as possible, after data processing and quality control have taken place.

2. Impact

2.1 Project pathways towards impact

2.1.1 How XpanDH uniquely contributes to the expected outcomes and wider impacts of the call

The XpanDH consortium is uniquely positioned to contribute to the wider adoption of the EEHRxF in different EU contexts because it has a mixture of partners that are very experienced in EU-funded collaborative projects on the topic of eHealth interoperability, as well as partners with concrete experience and footing on the ground. This combination of EU-wide perspective, eHealth historical perspective and wealth of experience associated with local, regional and national organisations on one side [such as, sets of HCPs (unique or in networks), regional authorities, and national level digital health actors] and most of the international Standards Developing Organisations (SDOs) relevant in the area of ehealth interoperability on the other side, is a guarantee for high impact. However, acknowledging that wider impacts in citizens, HCPs and concrete digital health services require a combination of engaged governments and national authorities as well as all health-related stakeholders, XpanDH envisioned and

will engage a Policy Board (this has already started with emails of support from more than 8 MS available to join, and a first informal meeting with MoH representatives held in April 2022) and ten XpanDH networks of stakeholders (the X-Nets) of which, Hospitals-on-FHIR X-Net has already been launched (April 2022)..

A **second element of impact that XpanDH will explore is the EEHRxF ethos**. The experimentation bubbles, building on linkages to other EU-funded projects or initiatives, particularly Interreg projects, and other projects that will require health data exchange between organisations (inside or cross-border), the X-Nets, and the 3C-3P communities as well as the activation of the national affiliates of HL7 and the national deployment committees of IHE-EUR, and stimulation of a Health Data Activism movement, are all mechanisms by which XpanDH aims to activate processes to close the gap between ehealth interoperability supply and demand. The project will build on lessons from the DigitalHealthEurope CSA, but instantiated to concrete adoption domains, in line with the EEHRxF information domains, i.e., in concrete services that add measurable, and feasibility verified value to patients, organisations and health systems in MS. By outputting not just sterile technical guidance, guidelines and policy recommendations, or abstract maturity models, XpanDH will impact MS and mature a pan-European Digital Health Ecosystem by providing live examples of usage, as well as, live examples of networks of players who, themselves, have to adopt, diffuse and ensure the EEHRxF truly becomes European and real. Making the EEHRxF something of Europeans is the ethos of XpanDH, rooted in its experimentation, experience sharing, and co-creation, intrinsic values and actions.

XpanDH will deliver all expected outcomes settled in the Call

Expected Outcome 1: ***Individuals, researchers, health services and the workforce across borders in the EU Digital Single Market use significantly improved and interoperable cross-border digital health solutions (…)***

Providing the interoperability asset X-Bundle and developing robust technical specifications and resources for the European EHRxF (through WP2). Elaborating standards and technical artefacts for specific EEHRxF use cases and application domains (WP2). Developing and experimenting with FHIR-based REST API specs based on HL7 FHIR for EEHRx and maintaining technical requirements for quality labelling of consumer health products and EHR systems (WP2). Maturing and nurturing a Pan-European ecosystem of EEHRxF early adopters (delivered by WP5). Developing and publishing a governance and an operating model for the maintenance of these bundles, Promoting and sustaining the XpanDH Asset Bundles (WP6). **Targeted beneficiaries**: Citizens, patients, HCPs, HC professionals and researchers. **KPI**: **one million eXchanges using the EEHRxF, through 300 organisations, by 2028**. **Pathways to outcome:** Personalised Actions for the targeted beneficiaries are foreseen in the D&C Plan (section 2.2.2).

Expected Outcome 2: ***"Individuals have an improved level of accessibility, control and portability of health data, including donation for research across Europe and jurisdictions." will be achieved through:***

Digital Services offered directly to patients and individuals, based on EHRxF specifications, that support a high-level usage in the Patient Health Data Space model[25]. Proving the feasibility of the establishment of a co-creation community where individuals as patients or professionals work alongside ISP and developers that is capable of supporting early adopters of the EHRxF will ensure an active role for individuals. Work involving the MetabERN will provide a basis for the conceptualization of new use cases where EEHRxF will allow cross-border donation of health data and data altruism for multisite research purposes. **Targeted beneficiaries**: Citizens, patients, HCPs, HC professionals and researchers. **KPIs**: **one million eXchanges using the EEHRxF, through 300 organisations, by 2028;** Nº of organisations assessing their EEHRxF maturity level. **Pathways to outcome:** Personalised Actions for the stakeholders are foreseen in the D&C Plan (section 2.2.2).

Expected Outcome 3: ***"Policy makers and members of the eHealth Network are better informed and advised regarding potential evolutions of the EEHRxF and its extension to other use cases.".*** The link to the eHealth Network and other policy spaces is considered of paramount importance to the successful adoption of the XpanDH efforts and for its support function. This expected outcome will be achieved through the establishment of the Policy Board (under T1.6) that, with the support of several partners (incl. the national and regional competence centers NICTIZ and NCZI) and experience of Iscte, will liaise with Policy and decision makers. **Targeted beneficiaries:** Members of eHealth Network and the MoH Representatives (as detailed in section 1.2), but not excluding

[25] Moen, A., Chronaki, C., Martins, H., Ferrari G., (in press) People centric model to harness user value: reflection on Personal Data Spaces in transformation of health and care. Issue on Healthcare Digitization Pathways, healthmanagement.org

Representatives from WHO Europe, WHO or Global Digital Health Partnership (GDHP) **KPI**: N. of meetings/workshops held with Policy Makers: Nº of Policy briefs. **Pathways to outcome**: Policy briefs, meetings and 2 Policy Dialogue workshops. Other personalised pathways are foreseen in the D&C Plan (section 2.2.2)

Expected Outcome 4: ***Different target populations such as designers, developers, health care professionals, and individuals have access to exploitation and capacity building support, such as training material, dedicated tools, guidelines, mentorship and collaboration programs.*** This outcome will be mainly achieved through the definition of an EEHRxF Readiness Model and preparation of a X-Bundle Readiness steppingstone guides and materials prepared under WP3. **Targeted beneficiaries:** HCP, ISP, Patients and professional associations, and digital health authorities. **KPI**: Nº of organisations benefiting from the X-Bundle Readiness guides; Nº of organisations that increased their level of EEHRxF maturity; % of improvement in the maturity level. **Pathways to outcome**: Workshops for capacity building personalised to developers, HC professionals and patients.

XpanDH Expected Impacts (wider long-term effects)

Moreover, the project will namely contribute to achieve the following Impacts established for the Destination: "*European standards, including for operations involving health data, ensure patient safety and quality of healthcare services as well as effectiveness and interoperability of health innovation and productivity of innovators.*" *as well as "Health industry is working more efficiently along the value chain from the identification of needs to the scale-up and take-up of solutions at national, regional or local level, including through early engagement with patients, health care providers, health authorities and regulators ensuring suitability and acceptance of solutions."*

Expected societal impacts:

- Citizens (patients, carers, healthy persons) will benefit from safer, low error, higher quality and better evidence-based health care that is seamlessly delivered anywhere in Europe. We will include patients as information creators and empowered knowledge consumers namely through the 3Cs-3Ps communities.
- Health and care professionals: Care to patients will be better informed by access to more complete EHRs, and care decisions will be better supported by smart applications taking advantage of interoperability and real-time value from structured and coded information that has already been captured.
- HCP organisations critically rely upon high-quality, fine-grained, real-time patient information to optimise service delivery, detect risk situations, monitor quality and outcomes. They will probably gain the fastest benefits realisation from interoperable services.
- Health authorities, healthcare payers: EU Organisations that pay for or commission health services today lack fine-grained patient level data to monitor outcomes. We envisage patient-sensitive outcomes-based reimbursements, and the ability for payers to accurately compare performance, outcomes and safety.
- MS will benefit from better information to support strategic decisions, which maximise the efficiency and safety of health services they govern, reducing direct or indirect costs through payer organisations.
- Environmental impacts: EHRxF wider adoption may reduce the need for large amounts of paper print-outs (e.g. laboratory results or hospital discharge reports), particularly as often patients are given these forms of health data supports as no other forms of communication with HCP exist (especially in Cross-border contexts).

Economic impacts:

- Health / ICT Industry: Better defined interoperability services, backed by harmonised assets, will lower the cost of standards adoption and of opening up standardised interfaces to a plug and play market. Interoperable component-based health ICT architectures and products are vital to stimulate the market, stimulate competitiveness, and enable innovation especially amongst SMEs. This is also essential in new ICT areas (e.g., personalised care, personal health systems and wellness), which have so far proved sluggish despite huge potential.
- SDOs: Standards will be more richly used, and many more will be needed. SDOs will demonstrate why standards need financial investment to improve productivity and quality, and how they can provide better support to standards adopters. SDOs will have greater clarity in how to work better together and produce better harmonised standards.

Scientific Impacts:

- Research: (big data) Research, especially population research such as epidemiology, will thrive as more and more patient level data resources can become integrated, and robustly de-identified.

- Open science and citizen participation in S&T development is poorly researched, XpanDH will create tools and contexts for original research on how patients and professionals can act as digital health co-creators.
- Research communities: IT and IT adoption research communities will thrive on the existence of a new EU common context of health IT usage, assuming the EEHRxF, and its adoption, as an object of research in itself.

2.1.2 Requirements and Potential Barriers for impact achievement

One of the main challenges of XpanDH will be to deal with the continuously changing EEHRxF landscape, and the legal heterogeneity of health data and digital health services regulation under the auspices of MS. Countries are in different levels of progression, and the context is changing constantly, namely at the level of legal domains, with different projects going on and new elements (such as changes in semantic agreements or results from projects seeking to promote interoperability) entering the landscape. Although engaging on local level through the Experimentation Bubbles (WP4), the project will invest the necessary efforts to follow closely the national landscapes, to capture the national EEHRxF priorities and maturities, and to interact and collect feedback at regional and national levels, namely through the Policy Board, that will expectedly involve representatives from all MS (Task 1.6). WP1 will ensure the awareness raising of Policy Makers in what respects the needs for health data interoperability. WP3 will ensure the EEHRxF readiness models (Task 3.1) have the necessary flexibility to accommodate the heterogeneity of organisations and MS, and appropriate advice and tools will be given to organisations with different maturity levels and integrated in different (legal) contexts (Task 3.3). With the Data Governance Act (DGA), we expect an increased trust in data sharing and the creation of new EU rules on the neutrality of data marketplaces, which will expectably facilitate the secondary use of certain data held by the public sector[26], such as health data. We expect the adoption of the Health Data Space Regulation to be adopted during the early part of the CSA. XpanDH foresees links with those new legislative frameworks at in more than one way. Feasibility (WP4) is partly related to use EHRxF for secondary use of administrative as well as clinically relevant data. In WP2, we will explore how the EEHRxF relates and could contribute to processes of EHR quality labelling that are envisioned in the EHDS regulation proposal (T2.3). This task is also how XpanDH partially deals with legal heterogeneity and the changing regulatory landscape to ensure the highest impact and usage of the EHRxF.

2.1.3 Scale

The **potential for scalability of the XpanDH project** relies predominantly on outreach efforts and ten sustainable X-Nets that will be enlarged throughout the project, even before its official start, and foreseen to continue after its completion. One of the selected starting points will be the experimentation bubble involving the partners that have inherent demonstration capabilities, concrete engagement with developers, patients, and professionals, so that feasibility is made tangible in concrete adoption domains. However, scalability depends on ensuring that the hundreds of X-Net partners are capable of being inspired and motivated to invest their own efforts and strategy to use the EHRxF in the same or similar adoption domains, creating an ever-expanding network of adopter networks.

2.2 Measures to maximise impact

XpanDH is a multi-stakeholder project that requires collective, coherent, and consistent mass action, from the very beginning of the project. Thus, communication and dissemination activities will include identifying trade-offs to better engage all stakeholders and support project activities, particularly those in WP5, WP6 and WP7.

2.2.1 Targeted stakeholders

The Figure below captures the target groups - and the segments within them - relevant to achieve and diffuse the ambition of XpanDH. Understanding these profiles in the value chain is essential for the desired impact. The project will focus points for communications and dissemination activities on the basis of the ever-changing needs of the project, and deliver the message aligned with the needs of the specific target group.

[26] https://www.europarl.europa.eu/news/pt/press-room/20220401IPR26534/data-governance-parliament-approves-new-rules-boosting-intra-eu-data-sharing

TARGET GROUP	SEGMENTS	
Policy makers	● European Commission ● Regulators	● Member States ● Regional governments ● Health authorities
DG CONNECT, DG SANTE, DG RTD, members of a government (national, regional) department, legislature, or other organisations responsible for making new policies and for promoting strategies for effective and sustainable digital transformation in the healthcare sector. They will be engaged in the project to foster Digital Health innovation that harbours interoperability (through the EEHRxF) at its core and to generate the synergies around the developments of the EHDS. Their increased understanding of the policy and practical implementation of EEHRxF will be crucial for future success of the EHDS.		
Healthcare-related organisations	● Hospitals management ● Professionals and associations ● Public health organisations	● Healthcare service providers ● Patient and caregivers organisations ● Healthcare workforce unions
Health systems' organisations and professionals will ultimately be the EEHRxF users on a daily basis and depend on the improved data interoperability for the efficiency of prevention, diagnostics and treatments. Unions and professional organisations are also targeted as they might be interested in the skilling, reskilling and upskilling of the health professionals to be fit for the digital transformation. Representatives from the health sector are extremely relevant when it comes to 1) obtaining requirements and feedback to support implementation, 2) developing X-Bundles, and 3) "3Cs-3Ps community".		
Payers	● Insurance companies ● Public Insurance funds	● Funding organisations ● Public Funding Payers (Regional or National)
Organisations responsible for financing the prevention, diagnostic and treatment on the regional and national level. Their involvement in the project, participation in the capacity building process, understanding the opportunities related to the improved data interoperability and wide adoption of the EEHRxF should generate the support to the EEHRxF and accelerate its implementation. Their involvement in the study of the economic and focused benefits of the EEHRxF per adoption domain may be very relevant. This category will be engaged in the project mainly through WP5 and in the X-Nets.		
Tech providers & academia	● Tech SMEs/ startups ● Spin-offs & RTOs ● Large Tech and Pharma Industry	● Privacy, security, legal agencies ● Standardisation bodies ● Academic communities and Researchers
Organisations involved in technology innovation, research contributions or business activities highly relevant to the application of digital health technologies in the healthcare value chain but also technology providers, and especially active partners engaged in finding resources and creating joint services based on the EEHRxF. Their involvement will be particularly relevant for scale up and generating pan-European impact, through improved capacity. They will take part in co-defining X-Bundle readiness models for the use of EEHRxF and will be engaged through WP5 ecosystem maturation activities.		
Society as a whole	● Citizens (Society as a whole) ● Patients /Patient Associations ● Advocacy organisations	● Informal healthcare providers ● Non-specialised media
XPanDH will encourage a common understanding of the benefits of EEHRxF, of data interoperability, data access, control and sharing for better health among the general public and patients, promoting Health Data Activism. They will be engaged through the Policy and external Advisory Boards (WP1), but specially via the X-Nets to become informal EEHRxF ambassadors		

Figure 3 - XpanDH targeted Stakeholders

2.2.2 Communication and Dissemination (CD) Plan

The CD Plan of activities will involve specific measures aimed at ensuring that the project and its outputs reach the most appropriate audiences for expected outcomes. A well-defined set of channels, tactics and KPIs will allow the consortium to execute actions effectively; monitor performance of such efforts; and refine or pivot approaches accordingly to build upon learnings and deliver even greater impact. Finally, in anticipation of potential future gaps in resources, timing or knowledge, the CD will include coordinating with external stakeholders (e.g., regulatory bodies or policymakers); projects/initiatives and events to leverage synergies and engagement/outreach.

4 PRIMARY STAGES OF D&C JOURNEY FOR AFOREMENTIONED STAKEHOLDERS **APPROACH: Description (incl. KPIs, if relevant)**
I - Awareness Stakeholders realise there is a problem or need and are open to a solution (EEHRxF and XpanDH activities). At the project start, we will perform research and search queries to increase our understanding and further definition.
1. **BRANDING**: Conceptualise and develop the project's visual identity that would serve to present the tenets of the project to the public whilst promoting first-touch contact with potential stakeholders 2. **WEBSITE**: Create the leading resource to promote project activities and outputs to all target audiences. First version will be ready by M3-4 and will undergo regular maintenance/updates. It will showcase the project's main characteristics and will integrate Google Analytics tracking for performance monitoring purposes. 3. **BLOG POSTS**: Streamlined content strategy that includes blog tidbits (monthly)—e.g., SME Highlight of The Week—and topic-focused blog posts (every 2 months)—e.g., Top 3 Challenges in Health Interoperability

4. **SOCIAL MEDIA (SoMe):** Build and expand Twitter and LinkedIn presence with targeted growth by approximately 15% per year; will leverage consortium SoMe reach (e.g., UiO (28.9K followers), ECHA (5.9K followers) and EHMA (4.4K followers). 5. **PRESS RELEASE**: Launched once a year (and additional, if necessary) to announce major project advances. Maximise use of partners' in-house communications channels to share press releases. 6. **WIKIPEDIA**: Publish and update the XpanDH Wikipedia page.
II Consideration Stakeholders have now clearly defined their need and are deciding whether to commit and engage with the solution. They are determining whether this solution will most likely fulfil their needs.
1. **WEBINARS & PODCASTS**: quarterly webinar recordings that invite 3 expert panellists to discuss and present on a topic related to interoperability (content will vary according to the targeted stakeholder's perspective and needs). Webinar discussions will be released as Podcasts. 2. **INFOGRAPHICS**: Prepare 1 eye-catching infographic per year to highlight either outputs or challenges being addressed 3. **OUTREACH EVENTS**: workshop and sessions organised in international event to enable a direct line of communication between the Consortium members and the relevant stakeholders 4. **PARTICIPATION IN THEMATIC INNOVATION ECOSYSTEMS**: ECHA (WP7 lead) will engage XpanDH in thematic innovation ecosystems (TIEs) for a global audience, to promote strong cross-border, multi-stakeholder collaborations.
III Decision Stakeholders have reached a point at which they will choose to engage and are grasping the unique value proposition to justify and support their decision to contribute to the project (e.g., even uptake outputs).
1. **EVENTS**: Participate and disseminate outputs at pre-selected strategic events (≥4 per year) including Digital Health Society, Digital Health Observatory, Medical Informatics Europe Conference, HL7 Connectathons, IHE Europe Connectathon, HIMSS events, EuroScience Open Forum (ESOF), etc. 2. **WORKSHOPS**: Organise a second (Outreach) workshop during a relevant international event to enable a direct communication between the XpanDH partners and the relevant stakeholders 3. **COLLABORATION WITH PROJECTS /INITIATIVES** - that are relevant, including Gravitate Health, X-eHealth, Smart4Health, DARWIN, InteropEHRate, Procure4Health, EHDEN, EUCanImagine, INTERVENE, Thematic Innovation Ecosystems; etc. 4. **EVANGELICAL EMAIL CAMPAIGNS**: Share specific outputs to targeted stakeholders in synopsis format that drive how such results provide a competitive advantage. 5. **SCIENTIFIC PUBLICATIONS**: will follow FAIR and Open-access best practices to disseminate scientific publications in peer-reviewed journals and "grey" (non-indexed) alliteration. 6. **QR CODE**: to direct to the website with relevant information, easily accessible by a mobile device 7. **POLICY BRIEFS**: prepared with concise information summaries to inform and support decision-making.
IV Loyalty Stakeholders have made their decision to engage with XpanDH, are interested in continually gaining more value from the project and hold the potential to become advocates.

Figure 4 – Preliminary XpanDH Dissemination and Communication Plan

2.2.3 Exploitation Plan, Sustainability and IPR management

To ensure the project achieves its maximum potential and impact, and its results are used within and beyond XpanDH, a **lean Exploitation Plan will be devised under WP6 (T6.1)**. The **main exploitable and sustainable results of the project will be well formulated definitions of interoperability adoption domains, an inventory of the corresponding interoperability assets needed to support the exchange of information, along with the specification of profiles, FHIR resources, value lists, licence requirements and any data protection impact analysis that applies**. The asset bundle will also include guidance for procurement officers so that the intact asset bundle can be specified and delivered through the procurement contract. There will also be guidance for single and multi-organisational change that may be needed to supply good quality data to be communicated and to benefit well from data that is received through interoperability interfaces. Finally, there may be educational resources that help inform different stakeholders about the benefits case and healthy economic value of implementing interoperability for each adoption domain. The value of the asset bundle is in its holistic coverage of many stakeholder needs, specifications, and actions. The individual ingredients within the asset bundles will usually not be the property of this consortium. It is more likely that the ingredients will be the intellectual property (and might need to be licensed from) different SDO organisations or other resource developers. The asset bundles are therefore not appropriate for any kind of direct commercial exploitation. **The exploitation strategy for the project lies in promoting their value and attracting support for their maintenance and expansion**. The asset bundles will need to be maintained over time, as standards become updated, new terminology value lists are composed, and to meet evolving requirements in each domain, which might require additional data items to be added, or new business case arguments to be incorporated. It is therefore intended that the project will nominate a primary sustaining entity to look after these above concerns and take ownership of the asset bundle specifications (even if most of the assets bundle contents remain under SDO ownership). It is currently envisaged that one of several partners in the

consortium would take on this responsibility. A further exploitation goal will be to attract future funding for further adoption domains that have been identified through Task 6.2 as having health outcome, health system and/or health economic priority. A business case will need to be made for each proposed new adoption domain, after the project, and a funded work plan will then need to be orchestrated. Industry related and SME partners such as Gnomon, EMPIRICA, Digital Europe and IHE-EUR will be supporting the preparation of business cases and identification of exploitation opportunities

Knowledge Management and Protection: The D&C strategy during and beyond the project was designed to ensure transparent access to information, while respecting all confidentiality and intellectual property rights (IPR) management issues. The IPR management will be set primarily by the **Consortium Agreement (CA)** to be signed before project start, drawn on the updated DESCA 2020 model agreement. Each partner is primarily responsible for taking the appropriate steps for securing IP of the knowledge or results created during the project. Project IPR management will be covered in Task 6.1. As mentioned, all non-commercial results will be widely disseminated via open access peer-reviewed scientific publications upon permission to publish by the partners involved in the knowledge creation. The same will take place for exploitable results after adequate protection has been ensured.

KEY ELEMENTS OF THE IMPACT SECTION

SPECIFIC NEEDS	EXPECTED RESULTS	OUTCOMES	D&E&C MEASURES	TARGET GROUPS	IMPACTS (EEHRxF)
- Manage increasingly complex clinical care - Connect care teams and multiple locations of care delivery - Deliver evidence-based health care and improve safety by reducing duplication, delay, errors and inequalities - Measure and optimise health outcomes - Improve cost effectiveness and health services values - Capture /combine computable evidence for public health strategies - Enrich population health mgt. and prevention - Empower and involve citizens - Improve the efficiency and speed of clinical trials through reusing networks of interoperable EHRs; - Better inform and enable bio-science (big data) research	**A Matured, sustainable and scalable interoperability environment** in Europe **for digital health innovations based on the EEHRxF, involving supply and demand sides of healthcare (HC) provision.** - Robust technical specifications and resources for the EEHRxF - X-Bundle Readiness model, and educational materials (ICT toolkit) for the relevant parties - Feasibility and usefulness of the X-Bundle demonstrated in real-world experiments -pan-European digital health ecosystem that adopts the EEHRxF as a common feature - Framework for Sustainable EEHRxF ecosystem maintenance and development	By 2028, XpanDH expects to have contributed to: - Improved and Interoperable cross boarder digital health solutions - Accessibility and control health data - Evidence based healthcare - Lower cost of standards adoption - Improved datasets for the academic community - Better informed policy and decision makers - More engaged and empowered citizens - Supporting capacity building	**D&C JOURNEY for 4 target groups, with personalised messages and bi-communication channels:** **I – Awareness** - Branding (visual identity) - Website - Blog posts - Social Media - Press release - WKIPEDIA page **II - CONSIDERATION** Webinars & Podcasts, Infographics, Outreach Workshop thematic innovation ecosystems **III – DECISION** Events, Workshops Collaboration with Projects /Initiatives Email Campaigns Scientific papers, QR Code, Policy Briefs **IV – LOYALTY** Ambassadors, and Final Conference	**-Policy makers**: EC, Regulators, MS, Regional governments, Health authorities **-Healthcare-related organisations**: Hospitals management; professionals & d associations, Public health org, HCP, Patient/caregivers organisations, HC workforce unions **Payers**: Insurance companies, Public Insurance funds, Funding organisations, Public Funding Payers **- Tech providers & academia**: SMEs/ start-ups, Spin-offs & RTOs, Large Tech and Pharma Industry, Privacy, security, legal agencies, SDOs, Academic org. and Researchers **-Citizens (Society as a whole):** Patients /Patient Associations, Advocacy organisations, media.	**Societal impacts**: 1) **For & with Citizens and HC professionals**: safer, low error, higher quality and better evidence-based care (3Cs-3Ps communities), by access to more complete EHRs, 2) **For HCP organisations: Health authorities/payers**: patient-sensitive outcomes-based reimbursements, enabling payers to accurately compare performance, outcomes and safety. **3) For MS**: Better information to support strategic decisions. **- Environmental impacts**: reduced need for large amounts of paper print-outs. **Economic impacts**: i) for Health / ICT Industry: Better defined interoperable services, backed by harmonised assets, lowering the cost of standards adoption ii) Standards will be more richly used, and many more will be needed.; iii) SDOs will have greater clarity in how to work better together and produce better harmonised standards. **Scientific Impacts**: benefits from integrated datasets (big data); Research will thrive; Increased research about open science and participatory research. XpanDH will create tools and contexts for original analysis of how patients and professionals can act as digital health co-creators.

3. Quality and efficiency of the implementation

3.1 Work plan and resources

The XpanDH work plan covers its 2-year duration and is structured in **7 interconnected WP** and 24 tasks, as depicted in the Pert Diagram (Figure 4) and Gantt Chart (Figure 5), to meet its objectives in a lean, effective and efficient way. A description of the project management structure is presented in Table 3.1 (WP1) and includes an Advisory Board (AB) which will involve between 11 and 13 organisations and individuals to be invited (e.g., COCIR, EFA-European Federation of Allergy and Airways Diseases, Sara Riggare, Jacqueline Bowman). This AB will include a subgroup of advisors who will also be called to provide ethical advice and chosen according to that capacity and the adoption domains to be finally defined in the early stages of the project.

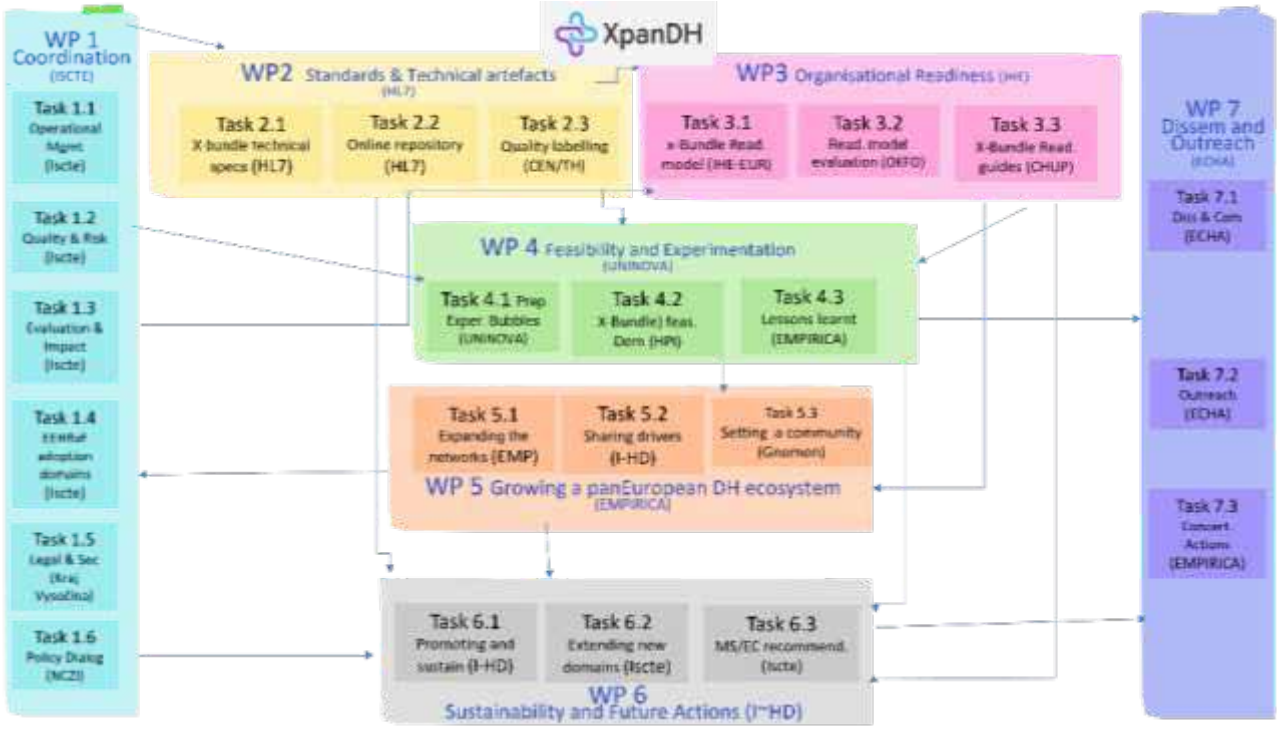


Figure 4 - XpanDH Pert Diagram (HPI was replaced replaced by Uninova, KV was replaced by Iscte)

X-panDH Consortium	Lead	Year 2															
		Q1		Q2		Q3		Q4		Q5		Q6		Q7		Q8	
WP1- Coordination	**ISCTE**																
Task 1.1 - Administrative and operational management	Iscte	MS1	D1.1.1						D1.1.2								D1.1.2
Task 1.2 - Quality Assurance, Risk management and Contingency	Iscte				D1.2				MS3						MS3		
Task 1.3 – Project evaluation and Impact Assessment	Iscte									D1.3							D1.3
Task 1.4 – Definition of EEHRxF adoption domains	Iscte			D1.4								D1.4					
Task 1.5 – Legal, Ethical, Cyber Security Issues	KV			D1.5.1													D1.5.1
Task 1.6 – Policy Dialogue	NCZI			D1.5.2										D1.5.2			
WP2 – Standards & Tecnhical artefacts	**HL7**																
Task 2.1 - X-bundle technical specs based on HL7 FHIR REST API for EHRxF	HL7				MS4		D2.1										
Task 2.2 -Creation of an only resource to harbour X-bundle assets, success stories, and online EEHRxF co-cr	HL7								D2.2								D2.2
Task 2.3 -Technical requirements for quality labelling of consumer health products and EHR systems	CEN/TH							MS6	D2.3	MS6		D2.3					
WP3 – Organizational Readiness	**IHE**																
Task 3.1: Define the x-Bundle Readiness model	IHE						D3.1.1					MS10	D3.1.2				
Task 3.2: Develop the readiness model evaluation process	OKFO									D3.2.1							
Task 3.3: X-Bundle Readiness steppingstone guides and capacitation	CHUP								D3.3	D3.2.2							D3.3
WP4 – Feasibility and Experimentation	**UNINOVA**																
Task 4.1 - Preparing the experimentation bubbles	UNINOVA				D4.1.1				D4.1.2					D4.1.2			
Task 4.2 - EHRxF-based infrastructure (X-Bundle) feasibility demonstration	UNINOVA				MS7			D4.2						D4.2			D4.3
Task 4.3 - Integrate lessons learnt from feasibility and experimentation	EMPIRICA																MS8
WP5 – Growing a panEuropean DH ecosystem	**EMPIRICA**																
Task 5.1 - Expanding the networks around XpanDH adoption domains and beyond	EMPIRICA												D5.1				
Task 5.2 - Sharing drivers and benefits of interoperability	IHD												D5.2				
Task 5.3 - Setting up a community of doers and co-creators	Gnomon								MS9								D5.3
WP6 – Conceptualizing further exploitation	**I-HD**																
Task 6.1 Promoting and sustaining the X-PanDH Asset Bundle	I-HD												D6.1.1				D6.1.2
Task 6.2 - EEHRxF new adoption domains: consumer use cases for remote visit, telehealth, and telemonito	Iscte											MS10					D6.2
Task 6.3 - Recommendations to Member States and the European Commission	NICTIZ												MS11				D6.3
WP7 – Dissemination and Outreach	**ECHA**																
Task 7.1 - Communication and Dissemination	ECHA	MS2		D7.1					D7.1								
Task 7.2 - Outreach and Stakeholder Engagement	ECHA								D7.2								D7.2
Task 7.3 - Concertation Activities	EMPIRICA								D7.3								D7.3

Figure 5 – XpanDH Gantt Chart

Table 3.1h:

'Purchase costs' items (travel and subsistence, and goods & services - other goods and services)

P1- Iscte	Cost (€)	Justification
Travel and subsistence	12350	- Costs for the participation of 2 Iscte's representatives in 2 consortium meetings (1 per year), for 7 participants attending the WP Leaders meetings, 4 participations in WP coordination meetings, and for the participation of the Coordinator in 4 relevant representation events. The average travel cost considered for each trip is 650€ (including subsistence and accommodation).
Other goods, works and service	9000	- 5000€ for two publications in open access journals. - 2000€ conference fees, - 2000€ costs for the organisation of the final XpanDH conference and Policy Dialogues, organised back to back with relevant meetings as much as possible (catering, renting of rooms, IT and media support)
Total	21350	

P2 - ECHA	Cost (€)	Justification
Travel and subsistence	2600	- Costs associated with travelling and subsistence of 4 participants for 1 WP coordination meeting. The average travel cost considered for each trip is 650€ (including subsistence and accommodation).
Other goods, works and services	22000	- Costs associated with conference fees (2000€) - Costs related with the creation of visual identity and communication materials of the project, printing of material to be produced in T7.1 and T7.2 -WP7 (15000€) - Costs for the organisation of two dissemination events (5000€ for renting and catering)
Total	24600	

P3 - HOPE	Cost (€)	Justification
Travel and subsistence	1950	- Covers the associated costs with travelling and subsistence of 3 participants for one WP coordination meeting. The average travel cost considered for each trip is 650€ (including subsistence and accommodation).
Total	1950	

P6 - EMPIRICA	Cost (€)	Justification
Travel and subsistence	13650	- Costs related with travelling and accommodation for representatives from 6 partners to attend WP coordination meetings (3900€) - Costs to support the attendance of 15 participants in *in person* workshops (9750€) including online participations. The average travel cost considered for each trip is 650€ (including subsistence and accommodation).
Other goods, works and services	10500	- Costs for conference fees (3000€) and the organisation of WP5 meetings (7500€, renting and catering)
Total	24150	

P10 - UNINNOVA	Cost (€)	Justification
Travel and subsistence	15600	- Costs related to travelling and accommodation of 6 members from partners to WP coordination meetings (3900€)

		- Costs associated with in person attendance of 18 participations to the WP4 Workshops - bubbles (11700€). The average travel cost considered for each trip is 650€ (including subsistence and accommodation).
Other goods, works and services	16000	- Costs related to the organisation of the coordination Workshop for WP3 and WP4 (3000€, for catering and renting) - Costs for conference fees (3000€) - Costs for the organisation of the experimentation bubbles Workshops, foreseen in WP4 with around 80-120 participants (10000€).
Total	31600	

P-12 IHE-EUR	**Cost (€)**	**Justification**
Travel and subsistence	9750	- Costs related to travelling and accommodation for 15 participants to attend WP3 Event (9750€). The average travel cost considered for each trip is 650€ (including subsistence and accommodation).
Other goods, works and services	10000	- Covers costs for the organisation of 2 WP2-WP3 coordination Workshops (7000€, 1st and 3rd semesters) and - Costs for conference fees (3000€)
Total	19750	
P-15 Scuba	**Cost (€)**	**Justification**
Travel and subsistence	2600	Covers the associated costs with travelling and subsistence of 4 participants for WP coordination meeting. The average travel cost considered for each trip is 650€ (including subsistence and accommodation).
Total	2600	
P-20 TechForLife	**Cost (€)**	**Justification**
Travel and subsistence	2600	Covers the associated costs with travelling and subsistence of 4 participants for WP coordination meetings. The average travel cost considered for each trip is 650€ (including subsistence and accommodation).
Total	2600	

Table 3.1j: 'In-kind contributions' provided by third parties

Participant Number/Short Name			
Third party name	**Category**	**Cost (€)**	**Justification**
Iscte-Instituto Universitário de Lisboa (PIC 998622567)	Seconded personnel	78 552,60	Iscte-Instituto Universitário de Lisboa is a third party giving in-kind contributions for free to the action (Article 9.2). These contributions will be in the form of human resources (13.40 PM) to the coordinator entity (P1) for the implementation of the project activities. This staff will be involved in all 7 WPs, leading WP1 and Tasks: 1.1, 1.2,1.3, 1.4, 6.2, 6.3

3.2 Capacity of participants and consortium as a whole

XpanDH coordinator (Prof. Henrique Martins, past Co-chair of the eHealth Network and past eHAction Coordinator, Iscte) set up a competitive horizontal and cross-capabilities consortium to really create a **large ecosystem for fostering, and above all, supporting the use of the EEHRxF in creating more interoperable eHealth in Europe.** The XpanDH consortium can be distinguished as a Consortium of **excellence and complementarity for EEHRxF**

deployment, aggregating a diversity of complementary technical and social skills and competences in eHealth and innovation. Ranging from interoperability experts, clinicians, technology developers, digital health organisations, to managers, and (professionals and patient) end-users, the partners, strongly committed to the XpanDH proposal, were involved based on their extensive **knowledge on interoperability and cross and intra-border health data exchange**, capacity to provide expertise in **the critical areas of the proposal,** and engagement in testing the feasibility of EEHRxF concrete use and seeding a thriving pan-European Ecosystem.

The **XpanDH consortium involves 26 partners, covering different types of organisations representative of the necessary EEHRxF diversity**. All XpanDH participants are internationally recognized leaders in their fields, and in digital transformation, and will bring to the project the necessary knowhow and experience, network interactions and stakeholders to foster and nurture the EEHRxF ecosystem and successfully deliver the XpanDH project: **Establishment of ecosystems and networks around digital society** (Iscte, ECHA, TechForLife, Digital Europe, EMPIRICA, HOPE, EHMA, UNEW, IHE-EUR, NICTIZ, UNINOVA, OKFO); **eHealth interoperability** (Iscte, EMPIRICA, Gnomon, I~HD, IHE-EUR, HL7, CHUP; ARIA, OKFO); **Development of interoperability asset tools**, **information and capacity building actions for HCP, professionals and patients/citizens** (EMPIRICA, I~HD, HL7, Gnomon, IHE-EUR, UiO); **Consolidation of Health interoperability standards** (HL7, CEN/TH, I~HD, UiO. IHE-EUR, TechForLife); **Development of technical artefacts for European level interoperability projects** (UNINOVA, HL7, Gnomon, UiO, IHE-EUR); **Design of community interventions, stakeholder and user engagement, co-creation citizen science for novel digital health services for patients and citizens** (EDHA, UiO, EMPIRICA, Iscte, Gnomon. I~HD, ECPC, SU); **Cyber security and legal** (I~HD, SU); **Cross and intra-border health data sharing services** (Gnomon, KETEKNY, SCUBA; NCZI, OKFO, CHUP, ASUFC); **Consideration of healthcare provider's needs, priorities and preferences regarding EEHRxF** (CHUP, EHMA, HOPE, KETEKNY, IHE-EUR, UNEW); **Impleme'ntation of EEHRxF use cases feasibility experiments** (UNINOVA, CHUP, KETEKNY, OKFO, ASUFC, etc.); **Liaison with National and Regional Governments, Policy and Decision Makers** (NCZI, NICTIZ, KETEKNY, OKFO, ARIA, Gnomon, SCUBA); **Liaison with digital transforming industry** (Digital Europe, IHE-EU, TechForLife) and international SDOs (NCZI - SNOMED International); **Establishment of sustainability and exploitation strategies, namely value from investments in interoperability** (I~HD, EMPIRICA, Iscte); **Preparation of Policy Recommendations** (Iscte, UNEW, ECHA, EMPIRICA, NICTIZ, NCZI, KETEKNY, OKFO, ARIA, Gnomon, ECPC, SU); **Engagement in outreach and dissemination** (ECHA, HOPE, Digital Europe, EHMA, EMPIRICA, ECPC, SU).

Almost all partners were previously involved in competitive and successful European and international projects and networks in eHealth, and WP leaders roles were assigned according to their experience in coordination relevant EU projects and initiatives (all XpanDH WP leaders have been successful EU coordinators): **X-eHealth (H2020):** ARIA, CEN/TH, HL7, IHE-EUR, NCZI, Nictiz, ECHA, SU, OKFO; **SMART4HEALTH (H2020**): **UNINOVA (XpanDH WP4 Lead), UNICOM (H2020)**: **EMPIRICA (coordinator, WP5 Lead)**, ARIA, CEN/TH, IHD, NICTIZ, Gnomon, HL7, IHE-EUR; **Trillium Bridge (H2020):** HL7 (Scientific **coordinator, XpanDH WP2 lead**), IHE-EUR, CEN/TH, I~HD, EMPIRICA, Gnomon, ECHA, ARIA (via LISPA previous designation); **Gravitate-Health (IMI2):** UiO, ECHA, HL7, EMPIRICA; **Antilope (CIP, IST-CSP):** IHE-EUR (**XpanDH WP3 Lead**), NICTIZ, CEN/TH, HL7, NCZI; **VALUeHEALTH (FP7):** I~HD (**coordinator**, **XpanDH WP6 Lead**), EMPIRICA; **DigitalHealthEurope (H2020 CSA)**: EMPIRICA (coordinator, XpanDH WP5 Lead), ECHA; **epSOS 1 and 2:** European Patient Smart Open Services: EMPIRICA, NCZI, ARIA, IHE-EUR, Gnomon, OKFO; **EU Joint Action TEHDAS:** I~HD, Digital Europe, ASUFC, ECHA, HL7, HOPE, OKFO, SU; **European mhealth HUB (H2020):** I~HD, HL7, EMPIRICA; **eHDSI** (eHealth Digital Service Infrastructure): ARIA, Gnomon, NCZI, **EUROCAS** (CEF): IHE-EUR; NICTIZ, Hope; **eStandards:** HL7, IHE-EUR; Hope, **CanCon Cancer Control Joint Action** (ECPC), EHMA.

As demonstrated above, almost all partners have jointly collaborated in several of the most relevant EU projects in the areas of eHealth and interoperability, but a few are new to this and coming from concrete HCP settings (CHUP or SCUBA) to ensure new ideas and critical thinking emerges. Through the involvement in projects and networks, such as the above, the partners will be able to engage an ecosystem of more than 15 stakeholder organisations in the 27 MSs and Observer countries. Several of the partners are strongly engaged in helping to build the European Health Data Space and will also ensure the appropriate bridge with the technical and semantic subgroups of the **eHealth Network** (ARIA; NCZI), **SNOMED International** (e.g., NCZI), and links with the **eHealth Stakeholder Group** that provides advice and expertise to the EC on its strategic initiatives and achievements (I~HD, HL7, ECHA). Finally, the PC will also capitalise his involvement as AB Member for the Smart & Healthy Ageing through People Engaging in Supportive Systems (**SHAPES**) Innovation Action, **ROSIA project,** and in **ICPerMed**.

Ethical dimension of the objectives, methodology and likely impact
The advisory board will have a subgroup of advisors who also will be called to provide ethical advice and chosen according to that capacity and the adoption domains to be determined in the early stages of the project. XpanDH is not envisioned to process sensitive clinical personal data asa project, but its partners may engage in data exchange processes between themselves that include health data, hence, sensitive personal data, such will be dealt according to the ethic sand legal rules of each partner/participating institution jurisdictions. If an overall appreciation of ethical and data processing issues may be required that will be dealt on a case by case analysis, involving the ethical subgroup of the advisory board, WP1 and eventually DPOs from participating institutions. Administrative data, including personal contact information and similar data (e.g. TCON recordings etc etc) will be processed and taken care of by the Coordinator according to legal requirements and that will be included in the project handbook for similar and homogeneous approaches by WP and Task leaders. The principles of minimization and legality will help decide any unforeseen situations Data that might eventually be collected from partners will follow all the national and international regulations regarding data privacy and informed consent. All data collected from these databases are anonymized, and XpanDH partners will not have access or handle personal data. All data will be securely stored in the Coordinator Iscte'sservers, and its use will comply with the General Data Protection Regulation (GDPR).

Compliance with ethical principles and relevant legislations
Every XpanDH partner will agree to follow all relevant national and EU legislation relating to the conduct of working with data. When necessary, each partner will gather approvals from theEthics Advisory Board and comply with the related European guidelines. Upon signing the Grant Agreement prior to the start of XpanDH, each partner will ensure it is compliant with any applicable national and international legislation outlined in the GA. The project will adopt the best practices according to the European and national laws for the collection, processing, handling or communication of personal or sensitive information, strictly following: ● Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons concerning the processing of personal data and the free movement of such data (GDPR), and its transposition to the Portuguese law. ● European Convention of Human Rights, the rules of the Convention of the Council of Europe for the protection of individuals concerning the automatic processing of personal data and especially the European Directive 95/46/EC, for personal data protection. ● The Universal Declaration of Human Rights and the Convention 108 for the Protection of Individuals about Automatic Processing of Personal Data. ● Directive 95/46/EC & Directive 2002/58/EC of the European Parliament regarding issues with privacy and protection of personal data and the free movement of such data. ● The Charter of Fundamental Rights of the EU. ● Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009 amending Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services.

ANNEX 2

ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)										Estimated EU contribution[2]			
	Direct costs								Indirect costs	Total costs	EU contribution to eligible costs			Maximum grant amount[6]
	A. Personnel costs			B. Subcontracting costs	C. Purchase costs			D. Other cost categories	E. Indirect costs[3]		Funding rate %[4]	Maximum EU contribution[5]	Requested EU contribution	
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners and natural person beneficiaries	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services	D.2 Internally invoiced goods and services	E. Indirect costs					
Forms of funding	Actual costs	Unit costs (usual accounting practices)	Unit costs[7]	Actual costs	Actual costs	Actual costs	Actual costs	Unit costs (usual accounting practices)	Flat-rate costs[8]					
	a1	a2	a3	b	c1	c2	c3	d2	e = 0,25 * (a1 + a2 + a3 + c1 + c2 + c3)	f = a + b + c + d + e	U	g = f * U%	h	m
1 - Iscte	133 191.00	0.00	0.00	0.00	12 350.00	0.00	9 000.00	0.00	38 635.25	193 176.25	100	193 176.25	193 176.25	193 176.25
2 - ECHA	91 732.00	0.00	0.00	0.00	2 600.00	0.00	22 000.00	0.00	29 083.00	145 415.00	100	145 415.00	145 415.00	145 415.00
3 - HOPE	9 450.00	0.00	0.00	0.00	1 950.00	0.00	0.00	0.00	2 850.00	14 250.00	100	14 250.00	14 250.00	14 250.00
4 - HL7	140 535.00	0.00	0.00	0.00	11 700.00	0.00	6 000.00	0.00	39 558.75	197 793.75	100	197 793.75	197 793.75	197 793.75
5 - Gnomon	54 900.00	0.00	0.00	0.00	2 600.00	0.00	0.00	0.00	14 375.00	71 875.00	100	71 875.00	71 875.00	71 875.00
6 - EMPIRICA	117 990.00	0.00	0.00	0.00	13 650.00	0.00	10 500.00	0.00	35 535.00	177 675.00	100	177 675.00	177 675.00	177 675.00
7 - CHUPorto	45 225.00	0.00	0.00	0.00	2 600.00	0.00	0.00	0.00	11 956.25	59 781.25	100	59 781.25	59 781.00	59 781.00
8 - I~HD	96 727.00	0.00	0.00	0.00	6 500.00	0.00	4 000.00	0.00	26 806.75	134 033.75	100	134 033.75	134 033.75	134 033.75
9 - KETEKNY	42 045.00	0.00	0.00	0.00	2 600.00	0.00	0.00	0.00	11 161.25	55 806.25	100	55 806.25	55 806.00	55 806.00
10 - UNINOVA	150 457.00	0.00	0.00	0.00	15 600.00	0.00	16 000.00	0.00	45 514.25	227 571.25	100	227 571.25	227 571.25	227 571.25
11 - NCZI	34 047.00	0.00	0.00	0.00	2 600.00	0.00	0.00	0.00	9 161.75	45 808.75	100	45 808.75	45 808.75	45 808.75
12 - IHE-EUR	116 437.00	0.00	0.00	0.00	9 750.00	0.00	10 000.00	0.00	34 046.75	170 233.75	100	170 233.75	170 233.75	170 233.75
13 - EHMA	21 802.00	0.00	0.00	0.00	1 950.00	0.00	0.00	0.00	5 938.00	29 690.00	100	29 690.00	29 690.00	29 690.00
14 - UiO	47 790.00	0.00	0.00	0.00	2 600.00	0.00	0.00	0.00	12 597.50	62 987.50	100	62 987.50	62 987.50	62 987.50
15 - SCUBA	11 542.00	0.00	0.00	0.00	2 600.00	0.00	0.00	0.00	3 535.50	17 677.50	100	17 677.50	17 677.50	17 677.50
16 - ARIA	42 795.00	0.00	0.00	0.00	2 600.00	0.00	0.00	0.00	11 348.75	56 743.75	100	56 743.75	56 743.75	56 743.75
17 - Digital Europe	25 245.00	0.00	0.00	0.00	1 950.00	0.00	0.00	0.00	6 798.75	33 993.75	100	33 993.75	33 993.75	33 993.75
18 - OKFO	39 150.00	0.00	0.00	0.00	2 600.00	0.00	0.00	0.00	10 437.50	52 187.50	100	52 187.50	52 187.50	52 187.50
19 - TechForLife	15 900.00	0.00	0.00	0.00	2 600.00	0.00	0.00	0.00	4 625.00	23 125.00	100	23 125.00	23 125.00	23 125.00
20 - Nictiz	26 490.00	0.00	0.00	0.00	1 950.00	0.00	0.00	0.00	7 110.00	35 550.00	100	35 550.00	35 500.00	35 500.00
21 - EDHA	28 350.00	0.00	0.00	0.00	2 600.00	0.00	0.00	0.00	7 737.50	38 687.50	100	38 687.50	38 687.50	38 687.50
22 - CEN/TH	45 562.00	0.00	0.00	0.00	1 950.00	0.00	0.00	0.00	11 878.00	59 390.00	100	59 390.00	59 390.00	59 390.00
23 - ASUFC	35 437.00	0.00	0.00	0.00	1 950.00	0.00	0.00	0.00	9 346.75	46 733.75	100	46 733.75	46 733.75	46 733.75
24 - ECPC	15 750.00	0.00	0.00	0.00	1 950.00	0.00	0.00	0.00	4 425.00	22 125.00	100	22 125.00	22 125.00	22 125.00
25 - SU														
26 - UNEW														
Σ consortium	1 388 549.00	0.00	0.00	0.00	111 800.00	0.00	77 500.00	0.00	394 462.25	1 972 311.25		1 972 311.25	1 972 260.75	1 972 260.75

[1] See Article 6 for the eligibility conditions. All amounts must be expressed in EUR (see Article 21 for the conversion rules).
[2] The consortium remains free to decide on a different internal distribution of the EU funding (via the consortium agreement; see Article 7).
[3] Indirect costs already covered by an operating grant (received under any EU funding programme) are ineligible (see Article 6.3). Therefore, a beneficiary/affiliated entity that receives an operating grant during the action duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action. This requires specific accounting tools. Please immediately contact us via the EU Funding & Tenders Portal for details.

[4] See Data Sheet for the funding rate(s).
[5] This is the theoretical amount of the EU contribution to costs, if the reimbursement rate is applied to all the budgeted costs. This theoretical amount is then capped by the 'maximum grant amount'.
[6] The 'maximum grant amount' is the maximum grant amount decided by the EU. It normally corresponds to the requested grant, but may be lower.
[7] See Annex 2a 'Additional information on the estimated budget' for the details (units, cost per unit).
[8] See Data Sheet for the flat-rate.

ANNEX 2a

ADDITIONAL INFORMATION ON UNIT COSTS AND CONTRIBUTIONS

SME owners/natural person beneficiaries without salary (Decision C(2020) 7115[1])

Type: unit costs

Units: days spent working on the action (rounded up or down to the nearest half-day)

Amount per unit (daily rate): calculated according to the following formula:

{EUR 5 080 / 18 days = **282,22**}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

The country-specific correction coefficients used are those set out in the Horizon Europe Work Programme (section Marie Skłodowska-Curie actions) in force at the time of the call (see Portal Reference Documents).

HE and Euratom Research Infrastructure actions[2]

Type: unit costs

Units[3]: see (for each access provider and installation) the unit cost table in Annex 2b

Amount per unit*: see (for each access provider and installation) the unit cost table in Annex 2b

* Amount calculated as follows:

For trans-national access:

$$\frac{\text{average annual total trans-national access costs to the installation (over past two years[4])}}{\text{average annual total quantity of trans-national access to the installation (over past two years[5])}}$$

For virtual access:

$$\frac{\text{total virtual access costs to the installation (over the last year[6])}}{\text{total quantity of virtual access to the installation (over the last year[7])}}$$

Euratom staff mobility costs[8]

Monthly living allowance

Type: unit costs

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1 Commission Decision of 20 October 2020 authorising the use of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary for the work carried out by themselves under an action or work programme (C(2020)7715).

2 Decision of 19 April 2021 authorising the use of unit costs for the costs of providing trans-national and virtual access in Research Infrastructure actions under the Horizon Europe Programme (2021-2027) and the Research and Training Programme of the European Atomic Energy Community (2021-2025).

3 Unit of access (e.g. beam hours, weeks of access, sample analysis) fixed by the access provider in proposal.

4 In exceptional and duly justified cases, the granting authority may agree to a different reference period.

5 In exceptional and duly justified cases, the granting authority may agree to a different reference period.

6 In exceptional and duly justified cases, the granting authority may agree to a different reference period.

7 In exceptional and duly justified cases, the granting authority may agree to a different reference period.

8 Decision of 15 March 2021 authorising the use of unit costs for mobility in co-fund actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025).

Units: months spent by the seconded staff member(s) on research and training in fission and fusion activities (person-month)

Amount per unit*: see (for each beneficiary/affiliated entity and secondment) the unit cost table in Annex 2b

* Amount calculated as follows from 1 January 2021:
{**EUR 4 300** multiplied by
country-specific correction coefficient** of the country where the staff member is seconded}[9]

**Country-specific correction coefficients as from 1 January 2021[10]

EU-Member States[11]

Country / Place	Coefficient (%)
Bulgaria	59,1
Czech Rep.	85,2
Denmark	131,3
Germany Bonn Karlsruhe Munich	101,9 95,8 98 113,9
Estonia	82,3
Ireland	129
Greece	81,4
Spain	94,2
France	120,5
Croatia	75,8
Italy Varese	95 90,7
Cyprus	78,2
Latvia	77,5
Lithuania	76,6
Hungary	71,9
Malta	94,7
Netherlands	113,9
Austria	107,9
Poland	70,9
Portugal	91,1
Romania	66,6
Slovenia	86,1

[9] Unit costs for living allowances are calculated by using a method of calculation similar to that applied for the secondment to the European Commission of seconded national experts (SNEs).

[10] ⚠ For the financial statements, the amount must be adjusted according to the actual place of secondment.
The revised coefficients were adopted in the Decision authorising the use of unit costs for the Fusion Programme co-fund action under the Research and training Programme of the European Atomic Energy Community 2021-2025. They are based on the 2020 Annual update of the remuneration and pensions of the officials and other servants of the European Union and the correction coefficients applied thereto (OJ C 428, 11.12.2020) to ensure purchasing power parity. The revised coefficient are applied as from 1 January 2021 through an amendment to the grant agreement.

[11] No correction coefficient shall be applicable in Belgium and Luxembourg.

Slovakia	80,6
Finland	118,4
Sweden	124,3

Third countries

Country/place	Coefficient (%)
China	82,2
India	72,3
Japan	111,8
Russia	92,7
South Korea	92,3
Switzerland	129.2
Ukraine	82.3
United Kingdom	97.6
United States	101,4 (New-York) 90,5 (Washington)

Mobility allowance

Type: Unit costs

Units: months spent by the seconded staff member(s) on research and training in fission and fusion activities (person-month)

Amount per unit: **EUR 600** per person-month; see (for each beneficiary/affiliated entity and secondment) the unit cost table in Annex 2b

Family allowance

Type: unit costs

Units: months spent by the seconded staff member(s) on research and training in fission and fusion activities (person-month)

Amount per unit: **EUR 660** per person-month; see (for each beneficiary/affiliated entity and secondment) the unit cost table in Annex 2b

Education allowance

Type: Unit costs

Units: months spent by the seconded staff member(s) on research and training in fission and fusion activities (person-month)

Amount per unit*: see (for each beneficiary/affiliated entity and secondment) the unit cost table in Annex 2b

*Amount calculated as follows from 1 January 2021:
{EUR 283.82 x number of dependent children[12]**}**

[12] For the estimated budget (Annex 2): an average should be used. (⚠ For the financial statements, the number of children (and months) must be adjusted according to the actual family status at the moment the secondment starts.)

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ECHALLIANCE COMPANY LIMITED BY GUARANTEE (ECHA), PIC 907578852, established in 13A BALLYHOY AVENUE RAHENY, DUBLIN DUBLIN 5, Ireland,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

FEDERATION EUROPEENNE DES HOPITAUX ET DES SOINS DE SANTE (HOPE), PIC 994557879, established in AVENUE MARNIX 30/17, BRUXELLES 1000, Belgium,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

HL7 INTERNATIONAL FONDATION (HL7), PIC 974224448, established in SQUARE DE MEEUS 38-40, BRUSSELS 1000, Belgium,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

GNOMON PLIROPHORIKIS AE (Gnomon), PIC 991636433, established in ANTONI TRITSI 21, PYLAIA THESSALONIKI 570 01, Greece,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

EMPIRICA GESELLSCHAFT FUR KOMMUNIKATIONS UND TECHNOLOGIEFORSCHUNG MBH (EMPIRICA), PIC 999801990, established in OXFORDSTRASSE 2, BONN 53111, Germany,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

CENTRO HOSPITALAR UNIVERSITARIO DO PORTO EPE (CHUPorto), PIC 950258852, established in LARGO PROFESSOR ABEL SALAZAR, PORTO 4099 001, Portugal,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH DATA (I~HD), PIC 923112723, established in OUDE MECHELSESTRAAT 165, STROMBEEK-BEVER 1853, Belgium,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

KENTRO TEKMIRIOSIS KAI KOSTOLOGISIS NOSOKOMEIAKON YPIRESION ANONYMI ETAIREIA (KETEKNY), PIC 889986641, established in VERANZEROU 13, ATHENS 10438, Greece,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNINOVA-INSTITUTO DE DESENVOLVIMENTO DE NOVAS TECNOLOGIAS-ASSOCIACAO (UNINOVA), PIC 999633889, established in CAMPUS DA CAPARICA QUINTA DA TORRE, CAPARICA 2829-516, Portugal,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

NARODNE CENTRUM ZDRAVOTNICKYCH INFORMACII (NCZI), PIC 998884370, established in LAZARETSKA 26, BRATISLAVA 811 09, Slovakia,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

INTEGRATING THE HEALTHCARE ENTERPRISE-EUROPE AISBL (IHE-EUR), PIC 998727133, established in BOULEVARD AUGUSTE REYERS 80, BRUXELLES 1030, Belgium,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

EUROPEAN HEALTH MANAGEMENT ASSOCIATION (EHMA), PIC 912703944, established in RUE BELLIARD 15-17, BRUXELLES 1040, Belgium,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITETET I OSLO (UiO), PIC 999975814, established in PROBLEMVEIEN 5-7, OSLO 0313, Norway,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

SPITALUL CLINIC DE URGENTA BAGDASAR-ARSENI (SCUBA), PIC 952500522, established in SOSEAUA BERCENI 10-12, BUCURESTI 041915, Romania,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

AZIENDA REGIONALE PER L'INNOVAZIONEE GLI ACQUISTI S.P.A. (ARIA), PIC 985380127, established in VIA TORQUATO TARAMELLI 26, MILANO 20124, Italy,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

DIGITALEUROPE AISBL* (Digital Europe), PIC 952919756, established in RUE DE LA SCIENCE 14, BRUXELLES 1040, Belgium,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ORSZAGOS KORHAZI FOIGAZGATOSAG (OKFO), PIC 891516331, established in DIOS AROK 3, BUDAPEST 1125, Hungary,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

FONDAZIONE CLUSTER REGIONALE LOMBARDO DELLE TECNOLOGIE PER GLI AMBIENTI DI VITA (TechForLife), PIC 919670096, established in VIA TONALE 28 30, LECCO 23900, Italy,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

STICHTING NATIONAAL ICT INSTITUUT IN DE ZORG (Nictiz), PIC 998830147, established in Oude Middenweg 55, Den Haag 2491AC, Netherlands,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

EUROPEAN DIGITAL HEALTH ACADEMY GGMBH (EDHA), PIC 886608907, established in MOHNBLUMENWEG 1, ABENSBERG 93326, Germany,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

STEGWEE ROBERT (CEN/TH), PIC 900965392, established in SPOORSTRAAT 31, GOOR 7471 BV, Netherlands,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

AZIENDA SANITARIA UNIVERSITARIA FRIULI CENTRALE (ASUFC), PIC 894464355, established in VIA POZZUOLO 330, UDINE 33100, Italy,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

EUROPEAN CANCER PATIENT COALITION (ECPC), PIC 984108263, established in AVENUE DES ARTS 6, BRUXELLES 1210, Belgium,

hereby agrees

to become beneficiary

in Agreement No 101095594 — XpanDH ('the Agreement')

between ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO - CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Iscte) **and** 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 mandates

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By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

FINANCIAL STATEMENT FOR [PARTICIPANT NAME] FOR REPORTING PERIOD [NUMBER]

	Eligible[1] costs (per budget category)																EU contribution[2]				Revenues
	Direct costs															Indirect costs	Total costs	EU contribution to eligible costs			Total requested EU contribution	Income generated by the action
	A. Personnel costs			B. Subcontracting costs	C. Purchase costs			D. Other cost categories								E. Indirect costs[2]		Funding rate %[3]	Maximum EU contribution[4]	Requested EU contribution		
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners and natural person beneficiaries	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services	[D.1 Financial support to third parties]	D.2 Internally invoiced goods and services	[D.3 Transnational access to research infrastructure unit costs]	[D.4 Virtual access to research infrastructure unit costs]	*[OPTION for HE PCP/PPI:* D.5 PCP/PPI procurement costs*]*	*[OPTION for Euratom Programme Cofund Actions:* D.6 Euratom Cofund staff mobility costs*]*	*[OPTION for HE ERC Grants:* D.7 ERC additional funding*]*	*[OPTION for HE ERC Grants:* D.8 ERC additional funding (subcontracting, FSTP and internally invoiced goods and services)*]*	E. Indirect costs						
Forms of funding	Actual costs	Unit costs (usual accounting practices)	Unit costs[5]	Actual costs	Actual costs	Actual costs	Actual costs	[Actual costs]	Unit costs (usual accounting practices)	[Unit costs[5]]	[Unit costs[5]]	[Actual costs]	[Unit costs[5]]	[Actual costs]	[Actual costs]	Flat-rate costs[6]						
	a1	a2	a3	b	c1	c2	c3	[d1a]	d2	[d3]	[d4]	[d5]	[d6]	[d7]	[d8]	e = 0,25 * (a1 + a2 + a3 ~~+ b~~ + c1 +c2 + c3 ~~+ d1a + d2 + d3 + d4 (+ d5[[+ d6]]~~ [+d7] ~~[+ d8])~~	f = a+b+c+d+e	U	g = f*U%	h	m	n
XX – [short name beneficiary/affiliated entity]																					

The beneficiary/affiliated entity hereby confirms 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 documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 19, 20 and 25).

For the last reporting period: that all the revenues have been declared (see Article 22).

① Please declare all eligible costs and contributions, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace costs/contributions that are found to be ineligible.

[1] See Article 6 for the eligibility conditions. All amounts must be expressed in EUR (see Article 21 for the conversion rules).

[2] If you have also received an EU operating grant during this reporting period, you cannot claim indirect costs - unless you can demonstrate that the operating grant does not cover any costs of the action. This requires specific accounting tools. Please contact us immediately via the Funding & Tenders Portal for details.

[3] See Data Sheet for the reimbursement rate(s).

[4] This is the *theoretical* amount of EU contribution to costs that the system calculates automatically (by multiplying the reimbursement rates by the costs declared). The amount you request (in the column 'requested EU contribution') may be less.

[5] See Annex 2a 'Additional information on the estimated budget' for the details (units, cost per unit).

[6] See Data Sheet for the flat-rate.

ANNEX 5

SPECIFIC RULES

CONFIDENTIALITY AND SECURITY (— ARTICLE 13)

Sensitive information with security recommendation

Sensitive information with a security recommendation must comply with the additional requirements imposed by the granting authority.

Before starting the action tasks concerned, the beneficiaries must have obtained all approvals or other mandatory documents needed for implementing the task. The documents must be kept on file and be submitted upon request by the coordinator to the granting authority. If they are not in English, they must be submitted together with an English summary.

For requirements restricting disclosure or dissemination, the information must be handled in accordance with the recommendation and may be disclosed or disseminated only after written approval from the granting authority.

EU classified information

If EU classified information is used or generated by the action, it must be treated in accordance with the security classification guide (SCG) and security aspect letter (SAL) set out in Annex 1 and Decision 2015/444[1] and its implementing rules — until it is declassified.

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

Action tasks involving EU classified information may be subcontracted only with prior explicit written approval from the granting authority and only to entities established in an EU Member State or in a non-EU country with a security of information agreement with the EU (or an administrative arrangement with the Commission).

EU 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.

ETHICS (— ARTICLE 14)

Ethics and research integrity

The beneficiaries must carry out the action in compliance with:

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

[1] 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).

and

- applicable EU, international and national law, including the EU Charter of Fundamental Rights and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Supplementary Protocols.

No funding can be granted, within or outside the EU, for activities that are prohibited in all Member States. No funding can be granted in a Member State for an activity which is forbidden in that Member State.

The beneficiaries must pay particular attention to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of persons, the right to non-discrimination, the need to ensure protection of the environment and high levels of human health protection.

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

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

- aim at human cloning for reproductive purposes
- intend to modify the genetic heritage of human beings which could make such modifications heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed)
- intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer, or
- lead to the destruction of human embryos (for example, for obtaining stem cells).

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the granting authority.

In addition, the beneficiaries must respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity[2].

This implies compliance with the following principles:

- reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources
- honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way

[2] European Code of Conduct for Research Integrity of ALLEA (All European Academies).

- respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment

- accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts

and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices including ensuring, where possible, openness, reproducibility and traceability and refrain from the research integrity violations described in the Code.

Activities raising ethical issues must comply with the additional requirements formulated by the ethics panels (including after checks, reviews or audits; see Article 25).

Before starting an action task raising ethical issues, the beneficiaries must have obtained all approvals or other mandatory documents needed for implementing the task, notably from any (national or local) ethics committee or other bodies such as data protection authorities.

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

VALUES (— ARTICLE 14)

Gender mainstreaming

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

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

Definitions

Access rights — Rights to use results or background.

Dissemination — The public disclosure of the results by appropriate means, other than resulting from protecting or exploiting the results, including by scientific publications in any medium.

Exploit(ation) — The use of results in further research and innovation activities other than those covered by the action concerned, including among other things, commercial exploitation such as developing, creating, manufacturing and marketing a product or process, creating and providing a service, or in standardisation activities.

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

FAIR principles — 'findability', 'accessibility', 'interoperability' and 'reusability'.

Open access — Online access to research outputs provided free of charge to the end-user.

Open science — An approach to the scientific process based on open cooperative work, tools and diffusing knowledge.

Research data management — The process within the research lifecycle that includes the organisation, storage, preservation, security, quality assurance, allocation of persistent identifiers (PIDs) and rules and procedures for sharing of data including licensing.

Research outputs — Results to which access can be given in the form of scientific publications, data or other engineered results and processes such as software, algorithms, protocols, models, workflows and electronic notebooks.

Scope of the obligations

For this section, references to 'beneficiary' or 'beneficiaries' do not include affiliated entities (if any).

Agreement on background

The beneficiaries must identify in a written agreement the background as needed for implementing the action or for exploiting its results.

Where the call conditions restrict control due to strategic interests reasons, background that is subject to control or other restrictions by a country (or entity from a country) which is not one of the eligible countries or target countries set out in the call conditions and that impact the exploitation of the results (i.e. would make the exploitation of the results subject to control or restrictions) must not be used and must be explicitly excluded from it in the agreement on background — unless otherwise agreed with the granting authority.

Ownership of results

Results are owned by the beneficiaries that generate them.

However, two or more beneficiaries own results jointly if:

- they have jointly generated them and
- it is not possible to:
  - establish the respective contribution of each beneficiary, or
  - separate them for the purpose of applying for, obtaining or maintaining their protection.

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

Unless otherwise agreed in the joint ownership agreement or consortium agreement, each joint owner may grant non-exclusive licences to third parties to exploit the jointly-owned results (without any right to sub-license), if the other joint owners are given:

- at least 45 days advance notice and
- fair and reasonable compensation.

The joint owners may agree — in writing — to apply another regime than joint ownership.

If third parties (including employees and other personnel) may claim rights to the results, the beneficiary concerned must ensure that those rights can be exercised in a manner compatible with its obligations under the Agreement.

The beneficiaries must indicate the owner(s) of the results (results ownership list) in the final periodic report.

Protection of results

Beneficiaries which have received funding under the grant must adequately protect their results — for an appropriate period and with appropriate territorial coverage — if protection is possible and justified, taking into account all relevant considerations, including the prospects for commercial exploitation, the legitimate interests of the other beneficiaries and any other legitimate interests.

Exploitation of results

Beneficiaries which have received funding under the grant must — up to four years after the end of the action (see Data Sheet, Point 1) — use their best efforts to exploit their results directly or to have them exploited indirectly by another entity, in particular through transfer or licensing.

If, despite a beneficiary's best efforts, the results are not exploited within one year after the end of the action, the beneficiaries must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results.

If results are incorporated in a standard, the beneficiaries must (unless otherwise agreed with the granting authority or unless it is impossible) ask the standardisation body to include the funding statement (see Article 17) in (information related to) the standard.

Additional exploitation obligations

Where the call conditions impose additional exploitation obligations (including obligations linked to the restriction of participation or control due to strategic assets, interests, autonomy or security reasons), the beneficiaries must comply with them — up to four years after the end of the action (see Data Sheet, Point 1).

Where the call conditions impose additional exploitation obligations in case of a public emergency, the beneficiaries must (if requested by the granting authority) grant for a limited period of time specified in the request, non-exclusive licences — under fair and reasonable conditions — to their results to legal entities that need the results to address the public emergency and commit to rapidly and broadly exploit the resulting products and services at fair and reasonable conditions. This provision applies up to four years after the end of the action (see Data Sheet, Point 1).

Additional information obligation relating to standards

Where the call conditions impose additional information obligations relating to possible standardisation, the beneficiaries must — up to four years after the end of the action (see Data Sheet, Point 1) — inform the granting authority, if the results could reasonably be expected to contribute to European or international standards.

Transfer and licensing of results

Transfer of ownership

The beneficiaries may transfer ownership of their results, provided this does not affect compliance with their obligations under the Agreement.

The beneficiaries must ensure that their obligations under the Agreement regarding their results are passed on to the new owner and that this new owner has the obligation to pass them on in any subsequent transfer.

Moreover, they must inform the other beneficiaries with access rights of the transfer at least 45 days in advance (or less if agreed in writing), unless agreed otherwise in writing for specifically identified third parties including affiliated entities or unless impossible under the applicable law. This notification must include sufficient information on the new owner to enable the beneficiaries concerned to assess the effects on their access rights. The beneficiaries may object within 30 days of receiving notification (or less if agreed in writing), if they can show that the transfer would adversely affect their access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

Granting licences

The beneficiaries may grant licences to their results (or otherwise give the right to exploit them), including on an exclusive basis, provided this does not affect compliance with their obligations.

Exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights.

Granting authority right to object to transfers or licensing — Horizon Europe actions

Where the call conditions in Horizon Europe actions provide for the right to object to transfers or licensing, the granting authority may — up to four years after the end of the action (see Data Sheet, Point 1) — object to a transfer of ownership or the exclusive licensing of results, if:

- the beneficiaries which generated the results have received funding under the grant
- it is to a legal entity established in a non-EU country not associated with Horizon Europe, and
- the granting authority considers that the transfer or licence is not in line with EU interests.

Beneficiaries that intend to transfer ownership or grant an exclusive licence must formally notify the granting authority before the intended transfer or licensing takes place and:

- identify the specific results concerned
- describe in detail the new owner or licensee and the planned or potential exploitation of the results, and
- include a reasoned assessment of the likely impact of the transfer or licence on EU interests, in particular regarding competitiveness as well as consistency with ethical principles and security considerations.

The granting authority may request additional information.

If the granting authority decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- pending the granting authority decision, within the period set out above
- if the granting authority objects
- until the conditions are complied with, if the granting authority objection comes with conditions.

A beneficiary may formally notify a request to waive the right to object regarding intended transfers or grants to a specifically identified third party, if measures safeguarding EU interests are in place. If the granting authority agrees, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

Granting authority right to object to transfers or licensing — Euratom actions

Where the call conditions in Euratom actions provide for the right to object to transfers or licensing, the granting authority may — up to four years after the end of the action (see Data Sheet, Point 1) — object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:

- the beneficiaries which generated the results have received funding under the grant
- it is to a legal entity established in a non-EU country not associated to the Euratom Research and Training Programme 2021-2025 and
- the granting authority considers that the transfer or licence is not in line with the EU interests.

Beneficiaries that intend to transfer ownership or grant a licence must formally notify the granting authority before the intended transfer or licensing takes place and:

- identify the specific results concerned
- describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and
- include a reasoned assessment of the likely impact of the transfer or licence on EU interests, in particular regarding competitiveness as well as consistency with

ethical principles and security considerations (including the defence interests of the EU Member States under Article 24 of the Euratom Treaty).

The granting authority may request additional information.

If the granting authority decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- pending the granting authority decision, within the period set out above
- if the granting authority objects
- until the conditions are complied with, if the granting authority objection comes with conditions.

A beneficiary may formally notify a request to waive the right to object regarding intended transfers or grants to a specifically identified third party, if measures safeguarding EU interests are in place. If the granting authority agrees, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

Limitations to transfers and licensing due to strategic assets, interests, autonomy or security reasons of the EU and its Member States

Where the call conditions restrict participation or control due to strategic assets, interests, autonomy or security reasons, the beneficiaries may not transfer ownership of their results or grant licences to third parties which are established in countries which are not eligible countries or target countries set out in the call conditions (or, if applicable, are controlled by such countries or entities from such countries) — unless they have requested and received prior approval by the granting authority.

The request must:

- identify the specific results concerned
- describe in detail the new owner and the planned or potential exploitation of the results, and
- include a reasoned assessment of the likely impact of the transfer or license on the strategic assets, interests, autonomy or security of the EU and its Member States.

The granting authority may request additional information.

Access rights to results and background

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

Requests to exercise access rights and the waiver of access rights must be in writing.

Unless agreed otherwise in writing with the beneficiary granting access, access rights do not include the right to sub-license.

If a beneficiary is no longer involved in the action, this does not affect its obligations to grant access.

If a beneficiary defaults on its obligations, the beneficiaries may agree that that beneficiary no longer has access rights.

Access rights for implementing the action

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

- informed the other beneficiaries that access to its background is subject to restrictions, or
- agreed with the other beneficiaries that access would not be on a royalty-free basis.

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

Access rights for exploiting the results

The beneficiaries must grant each other access — under fair and reasonable conditions — to results needed for exploiting their results.

The beneficiaries must grant each other access — under fair and reasonable conditions — to background needed for exploiting their results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to restrictions.

Requests for access must be made — unless agreed otherwise in writing — up to one year after the end of the action (see Data Sheet, Point 1).

Access rights for entities under the same control

Unless agreed otherwise in writing by the beneficiaries, access to results and, subject to the restrictions referred to above (if any), background must also be granted — under fair and reasonable conditions — to entities that:

- are established in an EU Member State or Horizon Europe associated country
- are under the direct or indirect control of another beneficiary, or under the same direct or indirect control as that beneficiary, or directly or indirectly controlling that beneficiary and
- need the access to exploit the results of that beneficiary.

Unless agreed otherwise in writing, such requests for access must be made by the entity directly to the beneficiary concerned.

Requests for access must be made — unless agreed otherwise in writing — up to one year after the end of the action (see Data Sheet, Point 1).

Access rights for the granting authority, EU institutions, bodies, offices or agencies and national authorities to results for policy purposes — Horizon Europe actions

In Horizon Europe actions, the beneficiaries which have received funding under the grant must grant access to their results — on a royalty-free basis — to the granting authority, EU institutions, bodies, offices or agencies for developing, implementing and monitoring EU policies or programmes. Such access rights do not extend to beneficiaries' background.

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

For actions under the cluster 'Civil Security for Society', such access rights also extend to national authorities of EU Member States for developing, implementing and monitoring their policies or programmes in this area. In this case, access is subject to a bilateral agreement to define specific conditions ensuring that:

- the access rights will be used only for the intended purpose and
- appropriate confidentiality obligations are in place.

Moreover, the requesting national authority or EU institution, body, office or agency (including the granting authority) must inform all other national authorities of such a request.

Access rights for the granting authority, Euratom institutions, funding bodies or the Joint Undertaking Fusion for Energy — Euratom actions

In Euratom actions, the beneficiaries which have received funding under the grant must grant access to their results — on a royalty-free basis — to the granting authority, Euratom institutions, funding bodies or the Joint Undertaking Fusion for Energy for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with non-EU countries and international organisations.

Such access rights include the right to authorise third parties to use the results in public procurement and the right to sub-license and are limited to non-commercial and non-competitive use.

Additional access rights

Where the call conditions impose additional access rights, the beneficiaries must comply with them.

COMMUNICATION, DISSEMINATION, OPEN SCIENCE AND VISIBILITY (— ARTICLE 17)

Dissemination

Dissemination of results

The beneficiaries must disseminate their results as soon as feasible, in a publicly available format, subject to any restrictions due to the protection of intellectual property, security rules or legitimate interests.

A beneficiary that intends to disseminate its results must give at least 15 days advance notice to the other beneficiaries (unless agreed otherwise), together with sufficient information on the results it will disseminate.

Any other beneficiary may object within (unless agreed otherwise) 15 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the results may not be disseminated unless appropriate steps are taken to safeguard those interests.

Additional dissemination obligations

Where the call conditions impose additional dissemination obligations, the beneficiaries must also comply with those.

Open Science

Open science: open access to scientific publications

The beneficiaries must ensure open access to peer-reviewed scientific publications relating to their results. In particular, they must ensure that:

- at the latest at the time of publication, a machine-readable electronic copy of the published version or the final peer-reviewed manuscript accepted for publication, is deposited in a trusted repository for scientific publications

- immediate open access is provided to the deposited publication via the repository, under the latest available version of the Creative Commons Attribution International Public Licence (CC BY) or a licence with equivalent rights; for monographs and other long-text formats, the licence may exclude commercial uses and derivative works (e.g. CC BY-NC, CC BY-ND) and

- information is given via the repository about any research output or any other tools and instruments needed to validate the conclusions of the scientific publication.

Beneficiaries (or authors) must retain sufficient intellectual property rights to comply with the open access requirements.

Metadata of deposited publications must be open under a Creative Common Public Domain Dedication (CC 0) or equivalent, in line with the FAIR principles (in particular machine-actionable) and provide information at least about the following: publication (author(s), title, date of publication, publication venue); Horizon Europe or Euratom funding; grant project name, acronym and number; licensing terms; persistent identifiers for the publication, the authors involved in the action and, if possible, for their organisations and the grant. Where applicable, the metadata must include persistent identifiers for any research output or any other tools and instruments needed to validate the conclusions of the publication.

Only publication fees in full open access venues for peer-reviewed scientific publications are eligible for reimbursement.

Open science: research data management

The beneficiaries must manage the digital research data generated in the action ('data') responsibly, in line with the FAIR principles and by taking all of the following actions:

- establish a data management plan ('DMP') (and regularly update it)

- as soon as possible and within the deadlines set out in the DMP, deposit the data in a trusted repository; if required in the call conditions, this repository must be federated in the EOSC in compliance with EOSC requirements

- as soon as possible and within the deadlines set out in the DMP, ensure open access — via the repository — to the deposited data, under the latest available version of the Creative Commons Attribution International Public License (CC BY) or Creative Commons Public Domain Dedication (CC 0) or a licence with equivalent rights, following the principle 'as open as possible as closed as necessary', unless providing open access would in particular:

    - be against the beneficiary's legitimate interests, including regarding commercial exploitation, or

    - be contrary to any other constraints, in particular the EU competitive interests or the beneficiary's obligations under this Agreement; if open access is not provided (to some or all data), this must be justified in the DMP

- provide information via the repository about any research output or any other tools and instruments needed to re-use or validate the data.

Metadata of deposited data must be open under a Creative Common Public Domain Dedication (CC 0) or equivalent (to the extent legitimate interests or constraints are safeguarded), in line with the FAIR principles (in particular machine-actionable) and provide information at least about the following: datasets (description, date of deposit, author(s), venue and embargo); Horizon Europe or Euratom funding; grant project name, acronym and number; licensing terms; persistent identifiers for the dataset, the authors involved in the action, and, if possible, for their organisations and the grant. Where applicable, the metadata must include persistent identifiers for related publications and other research outputs.

Open science: additional practices

Where the call conditions impose additional obligations regarding open science practices, the beneficiaries must also comply with those.

Where the call conditions impose additional obligations regarding the validation of scientific publications, the beneficiaries must provide (digital or physical) access to data or other results needed for validation of the conclusions of scientific publications, to the extent that their legitimate interests or constraints are safeguarded (and unless they already provided the (open) access at publication).

Where the call conditions impose additional open science obligations in case of a public emergency, the beneficiaries must (if requested by the granting authority) immediately deposit any research output in a repository and provide open access to it under a CC BY licence, a Public Domain Dedication (CC 0) or equivalent. As an exception, if the access would be against the beneficiaries' legitimate interests, the beneficiaries must grant non-exclusive licenses — under fair and reasonable conditions — to legal entities that need the research output to address the public emergency and commit to rapidly and broadly exploit the resulting products and services at fair and reasonable conditions. This provision applies up to four years after the end of the action (see Data Sheet, Point 1).

Plan for the exploitation and dissemination of results including communication activities

Unless excluded by the call conditions, the beneficiaries must provide and regularly update a plan for the exploitation and dissemination of results including communication activities.

SPECIFIC RULES FOR CARRYING OUT THE ACTION (— ARTICLE 18)

Implementation in case of restrictions due to strategic assets, interests, autonomy or security of the EU and its Member States

Where the call conditions restrict participation or control due to strategic assets, interests, autonomy or security, the beneficiaries must ensure that none of the entities that participate as affiliated entities, associated partners, subcontractors or recipients of financial support to third parties are established in countries which are not eligible countries or target countries set out in the call conditions (or, if applicable, are controlled by such countries or entities from such countries) — unless otherwise agreed with the granting authority.

The beneficiaries must moreover ensure that any cooperation with entities established in countries which are not eligible countries or target countries set out in the call conditions (or, if applicable, are controlled by such countries or entities from such countries) does not affect the strategic assets, interests, autonomy or security of the EU and its Member States.

Recruitment and working conditions for researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[3], in particular regarding:

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

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

Specific rules for access to research infrastructure activities

Definitions

Research Infrastructures — Facilities that provide resources and services for the research communities to conduct research and foster innovation in their fields. This definition includes the associated human resources, and it covers major equipment or sets of instruments; knowledge-related facilities such as collections, archives or scientific data infrastructures; computing systems, communication networks, and any other infrastructure, of a unique nature and open to external users, essential to achieve excellence in research and innovation. Where relevant, they may be used beyond research, for example

[3] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

for education or public services, and they may be 'single-sited', 'virtual' or 'distributed'[4]:

When implementing access to research infrastructure activities, the beneficiaries must respect the following conditions:

- for transnational access:
  - access which must be provided:

    The access must be free of charge, transnational access to research infrastructure or installations for selected user-groups.

    The access must include the logistical, technological and scientific support and the specific training that is usually provided to external researchers using the infrastructure. Transnational access can be either in person (hands-on), provided to selected users that visit the installation to make use of it, or remote, through the provision to selected user-groups of remote scientific services (e.g. provision of reference materials or samples, remote access to a high-performance computing facility).

  - categories of users that may have access:

    Transnational access must be provided to selected user-groups, i.e. teams of one or more researchers (users).

    The majority of the users must work in a country other than the country(ies) where the installation is located (unless access is provided by an international organisation, the Joint Research Centre (JRC), an ERIC or similar legal entity).

    Only user groups that are allowed to disseminate the results they have generated under the action may benefit from the access (unless the users are working for SMEs).

    Access for user groups with a majority of users not working in a EU Member State or Horizon Europe associated country is limited to 20% of the total amount of units of access provided under the grant (unless a higher percentage is foreseen in Annex 1).

  - procedure and criteria for selecting user groups:

    The user groups must request access by submitting (in writing) a description of the work that they wish to carry out and the names, nationalities and home institutions of the users.

    The user groups must be selected by (one or more) selection panels set up by the consortium.

[4] See Article 2(1) of the Horizon Europe Framework Programme Regulation 2021/695.

The selection panels must be composed of international experts in the field, at least half of them independent from the consortium (unless otherwise specified in Annex 1).

The selection panels must assess all proposals received and recommend a short-list of the user groups that should benefit from access.

The selection panels must base their selection on scientific merit, taking into account that priority should be given to user groups composed of users who:

- have not previously used the installation and
- are working in countries where no equivalent research infrastructure exist.

It will apply the principles of transparency, fairness and impartiality.

Where the call conditions impose additional rules for the selection of user groups, the beneficiaries must also comply with those.

- other conditions:

The beneficiaries must request written approval from the granting authority for the selection of user groups requiring visits to the installations exceeding 3 months (unless such visits are foreseen in Annex 1).

In addition, the beneficiaries must:

- advertise widely, including on a their websites, the access offered under the Agreement
- promote equal opportunities in advertising the access and take into account the gender dimension when defining the support provided to users
- ensure that users comply with the terms and conditions of the Agreement
- ensure that its obligations under Articles 12, 13, 17 and 33 also apply to the users
- keep records of the names, nationalities, and home institutions of users, as well as the nature and quantity of access provided to them

- for virtual access:
  - access which must be provided:

The access must be free of charge, virtual access to research infrastructure or installations.

'Virtual access' means open and free access through communication networks to digital resources and services needed for research, without selecting the users to whom access is provided.

The access must include the support that is usually provided to external users.

Where allowed by the call conditions, beneficiaries may in justified cases define objective eligibility criteria (e.g. affiliation to a research or academic institution) for specific users.

- other conditions:

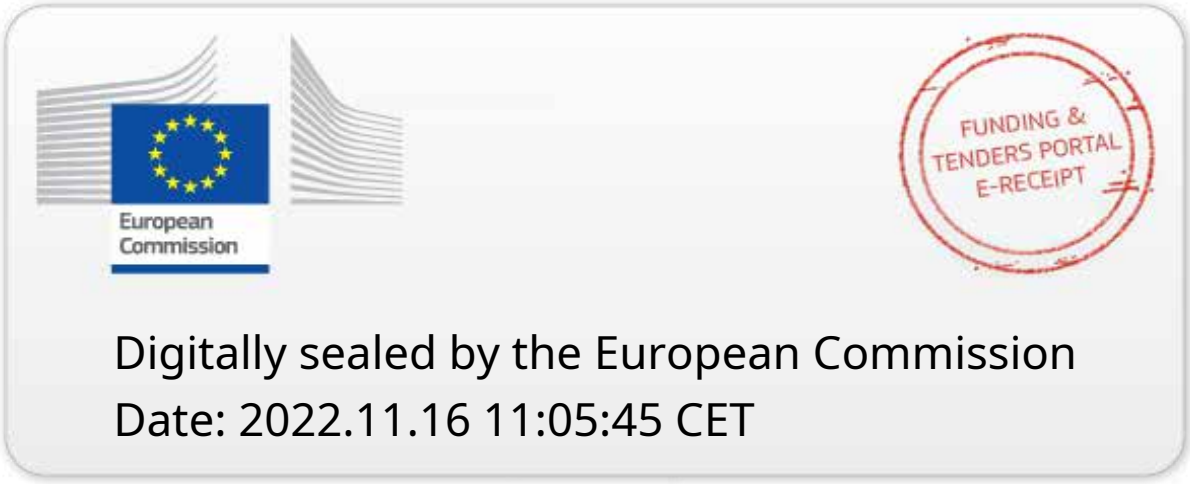
  The beneficiaries must have the virtual access services assessed periodically by a board composed of international experts in the field, at least half of whom must be independent from the consortium (unless otherwise specified in Annex 1). For this purpose, information and statistics on the users and the nature and quantity of the access provided, must be made available to the board.

  The beneficiaries must advertise widely, including on a dedicated website, the access offered under the grant and the eligibility criteria, if any.

  Where the call conditions impose additional traceability[5] obligations, information on the traceability of the users and the nature and quantity of access must be provided by the beneficiaries.

These obligations apply regardless of the form of funding or budget categories used to declare the costs (unit costs or actual costs or a combination of the two).

[5] According to the definition given in ISO 9000, i.e.: "Traceability is the ability to trace the history, application, use and location of an item or its characteristics through recorded identification data." The users can be traced, for example, by authentication and/or by authorization or by other means that allows for analysis of the type of users and the nature and quantity of access provided.



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