EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)

Director

GRANT AGREEMENT

Project 101128639 — HeDAB - SK

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':

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

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)

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

TERMS AND CONDITIONS

TABLE OF CONTENTS

DATA SHEET

1. General data

Project summary:

Project summary
Establishing Health Data Access Body (HDAB) in Slovak republic. The project will introduce Slovak National Data Access Application solution to process applications for accessing health data for secondary usage. The project will also introduce National Health Dataset Catalogue (Catalogue). The catalogue will help applicants for the access to health data for secondary usage to prepare their application based on the information from the Catalogue, which datasets are available at that moment in Slovak republic. Despite the fact that in the call document EU4H-2022-DGA-MS-IBA2 in the part E (Specific mandatory deliverables and/or milestones) of the call EU4H-2022-DGA-MS-IBA-4 (DI-g-22-22.01) there is mandatory deliverable on secure processing environment infrastructure required, we decided after the consultation with DG Santé C1 not to include this activity into our proposal. EC said that there would be very probably separate call on this topic in 2 years. The project will also introduce cross-border gateway to connect with the HealthData@EU infrastructure. We will also work on: - Improving the health data quality in Slovak republic, - Dissemination, training and support the activities of HDAB in Slovak republic, - Business Continuity plan for HDAB in Slovak republic, - Other activities described in this Part B of our proposal. The project is expected to support Slovak republic and other Member States to progress and align towards: - providing more patients the opportunity to benefit of cross-border health care; - increase capacity, resilience and readiness for Member States to participate in cross-border exchange and reuse of health data for research, innovation, policy-making, statistical purposes and regulatory activities; - scaling-up of HDABs IT infrastructures according to a common set of digital business capabilities necessary for secondary use of health data; - set the necessary pre-conditions to enable connectivity between HDABs in each Member State.

Keywords:

- Health Data Access Body in Slovak republic based on Regulation on EHDS.

Project number: 101128639

Project name: Establishing parts of Health Data Access Body in Slovak republic.

Project acronym: HeDAB - SK

Call: EU4H-2022-DGA-MS-IBA2

Topic: EU4H-2022-DGA-MS-IBA-4

Type of action: EU4H Project Grants

Granting authority: European Health and Digital Executive Agency

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

Project starting date: fixed date: 1 January 2024

Project end date: 30 November 2027

Project duration: 47 months

Consortium agreement: No

2. Participants

List of participants:

N°	Role	Short name	Legal name	Ctry	PIC	Total eligible costs (BEN and AE)	Max grant amount
1	COO	NCZI	NARODNE CENTRUM ZDRAVOTNICKYCH INFORMACII	SK	998884370	1 275 427.16	972 587.20
Total						1 275 427.16	972 587.20

Coordinator:

– NARODNE CENTRUM ZDRAVOTNICKYCH INFORMACII (NCZI)

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)
1 275 427.16	80	972 587.20	972 587.20

Grant form: Budget-based

Grant mode: Action grant

Budget categories/activity types:

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

Cost eligibility options:

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

Budget flexibility: Yes (no flexibility cap)

4. Reporting, payments and recoveries

4.1 Continuous reporting (art 21)

Deliverables: see Funding & Tenders Portal Continuous Reporting tool

4.2 Periodic reporting and payments

Reporting and payment schedule (art 21, 22):

Reporting					Payments	
Reporting periods			Type	Deadline	Type	Deadline (time to pay)
RP No	Month from	Month to				
					Initial prefinancing	30 days from entry into force/10 days before starting date/ financial guarantee (if required) – whichever is the latest
1	1	18	Periodic report	60 days after end of reporting period	Interim payment	90 days from receiving periodic report
2	19	36	Periodic report	60 days after end of reporting period	Interim payment	90 days from receiving periodic report
3	37	47	Periodic report	60 days after end of reporting period	Final payment	90 days from receiving periodic report

Prefinancing payments and guarantees:

Prefinancing payment		Prefinancing guarantee		
Type	Amount	Guarantee amount	Division per participant	
Prefinancing 1 (initial)	291 776.16	n/a	1 - NCZI	n/a

Reporting and payment modalities (art 21, 22):

Mutual Insurance Mechanism (MIM): No

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

No-profit rule: Yes

Late payment interest: ECB + 3.5%

Bank account for payments:

SK5281800000007000687510

Conversion into euros: Double conversion

Reporting language: Language of the Agreement

4.3 Certificates (art 24):

Certificates on the financial statements (CFS):

Conditions:

Schedule: interim/final payment, if threshold is reached

Standard threshold (beneficiary-level):

- financial statement: requested EU contribution to costs ≥ EUR 325 000.00

4.4 Recoveries (art 22)

First-line liability for recoveries:

Beneficiary termination: Beneficiary concerned

Final payment: Coordinator

After final payment: Beneficiary concerned

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

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

Joint and several liability of affiliated entities — n/a

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

Applicable law (art 43):

Standard applicable law regime: EU law + law of Belgium

Dispute settlement forum (art 43):

Standard dispute settlement forum:

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

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

6. Other

Specific rules (Annex 5): Yes

Standard time-limits after project end:

Confidentiality (for X years after final payment): 5

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

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

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

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

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

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

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

ARTICLE 2 — DEFINITIONS

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

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

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

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

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

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

Affiliated entities (AE) — Entities affiliated to a beneficiary within the meaning of Article 187 of EU Financial Regulation 2018/1046[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 **101128639 — HeDAB - SK** ('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 80% of the action's eligible costs.

Contributions are not subject to any funding rate.

5.4 Estimated budget, budget categories and forms of funding

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

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

Annex 2 also shows the types of costs and contributions (forms of funding)[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).

6.2 Specific eligibility conditions for each budget category

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

Direct costs

A. Personnel costs

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

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

{daily rate for the person

multiplied by

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

The daily rate must be calculated as:

{annual personnel costs for the person

divided by

215}.

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

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

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

- it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required

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

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

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

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

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

A.4 The work of **SME owners** for the action (i.e. owners of beneficiaries that are small and medium-sized enterprises[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

[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.

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

B. Subcontracting costs

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

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

Subcontracting may cover only a limited part of the action.

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

C. Purchase costs

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

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

C.1 Travel and subsistence

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

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

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

- subsistence: as unit costs in accordance with the method set out in Annex 2a if covered by

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

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

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

C.2 Equipment

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

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

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

C.3 Other goods, works and services

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

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

D. Other cost categories

D.1 Financial support to third parties

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

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

(a) for grants (or similar):

(i) the maximum amount of financial support for each third party ('recipient'); this amount may not exceed the amount set out in the Data Sheet (see Point 3) or otherwise agreed with the granting authority

(ii) the criteria for calculating the exact amount of the financial support

(iii) the different types of activity that qualify for financial support, on the basis of a closed list

(iv) the persons or categories of persons that will be supported and

(v) the criteria and procedures for giving financial support

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

(b) for prizes (or similar):

(i) the eligibility and award criteria

(ii) the amount of the prize and

(iii) the payment arrangements.

Indirect costs

E. Indirect costs

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

Contributions

Not applicable

6.3 Ineligible costs and contributions

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

(a) costs or contributions that do not comply with the conditions set out above (Article 6.1 and 6.2), in particular:

(i) costs related to return on capital and dividends paid by a beneficiary

(ii) debt and debt service charges

(iii) provisions for future losses or debts

(iv) interest owed

(v) currency exchange losses

(vi) bank costs charged by the beneficiary's bank for transfers from the granting authority

(vii) excessive or reckless expenditure

(viii) deductible or refundable VAT (including VAT paid by public bodies acting as public authority)

(ix) costs incurred or contributions for activities implemented during grant agreement suspension (see Article 31)

(x) in-kind contributions by third parties

(b) costs or contributions declared under other EU grants (or grants awarded by an EU Member State, non-EU country or other body implementing the EU budget), except for the following cases:

(i) Synergy actions: not applicable

(ii) if the action grant is combined with an operating grant[14] running during the same period and the beneficiary can demonstrate that the operating grant does not cover any (direct or indirect) costs of the action grant

(c) costs or contributions for staff of a national (or regional/local) administration, for activities that are part of the administration's normal activities (i.e. not undertaken only because of the grant)

(d) costs or contributions (especially travel and subsistence) for staff or representatives of EU institutions, bodies or agencies

(e) other :

(i) country restrictions for eligible costs: not applicable

(ii) costs or contributions declared specifically ineligible in the call conditions.

6.4 Consequences of non-compliance

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

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

CHAPTER 4 GRANT IMPLEMENTATION

SECTION 1 CONSORTIUM: BENEFICIARIES, AFFILIATED ENTITIES AND OTHER PARTICIPANTS

ARTICLE 7 — BENEFICIARIES

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

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

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

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

[14] For the definition, see Article 180(2)(b) of EU Financial Regulation 2018/1046: '**operating grant**' means an EU grant to finance "the functioning of a body which has an objective forming part of and supporting an EU policy".

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

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

(a) Each beneficiary must:

(i) keep information stored in the Portal Participant Register up to date (see Article 19)

(ii) inform the granting authority (and the other beneficiaries) immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 19)

(iii) submit to the coordinator in good time:

- the prefinancing guarantees (if required; see Article 23)
- the financial statements and certificates on the financial statements (CFS) (if required; see Articles 21 and 24.2 and Data Sheet, Point 4.3)
- the contribution to the deliverables and technical reports (see Article 21)
- any other documents or information required by the granting authority under the Agreement

(iv) submit via the Portal data and information related to the participation of their affiliated entities.

(b) The coordinator must:

(i) monitor that the action is implemented properly (see Article 11)

(ii) act as the intermediary for all communications between the consortium and the granting authority, unless the Agreement or granting authority specifies otherwise, and in particular:

- submit the prefinancing guarantees to the granting authority (if any)
- request and review any documents or information required and verify their quality and completeness before passing them on to the granting authority
- submit the deliverables and reports to the granting authority
- inform the granting authority about the payments made to the other beneficiaries (report on the distribution of payments; if required, see Articles 22 and 32)

(iii) distribute the payments received from the granting authority to the other beneficiaries without unjustified delay (see Article 22).

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

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

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

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

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

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

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

ARTICLE 8 — AFFILIATED ENTITIES

Not applicable

ARTICLE 9 — OTHER PARTICIPANTS INVOLVED IN THE ACTION

9.1 Associated partners

Not applicable

9.2 Third parties giving in-kind contributions to the action

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

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

[15] 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."

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

9.3 Subcontractors

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

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

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

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

9.4 Recipients of financial support to third parties

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

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

ARTICLE 10 — PARTICIPANTS WITH SPECIAL STATUS

10.1 Non-EU participants

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

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

[16] 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).

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[17] 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

[17] 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[18].

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[19]).

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.

[18] 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).

[19] 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.

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

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

In case of enforced recoveries (see Article 22.4):

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

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

22.3 Amounts due

22.3.1 Prefinancing payments

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

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

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

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

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

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

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

22.3.2 Amount due at beneficiary termination — Recovery

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

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

Step 1 — Calculation of the total accepted EU contribution

Step 1 — Calculation of the total accepted EU contribution

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

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

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

{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**).

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

22.3.3 Interim payments

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

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

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

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

Step 1 — Calculation of the total accepted EU contribution

Step 2 — Limit to the interim payment ceiling

Step 1 — Calculation of the total accepted EU contribution

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

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

Step 2 — Limit to the interim payment ceiling

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

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

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

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

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

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

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

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

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

Step 1 — Calculation of the total accepted EU contribution

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 1 — Calculation of the total accepted EU contribution

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

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

Step 2 — Limit to the maximum grant amount

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

Step 3 — Reduction due to the no-profit rule

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

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

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

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

{final grant amount

minus

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

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

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

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

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

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

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

- formally notifying the intention to recover, the final grant amount, the amount to be recovered and the reasons why

- requesting observations within 30 days of receiving notification.

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

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

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

If — after the final payment (in particular, after checks, reviews, audits or investigations; see Article 25) — the granting authority rejects costs or contributions (see Article 27) or reduces the grant (see Article 28), it will calculate the **revised final grant amount** for the beneficiary concerned.

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

Step 1 — Calculation of the revised total accepted EU contribution

Step 1 — Calculation of the revised total accepted EU contribution

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

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

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

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

{{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) by drawing on the financial guarantee(s) (if any)

(c) by holding other beneficiaries jointly and severally liable (if any; see Data Sheet, Point 4.4)

(d) by holding affiliated entities jointly and severally liable (if any, see Data Sheet, Point 4.4)

(e) by taking legal action (see Article 43) or, provided that the granting authority is the European Commission or an EU executive agency, by adopting an enforceable decision under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 100(2) of EU Financial Regulation 2018/1046.

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

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

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

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

22.5 Consequences of non-compliance

22.5.1 If the granting authority does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus the rate specified in the

[20] 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).

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 28) and the grant or the coordinator may be terminated (see Article 32).

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

ARTICLE 23 — GUARANTEES

23.1 Prefinancing guarantee

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

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

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

(a) be provided by a bank or approved financial institution established in the EU or — if requested by the coordinator and accepted by the granting authority — by a third party or a bank or financial institution established outside the EU offering equivalent security

(b) the guarantor stands as first-call guarantor and does not require the granting authority to first have recourse against the principal debtor (i.e. the beneficiary concerned) and

(c) remain explicitly in force until the final payment and, if the final payment takes the form of a recovery, until five months after the debit note is notified to a beneficiary.

They will be released within the following month.

23.2 Consequences of non-compliance

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

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

ARTICLE 24 — CERTIFICATES

24.1 Operational verification report (OVR)

Not applicable

24.2 Certificate on the financial statements (CFS)

If required by the granting authority (see Data Sheet, Point 4.3), the beneficiaries must provide certificates on their financial statements (CFS), in accordance with the schedule, threshold and conditions set out in the Data Sheet.

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

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

(a) be provided by a qualified approved external auditor which is independent and complies with Directive 2006/43/EC[21] (or for public bodies: by a competent independent public officer)

(b) the verification must be carried out according to the highest professional standards to ensure that the financial statements comply with the provisions under the Agreement and that the costs declared are eligible.

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

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

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

Not applicable

24.4 Systems and process audit (SPA)

Not applicable

24.5 Consequences of non-compliance

[21] 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).

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[22] and No 2185/96[23]
- 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

[22] 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).

[23] Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (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) additional GA suspension grounds: not applicable.

31.2.2 Procedure

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

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

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

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

Once the conditions for resuming implementation of the action are met, the granting authority will formally notify the coordinator a **lifting of suspension letter**, in which it will set the suspension end date and invite the coordinator to request an amendment of the Agreement to set the resumption date (one day after suspension end date), extend the duration and make other changes necessary to adapt the action to the new situation (see Article 39) — unless the grant has been terminated (see

Article 32). The suspension will be **lifted** with effect from the suspension end date set out in the lifting of suspension letter. This date may be before the date on which the letter is sent.

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

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

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

ARTICLE 32 — GRANT AGREEMENT OR BENEFICIARY TERMINATION

32.1 Consortium-requested GA termination

32.1.1 Conditions and procedure

The beneficiaries may request the termination of the grant.

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

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

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

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

32.1.2 Effects

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

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

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

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

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

32.2 Consortium-requested beneficiary termination

32.2.1 Conditions and procedure

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

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

- the reasons why
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing)
- the date the beneficiary ends work on the action ('end of work date')
- the date the termination takes effect ('termination date'); this date must be after the date of the submission of the amendment request.

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

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

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

32.2.2 Effects

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

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

(ii) a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, the financial statement, the explanation on the use of resources, and, if applicable, the certificate on the financial statement (CFS; see Articles 21 and 24.2 and Data Sheet, Point 4.3)

(iii) a second **request for amendment** (see Article 39) with other amendments needed (e.g. reallocation of the tasks and the estimated budget of the terminated beneficiary; addition of a new beneficiary to replace the terminated beneficiary; change of coordinator, etc.).

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

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

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

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

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

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

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

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

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

32.3 EU-initiated GA or beneficiary termination

32.3.1 Conditions

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

(a) one or more beneficiaries do not accede to the Agreement (see Article 40)

(b) a change to the action or the legal, financial, technical, organisational or ownership situation of a beneficiary is likely to substantially affect the implementation of the action or calls into question the decision to award the grant (including changes linked to one of the exclusion grounds listed in the declaration of honour)

(c) following termination of one or more beneficiaries, the necessary changes to the Agreement (and their impact on the action) would call into question the decision awarding the grant or breach the principle of equal treatment of applicants

(d) implementation of the action has become impossible or the changes necessary for its continuation would call into question the decision awarding the grant or breach the principle of equal treatment of applicants

(e) a beneficiary (or person with unlimited liability for its debts) is subject to bankruptcy proceedings or similar (including insolvency, winding-up, administration by a liquidator or court, arrangement with creditors, suspension of business activities, etc.)

(f) a beneficiary (or person with unlimited liability for its debts) is in breach of social security or tax obligations

(g) a beneficiary (or person having powers of representation, decision-making or control, or person

essential for the award/implementation of the grant) has been found guilty of grave professional misconduct

(h) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed fraud, corruption, or is involved in a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking

(i) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) was created under a different jurisdiction with the intent to circumvent fiscal, social or other legal obligations in the country of origin (or created another entity with this purpose)

(j) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions, submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.)

(k) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings from other grants to this grant; see Article 25)

(l) despite a specific request by the granting authority, a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its affiliated entities or associated partners that is in one of the situations under points (d), (f), (e), (g), (h), (i) or (j) and to reallocate its tasks, or

(m) other:

  (i) linked action issues: not applicable

  (ii) additional GA termination grounds: not applicable.

32.3.2 Procedure

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

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

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

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

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

32.3.3 Effects

(a) for **GA termination**:

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

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

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

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

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

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

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

(b) for **beneficiary termination**:

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

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

(ii) a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, the financial statement, the explanation on the use of resources, and, if applicable, the certificate on the financial statement (CFS; see Articles 21 and 24.2 and Data Sheet, Point 4.3)

(iii) a **request for amendment** (see Article 39) with any amendments needed (e.g. reallocation of the tasks and the estimated budget of the terminated beneficiary; addition of a new beneficiary to replace the terminated beneficiary; change of coordinator, etc.).

The granting authority will calculate the amount due to the beneficiary on the basis of the

report submitted and taking into account the costs incurred and contributions for activities implemented before termination takes effect (see Article 22). Costs relating to contracts due for execution only after termination are not eligible.

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

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

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

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

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

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

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

SECTION 3 OTHER CONSEQUENCES: DAMAGES AND ADMINISTRATIVE SANCTIONS

ARTICLE 33 — DAMAGES

33.1 Liability of the granting authority

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

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

33.2 Liability of the beneficiaries

The beneficiaries must compensate the granting authority for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement, provided that it was caused by gross negligence or wilful act.

The liability does not extend to indirect or consequential losses or similar damage (such as loss of

profit, loss of revenue or loss of contracts), provided such damage was not caused by wilful act or by a breach of confidentiality.

ARTICLE 34 — ADMINISTRATIVE SANCTIONS AND OTHER MEASURES

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

SECTION 4 FORCE MAJEURE

ARTICLE 35 — FORCE MAJEURE

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

'Force majeure' means any situation or event that:

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

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

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

CHAPTER 6 FINAL PROVISIONS

ARTICLE 36 — COMMUNICATION BETWEEN THE PARTIES

36.1 Forms and means of communication — Electronic management

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

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

[24] 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).

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[25], 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.

ARTICLE 40 — ACCESSION AND ADDITION OF NEW BENEFICIARIES

[25] 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).

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

EU4Health Programme (EU4H)

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:	101128639
Project name:	Establishing parts of Health Data Access Body in Slovak republic.
Project acronym:	HeDAB - SK
Call:	EU4H-2022-DGA-MS-IBA2
Topic:	EU4H-2022-DGA-MS-IBA-4
Type of action:	EU4H-PJG
Service:	HADEA/A/01
Project starting date:	fixed date: 1 January 2024
Project duration:	47 months

TABLE OF CONTENTS

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.

Establishing Health Data Access Body (HDAB) in Slovak republic. The project will introduce Slovak National Data Access Application solution to process applications for accessing health data for secondary usage. The project will also introduce National Health Dataset Catalogue (Catalogue). The catalogue will help applicants for the access to health data for secondary usage to prepare their application based on the information from the Catalogue, which datasets are available at that moment in Slovak republic.
Despite the fact that in the call document EU4H-2022-DGA-MS-IBA2 in the part E (Specific mandatory deliverables and/or milestones) of the call EU4H-2022-DGA-MS-IBA-4 (DI-g-22-22.01) there is mandatory deliverable on secure processing environment infrastructure required, we decided after the consultation with DG Santé C1 not to include this activity into our proposal. EC said that there would be very probably separate call on this topic in 2 years.
The project will also introduce cross-border gateway to connect with the HealthData@EU infrastructure. We will also work on:
- Improving the health data quality in Slovak republic,
- Dissemination, training and support the activities of HDAB in Slovak republic,
- Business Continuity plan for HDAB in Slovak republic,
- Other activities described in this Part B of our proposal.
The project is expected to support Slovak republic and other Member States to progress and align towards:
- providing more patients the opportunity to benefit of cross-border health care;
- increase capacity, resilience and readiness for Member States to participate in cross-border exchange and reuse of health data for research, innovation, policy-making, statistical purposes and regulatory activities;
- scaling-up of HDABs IT infrastructures according to a common set of digital business capabilities necessary for secondary use of health data;
- set the necessary pre-conditions to enable connectivity between HDABs in each Member State.

LIST OF PARTICIPANTS

PARTICIPANTS

Grant Preparation (Beneficiaries screen) — Enter the info.

Number	Role	Short name	Legal name	Country	PIC
1	COO	NCZI	NARODNE CENTRUM ZDRAVOTNICKYCH INFORMACII	SK	998884370

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	Management and Coordination.	1 - NCZI	44.00	1	47	D1.1 – D1.1 - Preliminary Governance Management and Participation Report D1.2 – D1.2 Final Governance, Management and participation Report
WP2	Dissemination, Training and Support.	1 - NCZI	22.00	1	47	D2.1 – D2.1 Dissemination, Education and Training Plan D2.2 – D2.2 Dissemination, Education and Training materials D2.3 – D2.3 Dissemination, Education and Training Monitoring Report D2.4 – D2.4 MS Service and Help Desk Plan D2.5 – D2.5: Web page dedicated to the HeDAB-SK project in the health portal of Slovak republic.
WP3	Evaluation of the project	1 - NCZI	6.00	1	47	D3.1 – D3.1: Report on the performance monitoring indicators framework D3.2 – D3.2: Overall evaluation report D3.3 – D3.3 Action level indicators report.
WP4	Sustainability of the outcomes of the project.	1 - NCZI	16.00	1	45	D4.1 – D4.1 Sustainability plan D4.2 – D4.2 Business Continuity Plan
WP5	National Data Access Applications management solution	1 - NCZI	16.00	1	45	D5.1 – D5.1 DAAMs: Requirements, Specifications and Prototype D5.2 – D5.2: DAAMs: Pilot Report

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
						D5.3 – D5.3: DAAMs: Operational Service Report
WP6	National Health Dataset Catalogue for health data	1 - NCZI	20.00	1	45	D6.1 – D6.1: nHDsC: Requirements and Specifications D6.2 – D6.2: nHDsC: Pilot report D6.3 – D6.3: nHDsC: Operational Service
WP7	Cross-border gateway to connect with the HealthData@EU infrastructure	1 - NCZI	42.00	1	45	D7.1 – D7.1: National Connector for Cross-border gateway: Requirements and Specifications D7.2 – D7.2: Cross-border gateway: Pilot D7.3 – D7.3: Cross-border gateway: Operational Service
WP8	Health data quality enhancement	1 - NCZI	23.00	1	33	D8.1 – D8.1: Quality of data: Analysis of the quality of the available health data including tools and standards to improve the quality D8.2 – D8.2: Quality of Data: Proposal on improving the quality of available health data including recommendations on usage of data quality tools and standards

Work package WP1 – Management and Coordination.

Work Package Number	WP1	Lead Beneficiary	1. NCZI
Work Package Name	Management and Coordination.		
Start Month	1	End Month	47

Objectives
- Establish the appropriate national management structure to enable the cross-border use of health data for research, innovation, policy making, educational activities, patient safety, regulatory activities or personalised medicine, in line with the purposes set out in the EHDS regulation proposal, - Monitor the overall progress of the different tasks of the project, - Participate in the European HealthData@EU temporary governance body and procedures, - Good practice identification.

Description
WP1 will be responsible for project management of HeDAB - SK project. Tasks of WP1: T1.1: Management of national activities. T1.2: Management of cross-border activities. T1.3: Monitoring and reporting. T1.4: Coordination. T1.5: Good practice identification.

Work package WP2 – Dissemination, Training and Support.

Work Package Number	WP2	Lead Beneficiary	1. NCZI
Work Package Name	Dissemination, Training and Support.		
Start Month	1	End Month	47

Objectives
- Raise awareness among citizens, data holders and data users of the health data access body function and responsibilities - Conduct training initiatives and orchestrate support initiatives for HDAB staff, data holders and data users.

Description
Work package 2: Dissemination, training and support will be responsible for: - dissemination campaigns, - conducting specific workshops and training activitzies, - creating Service and help Desk for the project HeDAB-SK. Tasks of WP2: T2.1: Dissemination. T2.2: Collecting feedback from stakeholders. T2.3: Education and training. T2.4: Service and Help Desk.

Work package WP3 – Evaluation of the project

Work Package Number	WP3	Lead Beneficiary	1. NCZI
Work Package Name	Evaluation of the project		

Start Month	1	End Month	47

Objectives
- Conduct performance monitoring and evaluation activities to assess the effectiveness of the implementation of the digital business capabilities in scope of this application.

Description
Work Package 3: Evaluation of the project will evaluate the outcomes of the project. Tasks of the work package: T3.1: Performance monitoring. T3.2: Evaluation.

Work package WP4 – Sustainability of the outcomes of the project.

Work Package Number	WP4	Lead Beneficiary	1. NCZI
Work Package Name	Sustainability of the outcomes of the project.		
Start Month	1	End Month	45

Objectives
- Ensure that the digital business capabilities implemented in the scope of this project have a sustainability plan and business continuity plan beyond the duration of the grant. - Ensure that the suggestions from stakeholders on smooth functioning of the business capabilities and services to be provided after the end of the project will be incorporated in Sustainability plan and in Business Continuity Plan.

Description
Work package outcomes will describe, how the improved activities and improved business capabilities of Slovak HDAB will be continued after the end of the project and what will be needed for it. Tasks of the work package: T4.1 Sustainability plan. T4.2: Business Continuity plan.

Work package WP5 – National Data Access Applications management solution

Work Package Number	WP5	Lead Beneficiary	1. NCZI
Work Package Name	National Data Access Applications management solution		
Start Month	1	End Month	45

Objectives
Enable the Slovak HDAB to receive, process and reply to data access applications: - Define requirements and specifications for the Data Access Applications Management solution (DAAMs), - Implement and pilot the Data Access Applications Management solution, - Launch an operational Data Access Applications Management solution.

Description
Work package will specify requirements, specifications and other aspects needed for the prototype of DAAMs. Based on specifications the work package will pilot the DAMMs and describe experience and proposals for improvement based

on the piloting of DAAMs. After implementing proposals the work package will operate DAMMs service and collect experience and improvement proposals for the DAMMS service which will be implemented after the end of the project.
Tasks of the work package:
T5.1: Data Access Applications Management solution (DAAMs): Analysis and design.
T5.2: DAAMs: Implementation and piloting.
T5.3: DAAMs: Deployment of an operational solution.

Work package WP6 – National Health Dataset Catalogue for health data

Work Package Number	WP6	**Lead Beneficiary**	1. NCZI
Work Package Name	National Health Dataset Catalogue for health data		
Start Month	1	**End Month**	45

Objectives
Enable the Slovak HDAB to provide data users a way to discover and assess the suitability of existing health datasets for the data users' intended purpose: - Define requirements and specifications for a national Health Dataset Catalogue (nHDsC) - Implement and pilot the national Health Dataset Catalogue - Launch an operation ready national Health Dataset Catalogue

Description
The first step for a successful implementation of the nHDsC solution is to undergo "Analysis and design" activities. These activities build upon the outputs from TEHDAS and upcoming Joint Actions on secondary uses, as well as on the lessons learnt on the HealthData@EU Pilot, to ensure alignment and interoperability with the other HDABs nHDsC. The implementation of nHDsC entails several challenges and risks. In order to address and tackle such challenges and risks in a controlled environment, the nHDsC will be piloted, before making it publicly available. After maturing the functionalities and security of nHDsC to a point where all required requirements are fulfilled, the solution will be made publicly available . Description of the tasks of work package: T6.1: National Health Dataset Catalogue (nHDsC): Analysis and design. T6.2: nHDsC: Implementation and piloting. T6.3: nHDsC: Deployment of operational solution.

Work package WP7 – Cross-border gateway to connect with the HealthData@EU infrastructure

Work Package Number	WP7	**Lead Beneficiary**	1. NCZI
Work Package Name	Cross-border gateway to connect with the HealthData@EU infrastructure		
Start Month	1	**End Month**	45

Objectives
Connect to the HealthData@EU infrastructure to enable cross-border workflows for secondary use of electronic health data at EU-scale. - Scrutinise existing requirements and specifications for the cross-border gateway for secondary use of electronic health data; - Analyse the requirements and design the national connector responsible to connect the cross-border gateway to the national infrastructure; - Implement and pilot the cross-border gateway for secondary use of electronic health data; - Launch an operational cross-border gateway for secondary use of electronic health data.

Description
The first steps for a successful implementation of the Cross-border gateway solution is to undergo “Analysis and design” activities. In particular, the analysis and design of the national connector responsible to connect the cross-border gateway to the national infrastructure. These activities build upon the outputs from TEHDAS and upcoming Joint Actions on secondary uses, as well as on the lessons learnt on the HealthData@EU Pilot, to ensure alignment and interoperability with the other HDABs nHDsC. The implementation of the cross-border gateway and connection to HealthData@EU (central services and other HDABs) entails several challenges and risks. In order to address and tackle such challenges and risks in a controlled environment, the connection to HealthData@EU will be piloted (taking advantage of test use cases) before making it widely available in an operational environment. After maturing the connection to HealthData@EU (central services and other HDABs) and ensuring that all required requirements are fulfilled, the cross-border gateway will be made available in an operational environment, enabling cross-border use of health data for real use cases. Description of the tasks of work package: T7.1: Cross-border gateway: Analysis and design. T7.2: Cross-border gateway: Implementation and piloting. T7.3: Cross-border gateway: Deployment of operation ready solution.

Work package WP8 – Health data quality enhancement

Work Package Number	WP8	Lead Beneficiary	1. NCZI
Work Package Name	Health data quality enhancement		
Start Month	1	End Month	33

Objectives
- Enhance the quality of electronic health data made available through the health data access body, - Develope new tools or implement already existing tools and standards to improve data quality, - Support data holders in enhancing the data quality of dataset descriptors (metadata) and raw data (data).

Description
Work package will analyse the quality of health datasets available for nHDsC in Slovak republic. The development of tools and standards to improve data quality will be co-ordinated intemporary HealthData@EU governance body level to ensure t̃he same standards on data quality in all participating countries. The tools on data quality assessment will be developed only after such consultations. The work package will propose improvement of the quality of the health data available for nHDsC. Description of the tasks of work package: T8.1: Analysis of the quality of the available data. T8.2: Development or implementation of already existing tools and standards to improve data quality. T8.3: Proposal on improving the quality of health data available for nHDsC.

STAFF EFFORT

Staff effort per participant

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

Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	Total Person-Months
1 - NCZI	44.00	22.00	6.00	16.00	16.00	20.00	42.00	23.00	189.00
Total Person-Months	44.00	22.00	6.00	16.00	16.00	20.00	42.00	23.00	189.00

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 - Preliminary Governance Management and Participation Report	WP1	1 - NCZI	R — Document, report	PU - Public	24
D1.2	D1.2 Final Governance, Management and participation Report	WP1	1 - NCZI	R — Document, report	PU - Public	47
D2.1	D2.1 Dissemination, Education and Training Plan	WP2	1 - NCZI	R — Document, report	PU - Public	16
D2.2	D2.2 Dissemination, Education and Training materials	WP2	1 - NCZI	R — Document, report	PU - Public	30
D2.3	D2.3 Dissemination, Education and Training Monitoring Report	WP2	1 - NCZI	R — Document, report	PU - Public	47
D2.4	D2.4 MS Service and Help Desk Plan	WP2	1 - NCZI	R — Document, report	PU - Public	36
D2.5	D2.5: Web page dedicated to the HeDAB-SK project in the health portal of Slovak republic.	WP2	1 - NCZI	DEC —Websites, patent filings, videos, etc	PU - Public	10
D3.1	D3.1: Report on the performance monitoring indicators framework	WP3	1 - NCZI	R — Document, report	PU - Public	16
D3.2	D3.2: Overall evaluation report	WP3	1 - NCZI	R — Document, report	PU - Public	46
D3.3	D3.3 Action level indicators report.	WP3	1 - NCZI	R — Document, report	PU - Public	47

Deliverables

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D4.1	D4.1 Sustainability plan	WP4	1 - NCZI	R — Document, report	PU - Public	44
D4.2	D4.2 Business Continuity Plan	WP4	1 - NCZI	R — Document, report	PU - Public	44
D5.1	D5.1 DAAMs: Requirements, Specifications and Prototype	WP5	1 - NCZI	R — Document, report	PU - Public	15
D5.2	D5.2: DAAMs: Pilot Report	WP5	1 - NCZI	R — Document, report	PU - Public	33
D5.3	D5.3: DAAMs: Operational Service Report	WP5	1 - NCZI	R — Document, report	PU - Public	45
D6.1	D6.1: nHDsC: Requirements and Specifications	WP6	1 - NCZI	R — Document, report	PU - Public	15
D6.2	D6.2: nHDsC: Pilot report	WP6	1 - NCZI	R — Document, report	PU - Public	33
D6.3	D6.3: nHDsC: Operational Service	WP6	1 - NCZI	R — Document, report	PU - Public	45
D7.1	D7.1: National Connector for Cross-border gateway: Requirements and Specifications	WP7	1 - NCZI	R — Document, report	PU - Public	15
D7.2	D7.2: Cross-border gateway: Pilot	WP7	1 - NCZI	R — Document, report	PU - Public	33
D7.3	D7.3: Cross-border gateway: Operational Service	WP7	1 - NCZI	R — Document, report	PU - Public	45
D8.1	D8.1: Quality of data: Analysis of the quality of the available health data including tools and standards to improve the quality	WP8	1 - NCZI	R — Document, report	PU - Public	12
D8.2	D8.2: Quality of Data: Proposal on	WP8	1 - NCZI	R — Document, report	PU - Public	30

Deliverables

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
	improving the quality of available health data including recommendations on usage of data quality tools and standards					

Associated with document Ref. Ares(2023)7236599 - 24/10/2023

Deliverable D1.1 – D1.1 - Preliminary Governance Management and Participation Report

Deliverable Number	D1.1	**Lead Beneficiary**	1. NCZI
Deliverable Name	D1.1 - Preliminary Governance Management and Participation Report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	24	**Work Package No**	WP1

Description
Preliminary Governance, Management and Participation report will focus on description of problems in project management of the HeDAB - SK project during the first 24 months of the project.

Deliverable D1.2 – D1.2 Final Governance, Management and participation Report

Deliverable Number	D1.2	**Lead Beneficiary**	1. NCZI
Deliverable Name	D1.2 Final Governance, Management and participation Report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	47	**Work Package No**	WP1

Description
Final Governance, Management and Participation report will focus on description of problems in project management of the HeDAB - SK project during the first 24 months of the project.

Deliverable D2.1 – D2.1 Dissemination, Education and Training Plan

Deliverable Number	D2.1	**Lead Beneficiary**	1. NCZI
Deliverable Name	D2.1 Dissemination, Education and Training Plan		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	16	**Work Package No**	WP2

Description
Detailed action plan on dissemination, education and training activities.

Deliverable D2.2 – D2.2 Dissemination, Education and Training materials

Deliverable Number	D2.2	**Lead Beneficiary**	1. NCZI
Deliverable Name	D2.2 Dissemination, Education and Training materials		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	30	**Work Package No**	WP2

Description
Deliverable containing all educational materials prepared for education and training of potential stakeholders.

Deliverable D2.3 – D2.3 Dissemination, Education and Training Monitoring Report

Deliverable Number	D2.3	**Lead Beneficiary**	1. NCZI
Deliverable Name	D2.3 Dissemination, Education and Training Monitoring Report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	47	**Work Package No**	WP2

Description
Report on progress of dissemination, education and training activities.

Deliverable D2.4 – D2.4 MS Service and Help Desk Plan

Deliverable Number	D2.4	**Lead Beneficiary**	1. NCZI
Deliverable Name	D2.4 MS Service and Help Desk Plan		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	36	**Work Package No**	WP2

Description
Detailed action plan on the introduction and operation of Service and Help desk in Slovak republic.

Deliverable D2.5 – D2.5: Web page dedicated to the HeDAB-SK project in the health portal of Slovak republic.

Deliverable Number	D2.5	**Lead Beneficiary**	1. NCZI
Deliverable Name	D2.5: Web page dedicated to the HeDAB-SK project in the health portal of Slovak republic.		
Type	DEC —Websites, patent filings, videos, etc	**Dissemination Level**	PU - Public
Due Date (month)	10	**Work Package No**	WP2

Description
Creation of web page dedicated to the HeDAB-SK project in health portal of Slovak republic.

Deliverable D3.1 – D3.1: Report on the performance monitoring indicators framework

Deliverable Number	D3.1	**Lead Beneficiary**	1. NCZI
Deliverable Name	D3.1: Report on the performance monitoring indicators framework		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	16	**Work Package No**	WP3

Description
Report on the set of performance indicators. MS Word document in EN.

Deliverable D3.2 – D3.2: Overall evaluation report

Deliverable Number	D3.2	Lead Beneficiary	1. NCZI
Deliverable Name	D3.2: Overall evaluation report		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	46	Work Package No	WP3

Description
Final report putting together the values of the process eva-luation indicators and an overview of outputs and outco-mesof the pro-ject.MS Word document in EN

Deliverable D3.3 – D3.3 Action level indicators report.

Deliverable Number	D3.3	Lead Beneficiary	1. NCZI
Deliverable Name	D3.3 Action level indicators report.		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	47	Work Package No	WP3

Description
Report on the set of action level indicators. MS Word document in EN.

Deliverable D4.1 – D4.1 Sustainability plan

Deliverable Number	D4.1	Lead Beneficiary	1. NCZI
Deliverable Name	D4.1 Sustainability plan		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	44	Work Package No	WP4

Description
The document will describe, how the improved activities of Slovak HDAB will be continued after the end of the project.

Deliverable D4.2 – D4.2 Business Continuity Plan

Deliverable Number	D4.2	Lead Beneficiary	1. NCZI
Deliverable Name	D4.2 Business Continuity Plan		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	44	Work Package No	WP4

Description
The document will describe, how the improved business capabilities of Slovak HDAB will be continued after the end of the project.

Deliverable D5.1 – D5.1 DAAMs: Requirements, Specifications and Prototype

Deliverable Number	D5.1	**Lead Beneficiary**	1. NCZI
Deliverable Name	D5.1 DAAMs: Requirements, Specifications and Prototype		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	15	**Work Package No**	WP5

Description
Document will include requi-rements, specifi-cations and other aspects needed for the prototype of DAAMs MS Word document in EN

Deliverable D5.2 – D5.2: DAAMs: Pilot Report

Deliverable Number	D5.2	**Lead Beneficiary**	1. NCZI
Deliverable Name	D5.2: DAAMs: Pilot Report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	33	**Work Package No**	WP5

Description
Document will des-cribe experience and proposals for improvement ba-sed on the piloting of DAAMs. MS Word doc. in EN.

Deliverable D5.3 – D5.3: DAAMs: Operational Service Report

Deliverable Number	D5.3	**Lead Beneficiary**	1. NCZI
Deliverable Name	D5.3: DAAMs: Operational Service Report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	45	**Work Package No**	WP5

Description
Document will des-cribe experience and proposals for improvement ba-sed on the operation of DAAMs. MS Word document in EN

Deliverable D6.1 – D6.1: nHDsC: Requirements and Specifications

Deliverable Number	D6.1	**Lead Beneficiary**	1. NCZI
Deliverable Name	D6.1: nHDsC: Requirements and Specifications		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	15	**Work Package No**	WP6

Description
Document will inclu-de requirements, specifications and other aspects nee-ded for the prototype of nHDsC. MS Word document in EN.

Deliverable D6.2 – D6.2: nHDsC: Pilot report

Deliverable Number	D6.2	Lead Beneficiary	1. NCZI
Deliverable Name	D6.2: nHDsC: Pilot report		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	33	Work Package No	WP6

Description
Document will des-cribe experience and proposals for impro-vement based on the piloting of nHDsC. MS Word doc. in EN.

Deliverable D6.3 – D6.3: nHDsC: Operational Service

Deliverable Number	D6.3	Lead Beneficiary	1. NCZI
Deliverable Name	D6.3: nHDsC: Operational Service		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	45	Work Package No	WP6

Description
Document will des-cribe experience and proposals for impro-vement based on the operation of nHDsC. MS Word document in EN.

Deliverable D7.1 – D7.1: National Connector for Cross-border gateway: Requirements and Specifications

Deliverable Number	D7.1	Lead Beneficiary	1. NCZI
Deliverable Name	D7.1: National Connector for Cross-border gateway: Requirements and Specifications		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	15	Work Package No	WP7

Description
Document will include require-ments, specifi-cations and other aspects needed for the prototype of National Connector for Cross-border gateway:. MS Word document in EN.

Deliverable D7.2 – D7.2: Cross-border gateway: Pilot

Deliverable Number	D7.2	Lead Beneficiary	1. NCZI
Deliverable Name	D7.2: Cross-border gateway: Pilot		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	33	Work Package No	WP7

Description

Document will des-cribe experience and proposals for improvement ba-sed on the piloting of National Co-nector for Cross-border gateway: MS Word document in EN

Deliverable D7.3 – D7.3: Cross-border gateway: Operational Service

Deliverable Number	D7.3	**Lead Beneficiary**	1. NCZI
Deliverable Name	D7.3: Cross-border gateway: Operational Service		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	45	**Work Package No**	WP7

Description
Document will des-cribe experience and proposals for improvement ba-sed on the opera-tion of National Co-nnector for Cross-border gateway: MS Word document in EN.

Deliverable D8.1 – D8.1: Quality of data: Analysis of the quality of the available health data including tools and standards to improve the quality

Deliverable Number	D8.1	**Lead Beneficiary**	1. NCZI
Deliverable Name	D8.1: Quality of data: Analysis of the quality of the available health data including tools and standards to improve the quality		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP8

Description
Document will contain the ana-lysis of the quali-ty of datasets for secondary usage in Slovak repub-lic. MS Word document in EN.

Deliverable D8.2 – D8.2: Quality of Data: Proposal on improving the quality of available health data including recommendations on usage of data quality tools and standards

Deliverable Number	D8.2	**Lead Beneficiary**	1. NCZI
Deliverable Name	D8.2: Quality of Data: Proposal on improving the quality of available health data including recommendations on usage of data quality tools and standards		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	30	**Work Package No**	WP8

Description
Document will contain proposal on how to impro-ve the quality of datasets for secondary usage in Slovak repub-lic. MS Word document in EN.

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	MS1.1 Establishment of a national governance and management structure	WP1	1-NCZI	Description: Presence of a functional governance management structure with identified roles, duties, and functions. Means of verification: Yes/ No	3
2	MS1.2 Accession into the temporary HealthData@EU cross-border governance body	WP1	1-NCZI	Description: Start of the participation and engagement of the MS representative in the meetings of the temporary HealthData@EU cross-border governance body. Means of verification: Yes/No	3
3	MS2.1 Accounts in social media dedicated to the project HeDAB-SK.	WP2	1-NCZI	Description: Creating accounts in social media dedicated to the project HeDAB -SK. Means of verification: Yes/No	10
4	MS2.2 Workshop for collecting feedback from stakeholders on new systems in HDAB.	WP2	1-NCZI	Description: The feedback from stakeholders of HDAB will be needed to include their comments and proposals to the recommendations collected during the piloting phase of new information systems. The workshop will be dedicated to collecting such feedback. Means of verification: Yes/No	22
5	MS2.3 Kick-off of education and training workshops.	WP2	1-NCZI	Description: At the end of pilots in WP5, WP6 and WP7 the training and education of potential customers will start with the firs workshop. Means of verification: Yes/No	30
6	MS2.4 Service and Help desk	WP2	1-NCZI	Description: Availability of a help desk with capability to give support to data users, data	40

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
				holders, and HDAB staff. Means of verification: Yes/No	
7	MS3.1 Definition of performance monitoring indicators framework.	WP3	1-NCZI	Description: Define a framework for performance indicators for the digital business capabilities of the health data access body. Means of verification: Yes/No	6
8	MS3.2 Final evaluation of the project	WP3	1-NCZI	Description: Final assessment of the effectiveness of the implementation of the digital business capabilities, on the basis of the performance monitoring indicators framework. Means of verification: Yes/No	46
9	MS4.1 Draft of a Sustainability Plan.	WP4	1-NCZI	Description: This milestone will ensure that the sustainability of the digital business capabilities is appropriately planned beyond the period covered by this grant. Draft will undergo review of key stakeholders. The standardized process of commenting will have probably more than one step. In the first step stakeholders from the healthcare sector will be asked to send the comments. The comments will be discussed by the authors of the draft and implemented, where it will make sense into the second draft. When necessary the recommendations based on the comments will be sent to PSC for endorsement. After that the second draft will be sent to stakeholders from the other relevant sectors. The procedure will be the same as in the first step, The outcomes of the commenting process will be published by WP2 on project – related web pages	37

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
				and on social media. Means of verification: Yes/ No	
10	MS4.2 Draft of a Business Continuity Plan	WP4	1-NCZI	Description: This milestone will ensure that the continuity of the digital business capabilities is appropriately planned in the face of disruptions. Draft will undergo review of key stakeholders. The standardized process of commenting will have probably more than one step. In the first step stakeholders from the healthcare sector will be asked to send the comments. The comments will be discussed by the authors of the draft and implemented, where it will make sense into the second draft. When necessary the recommendations based on the comments will be sent to PSC for endorsement. After that the second draft will be sent to stakeholders from the other relevant sectors. The procedure will be the same as in the first step, The outcomes of the commenting process will be published by WP2 on project – related web pages and on social media. Means of verification: Yes/No	37
11	MS5.1 DAAMs: Draft requirements, Specifications and Prototype	WP5	1-NCZI	Description: Draft version of requirements and specifications for the DAAMs. Requirements and specifications should be demonstrated with the use of a prototype supporting stakeholders to accurately understand and scrutinise the requirements and specifications for the DAAMs. Due date will be at the middle of Analysis and Design phase. Means of verification: Yes/No	12

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
12	MS5.2 DAAMs: Minimum Viable Product (MVP)	WP5	1-NCZI	Description: The Minimum Viable Product (MVP) for the DAAMs is an early version of the solution with just enough features to be usable by early users who can then provide feedback for future development of the DAAMs. The MVP features will be defined during the analysis and design phase. Due date will be at the end of first iteration of implementation. Means of verification: Yes/No	30
13	MS5.3:DAAMs: Operational Product (OP)	WP5	1-NCZI	Description: The Operational Product for the DAAMs is a consolidated and stable version of the solution fulfilling all the require-ments identified as necessary for an operational deploy-ment of the DAAMs. Due date will be at the end of second iteration of implementation. Means of verification: Yes/No	42
14	MS6.1: nHDsC: Draft Requirements and Specifications + Prototype (at the middle of Analysis and Design phase)	WP6	1-NCZI	Description: Draft version of requirements and specifications for the nHDsC. Requirements and specifications should be demonstrated with the use of a prototype supporting stakeholders to accurately understand and scrutinise the requirements and specifications for the nHDsC. Means of verification: Yes/No	12
15	MS6.2:nHDsC: Minimum Viable Product (MVP) (at the end of first iteration of implementation)	WP6	1-NCZI	Description: The Minimum Viable Product (MVP) for the nHDsC is an early version of the solution with just enough features to be usable by early users who can then provide feedback for future development of the nHDsC. The MVP features will be defined during the analysis and design phase. Means of verification: Yes/No	30

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
16	MS6.3: nHDsC: Operational Product (OP) (at the end of second iteration of implementation)	WP6	1-NCZI	Description: The Operational Product for the nHDsC is a consolidated and stable version of the solution fulfilling all the require-ments identified as necessary for an operational deploy-ment of the nHDsC. Means of verification: Yes/No	42
17	MS7.1: Cross-border gateway: Draft Requirements and Specifications + Prototype (at the middle of Analysis and Design phase)	WP7	1-NCZI	Description: Draft version of requirements and specifications for the national connector to the Cross-border gateway. Requirements and specifications should be demonstrated with the use of a prototype supporting stakeholders to accurately understand and scrutinise the requirements and specifications for the Cross-border gateway. Means of verification: Yes/No	12
18	MS7.2:Cross-border gateway: Minimum Viable Product (MVP) (at the end of first iteration of implementation)	WP7	1-NCZI	Description: The Minimum Viable Product (MVP) for the Cross-border gateway is an early version of the solution with just enough features to be usable by early users who can then provide feedback for future development of the Cross-border gateway. The MVP features will be defined during the analysis and design phase. Means of verification: Yes/No	30
19	MS7.3: Cross-border gateway: Operational Product (OP) (at the end of second iteration of implementation).	WP7	1-NCZI	Description: The Operational Product for the Cross-border gateway is a consolidated and stable version of the solution fulfilling all the requirements identified as necessary for an operational deployment of the Cross-border gateway. Means of verification: Yes/No	42
20	MS8.1: Final version of the analysis of the quality of available health data.	WP8	1-NCZI	Description: Final version of the analysis of the	12

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
				quality of data available for nHDsC. Means of verification: Yes/No	
21	MS8.2: Proposal on improving the quality of available health data.	WP8	1-NCZI	Description: Proposal on improvement of the quality of the data available for nHDsC. Means of verification: Yes/No	30

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	Inappropriate connection to national infrastructures and frameworks (technical, semantic, organisational) (Likelihood: high, Impact: high)	WP6, WP5, WP7	Ensuring appropriate participation of national entities and partners in the project to facilitate connections
2	Difficulties amending national legisla-tion to enable the access to health data-by-data users (also cross-border) and availability of datasets. (Likelihood: high, Impact: high	WP6, WP5, WP7	Implement measures to facilitate legal convergence with the upcoming European Health Data Space regulation
3	Multiple health datasets catalogues exist but are not linked (Likelihood: medium, Impact: high)	WP6	Harmonize standards and practices and federate existing dataset catalogues
4	National dataset catalogues descriptions are not publicly available (Likelihood: low, Impact: medium)	WP6	Establish appropriate frameworks and procedures for the submission, approval and maintenance of datasets descriptions in a publicly available data catalogue

Critical risks & risk management strategy

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

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
5	Poor data discovery and data user knowledge of the existence of the infrastructure (Likelihood: high, Impact: high)	WP6	Ensure proper training, promotion and communication activities of the project work to allow data users to find suitable data
6	Burdensome and complicated submission of data access application (Likelihood: high, Impact: high)	WP5	Streamline and harmonise the applica-tion process with other countries, inclu-ding the use of shared portals for data discovery and application submission and follow up
7	Burdensome and inefficient handling of data access applications (national and EU level) and issuance of data permits to data users/authorisation of data requests (Likelihood: high, Impact: high)	WP5	Foster automation, standardisation and convergence in the processing of data access applications
8	Irregular and inconsistent interaction between data users, data holders and Slovak HDAB (Likelih.: medium, Impact: medium)	WP5	Increase availability of services by health data access bodies to data holders and data users, and promote them through proper training, promotion and communication activities
9	Risk of improper functionality of national connector. (Likelihood: medium, Impact: high)	WP7	Ensuring appropriate implementation of national connector.

TECHNICAL DESCRIPTION (PART B)

COVER PAGE

PROJECT	
Project name:	Health Data Access Body Slovak republic.
Project acronym:	HeDAB - SK
Coordinator contact:	Pavol Rieger, Narodne centrum zdravotnickych informacii

HISTORY OF CHANGES	
ESR comment	**CHANGE**
Criterion 1 -Relevance	
It is not clear why the proposal aims at data quality without a secure processing environment in place.	After the consultation with DG Santé we have decided NOT to include the creation of secure processing environment infrastructure into the project, as the creation of national secure processing environment projects will not be very probably coordinated by the temporary governance structure until EC will open the new call dedicated to secure processing environment infrastructure. The call will be opened during next 2 years, when also legislative support on the European level will be in place. The secure processing environment infrastructure will be implemented by the project answering that call actually in preparation.
	The notice of ESR regarding the Criterion 1 – Relevance and the answer were added.

ESR comment	**CHANGE**
Criterion 2.1 Quality Project design and implementation	
In the proposal, it is stated that SK plans to have close cooperation with FINDATA, which is the HDAB in Finland, but it is not explained how advanced contacts are and how this will be operationalized in the work plan.	The following text was added: . The advanced contacts with HDAB in Finland (Findata) are not yet established and we plan to discuss the future co-operation during the first meetings of temporary HealthData@EU governance structure (Task 1.2). There could be also other offers from other member states in the beginning of HeDAB – SK project. The work plan of HeDAB – SK project will be operationalized based on that proposal we will decide for during the project HeDAB – SK.
	The new task T1.5 Good practice identification was added to WP1. Also the budget was changed: Trips formerly planned to Helsinki, Finland in connection with the activities of WP5 and WP6 were added to WP1 and deleted in WP5 and WP6 traveling budget. Administrative effort in WP1 was increased. Also description of WP1 in SYGMA was changed appropriately.
There seems to be some over reporting on WP1. The frequency of deliverables could be reduced.	Deliverables D1.3 and D1.4 were deleted from Part B and from SIGMA.
Some Milestones are not easily distinguishable from deliverables (WP4).	Milestones in WP4 were changed and connected with draft versions of deliverable.
MS1.2, MS1.3 and MS2.1 and MS2.2, MS3.2 for example, refer to a continuous process instead of a concrete achievement on which the project will build to progress.	The name of milestone MS1.2 was changed to Accession into the temporary HealthData@EU cross-border governance body. The related description was changed to Start of the participation and engagement of the MS representative in the meetings of the temporary HealthData@EU cross-border governance body. The due date was changed to M03.
	The milestone MS1.3 was deleted.
	The Due date of MS1.1 was changed to M03.
	The name of milestone MS1.2 was changed to Accession into the temporary HealthData@EU cross-border governance body. The related description was changed to Start of the participation and engagement of the MS representative in the meetings of the temporary HealthData@EU cross-border governance body. The due date was changed to M03.

ESR Comment	CHANGE
	The name of MS2.1 was changed to “Accounts in social media dedicated to the project HeDAB – SK”. The description of the milestone was changed to “Creating accounts in social media dedicated to the project HeDAB-SK”. The due date was changed from M47 to M10.
	The name of MS2.2 was changed to “Web page dedicated to the HeDAB-SK project in health portal of Slovak republic”. The description of the milestone was changed to “Creation of web page dedicated to the HeDAB-SK project in health portal of Slovak republic”. The due date was changed from M36 to M10.
	New MS2.3 was introduced. The name is “Kick-off of the education and training workshops”. The description is “At the end of pilots in WP5, WP6 and WP7 the training and education of potential customers will start with the first workshop.” The due date was set to M30.
	Former MS2.3 was renamed to MS2.4. The name was changed to “Service and Help desk”.
	The Due date of MS3.1 was changed from M1 to M6.
	The name of MS3.2 Was changed to ”Final evaluation of the project”. The description of the milestone was changed to “Final assessment of the effectiveness of the implementation of the digital business capabilities, on the basis of the performance monitoring indicators framework”.
	MS4.1: The milestone name was changed to “Draft of a Sustainability Plan. The Due Date was changed from M45 to M37. To the former text the new text was added in the Description, The actual text of the Description is: “This milestone will ensure that the sustainability of the digital business capabilities is appropriately planned beyond the period covered by this grant. Draft will undergo review of key stakeholders. The standardized process of commenting will have probably more than one step. In the first step stakeholders from the healthcare sector will be asked to send the comments. The comments will be discussed by the authors of the draft and implemented, where it will make sense into the second draft. When necessary the recommendations based on the comments will be sent to PSC for endorsement. After that the second draft will be sent to stakeholders from the other relevant sectors. The procedure will be the same as in the first step, The outcomes of the commenting process will be published by WP2 on project – related web pages and on social media.“
	MS4.2: The milestone name was changed to: “Draft of s Business Continuity Plan”. The Due Date was changed from M45 to M37. To the former text the new text was added in the Description, The actual text of the Description is: “This milestone will ensure that the continuity of the digital business capabilities is appropriately planned in the face of disruptions. Draft will undergo review of key stakeholders. The standardized process of commenting will have probably more than one step. In the first step stakeholders from the healthcare sector will be asked to send the comments. The comments will be discussed by the authors of the draft and implemented, where it will make sense into the second draft. When necessary the recommendations based on the comments will be sent to PSC for endorsement. After that the second draft will be sent to stakeholders from the other relevant sectors. The procedure will be the same as in the first step, The outcomes of the commenting process will be published by WP2 on project – related web pages and on social media.”

ESR Comment	CHANGE
Details are also lacking for the dissemination, training and education activities foreseen in WP2 (foreseen schedule, target groups etc.).	More detailed information was inserted into the Section 3.2 Communication, dissemination and visibility. Inserted text: "Dissemination, training and education activities foreseen in WP2 will start at the end of piloting phase in WP5, WP6 and WP7 – in M30. We can distinguish 2 target groups: - Stakeholders from the health sector, - Stakeholders outside of the health sector. Training and education materials will cover all themes of interest of stakeholders beginning from basic information about HDAB in Slovak republic to hands-on workshop on how to ask for access to health data for secondary use."
	The new task T2.2 was added. One of the workshops was dedicated to the collection of the feedback from stakeholders during the piloting phase of new information systems of HDAB. Also new milestone M2.3 was added. The numbering of milestones in WP2 was changed accordingly.
	The description of subcontracting was done in line with the subcontracting table. The description of subcontracting regarding WP2 was changed because of new task T2.2 and change of numbering of tasks in WP2.
	New MS2.3 was introduced. The name is "Kick-off of the education and training workshops". The description is "At the end of pilots in WP5, WP6 and WP7 the training and education of potential customers will start with the first workshop." The due date was set to M30. Former MS2.3 was renamed to MS2.4. The name was changed to "Service and Help desk".
	D2.2: Deliverable name was changed to "Dissemination, Education and Training materials", the Type was changed to R and Due Date was changed to M30.
The need to categorize a high number of deliverables as sensitive is not explained.	The dissemination level was changed from "sensitive" to "public" by the following deliverables: D1.1, D1.2, D2.1, D2.3, D2.4, D3.1, D4.1, D4.2, D5.1, D5.2, D6.2 and D7.2
	Other changes of the deliverables:
	D1.1: Deliverable name was changed to "Preliminary Governance, Management and Participation Report", Due Date was changed to M24 only.
	D1.2: Deliverable name was changed to "Final Governance, Management and Participation Report", Due Date was changed to M47.
	D1.3 and D1.4 were deleted.
	D2.1: Deliverable name was changed to "Dissemination, Education and training Plan", Type of the deliverable was changed to R.
	D2.2: Deliverable name was changed to "Dissemination, Education and Training materials", the Type was changed to R and Due Date was changed to M30.
	D2.2: Due Date was changed to M47 only. The Description was changed to "Deliverable containing all educational materials prepared for education and training of potential stakeholders.".

	D2.4: Deliverable name was changed to “MS Service and Help Desk Plan”, Type was changed to R.
	D9.1 was renamed to D8.1 and Work Package No was changed from 9 to 8.
	D9.2 was renamed to D8.2 and Work Package No was changed from 9 to 8.
	Changes in the tasks:
	Description of T2.2 was updated.
	Name of T2.3 was changed to “Service and Helpdesk.
	Other changes:
	Timeline o WP6 was inserted.
	Timelines of WP1, WP2, WP3, WP4 and WP8 were actualized.
	Work Package 9 was renamed to Work Package 8.
	New objective of WP4 “Ensure that the suggestions from stakeholders on smooth functioning of the business capabilities and services to be provided after the end of the project will be incorporated in Sustainability plan and in Business Continuity Plan.” was added.
WP8 - data quality does not include the development of some tools and standards to improve data quality which might reduce its effectiveness.	
	New objective for WP8 “Develop new tools or implement already existing tools and standards to improve data quality” was added to objectives of WP8.
	New task T8.2 was added to WP8.
	Former task T8.2 was changed to T8.3.
	The name of deliverable D8.1 was updated to “Quality of data: Analysis of the quality of the available health data including tools and standards to improve data quality.”
	The name of deliverable D8.2 was updated to “Quality of Data: Proposal on improving the quality of available health data including recommendations on usage of data quality tools and standards.”.
	New objective for WP8 “Develop new tools or implement already existing tools and standards to improve data quality” was added to objectives of WP8.
	New task T8.2 was added to WP8.
	Former task T8.2 was changed to T8.3.
	The name of deliverable D8.1 was updated to “Quality of data: Analysis of the quality of the available health data including tools and standards to improve data quality.”
	The name of deliverable D8.2 was updated to “Quality of Data: Proposal on improving the quality of available health data including recommendations on usage of data quality tools and standards.”.
	The name of subcontracting S7.1 was changed to “Support of the provider of national infrastructure during the piloting phase”.

ESR Comment	CHANGE
The proposal presents an indicator selection per specific objective with the aim to ensure the project delivers on the main aspects foreseen by the call. Since baselines are not quantified, it is difficult to understand some (baseline yes/no) from where the project will start.	
	New indicator No 1 was added: "Number of HDAB established".
	Numbering of indicators was changed.
	The baseline was added (repaired) in the indicators No (using new numbering): 1, 2, 3, 6, 8, 9, 10, 12, 13.
	The description text was changed to: "These indicators will be regularly measured as a part of WP3 activities during the project and outcomes of the measurement will be described in D3.1 and D3.2.
	The required indicators were added to the table. Some former indicators were deleted as they were derived from the indicators from the call document. Some descriptions were improved. Some baselines and targets were improved. Added indicators: • *"Number of data access applications that the health data access bodies established have processed per month"* • *"Number of health data access bodies providing secure processing environments to data users"* • *Number of health data access bodies offering tools and services to address data privacy as part of the secure processing environments"*
It is not clear though why the performance indicators will only be set up in M16 (MS3.1) by the time the project will report on them (D.3.1). This will give no opportunity to the project to steer set-up and implementation through the indicators.	The due date of MS3.1 was changed to M6.
It seems that a large part of the budget is allocated to the cross-border gateway with potentially hindering effects for other WPs.	As we do not knew any requirements for cross-border gateway, but have experience on costs of the national contact point for MyHealth@EU, we consider that such amount of money for cross-border gateway will be needed anyway.
Unit costs have not been used to calculate travel.	Unit costs were introduced into the budget proposal. Budget has changed.

ESR Comment	CHANGE
The proposal relies significantly on subcontracting to deliver IT programming-related tasks in WP5-8 and workshops in WP2. More details on scope and need would have helped to understand better what will be subcontracted.	More detailed description on scope and needs of subcontracting was included.
Criterion 2.2 – Project team and cooperation arrangements	
NCZI will be the sole beneficiary of the grant, hosting the Data Access Body, but the consortium set-up and division of roles, and governance structure within the project are not described although a PM2 typical structure is provided.	NCZI will be the sole beneficiary of the grant.
It seems that a large part of the managing weight is shifted towards the temporary governance structure. While the consideration of the temporary governance structure is important, it will only focus on high-level aspects or specific procedures/standards. This body will not carry out the tasks that will be needed to take decisions during the day-to-day work and will not be able to understand or recommend national specificities.	The strong cooperation between PSB and temporary governance structure will be needed anyway. The responsibility for carrying out tasks that will be needed to take decisions during the day-to-day work and for understanding national specifications will be on PSB in close cooperation with stakeholders.
The decision-making process at the national level is not described. It is not clear if/how the views of different stakeholders will be incorporated into the project.	The following text – explanation – was added: “The decision making process of the project on the national level organized by Project Steering Committee (PSC) will be based on the standard control mechanisms. The structure of PSC will be adapted to the needs of the project and also to the staus of Narodne centrum zdravotnickych informacii. Members of the PSB: - Project manager, - Project coordinator (responsible for the communication with HaDEA and also member of the temporary European governance body, - Finance and administrative project manager, - Technical project manager, - Delegated representative of Ministry of Health, Slovak republic, - Risk manager, - Leaders of work packages. The decision making process will be also influenced influenced by the feedback from stakeholders. The feedback from stakeholders will be collected by the WP2: Dissemination, training and support and WP2 leader will provide the feedback to PSC.
	The following text was inserted: “The decision making process of the project on the national level organized by Project Steering Committee (PSC) will be based on the standard control mechanisms. The structure of PSC will be adapted to the needs of the project and also to the staus of Narodne centrum zdravotnickych informacii. Members of the PSB: - Project manager, - Project coordinator (responsible for the communication with HaDEA and also member of the temporary European governance body, - Finance and administrative project manager, - Technical project manager, - Delegated representative of Ministry of Health, Slovak republic, - Risk manager, - Leaders of work packages.

	The decision making process will be also influenced influenced by the feedback from stakeholders. The feedback from stakeholders will be collected by the WP2: Dissemination, training and support and WP2 leader will provide the feedback to PSC. The decision making process of the project (on the national level) will be strongly influenced also by the decisions taken on the European level.".
	Draft will undergo review of key stakeholders. The standardized process of commenting will have probably more than one step. In the first step stakeholders from the healthcare sector will be asked to send the comments. The comments will be discussed by the authors of the draft and implemented, where it will make sense into the second draft. When necessary the recommendations based on the comments will be sent to PSC for endorsement. After that the second draft will be sent to stakeholders from the other relevant sectors. The procedure will be the same as in the first step, The outcomes of the commenting process will be published by WP2 on project – related web pages and on social media.
It is not clear which project management strategy will be followed as it is stated that PM2 will be used but adapted to the national preferences which are not outlined.	Primary the project strategy required by national legislation will be used.
Criterion 3 - Impact	
If the proposal would also pilot/deploy the secure processing environment, the proposal would deliver a fully functioning Health Data Access Body with an even greater impact.	After the consultation with DG Santé we have decided NOT to include the creation of secure processing environment infrastructure into the project, as the creation of national secure processing environment projects will not be very probably coordinated by the temporary governance structure until EC will open the new call dedicated to secure processing environment infrastructure. The call will be opened during next 2 years, when also legislative support on the European level will be in place. The secure processing environment infrastructure will be implemented by the project answering that call actually in preparation.
The short, medium, and long-term effects are described for different target groups, although some of them could be more elaborated.	The description of short, medium and long-term effects was updated.
The communication and dissemination strategy is described. Information to citizens will flow mainly through social networks, other channels have not been described. This might hinder the outreach to be expected.	The new channel – dedicated web pages – was added.
From the work plan, it is not clear how the team will work with other stakeholders in the country to ensure the smooth functioning of the business capabilities and services to be provided after the end of the project.	The new objective "Ensure that the suggestions from stakeholders on smooth functioning of the business capabilities and services to be provided after the end of the project will be incorporated in Sustainability plan and in Business Continuity Plan." Was added to WP4. Also task T2.2 "Collecting feedback from stakeholders" and MS2.3 "Workshop for collecting feedback from stakeholders on new systems in HDAB" were added in WP2.

Technical changes:

	CHANGE
Can you further specify if this is a national project you will be implementing and roughly its timeframe? (page 14)	The following text was inserted: "We expect that the project will be national project cofinanced by HaDEA. The type of the project will be Direct Grant based on the call that EK plans to open in 2025 or 2026. We expect that the project will take 3 years and may start in 2027 or 2028.".
You added progress reports. Since you will have official reporting periods in the project at which you will be required to provide progress reports these two deliverables might duplicate your work. The interim and final reporting have separate sections in the portal and require a technical and financial reporting. They open automatically and thus do not need to be covered by deliverables (Page 33)	Deliverables D1.3 and D1.4 were deleted from the Part B and from SIGMA.
Can you further specify what you mean with support? (Page 53)	The description of S7.1 was changed to "T7.2, NCZI will need support of the provider of national infrastructure during the piloting phase to connect cross-border gateway properly to national infrastructure.",
Compulsory deliverables	
MS2.2 Web page dedicated to the HeDAB-SK project in health portal of Slovak republic, due M10. Please convert this Milestone into a deliverable to comply with the call requirements of mandatory deliverables. You can keep title, description etc.	The new Deliverable D2.5 (Web page dedicated to HeDAB-SK …) was inserted. MS2.2 was deleted and other milestones were renumbered.
WP3: please add at least one separate deliverable to report on the Action level Indicators from the call document. If you opt for several ones, one deliverable should be scheduled ideally by the end of the project.	The new deliverable D3.3 (Action level indicators report) was inserted.
	New deliverables were added to the SYGMA.
Budget	
	Effort (personal costs) was increased in WP1 because of new delivery.
	Traveling budget of WP1 was increased and traveling budget of WP5 and WP6 was decreased because of more detailed information on travel (destination and purpose of travel).
	Subsistence costs were actualized based on the country of destination in WP1, WP5, WP6, WP7 and WP8..
Subcontracting	
Please make sure that the subcontracting costs in WP7 are aligned between Annex 1 part b (description of the action) and Annex 1 part b (detailed budget table)	Subcontracting costs in WP7 were aligned between Annex 1 part b (description of the action) and Annex 1 part b (detailed budget table)
Travel and subsistence	
Please specify the destination of travel in the detailed budget for all WP7 'visits to place of testing activities' and WP8 'coordination meetings on data quality'.	The specification of the destination of travel in the detailed budget for WP7 and WP8 was added.
Please bear in mind that normally the subsistence unit cost varies depending on the destination of the travel.	Subsistence unit costs were actualised in WP1, WP5, WP6, WP7 and WP8 based on newest version of unit costs specification.
Timeline	Timeline was actualized – expected start of the project was shifted to Q4 of 2023.

TABLE OF CONTENTS

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PROJECT SUMMARY

Project summary
Establishing Health Data Access Body (HDAB) in Slovak republic. The project will introduce Slovak National Data Access Application solution to process applications for accessing health data for secondary usage. The project will also introduce National Health Dataset Catalogue (Catalogue). The catalogue will help applicants for the access to health data for secondary usage to prepare their application based on the information from the Catalogue, which datasets are available at that moment in Slovak republic. Despite the fact that in the call document EU4H-2022-DGA-MS-IBA2 in the part E (Specific mandatory deliverables and/or milestones) of the call EU4H-2022-DGA-MS-IBA-4 (DI-g-22-22.01) there is mandatory deliverable on secure processing environment infrastructure required, we decided after the consultation with DG Santé C1 not to include this activity into our proposal. EC said that there would be very probably separate call on this topic in 2 years. The project will also introduce cross-border gateway to connect with the HealthData@EU infrastructure. We will also work on: - Improving the health data quality in Slovak republic, - Dissemination, training and support the activities of HDAB in Slovak republic, - Business Continuity plan for HDAB in Slovak republic, - Other activities described in this Part B of our proposal. The project is expected to support Slovak republic and other Member States to progress and align towards: - providing more patients the opportunity to benefit of cross-border health care; - increase capacity, resilience and readiness for Member States to participate in cross-border exchange and reuse of health data for research, innovation, policy-making, statistical purposes and regulatory activities; - scaling-up of HDABs IT infrastructures according to a common set of digital business capabilities necessary for secondary use of health data; - set the necessary pre-conditions to enable connectivity between HDABs in each Member State.

#§PRJ-SUM-PS§# #@REL-EVA-RE@# #@PRJ-OBJ-PO@#

1. RELEVANCE

1.1 Background and general objectives

2.	**Background and general objectives**
3.	The Data Governance Act[1] sets out the provision for bodies to support the re-use of protected public sector data, as it is personal data or commercially sensitive data, and the proposed European Health Data Space[2] (EHDS) builds upon this and extends this function for health. In the health area, several Member States (MS) have already set up HDABs to support the re-use of electronic health data, while other MS have laid out plans to establish such structures in the future. HDABs require specific digital business capabilities to enable the processing and management of data access applications, to support the secure processing of health data and to make sure that HDABs are well integrated in the EHDS.
4.	In the specific case of Slovak republic, in order to achieve the goals of the EHDS, there is a need to expand and enlarge digital business capabilities of Slovak HDAB **Narodne centrum zdravotnickych informacii** (NCZI) and establish its connection with HealthData@EU infrastructure and related services. NCZI provides only statistical data based on health data collected in Slovak republic at the moment.
5.	Project **HeDAB-SK** is based on the call DI-g-22-22.01. The project will cover the scope of the call with the exception of secure processing environment infrastructure. After the consultation with DG Santé we have decided NOT to include the creation of secure environment into the project. EC will very probably open the new call dedicated to secure processing environment infrastructure in 2 years, when also legislative support for the secure processing environment on the European level will be in place.
6.	Project addresses the general objectives of the call very closely. The Slovak HDAB is operating only with little digital business capabilities described in the call at the moment. The objectives of the project HeDAB-SK will improve and enlarge digital business capabilities of Slovak HDAB. At the end of the project, general objectives of the call with the exception of secure processing environment will be implemented in Slovak HDAB. The general objectives of the call will be achieved with the help of the work conducted by the joint action 'Towards the European Health Data Space' (TEHDaS), and by the outcomes of the pilot project for the EHDS infrastructure based on 5 use cases that will run from 2022-2024 to test the setting up of a European network for secondary uses of data.
7.	The contribution of this project to the priorities of the call is that it supports enlargement and improvement of digital business capabilities of Slovak HDAB. The project will also take into account requirements of specific areas of health data, including those linked to quality of health data and for statistical purposes, as part of the data and infrastructure ecosystem of the planned EHDS for secondary uses of health data.
8.	Additionally, this project complements Slovak republic's effort to expand to patients the health data sharing services provided by MyHealth@EU for ensuring the continuity of care for people while they are travelling abroad in the Union in the pillar of primary use of health data of the EHDS.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?pk_campaign=todays_OJ&pk_content=Regulation&pk_keyword=data+governance+act&pk_medium=TW&pk_source=EURLEX&uri=CELEX%3A32022R0868

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52022PC0197

1.2 Needs analysis and specific objectives

Needs analysis and specific objectives

Data Users, including researchers, policymakers, regulators and innovators, report a wide range of barriers to the cross-border sharing of health data. These are mostly caused by differing legal interpretations and data management practices in Europe. The current barriers result in health data being significantly underused for secondary purposes such as research and policymaking. As a result, this underuse reduces benefits for all, such as innovation and the development of more effective medicines and treatments.

This project aims to accelerate the establishment and capability enlargement of Slovak HDAB including the design of new business capabilities and their further development and the rollout of connection to the future EHDS infrastructure for secondary uses (HealthData@EU). It will facilitate the secondary use of health data in Slovak republic, for purposes such as research, innovation, personalised medicine, policy making, official statistics, patient safety and regulatory activities, while ensuring a common approach, as set out in the proposed EHDS legislation.

In the digital and administrative infrastructure actually supporting Slovak HDAB the following business capabilities are missing:

- The web based information system to electronically receive, process and reply to data access applications. Data access applications are at the moment received in the form of emails and all following communication is done also by emails,
- There is no national catalogue of health datasets available for the secondary use of health data. Data users have to specify, which health data are they interested in and Slovak HDAB replies with the information which of required data are available and which are not. There is also no possibility to combine health data for secondary use with the other personal data (social data etc.),
- To provide health datasets for secondary use to data users from abroad is partially a problem because of actual Slovak legislation. The foreign data users must communicate with the Slovak HDAB by emails. There is also no clear description of available health datasets available,
- There is no clear understanding in Slovak republic what is the standard required for quality of health data.

The described actual needs of Slovak HDAB explains why we selected specific milestones and deliverables from the ones mentioned in the call text. There is only one exception – implementation of secure processing environment infrastructure. After the consultation with DG Santé we have decided NOT to include the creation of secure processing environment infrastructure into the project. EC will very probably open the new call dedicated to secure processing environment infrastructure in 2 years, when also legislative support on the European level will be in place. The secure processing environment infrastructure will be implemented by the project answering that call actually in preparation.

To ensure a consistent rollout of improved and enlarged digital business capabilities of Slovak HDAB this project shall be consistent with and will build as much as possible on the ongoing cooperation in the joint action 'Towards the European Health Data Space' (TEHDaS), the pilot for the EHDS infrastructure for secondary uses and the proposed EHDS legislation. The specific objectives, milestones and indicators of the project are laid out below.

SPECIFIC OBJECTIVES

This proposal's general objective will be pursued through the completion of the following **specific objectives** during the project duration for 47 months:

- **Objective 1: Improve and enlarge the digital business capabilities of Slovak HDAB**: improve and enlarge the digital business capabilities of actual HDAB in Slovak republic by improving and enlarging services and infrastructure to allow the interaction between Slovak HDAB, data holders and data users. The services and infrastructure shall allow:
  - Slovak HDAB to receive, process and reply to data access applications using management system to record and process data access applications and issue data permits or record replies to data access applications;

- **Objective 2: Create publicly available catalogue of national datasets:** catalogue will register and facilitate the discovery of health datasets available for secondary use in Slovak republic.
  - provide access to data users to discoverable and accessible catalogue of metadata health datasets;
- **Objective 3:** Setting up **cross-border services and infrastructures**: setting up a digital gateway for the Slovak HDAB to participate in the cross-border infrastructure for secondary uses of health data (HealthData@EU), when it becomes available, by ensuring:
  - the connection of the Slovak HDAB to entities authorized to participate in the infrastructure for secondary uses of health data across borders;
  - the connection of the Slovak HDAB to the federation services in the EHDS infrastructure for secondary uses of health data. Federation services will be provided by the EC.
- **Objective 4: Enhancing data quality:** provide support and tools to enhance the quality of the health data made available by data holders to the Slovak HDAB and to ensure that the data available is semantically and technically interoperable between HDABs and data holders. Activities aiming at enhancing health data quality will be done in the close co-operation with the future project on secure processing environment that will be opened during the HeDAB – SK project. We expect that the project will be national project cofinanced by HaDEA. The type of the project will be Direct Grant based on the call that EK plans to open in 2025 or 2026. We expect that the project will take 3 years and may start in 2027 or 2028.

SPECIFIC MILESTONES

In terms of **specific mandatory milestones**, at the end of the project's implementation period, HDABs are expected to have in place appropriate infrastructure for secondary uses of health data, including the necessary **digital business capabilities.** On the basis of the analysis of needs, the following milestones are included in this project:

- **Milestone 1:** management system to record and process data access applications, issue data permits and reply to data access applications made by data users;
- **Milestone 2:** publicly available catalogue of national datasets including tools and descriptions to facilitate their discovery and use for secondary use;
- **Milestone 3:** digital gateway to connect with other authorized participants and with the core services of the EHDS infrastructure for secondary uses of health data (HealthData@EU);
- **Milestone 4:** initiatives targeting the enhancing the quality of electronic health data made available through the HDAB.

INDICATORS

In Slovak republic we have only one HDAB. Because of that the following proposed indicators from the call document are not actual:

- Number of HDABs established,
- Number of HDABs that are able to receive, process and reply to data access applications.

For the reasons described above also proposed indicators on secure processing environment infrastructure are not actual in this project.

The achievement of the objectives and milestones defined above will be measured with the following action-level indicators:

Indicators related to Objective 1

#	Indicator	Baseline	Target
1	Number of health data access bodies (HDAB) established in SR.	1	1
2	Number of HDABs in SR that are able to receive, process and reply to data access applications.	1	1
3	Number of data access applications processed by HDABs established in SR per month.	5	7
4	Number of data access applications that the HDABs established in SR have processed per month.	5	7
5	Average time to process a data access application per HDAB.	3 months	< 2 months

Indicators related to Objective 2

#	Indicator	Baseline	Target
6	Number of HDABs in SR that have a dataset catalogue publicly available per country.	0	1
7	Number of fully operational datasets that have been published in the dataset catalogue per country.	20	30
8	Number of HDABs providing secure processing environments to data users.	0	0

Indicators related to Objective 3

#	Indicator	Baseline	Target
9	Number of HDABs in SR connected to HealthData@EU infrastructure.	0	1
10	Number of HDABs in SR that are able to send, receive and process multi-country cross-border health data access applications through the cross-border infrastructure for secondary uses.	0	1

Indicators related to Objective 4

#	Indicator	Baseline	Target
11	Number of HDABs offering tools and services to address data privacy as part of the secure processing environments.	0	1
12	List of tools available for enhancing data quality.	NO	YES
13	Are the datasets semantically and technically interoperable?	NO	YES including cross-border and following a common format

These indicators will be regularly measured as the part of WP3 activities during the project and outcomes of the measurement will be described in D3.1 and D3.2.

#@COM-PLE-CP@#

1.3 Complementarity with other actions and innovation — European added value

Complementarity with other actions and innovation - European added value
Slovak republic faces challenges regarding the reuse of health data, including within and across national borders: - Lack of cross border interoperability of health data; - Partial lack of the necessary technical infrastructures and dedicated applications for enabling re-use of health data; - Lack of some digital business capabilities of common mechanism for receiving, processing and replying to health data access applications, mainly catalogue of metadata health datasets - Lower quality of health data. These challenges require common action between Member States and national HDABs to reduce legal diversity and boost secondary use of health data. The innovative aspect of the Regulation on EHDS is the deployment of an IT infrastructure and network to allow the secondary use of health data for researchers, innovators, regulators and policy makers in a trusted and secure way that preserves privacy. Therefore, this project aims to prepare the ground for the implementation of the Regulation on EHDS and for the future Regulations. Ultimately, this generates a European added value of increasing the potential for use of health data and effectiveness of measures on the basis a common legal basis for secondary use of health data. This will yield efficiency gains for data users in the area of health in the cross-border settings, and ultimately it will benefit European citizens through greater access to health innovations, better policy and regulatory decisions. In the long run, improving and enlarging of digital business capabilities of Slovak HDAB and a common European governance framework covering secondary uses of health data will facilitate coordination and cross-border mutual trust. The setting up of HDABs will also allow fostering cooperation with data users from third countries. This action represents one of the foundational actions in that direction. Project will build as much as possible on the ongoing cooperation in the joint action 'Towards the European Health Data Space' (TEHDaS), the pilot for the EHDS infrastructure for secondary uses and the proposed EHDS legislation. There are already some activities to improve and enlarge digital business capabilities of Slovak HDAB and the activities that will be carried out during this project will be supporting the actual activities. We will also inspire ourselves in the Finnish HDAB infrastructure as we find it very innovative. The efforts towards the deployment of a HealthData@EU infrastructure for secondary use of health data will also complement other health actions at European level, such as efforts towards the attainment of the Europe Beating Cancer Plan and other priorities in the EU4Health programme. All EU countries and later probably some third countries will benefit from the project, because the project will enable Slovak HDAB the connection to and communication with the other countries in the HealthData@EU infrastructure. The activities will take place inside the HealthData@EU infrastructure.

#§COM-PLE-CP§# #§PRJ-OBJ-PO§# #§REL-EVA-RE§# #@QUA-LIT-QL@# #@CON-MET-CM@#

2. QUALITY

2.1 Concept and methodology

Concept and methodology

Data Users, including researchers, policymakers, regulators and innovators, report a wide range of barriers to the cross-border sharing of health data. These are mostly caused by differing legal interpretations and data management practices in Europe. The current barriers result in health data being significantly underused for secondary purposes such as research and policymaking. As a result, this underuse reduces benefits for all, such as innovation and the development of more effective medicines and treatments.

The analysis of needs in Slovak republic has identified three digital business capabilities that are key for the strengthening of the Slovak HDAB, as shown in Section 1.2 of this proposal – Specific milestones. For each digital business capability, this project will:

- conduct the analysis of requirements and design of the solution;
- develop and test the technical solution;
- deploy and operate the technical solution.

Approach and methodology for the digital business capability "**Management system to record and process data access applications, issue data permits and reply to data access applications made by data users.**"

Our strategy regarding this digital business capability will be based on the common approach of European countries and EU-level governance. We expect that the common approach to this digital business capacity will be discussed in a future temporary governance body responsible for taking decisions concerning the development and operation of the HealthData@EU infrastructure.

We will support either reuse of an open source solution or we will procure (by public procurement) the solution. In this area we would like to closely cooperate with the Finnish company FINDATA. The advanced contacts with HDAB in Finland (Findata) are not yet established and we plan to discuss the future co-operation during the first meetings of temporary HealthData@EU governance structure (Task 1.2). There could be also other offers from other member states in the beginning of HeDAB – SK project. The work plan of HeDAB – SK project will be operationalized based on that proposal we will decide for during the project HeDAB – SK.

In the case we will use 3-step methodology:

- 1-st step: analyze of requirements regarding the management system,
- 2-nd step: pilot the solution of the management system,
- 3-rd step: operation of the final version of the management system.

The timeframe of different steps will be synchronized with the other participating member states projects in future temporary governance body.

Such an approach will support the sustainability of the digital business capability enhancement and enlargement by securing the innovation and synchronization of new versions of management system implemented in all European HDABs. More detailed description of sustainability aspects will be in the Deliverable D4.1 Sustainability plan.

Approach and methodology for the digital business capability "**Publicly available catalogue of national datasets including tools and descriptions to facilitate their discovery and use for secondary use.**"

Our strategy regarding this digital business capability will be based on the common approach of European countries and EU level governance. We expect that the experience of different European countries in this area will be discussed in a future temporary governance body responsible for taking decisions concerning the development and operation of the HealthData@EU infrastructure. We also expect that the participating countries will find common approach in this area. We would also like to closely cooperate with the Finnish company FINDATA.

In the case we will use 3 step methodology:

- 1-st step: analyze of requirements regarding the catalogue of national datasets, analyze the required structure of datasets, analyze the datasets available in Slovak republic,
- 2-nd step: pilot the solution of the catalogue of national datasets,

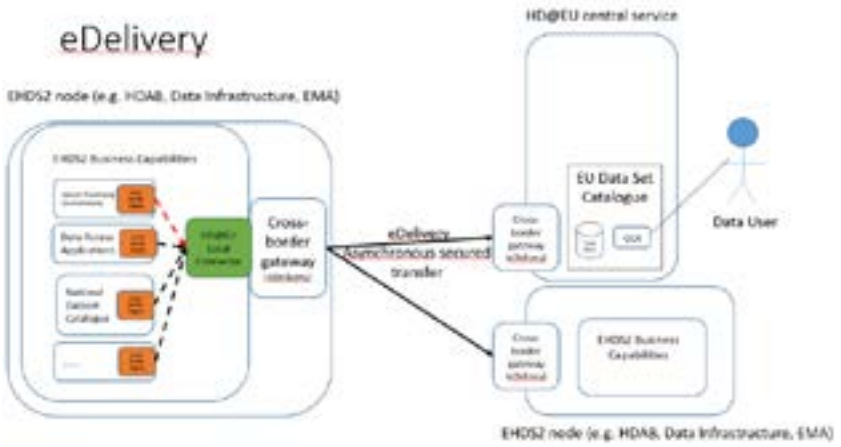
- 3-rd step: operation of the final version of the catalogue of national datasets.

The timeframe of different steps will be synchronized with the other participating member states projects using EU level temporary governance body.

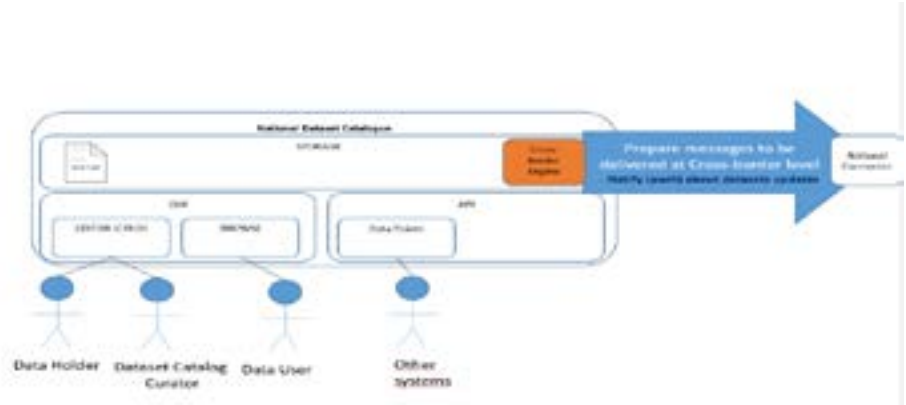
Such an approach will support the sustainability of the digital business capability enhancement and enlargement by securing the innovation and synchronization of new versions of catalogue implementation in all European HDABs. More detailed description of sustainability aspects will be in the Deliverable D4.1 Sustainability plan.

Approach and methodology for the digital business capability "**Digital gateway to connect with other authorized participants and with the core services of the EHDS infrastructure for secondary use of health data (HealthData@EU)**".

Our strategy regarding this digital business capability will be based on the common approach of European countries and EU level governance. We expect that the main parts of the digital gateway (EHDS2 node) will be the same for all participating countries and will be based on the European building block eDelivery (see the figure below). The coordination regarding the implementation of this building block on the national level will be discussed in a future temporary governance body responsible for taking decisions concerning the development and operation of the HealthData@EU infrastructure.



On the other hand we plan to develop our national connector for connecting the digital gateway with the national infrastructure for secondary use of health data. The place of the national connector in the national infrastructure supporting the secondary use of health data is illustrated in the figure below.



Regarding the national connector, we plan to procure the solution by public procurement. In the case will use 3 step methodology:

- 1-st step: analyze of requirements regarding the digital gateway and national connector,
- 2-nd step: pilot the solution of the digital gateway and national connector, prepare the public procurement,
- 3-rd step: operation of the digital gateway and national connector.

The timeframe of different steps will be synchronized with the other participating member states projects using EU governance body. Such an approach will support the sustainability of the digital business

capability enhancement and enlargement by securing the innovation and synchronization of new versions implementation in all European HDABs. More detailed description of sustainability aspects will be in the Deliverable D4.1 Sustainability plan.

Approach and methodology for the digital business capability: **"Initiatives targeting the enhancing the quality of electronic health data made available through the Slovak HDAB**".

Our strategy regarding this digital business capability will be based on 2 steps:

- Analyze the structure and quality of health datasets available in Slovak HDAB,
- Propose steps to improve quality of health datasets available in Slovak HDAB.

We expect that the quality of health datasets in participating countries will be discussed also on the level of EU governance level, where also indicators regarding the quality of health datasets will be proposed, agreed and synchronized. Such an approach will partially secure the sustainability of the quality of health datasets available in HDABs.

While for national HDAB every country have developed a network of local partners allowing the creation of national practices, secondary use of health data at cross-border level requires additional coordination layers and alignment of national practices to common ones.

The joint action Towards the European Health Data Space (TEHDAS) proposes the establishment of cross-border partnerships for sharing health data for secondary purposes. These partnerships will likely increase as the EU aims to accelerate the secondary use of health data with the forthcoming EHDS. Ideally, large-scale European collaborations in data sharing ensure there is an adequate amount of good quality health data for research. Large-scale European collaboration will also decrease the risk of bias in health data, create new potential for linking health data with data from other fields, and will support the deployment of artificial intelligence for real time assessments.

EU-level governance should involve representatives of HDABs participating in HealthData@EU and the EHDS, which could come together in a joint work group. This could follow a similar approach to the cooperation model established in the context of primary uses of health data (MyHealth@EU) and the collaboration in the HealthData@EU pilot project *further explained in chapter 2.4 regarding the EU level decision-making process)*.

To ensure the national and cross-border alignment of this project, the following measures will be implemented:

a) Close observation and scrutiny of the ongoing work at the HealthData@EU pilot project and close collaboration with HDABs of the other EU countries;
b) Re-use and scale-up outcomes of HealthData@EU Pilot project;
c) Engage and promote a temporary (until the EHDS regulation is adopted in its final form) EU-level governance work group of participants in the HealthData@EU infrastructure (*further explained in chapter 2.4 regarding the EU level decision making process);*
d) Adopt and act upon common procedures and timelines to participate in HealthData@EU infrastructure;
e) Conduct cross-border use cases for testing the infrastructure;
f) Engage national partners to create a rich and representative national ecosystem for secondary use of health data.

Regarding a) and b), Slovak republic will engage in stakeholder fora organised by the HealthData@EU Pilot project as well as will make a feasibility assessment the national implementation of HealthData@EU Pilot project outcomes.

Regarding c), d) and e), and following the concept behind the Art 66 in the EHDS proposal, Slovak republic will promote and engage into a temporary governance body responsible for taking decisions concerning the development and operation of the HealthData@EU infrastructure.

Beside the cooperation on the European level we plan closer cooperation with Finland, Finnish company FINDATA, which is HDAB in Finland.

Regarding f), Slovak republic will engage national stakeholders by organising workshops, training, communicate using national portal of health and social media, as described in the description of WP2 below.

2.2 Consortium set-up

Consortium cooperation and division of roles (if applicable)
This project will be carried out by the main beneficiary, who is the appointed Competent Authority representing Slovak republic. This work will enable the main beneficiary to work towards the improvement and enlargement of the digital business capacities of the Slovak HDAB. Slovak HDAB is operating as an organisational part of main beneficiary. To ensure the necessary competence and capacity to deliver on the expected outcomes, the main beneficiary will use own experts or hire some, if it will be needed. As NCZI in the role of main beneficiary is the state owned company financed from the state budget, it will provide adequate resources to the project.

2.3 Project teams, staff and experts

Project teams and staff		
Name and function	Organisation	Role/tasks/professional profile and expertise
Liliana Menhartova Project Manager	NCZI	Manages the project every day, coordinates the Project management Team, communicates with HaDEA and EC, controls reporting and quality.
Rozália Ovari Senior Expert	NCZI	She will be responsible for the analysis of requirements regarding the management system for data access application, regarding the IS for National dataset catalogue and regarding the cross-border gateway.
Martina Vrbikova Senior Expert	NCZI	She will be responsible for the collection of health datasets and for the proposal on how to enhance health datasets quality.
Zuzana Vallova Senior Expert	NCZI	She will be responsible for the collection of health datasets and for the proposal on how to enhance health datasets quality.
Alena Gerhárdtová Senior Expert	NCZI	She will be responsible for the collection of health datasets and for the proposal on how to enhance health datasets quality.
Ľubica Kontrová Legal Expert	NCZI	She will be responsible for the preparation of the proposal of national legislation on implementing Slovak HDAB into Slovak legislation.
TBH Senior Expert	NCZI	Legislation expert No. 1 – Will help with the preparation of the proposal of national legislation on implementing Slovak HDAB into Slovak legislation.
TBH Senior Expert	NCZI	Legislation expert No. 2 - Will help with the preparation of the proposal of national legislation on implementing Slovak HDAB into Slovak legislation.
Lucia Gajdošová Project Administrator	NCZI	She will be responsible for administrative work in the project.
Pavol Rieger Senior Expert	NCZI	He will be responsible for financial planning, reporting and for the communication with HADEA on financial topics. He will be also responsible for the sustainability plan, for the business continuity plan and strategy of Slovak HDAB after the end of the project. Responsible for the coordination of the work in WP4 and WP7.

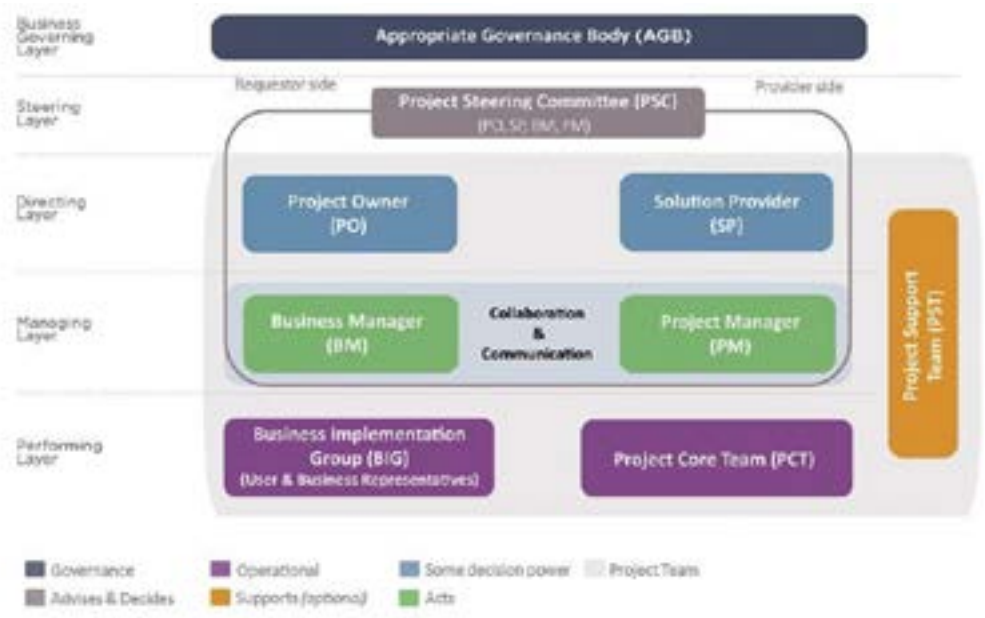
Marek Ternény Senior Expert	NCZI	Chair of the executive board. Responsible for the integration of the gateway into national HDAB infrastructure.
Martin Šimoník Junior Expert	NCZI	Responsible for the integration of the gateway into national HDAB infrastructure.
Florián Bálint Senior Expert	NCZI	Responsible for risk assessment and risk mitigation proposals. Quality manager. WP5 leader.
Veronika Daničová Senior Expert	NCZI	Responsible for dissemination of the project, of the project outcomes and other activities. Also responsible for the communication with stakeholders (stakeholders board). WP 2 leader.
Bibiana Štepániková Senior Expert	NCZI	Responsible for organization of project related workshops, for social media, web presentation of the project etc.
TBH Senior Expert	NCZI	Training activities specialist. Responsible for specific training activities for HDAB staff, data holders and data users.
Libor Janovec Senior Expert	NCZI	Responsible for the Service Desk Plan, help desk services etc.
Michal Juhás Junior Expert	NCZI	Responsible for evaluation of the project - establishing and monitoring performance indicators, assessing the effectiveness of the implementation of the digital business capabilities. WP3 leader.
Radovan Jurovčák Senior Expert	NCZI	Responsible for the proposal on how to implement the data access application management solution and for the implementation of data access application management solution.
Andrej Holík Junior Expert	NCZI	Responsible for analysis, proposal and implementation of the data access application management solution from the databases point of view.
Miroslav Dokupil Senior Expert	NCZI	Responsible for the proposal on how from the IT architect point of view implement the data access application management solution and the cross-border gateway into the actual IT architecture available in NCZI. Chair of the technical board of the project.
Lukáš Kmeťo Senior Expert	NCZI	WP6 and WP8 leader.
Martin Laubert Senior Expert	NCZI	Responsible for analysis, proposal and implementation of the cross-border gateway from the IT Security point of view.
Adriana Jakliová Senior Expert	NCZI	Responsible for testing the cross-border interoperability of the cross-border gateway.

Outside resources (subcontracting, seconded staff, etc)
We will subcontract external experts for the second opinion on proposal of enhancement and improvement of the quality of Slovak health datasets for the second opinion. We will also subcontract auditors for financial audit of the project (during, when needed and) at the end of the project.

Experts (if applicable)
Experts from NCZI will collaborate on tasks of the project.

2.4 Consortium management and decision-making

Consortium management and decision-making (if applicable)
National level of decision making. There will be only main beneficiary in the project. The main beneficiary will be fully responsible for the project management. The standard methodology AGB will be applied and will be adopted to the complexity and scale of the project.



The decision making process of the project on the national level organized by Project Steering Committee (PSC) will be based on the standard control mechanisms. The structure of PSC will be adapted to the needs of the project and also to the status of Narodne centrum zdravotnickych informacii. Members of the PSB:

- Project manager,
- Project coordinator (responsible for the communication with HaDEA and also member of the temporary European governance body,
- Finance and administrative project manager,
- Technical project manager,
- Delegated representative of Ministry of Health, Slovak republic,

- Risk manager,
- Leaders of work packages.

The decision making process will be also influenced influenced by the feedback from stakeholders. The feedback from stakeholders will be collected by the WP2: Dissemination, training and support and WP2 wp leader will provide the feedback to PSC. The decision making process of the project (on the national level) will be strongly influenced also by the decisions taken on the European level.

EU-level decision making
For cross-border decision making, outside the project but in relation to HealthData@EU, the representatives of the project will promote and engage in a temporary (until the EHDS regulation is adopted in its final form) EU-level governance work group of participants in the HealthData@EU infrastructure, as mentioned in 2.1:

1. The representatives of national projects from different EU countries will support the establishment of an EU-level temporary governance work group on HealthData@EU at the beginning of the implementation of this project and the other similar projects in the other EU countries.
2. The main responsibility of the work group will be to coordinate and decide on the development and operation of the HealthData@EU infrastructure, building on the work done by the HealthData@EU pilot. This will drive the adoption of common timelines, requirements, specifications and procedures, as well as set the standard for on-boarding authorised participants.
3. Main beneficiary NCZI will nominate representatives of this project to the temporary EU-level governance work group on HealthData@EU. We also expect that later after the beginning of the projects on national HDABs subgroups of the temporary EU level governance work group will be established. Subgroups will solve concrete tasks. Main beneficiary NCZI will nominate representatives of the project – experts in the certain areas – also to the subgroups.

The participation of the project participants in this temporary governance work group on HealthData@EU (EU-level decision-making) will be covered through the resources allocated to this project.

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2.5 Project management, quality assurance and monitoring and evaluation strategy

Project management, quality assurance and monitoring and evaluation strategy

Project Management: Governance methods are outlined to ensure high-quality outputs and progress reporting: A stringent quality control will cover all deliverables. The project will produce a limited number of deliverables, using milestones, to ensure timely completion of key aspects of the project, mainly in the technical work packages and in the deliverables connected with the piloting phase and the phase of operation of the IT systems, which will be introduced during the project.

For the project management, the PM2 methodology will be used. The methodology will be adapted to the national preferences.

The key quality indicators to monitor the quality of the deliverables will be discussed and agreed in the temporary (until the EHDS regulation is adopted in its final form) EU-level governance work group of participants in the HealthData@EU infrastructure. Then they will be applied on the national level in the project. It will ensure that the quality of deliverables of separate national projects will be measured the same way.

The same will apply on monitoring of the project, planning in the project (here the synchronisation of different national project in the phase of piloting and operation is very important) and control of the project.

WP1 will follow each WP through regular meetings where standard progress reports will be required from each WP leader. Change management for all subjects related to Grant agreement or project Deliverables will be managed centrally within the WP1 (major changes). Minor changes in the project that will not have an impact on Deliverables will be managed within WPs. The coordination WP1 will keep track of project risks and advises meetings.

The evaluation methods and indicators to monitor and verify the outreach and coverage of the activities will be also discussed and agreed in the temporary EU-level governance work group of participants in the HealthData@EU infrastructure. Then they will be applied in the national project. Some of the proposed indicators are described in the part 1.2.

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2.6 Cost effectiveness and financial management

Cost effectiveness and financial management
The financial management of the project will be undertaken by the experienced and dedicated Financial Officer from the PMT, who is well acquainted with the rules and regulations of the funding mechanism and has experience in financial management and partner budgets from other JA projects. The PMT will be requiring all members of the project team to fill in timesheets. The accounting of the project will be done inside the accounting of the main beneficiary, will be based on national accounting legislation and on the rules of JA projects, but the project money will be held in separate bank account. This will allow to have a greater overview of the project budget and expenditure according to the planned budget. To monitor expenditure, PMT will require from accounting team of NCZI to prepare a financial progress report every 6 months. The reports will be carefully reviewed, with specific recommendations/action points to be issued for the project. The budget of the project is cost effective because of following reasons: - The main part of the work will be done by internal experts of the main beneficiary, where the salaries are lower than the price of external experts, - Subcontracting will be procured by public procurement, based on national legislation, so the procurement will be also cost saving.

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2.7 Risk management

Critical risks and risk management strategy			
Risk No	Description	WP No	Proposed risk-mitigation measures
GENERAL RISKS ON ENHANCING and IMPROVING Slovak HDAB			
1.	Inappropriate connection to national infrastructures and frameworks (technical, semantic, organisational) (Likelihood: high, Impact: high)	**WP5, WP6, WP7**	Ensuring appropriate participation of national entities and partners in the project to facilitate connections
2.	Difficulties amending national legislation to enable the access to health data-by-data users (also cross-border) and availability of datasets. (Likelihood: high, Impact: high)	**WP5, WP6, WP7**	Implement measures to facilitate legal convergence with the upcoming European Health Data Space regulation
RISKS CONCERNING DATA DISCOVERY AND PRESTUDY			
3.	Multiple health datasets catalogues exist but are not linked (Likelihood: medium, Impact: high)	**WP6**	Harmonize standards and practices and federate existing dataset catalogues
4.	National dataset catalogues descriptions are not publicly available (Likelihood: low, Impact: medium)	**WP6**	Establish appropriate frameworks and procedures for the submission, approval and maintenance of datasets descriptions in a publicly available data catalogue
5.	Poor data discovery and data user knowledge of the existence of the infrastructure (Likelihood: high, Impact: high)	**WP6**	Ensure proper training, promotion and communication activities of the project work to allow data users to find suitable data
RISKS CONCERNING DATA ACCESS APPLICATIONS			
6.	Burdensome and complicated submission of data access application (Likelihood: high, Impact: high)	**WP5**	Streamline and harmonise the application process with other countries, including the use of shared portals for data discovery and application submission and follow up
7.	Burdensome and inefficient handling of data access applications (national and EU level) and issuance of data permits to data users/authorisation of data requests (Likelihood: high, Impact: high)	**WP5**	Foster automation, standardisation and convergence in the processing of data access applications
8.	Irregular and inconsistent interaction between data users, data holders and Slovak HDAB (Likelih.: medium, Impact: medium)	**WP5**	Increase availability of services by health data access bodies to data holders and data users, and promote them through proper training, promotion and communication activities
RISKS CONCERNING CROSS-BORDER GATEWAY			
9.	Risk of improper functionality of national connector. (Likelihood: medium, Impact: high)	**WP7**	Ensuring appropriate implementation of national connector.

#§RSK-MGT-RM§# #§QUA-LIT-QL§# #@IMP-ACT-IA@#

3. IMPACT

3.1 Impact and ambition

Impact and ambition — Progress beyond the state-of-the-art

The project will have mainly medium and long-term impact. The project effects the following target groups:

- Competent authority of Slovak HDAB;
- Data users;
- Other data holders;
- Slovak republic citizens and all EU citizens.

Primarily, Slovak republic's competent authority, that is the actual HDAB, is directly impacted by the project implementation in the short term. This body, together with other relevant public sector bodies, is responsible for enabling the resources necessary to set up and deploy the technical infrastructures and to connect it to the HealthData@EU infrastructure. This target group will benefit from the capacity enlargement of its key digital business capabilities. The project will trigger innovation. The progress will be beyond the status quo.

Expected societal impacts:
Competent authority of Slovak HDAB: in the medium-term will be able more accurately compare performance, outcomes and safety of the provision of health data for secondary usage. In the long-term will be able to provide health data in higher quality.

Expected economic impacts:
Competent authority of Slovak HDAB:
The work to be done to improve the quality of health data will also improve the efficiency of the process of collecting health data. It will have positive economic impact on the Slovak HDAB. In addition, the possibility to charge the provision of health data for secondary usage will have long-term positive economic impact on Slovak HDAB.

Expected personal impacts:
Competent authority of Slovak HDAB:
The improvement of the work of the actual Slovak HDAB as an outcome of this project will need more qualified workforce. The people will be more educated and trained with the experience of cross-border cooperation. It will have positive personal mid-term and long-term impact on the Slovak HDAB activities.

Expected technical impacts:
Competent authority of Slovak HDAB:
The technical (IT) infrastructure of the actual Slovak HDAB will be partly improved or restructured because of technical requirements, which are defined in this project and because of new technologies that will be used.. There will be positive long-term impact of the project on the technical infrastructure of the Slovak HDAB.

Expected administrative impacts:
Competent authority of Slovak HDAB:
The actual organizational structure and administrative and business processes of the Slovak HDAB will be improved after implementing this project. It will have positive long-term impact on the organisational structure and administrative and business processes of the actual Slovak HDAB.

Secondly, the project directly affects data users (for secondary usage), such as researchers, regulators, innovators, and policy makers, who will request access to health datasets from Slovak HDAB. The project will trigger innovation. The progress will be beyond the status quo.

Expected societal impacts:
Data users:
More researchers in Slovak republic and abroad will be motivated to research health data because of the higher quality of health data available for secondary usage.. New policies based on higher quality and

accessibility of health data will have positive impact on patients. Innovators will be able to provide more sophisticated products with the positive impact on patients.

Expected economic impacts:
Data users:
Researchers, regulators, innovators and policy makers will gain access based on permit using new IT tools and procedures in order to access health datasets, which will reduce their resources and time needed for conducting work that requires processing of health data.

Expected personal impacts:
Data users:
Researchers, regulators, innovators and policy makers will be able to improve their qualification working with Slovak HDAB. It will have positive impact on their qualification.

Expected technical impacts:
Data users:
Researchers, regulators, innovators and policy makers will be able to use more sophisticated and complex approaches based on new IT systems. It will have positive technical impact on their IT systems.

Expected administrative impacts:
Data users:
The outcomes of this project will probably reduce some needs for administrative workforce on the side of researchers, regulators, innovators and policy makers, as the administrative part of the work will be partly automated.. It will have positive impact on the quality of their work.

Thirdly, the project will also influence data holders in Slovak republic who control relevant datasets of health data. Data holders will be expected to submit dataset descriptions and later, in some cases, a data quality and utility label for datasets they hold. Moreover, once a permit is issued, they will need to make data identified in this permit available to their HDAB. Through this project, they will have a streamlined process to enable the reuse of their health data. The project will trigger innovation. The progress will be beyond the status quo. As the secure environment is not a subject of this project, later, when the other project on secure environment will be finished, the process will follow, through the appropriate safeguards and will be supported by Slovak HDAB.

Expected societal impacts:
Other data holders:
Users like health insurance companies in Slovak republic will be also in medium-term able to compare performance, outcomes and patient safety in the area of health care provision using the combination of their data with the other societal data available in Slovak HDAB. It will have positive mid-term and long-term impact on the quality of the health care provision in Slovak republic.

Expected economic impacts:
Other data holders:
Outcomes of the project will serve health insurance companies to improve also the structure and volume of the health care services provided in Slovak republic. It will have positive mid-term and long-term impact on the efficiency of health insurance companies. The same is also for health care providers, who will be able to compare their data with the data of other health care providers thus improving their efficiency.

Expected personal impacts:
Other data holders:
The stuff of health insurance companies and health data providers will need to improve their qualification to be able to use all functionalities of Slovak HDAB after the end of this project. It will as a positive impact of this project improve in the mid-term the qualification of the mentioned stuff.

Expected technical impacts:
Other data holders:
Data holders will be able to use more sophisticated and more complex approaches based on new IT systems. It will have positive technical impact on their IT systems.

Expected administrative impacts:
Other data holders:

The outcomes of this project will probably reduce some needs for administrative workforce on the side of data holders. It will have positive impact on their administrative structure.

Finally, Slovak and all European citizens are the indirect project beneficiaries from increased and improved research studies, personalised medicine and targeted policy-making and regulatory activities. The ambitiousness of the proposal stems from the deepening of the digital single market and further integration of cross-border rules that will facilitate access to health services and goods.

#§IMP-ACT-IA§# #@COM-DIS-VIS-CDV@#

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

The objectives of the communication and dissemination activities will be:

- to raise awareness and demand among data users and data holders about the services provided by the Slovak HDAB regarding the provision of national and cross-border access to health datasets, and
- to inform citizens of Slovak republic (mainly using social networks and dedicated web pages in www.nczisk.sk, www.npz.sk and in other portals) on the secondary usage of their heath data and their rights in respect of privacy provisions.

Additionally, communication activities will entail educational and training initiatives and will support orchestration initiatives for Slovak HDAB staff, data holders, data users and other relevant stakeholders.

As detailed in WP2, the project will put in place and exploit differentiated communication channels:

- Part of the National portal of health **(www.npz.sk).** The part informing about all aspects of secondary usage of health data will be added there. The portal will also support training and educational activities regarding the secondary usage of health data in Slovak republic. The structure of Slovak national portal of health dedicated to secondary usage of health data in Slovak republic will be co-ordinated with the similar web portals of the other Member States.
- Training tools; training and educational materials (leaflets, presentations, tests etc.
- Social media and web channels (mainly those operated by NCZI).
- 3 educational workshops and 1 training session for relevant stakeholders.

An overall communication strategy with activities targeted at relevant stakeholders will be defined in the beginning of the project. The first relevant outcomes of the activities in work packages will be used to raise awareness of relevant stakeholders. Later in the project, more targeted communication, education and training activities will be done to prepare relevant stakeholders for regular usage of Slovak HDAB.

Dissemination, training and education activities foreseen in WP2 will start at the end of piloting phase in WP5, WP6 and WP7 – in M30. We can distinguish 2 target groups:

- Stakeholders from the health sector,
- Stakeholders outside of the health sector.

Training and education materials will cover all themes of interest of stakeholders beginning from basic information about HDAB in Slovak republic to hands-on workshop on how to ask for access to health data for secondary use.

All dissemination, education and training activities in this project will be as far as possible aligned with the other Member States and with the communication activities on the European level to support the targeted communication on the European level.

The visibility of the EU funding will be ensured by:

- Standard table in the entrance to the building of Narodne centrum zdravotnickych informacii with the information about the project and about EU funding of the project,
- Information about the project and about the EU funding in the web page of Narodne centrum zdravotnickych informacii, National health portal and in relevant information in social media operated by Narodne centrum zdravotnickych informacii.

#§COM-DIS-VIS-CDV§# #@SUS-CON-SC@#

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

The actual Slovak HDAB is part of the institution Narodne centrum zdravotnickych informacii (NCZI). As NCZI is public institution financed from the state budget, the Slovak HDAB is financed from the state budget. Improved and enlarged digital business capabilities of Slovak HDAB will be financed from the state budget also after the end of the project. In addition, the new related legislation regarding the Slovak HDAB will be introduced. It will ensure that the impact of the project described in the text above will be ensured and sustained. Practically all parts of the project will continue to operate as a “business as usual” activity of actual Slovak HDAB after the project.

The following activities will be done:

- Update of the actual Slovak legislation on secondary use of health data,
- Update the contract between Ministry of Health of Slovak republic and NCZI in the part regarding the operation of Slovak HDAB.

Parts of the project dealing with the enlargement and improvement of the digital business capabilities of Slovak HDAB will be continued and maintained also after the end of the project.

This will be achieved by:

- Update of the actual Slovak legislation on secondary use of health data,
- Update the contract between Ministry of Health of Slovak republic and NCZI in the part regarding the operation of Slovak HDAB.
- Hiring new necessary experts and stuff,
- Cooperation with the other HDABs inside of HealthData@EU infrastructure.

We expect that resources from state budget will be enough to continue the operation of the improved Slovak HDAB.

The results of the project will be used in the operation of Slovak HDAB after the end of the project. This project will support the enhancement and increasing of digital business capabilities of actual Slovak HDAB including the cross-border aspects of the secondary usage of health data. The most important is the expected increasing of the quality of the available health data. After the end of the project, the HealthData@EU cross-border infrastructure for secondary use of health data will enable the public, private, not for profit entities, as well as individual researchers to have access to health data for research, innovation, policy making, educational activities, patient safety, regulatory activities or personalised medicine, as foreseen in the context of the Regulation of EHDS. Access to data for secondary use should contribute to the general interest of the society. This project will support the enhancement and increasing of digital business capabilities of actual Slovak HDAB including the cross-border aspects of the secondary usage of health data. The most important is the increasing of the quality of the available health data.

The provision of the data should also support activities related to scientific research (including private research), development and innovation, producing goods and services for the health or care sectors, such as innovation activities or training of AI algorithms that could protect the health of natural persons. The Slovak HDAB will contribute to these activities also after the end of the project.

Cooperation between Member States’ respective HDABs, and with the Commission, will be crucial to achieve a high level of trust and later also security, enhancing the long-term impact of this project.

This project will complement other EU-funded activities promoted under the EU4Health programme, such as the Europe Beating Cancer Plan, or other programmes such as Connecting Europe Facility (CEF), the Digital Europe Programme (DEP), the Recovery and Resilience Facility (RRF), or the European Regional Development Fund (ERDF).

We see also possible synergies / complementarities with the second joint action ‘Towards the European Health Data Space’ (TEHDaS2) – actually in preparation - and with the outcomes of the pilot project for the EHDS infrastructure based on 5 use cases that will run from 2022-2024 to test the setting up of a European network for secondary uses of data.

#§SUS-CON-SC§#

4. Subcontracting and timetable

Subcontracting

Subcontracting						
Work Package No	Subcontract No	Subcontract Name	Description	Estimated Costs	Justification	Best-Value-for-Money
WP2	S2.1	Workshop No1	T2.2, NCZI, room rental, catering and printing of supportive materials (leaflets etc.)	20 000 Euro	NCZI as main beneficiary has no appropriate room for workshop	Public procurement
WP2	S2.2	Workshop No2	T2.3, NCZI, room rental, catering and printing of supportive materials (leaflets etc.)	20 000 Euro	NCZI as main beneficiary has no appropriate room for workshop	Public procurement
WP2	S2.3	Workshop No 3	T2.3, NCZI, room rental, catering and printing of supportive materials (leaflets etc.)	20 000 Euro	NCZI as main beneficiary has no appropriate room for workshop	Public procurement
WP2	S2.4	Specific training	T2.3, NCZI, room rental, catering and printing of supportive materials (leaflets etc.)	10 000 Euro	NCZI as main beneficiary has no appropriate room for specific training	Public procurement
WP5	S5.1	Software and support	T5.2, NCZI, software and support for National Data Access Application Solution	110 000 Euro	NCZI as main beneficiary has no own programmers.	Public procurement
WP6	S6.1	Software and support	T6.2, NCZI, software and support for National Datasets catalogue	110 000 Euro	NCZI as main beneficiary has no own programmers	Public procurement
WP7	S7.1	Support of the provider of national infrastructure during the piloting phase.	T7.2, NCZI will need support of the provider of national infrastructure during the piloting phase to connect cross-border gateway properly to national infrastructure.	250 000 Euro	NCZI as main beneficiary has no own programmers	Public procurement
WP8	S8.1	Support	T8.1, NCZI, support during analysis of the quality of available health datasets.	15 000 Euro	NCZI will need external experts on quality of health datasets for second opinion.	Public procurement

Other issues: *If subcontracting for the project goes beyond 30% of the total eligible costs, give specific reasons.*	NCZI as main beneficiary of the grant has no own programmers. Detailed requirements on the information systems National Data Access Application Management solution, National Dataset Catalogue, Cross Border gateway for HD@EU are not clear now, we have estimated the price that could be achieved using public procurement. As the mentioned information systems are main outcomes of the project, we cannot lower the subcontracting in the project below 30% of the total eligible costs, but subcontracting costs will be below 50% of the total eligible costs.

More detailed description on scope and needs of subcontracting.

In WP5, WP6 and WP7 new IT systems will be introduced. Only after the beginning of the project (during the analyse phase and coordination on European level will be clear, what possibilities will be available:

- Already available Open source IT systems,
- Already functional IT systems produced by member countries (for example Data Access Application Solution from Findata, Finland),
- Centralized solutions offered by EC,
- The need to develop own IT solution.

Because of the fact that Narodne centrum zdravotnickych informacii has no own programming capacities, we will have to buy IT systems for WP5, WP6 and WP7 anyway. We will decide based on the outcomes of analyse phase in WP5, WP6 and WP7 and on the outcomes of the consolidated approach on the level of the dedicated European temporary governance structure. Because of that we are not able to calculate the exact price of the future subcontracting at the moment.

Timetable

ACTIVITY	YEAR 2023	YEAR 2 - 2024				YEAR 3 - 2025				YEAR 4 - 2026				YEAR 5 - 2027		
	Q4 M1-3	Q1 M4-6	Q2 M7-9	Q3 M10-12	Q4 M13-15	Q1 M16-18	Q2 M19-21	Q3 M22-24	Q4 M25-27	Q1 M28-30	Q2 M31-33	Q3 M34-36	Q4 M37-39	Q1 M40-42	Q2 M43-45	Q3 M46-48
WP1: Management and Coordination																
T1.1 Management of national activities	MS1.1															
T1.2 Management of cross-border activities	MS1.2															
T1.3 Monitoring and reporting								D1.1								D1.2
T1.4 Coordination																
T1.5 Good practice identification																

ACTIVITY	YEAR 2023	YEAR 2 - 2024				YEAR 3 - 2025				YEAR 4 - 2026				YEAR 5 - 2027		
	Q4 M1-3	Q1 M4-6	Q2 M7-9	Q3 M10-12	Q4 M13-15	Q1 M16-18	Q2 M19-21	Q3 M22-24	Q4 M25-27	Q1 M28-30	Q2 M31-33	Q3 M34-36	Q4 M37-39	Q1 M40-42	Q2 M43-45	Q3 M46-48
WP2: Dissemination, training and support																
T2.1 Dissemination				MS2.1 D2.5		D2.1										
T2.2 Collecting feedback from stakeholders										MS2.3						
T2.3 Education and training								MS2.2		D2.2						D2.3
T2.4 Service and Help Desk												D2.4		MS2.4		

ACTIVITY	YEAR 2023	YEAR 2 - 2024				YEAR 3 - 2025				YEAR 4 - 2026				YEAR 5 - 2027		
	Q4 M1-3	Q1 M4-6	Q2 M7-9	Q3 M10-12	Q4 M13-15	Q1 M16-18	Q2 M19-21	Q3 M22-24	Q4 M25-27	Q1 M28-30	Q2 M31-33	Q3 M34-36	Q4 M37-39	Q1 M40-42	Q2 M43-45	Q3 M46-48
WP3: Evaluation																
T3.1 Performance monitoring		MS3.1				D3.1										
T3.2 Evaluation																MS3.2 D3.2 D3.3

ACTIVITY	YEAR 2023	YEAR 2 - 2024				YEAR 3 - 2025				YEAR 4 - 2026				YEAR 5 - 2027		
	Q4 M1-3	Q1 M4-6	Q2 M7-9	Q3 M10-12	Q4 M13-15	Q1 M16-18	Q2 M19-21	Q3 M22-24	Q4 M25-27	Q1 M28-30	Q2 M31-33	Q3 M34-36	Q4 M37-39	Q1 M40-42	Q2 M43-45	Q3 M46-48
WP4: Sustainability																
T4.1 Sustainability plan													MS4.1		D4.1	
T4.2 Business Continuity plan													M4.2		D4.2	

ACTIVITY	YEAR 2023	YEAR 2 - 2024				YEAR 3 - 2025				YEAR 4 - 2026				YEAR 5 - 2027		
	Q4 M1-3	Q1 M4-6	Q2 M7-9	Q3 M10-12	Q4 M13-15	Q1 M16-18	Q2 M19-21	Q3 M22-24	Q4 M25-27	Q1 M28-30	Q2 M31-33	Q3 M34-36	Q4 M37-39	Q1 M40-42	Q2 M43-45	Q3 M46-48
WP5: DAAMs																
T5.1 DAAMs: Analysis and design				MS5.1	D5.1											
T5.2 DAAMs: Implementation and piloting										MS5.2	D5.2					
T5.3 DAAMs: Deployment of an operational solution														MS5.3	D5.3	

ACTIVITY	YEAR 2023	YEAR 2 - 2024				YEAR 3 - 2025				YEAR 4 - 2026				YEAR 5 - 2027		
	Q4 M1-3	Q1 M4-6	Q2 M7-9	Q3 M10-12	Q4 M13-15	Q1 M16-18	Q2 M19-21	Q3 M22-24	Q4 M25-27	Q1 M28-30	Q2 M31-33	Q3 M34-36	Q4 M37-39	Q1 M40-42	Q2 M43-45	Q3 M46-48
WP6: nHDsC																
T6.1 nHDsC: Analysis and design				MS6.1	D6.1											
T6.2 nHDsC: Implementation and piloting										MS6.2	D6.2					
T6.3 nHDsC: Deployment of operational solution														MS6.3	D6.3	

ACTIVITY	YEAR 2023	YEAR 2 - 2024				YEAR 3 - 2025				YEAR 4 - 2026				YEAR 5 - 2027		
	Q4 M1-3	Q1 M4-6	Q2 M7-9	Q3 M10-12	Q4 M13-15	Q1 M16-18	Q2 M19-21	Q3 M22-24	Q4 M25-27	Q1 M28-30	Q2 M31-33	Q3 M34-36	Q4 M37-39	Q1 M40-42	Q2 M43-45	Q3 M46-48
WP7: Cross-border gateway to connect with the HealthData@EU infrastructure																
T7.1 Cross-border gateway: Analysis and design				MS7.1	D7.1											
T7.2 Cross-border gateway: Implementation and piloting										MS7.2	D7.2					
T7.3 Cross-border gateway: Deployment of operation ready solution														MS7.3	**D7.3**	

ACTIVITY	YEAR 2023	YEAR 2 - 2024				YEAR 3 - 2025				YEAR 4 - 2026				YEAR 5 - 2027		
	Q4 M1-3	Q1 M4-6	Q2 M7-9	Q3 M10-12	Q4 M13-15	Q1 M16-18	Q2 M19-21	Q3 M22-24	Q4 M25-27	Q1 M28-30	Q2 M31-33	Q3 M34-36	Q4 M37-39	Q1 M40-42	Q2 M43-45	Q3 M46-48
WP8: Health data quality enhancement																
T8.1 Analysis of the quality of the available health data				MS8.1 D8.1												
T8.2 Development or implementation of already existing tools and standards to improve data quality.																
T8.3 Proposal on improving the quality of health data available for nHDsC.										MS8.2 D8.2						

#§WRK-PLA-WP§#

#@ETH-ICS-EI@#

5. OTHER

5.1 Ethics

Ethics
We see the following ethics issues that may arise during the project: - Risk of re-identification of natural persons from the dataset provided, - Risk of storage of electronic health data for a longer period of time exceeding the initial 5 years allowed by data permits, - Risk of the unauthorised reading, copying, modification or removal of electronic health data hosted in the secure processing environment through state-of-the-art technological means. Ethics in health data use is of utmost importance in this project. People working in the project will be committed to comply with relevant international and EU level fundamental ethical and privacy legislation and regulations: - 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 (General Data Protection Regulation) - The Oviedo Convention on Human Rights and Biomedicine.

#§ETH-ICS-EI§# #@SEC-URI-SU@#

5.2 Security

Security
Health data security is of utmost importance in the project, as the Slovak HDAB will be dealing with health data (GDPR Art 9 special category data) and needs to be trustworthy for both citizens and stakeholders of the Slovak HDAB. The project will build on existing security standards and frameworks that are in place in Slovak HDAB and will improve them with the introduction of new and improved digital business capabilities. Project will also build on existing international security standards and frameworks on the European level (as implemented for example by MyHealth@EU infrastructure). Security aspects will be handled by design in WP5, Wp6 and WP7.

#§SEC-URI-SU§# #@DEC-LAR-DL@#

6. DECLARATIONS

Higher funding rate (if applicable)	YES/NO
Do you fulfil the conditions set out in the Call document for a higher funding rate?	**YES**

Gross national income 2019	GNI	population	GNI per capita	90% threshold
European Union - 27	14.022.479	447.474	31.337	28.203
Belgium	482.136	11.489	41.965	above
Bulgaria*	52.341	7.076	7.397	below
Czechia	211.933	10.669	19.864	below
Denmark	319.268	5.817	54.885	above
Germany	3.542.818	83.093	42.637	above
Estonia	27.476	1.325	20.739	below
Ireland	275.462	4.927	55.907	above
Greece	181.911	10.722	16.967	below
Spain	1.246.831	47.104	26.485	below
France	2.475.992	67.624	36.614	above
Croatia	53.962	4.067	13.268	below
Italy	1.806.554	59.729	30.246	above
Cyprus	21.391	882	24.254	below
Latvia	30.033	1.913	15.696	below
Lithuania	47.110	2.794	16.860	below
Luxembourg**	38.256	609	62.837	above
Hungary	142.274	9.771	14.561	below
Malta**	11.352	485	23.395	below
Netherlands	816.447	17.345	47.071	above
Austria	399.558	8.878	45.007	above
Poland	511.141	38.386	13.316	below
Portugal	208.565	10.286	20.276	below
Romania	220.200	19.376	11.365	below
Slovenia	47.617	2.089	22.794	below
Slovakia	92.243	5.453	16.915	below
Finland	241.311	5.522	43.703	above
Sweden	490.756	10.279	47.744	above
*data from 2017	Source: Eurostat	Source: Eurostat		
**data from 2018				HaDEA A1 03Sep2021

We have received the table above from HaDEA as the reference table for decision if the project is of “exceptional utility”. The criteria concerns actions by Member States whose GNI per inhabitant is less than 90% of the EU average.

From the above table is clearly seen, that Slovak republics GNI is less than 90% of the EU average. Therefore, this project fulfils the criteria for higher funding rate (80 %) due to exceptional utility.

Double funding	
Information concerning other EU grants for this project *Please note that there is a strict prohibition of double funding from the EU budget (except under EU Synergies actions).*	**YES/NO**
We confirm that to our best knowledge neither the project as a whole nor any parts of it have benefitted from any other EU grant *(including EU funding managed by authorities in EU Member States or other funding bodies, e.g. EU Regional Funds, EU Agricultural Funds, etc.)*. If NO, explain and provide details.	YES
We confirm that to our best knowledge neither the project as a whole nor any parts of it are (nor will be) submitted for any other EU grant *(including EU funding managed by authorities in EU Member States or other funding bodies, e.g. EU Regional Funds, EU Agricultural Funds, etc.)*. If NO, explain and provide details.	YES

Financial support to third parties (if applicable)
If in your project the maximum amount per third party will be more than the threshold amount set in the Call document, justify and explain why the higher amount is necessary in order to fulfil your project's objectives.
NOT APPLICABLE

#§DEC-LAR-DL§#

ANNEXES

LIST OF ANNEXES

Standard
Detailed budget table (annex 1 to Part B) — *mandatory*
CVs (annex 2 to Part B) — *mandatory, if required in the Call document*
List of previous projects (annex 4 to Part B) — *mandatory, if required in the Call document*

DETAILED BUDGET TABLE (ACTION GRANTS)

Project number:	**210914748**
Project acronym:	**HeDAB - SK**
Participant short name:	**NCZI**
Participant PIC:	**998884370**

12.10.2023 9:19

ATTENTION: This table should be filled out one per participant (beneficiary, affiliated entity)

ATTENTION: This table may ONLY contain eligible costs (i.e. costs that comply with the eligibility rules of the grant agreement that is part of your call documents). At proposal stage and during grant preparation, it should contain estimated costs/income. Costs must be estimated in EUR.

ATTENTION! List each budgeted cost item ONLY once in this table, for the main WP.

ATTENTION! White cells mean that you are required to enter data. Blue cells are calculated automatically.

ACTION GRANT BUDGET TABLE (PER PARTICIPANT)

PROJECT COSTS

A. Personnel costs

! monthly rates allowed for budgeting because simpler to establish the approximate costs; cost reporting will have to be done according to MGA (usually daily rates)		Costs (actual or unit costs)				Also working for other work packages? YES/NO and which WP	Description of project role/activities/responsibilities
	Type of rate (monthly/other)	Rate (amount)	Time (months/other of work on the action)	Total (EUR)			
		a	b	c = a * b			
WORK PACKAGE 1	**WP1: MANAGEMENT & COORDINATION**						
	A.1 Employees (or equivalent)						
	Project managers	monthly	3 500,00	12,00	**42 000,00**	NO	Responsible for overall project managemet, organization of meetings of executive board of the project (WP leaders), technical board of the project, controll of financial manager, handling change requests etc. (Menhartova)
	Administrative personnel	monthly	2 000,00	18,00	**36 000,00**	NO	Administrative support for project manager, financial project manager and risk manager. (Gajdosova)
	Other						
	Financial project manager	monthly	3 100,00	4,00	**12 400,00**	YES/WP4, WP7	Responsible for financial planning, reporting and for the communication with HADEA on financial topics. (Rieger)
	Technical project manager	monthly	3 000,00	4,00	**12 000,00**	YES/WP7	Chair of the executive board. (Terneny)
	Risk assessment manager	monthly	3 000,00	6,00	**18 000,00**	YES/WP5	Responsible for risk assessment and risk mitigation proposals. Quality manager. (Balint)
				Total employees (or equivalent)	**120 400,00**		
	A.2 + A.3 Natural persons under direct contract and seconded persons						
	Select a staff category	monthly	0,00	0,00	**0,00**		
	Select a staff category	monthly	0,00	0,00	**0,00**		
	Other						
	[category 1]	monthly	0,00	0,00	**0,00**		
	[category 2]	monthly	0,00	0,00	**0,00**		
				Total natural persons under direct contract and seconded persons	**0,00**		
	A.4 SME owners and natural person beneficiaries without salary						

	SME owners/natural person beneficiaries without salary	daily	0,00	0,00	**0,00**			
				Total SME owners and natural person beneficiaries without salary	**0,00**			
				Total personnel for this WP	**120 400,00**			
WORK PACKAGE 2	**WP2: DISSEMINATION, TRAINING AND SUPPORT**							
	A.1 Employees (or equivalent)							
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Other							
	Communication and dissemination manager	monthly	3 500,00	6,00	**21 000,00**		NO	Responsible for dissemination of the project, of the project outcomes and other activities. Also responsible for the communication with stakeholders. WP 2 leader. (Danicova)
	Communication and dissemination specialist	monthly	2 500,00	8,00	**20 000,00**		NO	Responsible for organization of project related workshops, for social media, web presentation of the project etc. (Stepanikova)
	Training activities specialist	monthly	3 500,00	4,00	**14 000,00**		NO	Responsible for specific training activities for HDAB staff, data holders and data users. TBH
	Dedicated staff from help desk	monthly	3 500,00	4,00	**14 000,00**		NO	Responsible for the Service Desk Plan, help desk services etc. (Janovec)
				Total employees (or equivalent)	**69 000,00**			
	A.2 + A.3 Natural persons under direct contract and seconded persons							
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Other							
	[category 1]	monthly	0,00	0,00	**0,00**			
	[category 2]	monthly	0,00	0,00	**0,00**			
				Total natural persons under direct contract and seconded persons	**0,00**			
	A.4 SME owners and natural person beneficiaries without salary							
	SME owners/natural person beneficiaries without salary	daily	0,00	0,00	**0,00**			
				Total SME owners and natural person beneficiaries without salary	**0,00**			
				Total personnel for this WP	**69 000,00**			
WORK PACKAGE 3	**WP3: EVALUATION OF THE PROJECT**							
	A.1 Employees (or equivalent)							
	Junior experts/advisors/researchers	monthly	2 700,00	6,00	**16 200,00**		NO	Responsible for evaluation of the project - establishing and monitoring performance indicators, assessing the effectiveness of the implementation of the digital business capabilities. WP3 leader. (Juhas)
	Other							
	[category 1]	monthly	0,00	0,00	**0,00**			
	[category 2]	monthly	0,00	0,00	**0,00**			
				Total employees (or equivalent)	**16 200,00**			
	A.2 + A.3 Natural persons under direct contract and seconded persons							
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Other							
	[category 1]	monthly	0,00	0,00	**0,00**			
	[category 2]	monthly	0,00	0,00	**0,00**			
				Total natural persons under direct contract and seconded persons	**0,00**			
	A.4 SME owners and natural person beneficiaries without salary							

	SME owners/natural person beneficiaries without salary	daily	0,00	0,00	**0,00**			
				Total SME owners and natural person beneficiaries without salary	**0,00**			
				Total personnel for this WP	**16 200,00**			
WORK PACKAGE 4	**WP4: SUSTAINABILITY OF THE PROJECT**							
	A.1 Employees (or equivalent)							
	Senior experts/advisors/researchers	monthly	3 000,00	5,00	**15 000,00**		NO	Responsible for the preparation of the proposal of national legislation on implementing slovak HDAB into slovak legislation. (Kontrova)
	Senior experts/advisors/researchers	monthly	3 100,00	5,00	**15 500,00**		YES/WP1, WP7	Responsible for the sustainability plan, for the business continuity plan and strategy of slovak HDAB after the end of the project. WP4 leader. (Rieger)
	Other							
	legislation expert I.	monthly	3 600,00	3,00	**10 800,00**		NO	Responsible for the preparation of the proposal of national legislation on implementing slovak HDAB into slovak legislation. (TBH)
	legislation expert II.	monthly	3 600,00	3,00	**10 800,00**		NO	Responsible for the preparation of the proposal of national legislation on implementing slovak HDAB into slovak legislation. (TBH)
				Total employees (or equivalent)	**52 100,00**			
	A.2 + A.3 Natural persons under direct contract and seconded persons							
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Other							
	[category 1]	monthly	0,00	0,00	**0,00**			
	[category 2]	monthly	0,00	0,00	**0,00**			
				Total natural persons under direct contract and seconded persons	**0,00**			
	A.4 SME owners and natural person beneficiaries without salary							
	SME owners/natural person beneficiaries without salary	daily	0,00	0,00	**0,00**			
				Total SME owners and natural person beneficiaries without salary	**0,00**			
				Total personnel for this WP	**52 100,00**			
WORK PACKAGE 5	**WP5: NATIONAL DATA ACCESS APPLICATION MANAGEMENT SOLUTION**							
	A.1 Employees (or equivalent)							
	Other	monthly	0,00	0,00	**0,00**			
	Other							
	technical personell - IT analist	monthly	3 000,00	3,00	**9 000,00**		YES/WP6, WP7	Responsible for the analysis of requirements regarding the data access app. (Ovari)
	technical personell - expert on implementation and integration of IT systems	monthly	3 300,00	6,00	**19 800,00**		YES/WP7	Responsible for the proposal on how to implement the data access application management solution and for the implementation of data access application management solution. (Jurovcak)
	technical personell - DB specialist	monthly	3 000,00	3,00	**9 000,00**		NO	Responsible for analysis, proposal and implementation of the data access application management solution from the databases point of view. (Holik)
	technical personell - IT architect	monthly	3 100,00	2,00	**6 200,00**		YES/WP7	Responsible for the proposal on how from the IT architect point of view implement the data access application management solution into the actual IT architecture available in NCZI. (Dokupil)
	technical personell - WP leader	monthly	3 000,00	2,00	**6 000,00**		YES/WP1	Responsible for the coordination of the work in the WP. (Balint)
				Total employees (or equivalent)	**50 000,00**			
	A.2 + A.3 Natural persons under direct contract and seconded persons							
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Other							

	[category 1]	monthly	0,00	0,00	**0,00**			
	[category 2]	monthly	0,00	0,00	**0,00**			
	Total natural persons under direct contract and seconded persons				**0,00**			
	A.4 SME owners and natural person beneficiaries without salary							
	SME owners/natural person beneficiaries without salary	daily	0,00	0,00	**0,00**			
	Total SME owners and natural person beneficiaries without salary				**0,00**			
	Total personnel for this WP				**50 000,00**			
WORK PACKAGE 6	**WP6: NATIONAL DATASET CATALOGUE FOR HEALTH DATA**							
	A.1 Employees (or equivalent)							
	Senior experts/advisors/researchers	monthly	3 500,00	5,00	**17 500,00**		YES/WP8	Responsible for the collection of datasets for national health dataset catalogue. (Vrbikova)
	Senior experts/advisors/researchers	monthly	3 100,00	5,00	**15 500,00**		YES/WP8	Responsible for the collection of datasets for national health dataset catalogue. (Vallova)
	Senior experts/advisors/researchers	monthly	3 100,00	5,00	**15 500,00**		NO	Responsible for the collection of datasets for national health dataset catalogue. (Gerhardtova)
	Other							
	technical personell - IT analist	monthly	3 000,00	3,00	**9 000,00**		YES/WP5, WP7	Responsible for the analysis of requirements regarding the National dataset catalogue. (Ovari)
	technicall personell - WP leader	monthly	3 200,00	2,00	**6 400,00**		YES/WP8	Responsible for the coordination of the work in the WP6. (Kmeto)
	Total employees (or equivalent)				**63 900,00**			
	A.2 + A.3 Natural persons under direct contract and seconded persons							
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Other							
	[category 1]	monthly	0,00	0,00	**0,00**			
	[category 2]	monthly	0,00	0,00	**0,00**			
	Total natural persons under direct contract and seconded persons				**0,00**			
	A.4 SME owners and natural person beneficiaries without salary							
	SME owners/natural person beneficiaries without salary	daily	0,00	0,00	**0,00**			
	Total SME owners and natural person beneficiaries without salary				**0,00**			
	Total personnel for this WP				**63 900,00**			
WORK PACKAGE 7	**WP7: CROSS-BORDER GATEWAY FOR HD@EU**							
	A.1 Employees (or equivalent)							
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Other							
	administrative personell - WP leader	monthly	3 100,00	10,00	**31 000,00**		YES/WP1, WP4	Responsible for the coordination of the work in the WP7. (Rieger)
	technical personell - IT analist	monthly	3 000,00	10,00	**30 000,00**		YES/WP5, WP6	Responsible for the analysis of requirements regarding the cross-border gateway. (Ovari)
	technical personell - expert on implementation and integration of IT systems	monthly	3 300,00	6,00	**19 800,00**		YES/WP5	Responsible for the proposal on how to implement the cross-border gateway in Slovak republic and also for the implementation of the cross-border gateway. (Jurovcak)
	technical personell - IT Security specialist	monthly	3 200,00	2,00	**6 400,00**		NO	Responsible for analysis, proposal and implementation of the cross-border gateway from the IT Security point of view. (Laubert)
	technical personell - IT architect	monthly	3 100,00	3,00	**9 300,00**		YES/WP5	Responsible for the proposal on how from the IT architect point of view implement the cross-border gateway into the actual IT architecture available in NCZI. (Dokupil)
	technical personell - tester	monthly	2 900,00	5,00	**14 500,00**		NO	Responsible for testing the cross-border interoperability of the cross-border gateway. (Jakliova)
	technical personell - integration	monthly	3 000,00	3,00	**9 000,00**		YES/WP1	Responsible for the integration of the gateway into national HDAB infrastructure. (Terneny)
	technical personell - integration	monthly	2 500,00	3,00	**7 500,00**		NO	Responsible for the integration of the gateway into national HDAB infrastructure. (Simonik)

	[category 2]	monthly	0,00	0,00	**0,00**			
				Total employees (or equivalent)	**127 500,00**			
	A.2 + A.3 Natural persons under direct contract and seconded persons							
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Other							
	[category 1]	monthly	0,00	0,00	**0,00**			
	[category 2]	monthly	0,00	0,00	**0,00**			
				Total natural persons under direct contract and seconded persons	**0,00**			
	A.4 SME owners and natural person beneficiaries without salary							
	SME owners/natural person beneficiaries without salary	daily	0,00	0,00	**0,00**			
				Total SME owners and natural person beneficiaries without salary	**0,00**			
				Total personnel for this WP	**127 500,00**			
WORK PACKAGE 8	**WP8: HEALTH DATA QUALITY ENHANCEMENT**							
	A.1 Employees (or equivalent)							
	Senior experts/advisors/researchers	monthly	3 500,00	7,00	**24 500,00**		YES/WP6	Responsible for the analysis of the available health datasets and for proposals on how to enhance health datasets quality. (Vrbikova)
	Senior experts/advisors/researchers	monthly	3 100,00	7,00	**21 700,00**		YES/WP6	Responsible for the analysis of the available health datasets and for proposals on how to enhance health datasets quality. (Vallova)
	Senior experts/advisors/researchers	monthly	3 100,00	7,00	**21 700,00**		YES/WP6	Responsible for the analysis of the available health datasets and for proposals on how to enhance health datasets quality. (Gerhardtova)
	Other							
	administrative personell - WP leader.	monthly	3 200,00	2,00	**6 400,00**		YES/WP6	Responsible for the coordination of the work in the WP8. (Kmeto)
	[category 2]	monthly	0,00	0,00	**0,00**			
				Total employees (or equivalent)	**74 300,00**			
	A.2 + A.3 Natural persons under direct contract and seconded persons							
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Select a staff category	monthly	0,00	0,00	**0,00**			
	Other							
	[category 1]	monthly	0,00	0,00	**0,00**			
	[category 2]	monthly	0,00	0,00	**0,00**			
				Total natural persons under direct contract and seconded persons	**0,00**			
	A.4 SME owners and natural person beneficiaries without salary							
	SME owners/natural person beneficiaries without salary	daily	0,00	0,00	**0,00**			
				Total SME owners and natural person beneficiaries without salary	**0,00**			
				Total personnel for this WP	**74 300,00**			
				Total personnel (all WPs)	**573 400,00**			

B. Subcontracting costs

		Costs (actual costs)		Also used for other work packages? YES/NO and which WP	Description of subcontracted project tasks/activities
WORK PACKAGE 1	**WP1: MANAGEMENT & COORDINATION**				
	1 [Subcontract short name]	0,00			

	2 [Subcontract short name]	0,00			
	Total subcontracting for this WP	**0,00**			
WORK PACKAGE 2	**WP2: DISSEMINATION, TRAINING AND SUPPORT**				
	S2.1	20 000,00		NO	Preparation of the workshop for stakeholders on usage of national data access application, sucontracting partial supporting services.
	S2.2	20 000,00		NO	Preparation of the workshop for stakeholders on usage of national data access application, sucontracting partial supporting services.
	S2.3	20 000,00		NO	Preparation of the workshop for stakeholders on usage of national data access application, sucontracting partial supporting services.
	S2.4	10 000,00		NO	Specific training activities, subcontracting partial supporting services.
	Total subcontracting for this WP	**70 000,00**			
WORK PACKAGE 3	**WP3: EVALUATION OF THE PROJECT**				
	1 [Subcontract short name]	0,00			
	2 [Subcontract short name]	0,00			
	Total subcontracting for this WP	**0,00**			
WORK PACKAGE 4	**WP4: SUSTAINABILITY OF THE PROJECT**				
	1 [Subcontract short name]	0,00			
	2 [Subcontract short name]	0,00			
	Total subcontracting for this WP	**0,00**			
WORK PACKAGE 5	**WP5: NATIONAL DATA ACCESS APPLICATION MANAGEMENT SOLUTION**				
	S5.1 (DAAMs)	110 000,00		NO	External licence and support for implementing information system - national data access application management solution (DAAMs) - in Slovak republic.
	2 [Subcontract short name]	0,00			
	Total subcontracting for this WP	**110 000,00**			
WORK PACKAGE 6	**WP6: NATIONAL DATASET CATALOGUE FOR HEALTH DATA**				
	S6.1 (nHDsC)	110 000,00		NO	External support for implementing national dataset catalogue in Slovak republic. Licence and support during the project duration for the information system
	2 [Subcontract short name]	0,00			
	Total subcontracting for this WP	**110 000,00**			
WORK PACKAGE 7	**WP7: CROSS-BORDER GATEWAY FOR HD@EU**				
	S7.1	250 000,00		NO	External support for implementing national connector to connect the HDAB Gateway with the National Health Information System.
	2 [Subcontract short name]	0,00			
	Total subcontracting for this WP	**250 000,00**			
WORK PACKAGE 8	**WP8: HEALTH DATA QUALITY ENHANCEMENT**				
	S8.1	15 000,00		NO	External advisors on Data Quality.
	2 [Subcontract short name]	0,00			
	Total subcontracting for this WP	**15 000,00**			

Total subcontracting (all WPs)	**555 000,00**	

C. Purchase costs

C.1 Travel and subsistence

		Costs (actual costs)	Costs (unit cost)			Also part of other work packages? (e.g. WP1 and WP2 and WP3)	Description (e.g. international/not international; place of activity/destination; number of days; number of persons (speakers, personnel and participants whose costs are covered); transport means; average price per person; subsistence costs/daily allowances)
			Amount per unit	Number of units	Total (EUR)		
WORK PACKAGE 1	**WP1: MANAGEMENT & COORDINATION**						
	HDMSEG coordination meeting in Brussels No. 1						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 2						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 3						
	Speakers						

	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 4						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 5						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		

	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 6						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 7						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.

	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 8						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 9						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					

	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 10						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 11						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 12						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		

	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 13						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 14						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		

	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 15						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	HDMSEG coordination meeting in Brussels No. 16						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	1,00	**276,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Accommodation costs	0,00	137,00	1,00	**137,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.

	Subsistence costs	0,00	102,00	2,00	**204,00**	NO	Participation in the European HealthData@EU temporary governance body meeting in Brussels, international, 1 day, 1 person, plane.
	Total travel costs for this travel	**276,00**					
	Total accommodation costs for this travel	**137,00**					
	Total subsistence costs for this travel	**204,00**					
	Total travel	**617,00**					
	Excursion to Helsinki, Finnland to assess the information system (DAAMs - WP5).						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	288,00	3,00	**864,00**	NO	Excursion to Finnland, international, 2 days, 3 persons, plane.
	Accommodation costs	0,00	146,00	3,00	**438,00**	NO	Excursion to Finnland, international, 2 days, 3 persons, plane.
	Subsistence costs	0,00	113,00	6,00	**678,00**	NO	Excursion to Finnland, international, 2 days, 3 persons, plane.
	Total travel costs for this travel	**864,00**					
	Total accommodation costs for this travel	**438,00**					
	Total subsistence costs for this travel	**678,00**					
	Total travel	**1 980,00**					
	Visit to Helsinki, Finland - subcontracting discussions (DAAMs - WP5).						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	288,00	3,00	**864,00**	NO	Visit to Finnland, international, 2 days, 3 persons, plane.
	Accommodation costs	0,00	146,00	3,00	**438,00**	NO	Visit to Finnland, international, 2 days, 3 persons, plane.
	Subsistence costs	0,00	113,00	6,00	**678,00**	NO	Visit to Finnland, international, 2 days, 3 persons, plane.
	Total travel costs for this travel	**864,00**					
	Total accommodation costs for this travel	**438,00**					
	Total subsistence costs for this travel	**678,00**					
	Total travel	**1 980,00**					
	Visit to Helsinki, Finland - coordination meeting (DAAMs - WP5).						
	Speakers						

	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	288,00	2,00	**576,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Accommodation costs	0,00	146,00	2,00	**292,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Subsistence costs	0,00	113,00	4,00	**452,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Total travel costs for this travel	**576,00**					
	Total accommodation costs for this travel	**292,00**					
	Total subsistence costs for this travel	**452,00**					
	Total travel	**1 320,00**					
	Visit to Helsinki, Finland - coordination meeting (DAAMs - WP5).						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	288,00	2,00	**576,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Accommodation costs	0,00	146,00	2,00	**292,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Subsistence costs	0,00	113,00	4,00	**452,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Total travel costs for this travel	**576,00**					
	Total accommodation costs for this travel	**292,00**					
	Total subsistence costs for this travel	**452,00**					
	Total travel	**1 320,00**					
	Excursion to Helsinki, Finnland to assess the information system (nHDsC - WP6).						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		

	Participants						
	Travel costs	0,00	288,00	2,00	**576,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Accommodation costs	0,00	146,00	2,00	**292,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Subsistence costs	0,00	113,00	4,00	**452,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Total travel costs for this travel	**576,00**					
	Total accommodation costs for this travel	**292,00**					
	Total subsistence costs for this travel	**452,00**					
	Total travel	**1 320,00**					
	Visit to Helsinki, Finland - subcontracting discussions (nHDsC - WP6).						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	288,00	2,00	**576,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Accommodation costs	0,00	146,00	2,00	**292,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Subsistence costs	0,00	113,00	4,00	**452,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Total travel costs for this travel	**576,00**					
	Total accommodation costs for this travel	**292,00**					
	Total subsistence costs for this travel	**452,00**					
	Total travel	**1 320,00**					
	Visit to Helsinki, Finland - coordination meeting No.1 (nHDsC - WP6).						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	288,00	2,00	**576,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Accommodation costs	0,00	146,00	2,00	**292,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Subsistence costs	0,00	113,00	4,00	**452,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Total travel costs for this travel	**576,00**					
	Total accommodation costs for this travel	**292,00**					
	Total subsistence costs for this travel	**452,00**					

	Total travel	**1 320,00**					
	Visit to Helsinki, Finland - coordination meeting No.2 (nHDsC - WP6).					Associated with document Ref. Ares(2023)7236599 - 24/10/2023	
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	288,00	2,00	**576,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Accommodation costs	0,00	146,00	2,00	**292,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Subsistence costs	0,00	113,00	4,00	**452,00**	NO	Visit to Finnland, international, 2 days, 2 persons, plane.
	Total travel costs for this travel	**576,00**					
	Total accommodation costs for this travel	**292,00**					
	Total subsistence costs for this travel	**452,00**					
	Total travel	**1 320,00**					
	Total travel costs for this WP	**9 600,00**					
	Total accommodation costs for this WP	**4 820,00**					
	Total subsistence costs for this WP	**7 332,00**					
	Total travel for this WP	**21 752,00**					
WORK PACKAGE 2	**WP2: DISSEMINATION, TRAINING AND SUPPORT**						
	Total travel costs for this WP	**0,00**					
	Total accommodation costs for this WP	**0,00**					
	Total subsistence costs for this WP	**0,00**					
	Total travel for this WP	**0,00**					
WORK PACKAGE 3	**WP3: EVALUATION OF THE PROJECT**						
	Total travel costs for this WP	**0,00**					
	Total accommodation costs for this WP	**0,00**					
	Total subsistence costs for this WP	**0,00**					
	Total travel for this WP	**0,00**					
WORK PACKAGE 4	**WP4: SUSTAINABILITY OF THE PROJECT**						
	Total travel costs for this WP	**0,00**					
	Total accommodation costs for this WP	**0,00**					
	Total subsistence costs for this WP	**0,00**					
	Total travel for this WP	**0,00**					
WORK PACKAGE 5	**WP5: NATIONAL DATA ACCESS APPLICATION MANAGEMENT SOLUTION**						
	Total travel costs for this WP	**0,00**					
	Total accommodation costs for this WP	**0,00**					
	Total subsistence costs for this WP	**0,00**					
	Total travel for this WP	**0,00**					
WORK PACKAGE 6	**WP6: NATIONAL DATASET CATALOGUE FOR HEALTH DATA**						

	Total travel costs for this WP	**0,00**						
	Total accommodation costs for this WP	**0,00**						
	Total subsistence costs for this WP	**0,00**						
	Total travel for this WP	**0,00**						
WORK PACKAGE 7	**WP7: CROSS-BORDER GATEWAY FOR HD@EU**							
	Participation in testing events No. 1, Brussels, Belgium							
	Speakers							
	Travel costs	0,00	0,00	0,00	**0,00**			
	Accommodation costs	0,00	0,00	0,00	**0,00**			
	Subsistence costs	0,00	0,00	0,00	**0,00**			
	Personnel							
	Travel costs	0,00	0,00	0,00	**0,00**			
	Accommodation costs	0,00	0,00	0,00	**0,00**			
	Subsistence costs	0,00	0,00	0,00	**0,00**			
	Participants							
	Travel costs	0,00	276,00	2,00	**552,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.	
	Accommodation costs	0,00	137,00	6,00	**822,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.	
	Subsistence costs	0,00	102,00	8,00	**816,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.	
	Total travel costs for this travel	**552,00**						
	Total accommodation costs for this travel	**822,00**						
	Total subsistence costs for this travel	**816,00**						
	Total travel	**2 190,00**						
	Participation in testing events No. 2, Brussels, Belgium							
	Speakers							
	Travel costs	0,00	0,00	0,00	**0,00**			
	Accommodation costs	0,00	0,00	0,00	**0,00**			
	Subsistence costs	0,00	0,00	0,00	**0,00**			
	Personnel							
	Travel costs	0,00	0,00	0,00	**0,00**			
	Accommodation costs	0,00	0,00	0,00	**0,00**			
	Subsistence costs	0,00	0,00	0,00	**0,00**			
	Participants							
	Travel costs	0,00	276,00	2,00	**552,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.	
	Accommodation costs	0,00	137,00	6,00	**822,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.	
	Subsistence costs	0,00	102,00	8,00	**816,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.	
	Total travel costs for this travel	**552,00**						
	Total accommodation costs for this travel	**822,00**						
	Total subsistence costs for this travel	**816,00**						
	Total travel	**2 190,00**						
	Participation in testing events No. 3, Brussels, Belgium							
	Speakers							
	Travel costs	0,00	0,00	0,00	**0,00**			

	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	2,00	**552,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Accommodation costs	0,00	137,00	6,00	**822,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Subsistence costs	0,00	102,00	8,00	**816,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Total travel costs for this travel	**552,00**					
	Total accommodation costs for this travel	**822,00**					
	Total subsistence costs for this travel	**816,00**					
	Total travel	**2 190,00**					
	Participation in testing events No. 4, Brussels, Belgium						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	2,00	**552,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Accommodation costs	0,00	137,00	6,00	**822,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Subsistence costs	0,00	102,00	8,00	**816,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Total travel costs for this travel	**552,00**					
	Total accommodation costs for this travel	**822,00**					
	Total subsistence costs for this travel	**816,00**					
	Total travel	**2 190,00**					
	Participation in testing events No. 5, Brussels, Belgium						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						

	Travel costs	0,00	276,00	2,00	**552,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Accommodation costs	0,00	137,00	6,00	**822,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Subsistence costs	0,00	102,00	8,00	**816,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Total travel costs for this travel	**552,00**					
	Total accommodation costs for this travel	**822,00**					
	Total subsistence costs for this travel	**816,00**					
	Total travel	**2 190,00**					
	Participation in testing events No. 6, Brussels, Belgium						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	2,00	**552,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Accommodation costs	0,00	137,00	6,00	**822,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Subsistence costs	0,00	102,00	8,00	**816,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Total travel costs for this travel	**552,00**					
	Total accommodation costs for this travel	**822,00**					
	Total subsistence costs for this travel	**816,00**					
	Total travel	**2 190,00**					
	Participation in testing events No. 7, Brussels, Belgium						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	2,00	**552,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Accommodation costs	0,00	137,00	6,00	**822,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Subsistence costs	0,00	102,00	8,00	**816,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Total travel costs for this travel	**552,00**					
	Total accommodation costs for this travel	**822,00**					
	Total subsistence costs for this travel	**816,00**					
	Total travel	**2 190,00**					

	Participation in testing events No. 8, Brussels, Belgium						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	2,00	**552,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Accommodation costs	0,00	137,00	6,00	**822,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Subsistence costs	0,00	102,00	8,00	**816,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Total travel costs for this travel	**552,00**					
	Total accommodation costs for this travel	**822,00**					
	Total subsistence costs for this travel	**816,00**					
	Total travel	**2 190,00**					
	Participation in testing events No. 9, Brussels, Belgium						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	2,00	**552,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Accommodation costs	0,00	137,00	6,00	**822,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Subsistence costs	0,00	102,00	8,00	**816,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Total travel costs for this travel	**552,00**					
	Total accommodation costs for this travel	**822,00**					
	Total subsistence costs for this travel	**816,00**					
	Total travel	**2 190,00**					
	Participation in testing events No. 10, Brussels, Belgium						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		

	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	2,00	**552,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Accommodation costs	0,00	137,00	6,00	**822,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Subsistence costs	0,00	102,00	8,00	**816,00**	NO	Visit to place of testing activities, 4 days,2 persons, international, plane.
	Total travel costs for this travel	**552,00**					
	Total accommodation costs for this travel	**822,00**					
	Total subsistence costs for this travel	**816,00**					
	Total travel	**2 190,00**					
	Total travel costs for this WP	**5 520,00**					
	Total accommodation costs for this WP	**8 220,00**					
	Total subsistence costs for this WP	**8 160,00**					
	Total travel for this WP	**21 900,00**					
WORK PACKAGE 8	**WP8: HEALTH DATA QUALITY ENHANCEMENT**						
	Coordination meeting No.1 on data quality, Brussels, Belgium						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	2,00	**552,00**	NO	Mutualy coordination meeting with the other partners, international, 2 days,2 persons, plane.
	Accommodation costs	0,00	137,00	2,00	**274,00**	NO	Mutualy coordination meeting with the other partners, international, 2 days,2 persons, plane.
	Subsistence costs	0,00	102,00	4,00	**408,00**	NO	Mutualy coordination meeting with the other partners, international, 2 days,2 persons, plane.
	Total travel costs for this travel	**552,00**					
	Total accommodation costs for this travel	**274,00**					
	Total subsistence costs for this travel	**408,00**					
	Total travel	**1 234,00**					
	Coordination meeting No.2 on data quality, Brussels, Belgium						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						

	Travel costs	0,00	276,00	2,00	**552,00**	NO	Mutualy coordination meeting with the other partners, international, 2 days,2 persons, plane.
	Accommodation costs	0,00	137,00	2,00	**274,00**	NO	Mutualy coordination meeting with the other partners, international, 2 days,2 persons, plane.
	Subsistence costs	0,00	102,00	4,00	**408,00**	NO	Mutualy coordination meeting with the other partners, international, 2 days,2 persons, plane.
	Total travel costs for this travel	**552,00**					
	Total accommodation costs for this travel	**274,00**					
	Total subsistence costs for this travel	**408,00**					
	Total travel	**1 234,00**					
	Coordination meeting No.3 on data quality, Brussels, Belgium						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	2,00	**552,00**	NO	Mutualy coordination meeting with the other partners, international, 2 days,2 persons, plane.
	Accommodation costs	0,00	137,00	2,00	**274,00**	NO	Mutualy coordination meeting with the other partners, international, 2 days,2 persons, plane.
	Subsistence costs	0,00	102,00	4,00	**408,00**	NO	Mutualy coordination meeting with the other partners, international, 2 days,2 persons, plane.
	Total travel costs for this travel	**552,00**					
	Total accommodation costs for this travel	**274,00**					
	Total subsistence costs for this travel	**408,00**					
	Total travel	**1 234,00**					
	Coordination meeting No.4 on data quality, Brussels, Belgium						
	Speakers						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Personnel						
	Travel costs	0,00	0,00	0,00	**0,00**		
	Accommodation costs	0,00	0,00	0,00	**0,00**		
	Subsistence costs	0,00	0,00	0,00	**0,00**		
	Participants						
	Travel costs	0,00	276,00	2,00	**552,00**	NO	Mutualy coordination meeting with the other partners, international, 2 days,2 persons, plane.
	Accommodation costs	0,00	137,00	2,00	**274,00**	NO	Mutualy coordination meeting with the other partners, international, 2 days,2 persons, plane.
	Subsistence costs	0,00	102,00	4,00	**408,00**	NO	Mutualy coordination meeting with the other partners, international, 2 days,2 persons, plane.
	Total travel costs for this travel	**552,00**					
	Total accommodation costs for this travel	**274,00**					
	Total subsistence costs for this travel	**408,00**					
	Total travel	**1 234,00**					

Total travel costs for this WP	2 208,00	
Total accommodation costs for this WP	1 096,00	
Total subsistence costs for this WP	1 632,00	
Total travel for this WP	4 936,00	

Total travel costs (all WPs)	17 328,00
Total accommodation (all WPs)	14 136,00
Total subsistence (all WPs)	17 124,00
Total travel and subsistence (all WPs)	48 588,00

C.2 Equipment

WORK PACKAGE 1 — **WP1: MANAGEMENT & COORDINATION**

C.2.1 Purchase (depreciation/full cost)

	Costs (actual costs)					Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
	Price	Depreciation method (e.g. 36 month or 60 month)	Number of months allocated to the action	Rate of use for the action (100% or less if used also for other	Total (EUR)		
	a	b	c	d	e =(c/b *d) * a		
1 [Equipment short name]	0,00	0	0,00	0%	**0,00**		
2 [Equipment short name]	0,00	0	0,00	0%	**0,00**		
3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement			**0,00**		
Total depreciation					**0,00**		

C.2.2 Rental and leasing (rate of use/full cost)

	Costs (actual costs)				Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
	Monthly rent/fee	Number of months of use for the action	Rate of use for the action (100% or less if used also for other purposes)	Total (EUR)		
	a	b	c	d= a*b*c		
1 [Equipment short name]	0,00	0,00	0%	**0,00**		
2 [Equipment short name]	0,00	0,00	0%	**0,00**		
3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement		**0,00**		
Total rental and leasing				**0,00**		
Total equipment for this WP				**0,00**		

WORK PACKAGE 2 — **WP2: DISSEMINATION, TRAINING AND SUPPORT**

C.2.1 Purchase (depreciation/full cost)

	Costs (actual costs)					Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
	Price	Depreciation method (e.g. 36 month or 60 month)	Number of months allocated to the action	Rate of use for the action (100% or less if used also for other	Total (EUR)		
	a	b	c	d	e =(c/b *d) * a		
1 [Equipment short name]	0,00	0	0,00	0%	**0,00**		
2 [Equipment short name]	0,00	0	0,00	0%	**0,00**		
3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement			**0,00**		
Total depreciation					**0,00**		

C.2.2 Rental and leasing (rate of use/full cost)

	Costs (actual costs)				Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed

		Monthly rent/fee	Number of months of use for the action	Rate of use for the action (100% or less if used also for other purposes)	Total	Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		a	b	c	d= a*b*c		
	1 [Equipment short name]	0,00	0,00	0%	**0,00**		
	2 [Equipment short name]	0,00	0,00	0%	**0,00**		
	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement		**0,00**		
				Total rental and leasing	**0,00**		
				Total equipment for this WP	**0,00**		
WORK PACKAGE 3	**WP3: EVALUATION OF THE PROJECT**						
	C.2.1 Purchase (depreciation/full cost)						
		Costs (actual costs)				Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		Price	Depreciation method (e.g. 36 month or 60 month)	Number of months allocated to the action	Rate of use for the action (100% or less if used also for other	Total (EUR)	
		a	b	c	d	e =(c/b *d) * a	
	1 [Equipment short name]	0,00	0	0,00	0%	**0,00**	
	2 [Equipment short name]	0,00	0	0,00	0%	**0,00**	
	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement			**0,00**	
					Total depreciation	**0,00**	
	C.2.2 Rental and leasing (rate of use/full cost)						
		Costs (actual costs)				Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		Monthly rent/fee	Number of months of use for the action	Rate of use for the action (100% or less if used also for other purposes)	Total (EUR)		
		a	b	c	d= a*b*c		
	1 [Equipment short name]	0,00	0,00	0%	**0,00**		
	2 [Equipment short name]	0,00	0,00	0%	**0,00**		
	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement		**0,00**		
				Total rental and leasing	**0,00**		
				Total equipment for this WP	**0,00**		
WORK PACKAGE 4	**WP4: SUSTAINABILITY OF THE PROJECT**						
	C.2.1 Purchase (depreciation/full cost)						
		Costs (actual costs)				Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		Price	Depreciation method (e.g. 36 month or 60 month)	Number of months allocated to the action	Rate of use for the action (100% or less if used also for other	Total (EUR)	
		a	b	c	d	e =(c/b *d) * a	
	1 [Equipment short name]	0,00	0	0,00	0%	**0,00**	
	2 [Equipment short name]	0,00	0	0,00	0%	**0,00**	
	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement			**0,00**	
					Total depreciation	**0,00**	
	C.2.2 Rental and leasing (rate of use/full cost)						
		Costs (actual costs)				Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		Monthly rent/fee	Number of months of use for the action	Rate of use for the action (100% or less if used also for other purposes)	Total (EUR)		
		a	b	c	d= a*b*c		
	1 [Equipment short name]	0,00	0,00	0%	**0,00**		
	2 [Equipment short name]	0,00	0,00	0%	**0,00**		

	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement		**0,00**		
				Total rental and leasing	**0,00**		
				Total equipment for this WP	**0,00**		
WORK PACKAGE 5	**WP5: NATIONAL DATA ACCESS APPLICATION MANAGEMENT SOLUTION**						
	C.2.1 Purchase (depreciation/full cost)						
		Costs (actual costs)				Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		Price	Depreciation method (e.g. 36 month or 60 month)	Number of months allocated to the action	Rate of use for the action (100% or less if used also for other	Total (EUR)		
		a	b	c	d	e =(c/b *d) * a		
	1 [Equipment short name]	0,00	0	0,00	0%	**0,00**		
	2 [Equipment short name]	0,00	0	0,00	0%	**0,00**		
	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement			**0,00**		
					Total depreciation	**0,00**		
	C.2.2 Rental and leasing (rate of use/full cost)						
		Costs (actual costs)				Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		Monthly rent/fee	Number of months of use for the action		Rate of use for the action (100% or less if used also for other purposes)	Total (EUR)		
		a	b		c	d= a*b*c		
	1 [Equipment short name]	0,00	0,00		0%	**0,00**		
	2 [Equipment short name]	0,00	0,00		0%	**0,00**		
	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement			**0,00**		
					Total rental and leasing	**0,00**		
					Total equipment for this WP	**0,00**		
WORK PACKAGE 6	**WP6: NATIONAL DATASET CATALOGUE FOR HEALTH DATA**						
	C.2.1 Purchase (depreciation/full cost)						
		Costs (actual costs)				Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		Price	Depreciation method (e.g. 36 month or 60 month)	Number of months allocated to the action	Rate of use for the action (100% or less if used also for other	Total (EUR)		
		a	b	c	d	e =(c/b *d) * a		
	1 [Equipment short name]	0,00	0	0,00	0%	**0,00**		
	2 [Equipment short name]	0,00	0	0,00	0%	**0,00**		
	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement			**0,00**		
					Total depreciation	**0,00**		
	C.2.2 Rental and leasing (rate of use/full cost)						
		Costs (actual costs)				Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		Monthly rent/fee	Number of months of use for the action		Rate of use for the action (100% or less if used also for other purposes)	Total (EUR)		
		a	b		c	d= a*b*c		
	1 [Equipment short name]	0,00	0,00		0%	**0,00**		
	2 [Equipment short name]	0,00	0,00		0%	**0,00**		
	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement			**0,00**		
					Total rental and leasing	**0,00**		
					Total equipment for this WP	**0,00**		
WORK PACKAGE 7	**WP7: CROSS-BORDER GATEWAY FOR HD@EU**						
	C.2.1 Purchase (depreciation/full cost)						

		Costs (actual costs)					Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		Price	Depreciation method (e.g. 36 month or 60 month)	Number of months allocated to the action	Rate of use for the action (100% or less if used also for other	Total		
		a	b	c	d	e =(c/b *d) * a		
	1 [Equipment short name]	0,00	0	0,00	0%	**0,00**		
	2 [Equipment short name]	0,00	0	0,00	0%	**0,00**		
	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement			**0,00**		
					Total depreciation	**0,00**		
	C.2.2 Rental and leasing (rate of use/full cost)							
		Costs (actual costs)					Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		Monthly rent/fee	Number of months of use for the action		Rate of use for the action (100% or less if used also for other purposes)	Total (EUR)		
		a	b		c	d= a*b*c		
	1 [Equipment short name]	0,00	0,00		0%	**0,00**		
	2 [Equipment short name]	0,00	0,00		0%	**0,00**		
	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement			**0,00**		
					Total rental and leasing	**0,00**		
					Total equipment for this WP	**0,00**		
WORK PACKAGE 8	**WP8: HEALTH DATA QUALITY ENHANCEMENT**							
	C.2.1 Purchase (depreciation/full cost)							
		Costs (actual costs)					Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		Price	Depreciation method (e.g. 36 month or 60 month)	Number of months allocated to the action	Rate of use for the action (100% or less if used also for other	Total (EUR)		
		a	b	c	d	e =(c/b *d) * a		
	1 [Equipment short name]	0,00	0	0,00	0%	**0,00**		
	2 [Equipment short name]	0,00	0	0,00	0%	**0,00**		
	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement			**0,00**		
					Total depreciation	**0,00**		
	C.2.2 Rental and leasing (rate of use/full cost)							
		Costs (actual costs)					Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the equipment is needed
		Monthly rent/fee	Number of months of use for the action		Rate of use for the action (100% or less if used also for other purposes)	Total (EUR)		
		a	b		c	d= a*b*c		
	1 [Equipment short name]	0,00	0,00		0%	**0,00**		
	2 [Equipment short name]	0,00	0,00		0%	**0,00**		
	3 [Equipment short name]	0,00	ATTENTION! Can be used only if full cost option in the grant agreement			**0,00**		
					Total rental and leasing	**0,00**		
					Total equipment for this WP	**0,00**		
					Total equipment (all WPs)	**0,00**		
C.3 Other goods, works and services								
WORK PACKAGE 1	**WP1: MANAGEMENT & COORDINATION**							
		Costs (actual costs)					Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the goods/services are needed; types of goods services needed; how much
	Consumables	0,00						

	Conferences, seminars, workshops, trainings & events	0,00			
	Information & publications	0,00			
	Other expenses				
	1 IPR costs	0,00			
	2 Bank fees (pre-financing guarantee)	0,00			
	3 Audit fees (CFS)	15 000,00		NO	Final financial audit after the end of the project.
	4 Project evaluation	0,00			
	[5 short name other]	0,00			
	[6 short name other]	0,00			
	Total goods, works and services for this WP	**15 000,00**			
WORK PACKAGE 2	**WP2: DISSEMINATION, TRAINING AND SUPPORT**				
		Costs (actual costs)		Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the goods/services are needed; types of goods services needed; how much
	Consumables	0,00			
	Conferences, seminars, workshops, trainings & events	0,00			
	Information & publications	0,00			
	Other expenses				
	1 IPR costs	0,00			
	2 Bank fees (pre-financing guarantee)	0,00			
	3 Audit fees (CFS)	0,00			
	4 Project evaluation	0,00			
	[5 short name other]	0,00			
	[6 short name other]	0,00			
	Total goods, works and services for this WP	**0,00**			
WORK PACKAGE 3	**WP3: EVALUATION OF THE PROJECT**				
		Costs (actual costs)		Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the goods/services are needed; types of goods services needed; how much
	Consumables	0,00			
	Conferences, seminars, workshops, trainings & events	0,00			
	Information & publications	0,00			
	Other expenses				
	1 IPR costs	0,00			
	2 Bank fees (pre-financing guarantee)	0,00			
	3 Audit fees (CFS)	0,00			
	4 Project evaluation	0,00			
	[5 short name other]	0,00			
	[6 short name other]	0,00			
	Total goods, works and services for this WP	**0,00**			
WORK PACKAGE 4	**WP4: SUSTAINABILITY OF THE PROJECT**				
		Costs (actual costs)		Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the goods/services are needed; types of goods services needed; how much
	Consumables	0,00			
	Conferences, seminars, workshops, trainings & events	0,00			

	Information & publications	0,00			
	Other expenses				
	1 IPR costs	0,00			
	2 Bank fees (pre-financing guarantee)	0,00			
	3 Audit fees (CFS)	0,00			
	4 Project evaluation	0,00			
	[5 short name other]	0,00			
	[6 short name other]	0,00			
	Total goods, works and services for this WP	**0,00**			
WORK PACKAGE 5	**WP5: NATIONAL DATA ACCESS APPLICATION MANAGEMENT SOLUTION**				
		Costs (actual costs)		Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the goods/services are needed; types of goods services needed; how much
	Consumables	0,00			
	Conferences, seminars, workshops, trainings & events	0,00			
	Information & publications	0,00			
	Other expenses				
	1 IPR costs	0,00			
	2 Bank fees (pre-financing guarantee)	0,00			
	3 Audit fees (CFS)	0,00			
	4 Project evaluation	0,00			
	[5 short name other]	0,00			
	[6 short name other]	0,00			
	Total goods, works and services for this WP	**0,00**			
WORK PACKAGE 6	**WP6: NATIONAL DATASET CATALOGUE FOR HEALTH DATA**				
		Costs (actual costs)		Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the goods/services are needed; types of goods services needed; how much
	Consumables	0,00			
	Conferences, seminars, workshops, trainings & events	0,00			
	Information & publications	0,00			
	Other expenses				
	1 IPR costs	0,00			
	2 Bank fees (pre-financing guarantee)	0,00			
	3 Audit fees (CFS)	0,00			
	4 Project evaluation	0,00			
	[5 short name other]	0,00			
	[6 short name other]	0,00			
	Total goods, works and services for this WP	**0,00**			
WORK PACKAGE 7	**WP7: CROSS-BORDER GATEWAY FOR HD@EU**				
		Costs (actual costs)		Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the goods/services are needed; types of goods services needed; how much
	Consumables	0,00			
	Conferences, seminars, workshops, trainings & events	0,00			
	Information & publications	0,00			

	Other expenses				
	1 IPR costs	0,00			
	2 Bank fees (pre-financing guarantee)	0,00			
	3 Audit fees (CFS)	0,00			
	4 Project evaluation	0,00			
	[5 short name other]	0,00			
	[6 short name other]	0,00			
	Total goods, works and services for this WP	**0,00**			
WORK PACKAGE 8	**WP8: HEALTH DATA QUALITY ENHANCEMENT**				
		Costs (actual costs)		Also part of other work packages? YES/NO and which WP	Description of tasks/activities for which the goods/services are needed; types of goods services needed; how much
	Consumables	0,00			
	Conferences, seminars, workshops, trainings & events	0,00			
	Information & publications	0,00			
	Other expenses				
	1 IPR costs	0,00			
	2 Bank fees (pre-financing guarantee)	0,00			
	3 Audit fees (CFS)	0,00			
	4 Project evaluation	0,00			
	[5 short name other]	0,00			
	[6 short name other]	0,00			
	Total goods, works and services for this WP	**0,00**			
	Total goods, works and services (all WPs)	**15 000,00**			
			Total purchase costs (all WPs)	**63 588,00**	

D. Other cost categories

D.1. Financial support to third parties

WORK PACKAGE 1	**WP1: MANAGEMENT & COORDINATION**				
	Financial support to third parties	Costs (actual costs)		Also used for other work packages? YES/NO and which WP	Description of support scheme (estimated number of recipients; maximum amount per recipient)
	[Support scheme short name]	0,00			
	[Support scheme short name]	0,00			
		0,00			
	Total other cost category D.1 for this WP	**0,00**			
WORK PACKAGE 2	**WP2: DISSEMINATION, TRAINING AND SUPPORT**				
	Financial support to third parties	Costs (actual costs)		Also used for other work packages? YES/NO and which WP	Description of support scheme (estimated number of recipients; maximum amount per recipient)
	[Support scheme short name]	0,00			
	[Support scheme short name]	0,00			

		0,00			
	Total other cost category D.1 for this WP	**0,00**			
WORK PACKAGE 3	**WP3: EVALUATION OF THE PROJECT**				
	Financial support to third parties	Costs (actual costs)		Also used for other work packages? YES/NO and which WP	Description of support scheme (estimated number of recipients; maximum amount per recipient)
	[Support scheme short name]	0,00			
	[Support scheme short name]	0,00			
		0,00			
	Total other cost category D.1 for this WP	**0,00**			
WORK PACKAGE 4	**WP4: SUSTAINABILITY OF THE PROJECT**				
	Financial support to third parties	Costs (actual costs)		Also used for other work packages? YES/NO and which WP	Description of support scheme (estimated number of recipients; maximum amount per recipient)
	[Support scheme short name]	0,00			
	[Support scheme short name]	0,00			
		0,00			
	Total other cost category D.1 for this WP	**0,00**			
WORK PACKAGE 5	**WP5: NATIONAL DATA ACCESS APPLICATION MANAGEMENT SOLUTION**				
	Financial support to third parties	Costs (actual costs)		Also used for other work packages? YES/NO and which WP	Description of support scheme (estimated number of recipients; maximum amount per recipient)
	[Support scheme short name]	0,00			
	[Support scheme short name]	0,00			
		0,00			
	Total other cost category D.1 for this WP	**0,00**			
WORK PACKAGE 6	**WP6: NATIONAL DATASET CATALOGUE FOR HEALTH DATA**				
	Financial support to third parties	Costs (actual costs)		Also used for other work packages? YES/NO and which WP	Description of support scheme (estimated number of recipients; maximum amount per recipient)
	[Support scheme short name]	0,00			
	[Support scheme short name]	0,00			
		0,00			
	Total other cost category D.1 for this WP	**0,00**			
WORK PACKAGE 7	**WP7: CROSS-BORDER GATEWAY FOR HD@EU**				
	Financial support to third parties	Costs (actual costs)		Also used for other work packages? YES/NO and which WP	Description of support scheme (estimated number of recipients; maximum amount per recipient)
	[Support scheme short name]	0,00			
	[Support scheme short name]	0,00			
		0,00			

	Total other cost category D.1 for this WP	**0,00**	
WORK PACKAGE 8	**WP8: HEALTH DATA QUALITY ENHANCEMENT**		

Financial support to third parties		Costs (actual costs)		Also used for other work packages? YES/NO and which WP	Description of support scheme (estimated number of recipients; maximum amount per recipient)
	[Support scheme short name]	0,00			
	[Support scheme short name]	0,00			
		0,00			
	Total other cost category D.1 for this WP	**0,00**			

Total D.1 (all WPs)	**0,00**	
Total other cost categories (all WPs)	**0,00**	

E. Indirect costs

		Costs (flat-rate)	
ALL WORK PACKAGES	Total estimated direct costs (on which indirect cost flat-rate is based, see GA eligibility article)	1 191 988,00	
	Flat-rate (%)	7%	ATTENTION**!** Check that the rate is in line with the call conditions. Put 0% if you receive an EU Operating Grant and are not eligible to charge indirect costs"
	Total indirect costs	83 439,16	
	Total indirect costs	**83 439,16**	

TOTAL COSTS PARTICIPANT	**1 275 427,16**	

PROJECT INCOME

EU CONTRIBUTION (GRANT)

		Amount (EUR)	
	Total costs	1 275 427,16	
	Single Funding rate (%)	80%	ATTENTION**!** Enter funding rate from the call conditions.
	Maximum EU contribution	1 020 341,73	
	Requested EU contribution	**972 587,20**	ATTENTION**!** In order to avoid rounding issues, please request 1 cent less than the maximum EU contribution.
	EU CONTRIBUTION	**972 587,20**	

REVENUES AND CONTRIBUTIONS BY THIRD PARTIES

Revenues

Income generated by the action

	Amount (EUR)	Description of the income (type of generated income and number of users, etc)

ALL WORK PACKAGES	Estimated income generated by the action	0,00		
	Total income generated by the action	**0,00**		
	Revenues	**0,00**		

In-kind contributions by third parties

In-kind contributions by third parties

		Amount (EUR)	Description of the contribution (type of contribution, donor, purpose etc)
ALL WORK PACKAGES	Estimated in-kind contributions by third parties	0,00	
	Total in-kind contributions	**0,00**	
	In-kind contributions	**0,00**	

Financial contributions by third parties

Financial contributions by third parties

		Amount (EUR)	Description of the contribution (type of contribution, donor, purpose, etc)
ALL WORK PACKAGES	Estimated financial contributions by third parties	0,00	
	Total financial contributions	**0,00**	
	Financial contributions	**0,00**	
	TOTAL REVENUES AND CONTRIBUTIONS BY THIRD PARTIES	**0,00**	

OWN RESOURCES

		Amount (EUR)
	Own resources	302 839,96
	OWN RESOURCES	**302 839,96**
	TOTAL INCOME PARTICIPANT	**1 275 427,16**

DETAILED BUDGET TABLE (ACTION GRANTS)

Associated with document Ref. Ares(2023)7236599 - 24/10/2023

Project number:	210914748
Project acronym:	HeDAB - SK
Participant short name:	NCZI
Participant PIC:	998884370

CONSOLIDATED COSTS PER WORK PACKAGE (PER PARTICIPANT)

COSTS PER WORK PACKAGE

	A.1 Employees A.2 + A.3 Natural persons under direct contract and seconded persons a1 - a2	A.4 SME owners a3	B. Subcontracting costs b	C. Purchase costs						D. Other cost categories	E. Indirect costs	Total
				C.1 Travel and subsistence c1	C.1 Travel c1a	C.1 Accommodation c1b	C.1 Subsistence c1c	C.2 Equipment c2	C.3 Other goods, work and services c3	D.1 Financial support to third parties d1	e = flat-rate * (a1 + a2 + a3 + a5 + b [+ c1] + [c1a + c1b + c1c] + c2 + c3 + d1 + d2 + d3 + d4 + d5 + d6)	
WP1 WP1: MANAGEMENT & COORDINATION	120 400,00	0,00	0,00	21 752,00	9 600,00	4 820,00	7 332,00	0,00	15 000,00	0,00		157 152,00
WP2 WP2: DISSEMINATION, TRAINING AND SUPPORT	69 000,00	0,00	70 000,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00		139 000,00
WP3 WP3: EVALUATION OF THE PROJECT	16 200,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00		16 200,00
WP4 WP4: SUSTAINABILITY OF THE PROJECT	52 100,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00		52 100,00
WP5 WP5: NATIONAL DATA ACCESS APPLICATION MANAGEMENT SOLUTION	50 000,00	0,00	110 000,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00		160 000,00
WP6 WP6: NATIONAL DATASET CATALOGUE FOR HEALTH DATA	63 900,00	0,00	110 000,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00		173 900,00
WP7 WP7: CROSS-BORDER GATEWAY FOR HD@EU	127 500,00	0,00	250 000,00	21 900,00	5 520,00	8 220,00	8 160,00	0,00	0,00	0,00		399 400,00
WP8 WP8: HEALTH DATA QUALITY ENHANCEMENT	74 300,00	0,00	15 000,00	4 936,00	2 208,00	1 096,00	1 632,00	0,00	0,00	0,00		94 236,00
TOTAL COSTS PARTICIPANT	573 400,00	0,00	555 000,00	48 588,00	17 328,00	14 136,00	17 124,00	0,00	15 000,00	0,00	83 439,16	1 275 427,16

DETAILED BUDGET TABLE (ACTION GRANTS)

Project number:	210914748
Project acronym:	HeDAB - SK

ATTENTION! Delete columns that do not apply for your grant.

CONSOLIDATED COSTS PER WORK PACKAGE (PROJECT)

PROJECT COSTS PER WORK PACKAGE

	A.1 Employees A.2 + A.3 Natural persons under direct contract and seconded persons a1 - a2	A.4 SME owners a3	B. Subcontracting costs b	C. Purchase costs						D. Other cost categories	E. Indirect costs	Total
				C.1 Travel and subsistence c1	C.1 Travel c1a	C.1 Accommodation c1b	C.1 Subsistence c1c	C.2 Equipment c2	C.3 Other goods, works and services c3	D.1 Financial support to third parties d1	e = flat-rate * (a1 + a2 + a3 + a5 + b [+ c1] + [c1a + c1b + c1c] + c2 + c3 + d1 + d2 + d3 + d4 + d5 + d6)	
PARTICIPANT NCZI												
TOTAL COSTS PARTICIPANT (Proposal Step)	561 400,00	0,00	555 000,00	103 700,00	77 000,00	18 500,00	8 200,00	0,00	15 000,00	0,00	86 457,00	1 321 557,00
TOTAL COSTS PARTICIPANT (Grant Preparation Step)	573 400,00	0,00	555 000,00	48 588,00	17 328,00	14 136,00	17 124,00	0,00	15 000,00	0,00	83 439,16	1 275 427,16
PARTICIPANT [name]												
TOTAL COSTS PARTICIPANT (Proposal Step)												0,00
TOTAL COSTS PARTICIPANT (Grant Preparation Step)												0,00
PARTICIPANT [name]												
TOTAL COSTS PARTICIPANT (Proposal Step)												0,00
TOTAL COSTS PARTICIPANT (Grant Preparation Step)												0,00

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.1 Financial support to third parties	E. Indirect costs					
				Travel	Accommodation	Subsistence									
Forms of funding	Actual costs	Unit costs[7]	Actual costs	Unit[7] or actual costs	Unit[7] or actual costs	Unit[7] or actual costs	Actual costs	Actual costs	Actual costs	Flat-rate costs[8]					
	a1	a3	b	c1a	c1b	c1c	c2	c3	d1	e = flat-rate * (a1 + a3 + b + c1a + c1b + c1c + c2 + c3 + d1)	f = a + b + c + d + e	U	g = f * U%	h	m
1 - NCZI	573 400.00	0.00	555 000.00	17 328.00	14 136.00	17 124.00	0.00	15 000.00	0.00	83 439.16	1 275 427.16	80	1 020 341.73	972 587.20	972 587.20

[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

See Additional information on unit costs and contributions (Annex 2a and 2b)

Travel and subsistence

See Additional information on unit costs and contributions (Annex 2a and 2b)

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.X Financial support to third parties	E. Indirect costs						
				Travel	Accommodation	Subsistence										
Forms of funding	Actual costs	Unit costs[5]	Actual costs	Unit[5] or actual costs	Unit[5] or actual costs	Unit[5] or actual costs	Actual costs	Actual costs	Actual costs	Flat-rate costs[6]						
	a1	a3	b	c1a	c1b	c1c	c2	c3	d1a	e = flat-rate * (a1 + a3 + b + c1a + c1b + c1c + c2 + c3 + d1a)	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).

ⓘ 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

ETHICS (— ARTICLE 14)

Ethics

Actions involving activities raising ethics issues must be carried out in compliance with:

- ethical principles

and

- applicable EU, international or national law, including Directive 2005/28[1] and Regulation 536/2014[2] .

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 a person, the right to non-discrimination, the need to ensure protection of the environment and high levels of human health protection.

Before the beginning of an action task raising an ethical issue, 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).

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

List of background

The beneficiaries must, where industrial and intellectual property rights (including rights of third parties) exist prior to the Agreement, establish a list of these pre-existing industrial and intellectual property rights, specifying the rights owners.

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

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[1] Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).

[2] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

Rights of use of the granting authority on results for information, communication, dissemination and publicity purposes

The granting authority also has the right to exploit non-sensitive results of the action for information, communication, dissemination and publicity purposes, using any of the following modes:

- **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)

- **distribution to the public** in hard copies, in electronic or digital format, on the internet including social networks, as a downloadable or non-downloadable file

- **editing** or **redrafting** (including shortening, summarising, changing, correcting, cutting, inserting elements (e.g. meta-data, legends or other graphic, visual, audio or text elements extracting parts (e.g. audio or video files), dividing into parts or use in a compilation

- **translation** (including inserting subtitles/dubbing) in all official languages of EU

- **storage** in paper, electronic or other form

- **archiving** in line with applicable document-management rules

- the right to authorise **third parties** to act on its behalf or sub-license to third parties, including if there is licensed background, any of the rights or modes of exploitation set out in this provision

- **processing**, analysing, aggregating the results and **producing derivative works**

- **disseminating** the results in widely accessible databases or indexes (such as through 'open access' or 'open data' portals or similar repositories, whether free of charge or not.

The beneficiaries must ensure these rights of use for the whole duration they are protected by industrial or intellectual property rights.

If results 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).

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

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

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

The access rights also extend to national authorities of EU Member States or associated countries, 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 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 third parties to ensure continuity and interoperability

Where the call conditions impose continuity or interoperability obligations, the beneficiaries must make the materials, documents and information and results produced in the framework of the action available to the public (freely accessible on the Internet under open licences or open source licences).

COMMUNICATION, DISSEMINATION AND VISIBILITY (— ARTICLE 17)

Communication and dissemination plan

The beneficiaries must provide a detailed communication and dissemination plan, setting out the objectives, key messaging, target audiences, communication channels, social media plan, planned budget and relevant indicators for monitoring and evaluation.

Additional communication and dissemination activities

The beneficiaries must engage in the following additional communication and dissemination activities:

- **present the project** (including project summary, coordinator contact details, list of participants, European flag and funding statement and project results) on the beneficiaries' **websites** or **social media accounts**
- for actions involving **publications**, mention the action and the European flag and funding statement on the cover or the first pages following the editor's mention
- for actions involving public **events**, display signs and posters mentioning the action and the European flag and funding statement
- upload the public **project results** to the EU4Health Project Results platform, available through the Funding & Tenders Portal .

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

Durability

Unless exempted by the granting authority, the beneficiaries must commit to continue to use and maintain after the end of the action equipment bought and eligible at full cost, for activities pursuing the action's objectives. Such equipment must be used for these purposes — for at least five years after the end of the action (see Data Sheet, Point 1) or until the end of its economic lifespan (i.e. until it has been fully depreciated) — whichever is earlier.

Specific rules for blending operations

When implementing blending operations, the beneficiaries acknowledge and accept that:

- the grant depends on the approved financing from the Implementing Partner and/or public or private investors for the project
- they must inform the granting authority both about the approval for financing and the financial close — within 15 days
- the payment deadline for the first prefinancing is automatically suspended until the granting authority is informed about the approval for financing
- both actions will be managed and monitored in parallel and in close coordination with the Implementing Partner, in particular:
    - all information, data and documents (including the due diligence by the Implementing Partner and the signed agreement) may be exchanged and may be relied on for the management of the other action (if needed)
    - issues in one action may impact the other (e.g. suspension or termination in one action may lead to suspension also of the other action; termination of the grant will normally suspend and exit from further financing and vice versa, etc.)
- the granting authority may disclose confidential information also to the Implementing Partner.

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