EUROPEAN RESEARCH COUNCIL EXECUTIVE AGENCY (ERCEA)

ERCEA.C – Grant Management Department
C.2 – Grant Management & Amendments Coordination

GRANT AGREEMENT

Project 101189340 — ELIDIS

PREAMBLE

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

on the one part,

the **European Research Council Executive Agency (ERCEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and

on the other part,

1. 'the coordinator':

ISTITUTO NAZIONALE DI BIOSTRUTTURE E BIOSISTEMI (INBB), PIC 998052207, established in VIA DEI CARPEGNA 19, ROMA 00165, Italy,

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

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

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

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

The Agreement is composed of:

Preamble

Terms and Conditions (including Data Sheet)

Annex 1 Description of the action[1]

Annex 2 Estimated budget for the action

Annex 3 Accession forms (if applicable)[2]

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

Annex 4 Model for the financial statements

Annex 5 Specific rules (if applicable)

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

TERMS AND CONDITIONS

TABLE OF CONTENTS

DATA SHEET

1. General data

Project summary:

Project summary
Since its introduction more than 50 years ago, ELISA (Enzyme-Linked Immunosorbent Assay) remains one of the most widely used technologies for research, drug discovery and diagnosis. The reasons for this extraordinary longevity are manifold: ELISA combines the high specificity of antibody-antigen interactions with the high sensitivity of enzyme amplification. However, ELISA also has disadvantages: multiple washing steps and reagents are required and a specialized instrument is needed, which is not always available in all laboratories. An innovative immunoassay technology that can overcome the limitations of ELISA while retaining all of its best features would therefore represent a turning point in the global immunoassay market (> $35 billion in 2023). Under the ERC Consolidator Grant PRO-TOOLKITS, we have developed a novel immunoassay, which we have named Enzyme-Linked DNA Displacement (ELIDIS), which has all the characteristics to meet this need and become an alternative to ELISA. In short, ELIDIS involves 2 steps and is based on the use of enzyme-conjugated DNA strands and disposable electrodes. ELIDIS retains the advantageous properties of ELISA (high sensitivity and specificity) but, unlike ELISA, is easier to perform, does not require enzyme-labeled antibodies and, more importantly, can be performed using portable electronic devices such as a laptop or smartphone without the need for additional instruments. With these considerations in mind, in this PoC project we will validate the ELIDIS assay as a candidate to replace ELISA in any biotech and biopharma laboratory. To achieve the above goal, we will: 1) Validate the ELIDIS assay for the detection of two model targets (Trastuzumab and EGFR); 2) Develop two prototype kits using disposable sensor arrays and a portable device (or an app/software). 3) Create a “manufacturing plan” for assay production; 4) Develop an IP strategy for patent filing/maintenance; 5) Create a plan for business/commercialization.

Keywords: not defined

Project number: 101189340

Project name: Enzyme-Linked DNA Displacement (ELIDIS) Assay as an innovative immunoassay platform

Project acronym: ELIDIS

Call: ERC-2024-POC

Topic: ERC-2024-POC

Type of action: HORIZON ERC Proof of Concept Grants

Granting authority: European Research Council Executive Agency

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

Project starting date: first day of the month following the entry into force date

Project end date: starting date + months of duration

Project duration: 18 months

Consortium agreement: No

2. Participants

List of participants:

N°	Role	Short name	Legal name	Ctry	PIC	Max grant amount
1	COO	INBB	ISTITUTO NAZIONALE DI BIOSTRUTTURE E BIOSISTEMI	IT	998052207	150 000.00
Total						150 000.00

Coordinator:

– ISTITUTO NAZIONALE DI BIOSTRUTTURE E BIOSISTEMI (INBB)

3. Grant

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

Maximum grant amount (Annex 2)	Maximum grant amount (award decision)
150 000.00	150 000.00

Grant form: Lump Sum

Grant mode: Action grant

Budget categories/activity types: Lump sum contributions

Cost eligibility options: n/a

Budget flexibility: No

4. Reporting, payments and recoveries

4.1 Continuous reporting (art 21)

Deliverables: see Funding & Tenders Portal Continuous Reporting tool

4.2 Periodic reporting and payments

Reporting and payment schedule (art 21, 22):

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

Prefinancing payments and guarantees:

Prefinancing payment	
Type	Amount
Prefinancing 1 (initial)	120 000.00

Reporting and payment modalities (art 21, 22):

Mutual Insurance Mechanism (MIM): Yes

MIM contribution: 5% of the maximum grant amount (7 500.00), retained from the initial prefinancing

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

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

No-profit rule: n/a

Late payment interest: ECB + 3.5%

Bank account for payments:

IT67H0569603226000004600X79 POSOIT22

Conversion into euros: n/a

Reporting language: Language of the Agreement

4.3 Certificates (art 24): n/a

4.4 Recoveries (art 22)

First-line liability for recoveries:

Beneficiary termination: Beneficiary concerned

Final payment: Each beneficiary for their own debt

After final payment: Beneficiary concerned

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

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

Joint and several liability of affiliated entities — n/a

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

Suspension and termination:

Additional suspension grounds (art 31)

Additional termination grounds (art 32)

Applicable law (art 43):

Standard applicable law regime: EU law + law of Belgium

Dispute settlement forum (art 43):

Standard dispute settlement forum:

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

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

6. Other

Specific rules (Annex 5): Yes

Standard time-limits after project end:

Confidentiality (for X years after final payment): 5

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

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

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

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

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

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

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

ARTICLE 2 — DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

[4] For the definition, see Article 187 Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 ('EU Financial Regulation') (OJ L 193, 30.7.2018, p. 1): "**affiliated entities** [are]:
(a) entities that form a sole beneficiary [(i.e. where an entity is formed of several entities that satisfy the criteria for being awarded a grant, including where the entity is specifically established for the purpose of implementing an action to be financed by a grant)];
(b) entities that satisfy the eligibility criteria and that do not fall within one of the situations referred to in Article 136(1) and 141(1) and that have a link with the beneficiary, in particular a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation".

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

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

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

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

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

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

CHAPTER 2 ACTION

ARTICLE 3 — ACTION

The grant is awarded for the action **101189340** — **ELIDIS** ('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

[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).

The grant is an action grant[8] which takes the form of a lump sum grant for the completion of work packages.

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

Not applicable

5.4 Estimated budget, budget categories and forms of funding

The estimated budget for the action (lump sum breakdown) is set out in Annex 2.

It contains the estimated eligible contributions for the action (lump sum contributions), broken down by participant and work package.

Annex 2 also shows the types of contributions (forms of funding)[9] to be used for each work package.

5.5 Budget flexibility

Budget flexibility does not apply; changes to the estimated budget (lump sum breakdown) always require an amendment (see Article 39).

Amendments for transfers between *work packages* are moreover possible only if:

- the work packages concerned are not already completed (and declared in a financial statement) and
- the transfers are justified by the technical implementation of the action.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE CONTRIBUTIONS

6.1 and 6.2 General and specific eligibility conditions

Lump sum contributions are eligible ('eligible contributions'), if:

(a) they are set out in Annex 2 and

(b) the work packages are completed and the work is properly implemented by the beneficiaries and/or the results are achieved, in accordance with Annex 1 and during in the period set out in Article 4 (with the exception of work/results relating to the submission of the final periodic report, which may be achieved afterwards; see Article 21)

They will be calculated on the basis of the amounts set out in Annex 2.

[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".

[9] See Article 125 EU Financial Regulation 2018/1046.

6.3 Ineligible contributions

'Ineligible contributions' are:

(a) lump sum contributions that do not comply with the conditions set out above (see Article 6.1 and 6.2)

(b) lump sum contributions for activities already funded 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 case:

(i) Synergy actions: not applicable

(c) other:

(i) country restrictions for eligible costs: not applicable.

6.4 Consequences of non-compliance

If a beneficiary declares lump sum 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.

The beneficiaries (and their action) must remain eligible under the EU programme funding the grant

for the entire duration of the action. Lump sum 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): not applicable
- 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'[10] (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 contributions to the action (no lump sum contributions) and their costs are considered entirely covered by the lump sum contributions paid to the beneficiaries.

[10] 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 beneficiaries' costs for subcontracting are considered entirely covered by the lump sum contributions for implementing the work packages (irrespective of the actual subcontracting costs incurred, if any).

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: use qualified external auditors which are independent and comply with comparable standards as those set out in EU Directive 2006/43/EC[11]
- for the controls under Article 25: 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.).

[11] 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 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[12] 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

[12] 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[13].

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[14]).

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.

[13] 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).

[14] 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 and

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

Funded by the
European Union

Co-funded by the
European Union

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 lump sum 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 (proper implementation of the work and/or achievement of the results as described in Annex 1) in line with the accepted standards in the respective field (if any); beneficiaries do not need to keep specific records on the actual costs incurred.

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, lump sum 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 statement (consolidated statement for the consortium)
- the explanation on the use of resources (or detailed cost reporting table): not applicable
- the certificates on the financial statements (CFS): not applicable.

The **financial statement** must contain the lump sum contributions indicated in Annex 2, for the work packages that were completed during the reporting period.

For the last reporting period, the beneficiaries may exceptionally also declare partial lump sum

contributions for work packages that were not completed (e.g. due to force majeure or technical impossibility).

Lump sum contributions which are not declared in a financial statement will not be taken into account by the granting authority.

By signing the financial statement (directly in the Portal Periodic Reporting tool), the coordinator confirms (on behalf of the consortium) that:

- the information provided is complete, reliable and true
- the lump sum contributions declared are eligible (in particular, the work packages have been completed, that the work has been properly implemented and/or the results were achieved in accordance with Annex 1; see Article 6)
- the proper implementation and/or achievement 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).

In case of recoveries (see Article 22), beneficiaries will be held responsible also for the lump sum contributions declared for their affiliated entities (if any).

21.3 Currency for financial statements and conversion into euros

The financial statements must be drafted in euro.

21.4 Reporting language

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

21.5 Consequences of non-compliance

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

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

ARTICLE 22 — PAYMENTS AND RECOVERIES — CALCULATION OF AMOUNTS DUE

22.1 Payments and payment arrangements

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

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

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

The cost of payment transfers will be borne as follows:

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

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

22.2 Recoveries

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

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

In case of enforced recoveries (see Article 22.4), affiliated entities will be held liable for repaying debts of their beneficiaries, if required by the granting authority (see Data Sheet, Point 4.4).

22.3 Amounts due

22.3.1 Prefinancing payments

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

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

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

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

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

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

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

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

22.3.2 Amount due at beneficiary termination — Recovery

In case of beneficiary termination, the granting authority will determine the provisional amount due for the beneficiary concerned.

This will be done on the basis of work packages already completed in previous interim payments. Payments for ongoing/not yet completed work packages which the beneficiary was working on before termination (if any) will therefore be made only later on, with the next interim or final payments when those work packages have been completed.

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, on the basis of the beneficiary's lump sum contributions for the work packages which were approved in previous interim payments.

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

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

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

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

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

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

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

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

22.3.3 Interim payments

Interim payments reimburse the eligible lump sum contributions claimed for work packages implemented 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 and the work packages declared. Their approval does not imply recognition of compliance, authenticity, completeness or correctness of their content.

Incomplete work packages and work packages that have not been delivered or cannot be approved will be rejected (see Article 27).

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 first calculate the 'accepted EU contribution' for the action for the reporting period, by calculating the lump sum contributions for the approved work packages.

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 eligible lump sum contributions claimed for the implemented work packages (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 and the work packages declared. Their approval does not imply recognition of compliance, authenticity, completeness or correctness of their content.

Work packages (or parts of them) that have not been delivered or cannot be approved will be rejected (see Article 27).

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 lump sum contributions for the approved work packages.

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

Not applicable

Step 3 — Reduction due to the no-profit rule

Not applicable

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

{final grant amount

minus

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

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

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

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

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

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

If — despite the release of the Mutual Insurance Mechanism contribution — the balance is **negative**, it will be **recovered** in accordance with the following procedure:

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

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

If no observations are submitted (or the granting authority decides to pursue recovery despite the observations it has received) and the coordinator has submitted the report on the distribution of payments, it will calculate the **share of the debt per beneficiary**, by:

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

{{{total accepted EU contribution for the beneficiary

divided by

total accepted EU contribution for the action}

multiplied by

final grant amount for the action},

minus

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

and

(b) dividing the debt:

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

divided by

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

multiplied by

the amount to be recovered}.

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

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

If the coordinator has not submitted the report on the distribution of payments, the granting authority

will **recover** the full amount from the coordinator (**confirmation letter** and **debit note** with the terms and date for payment).

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

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

If — after the final payment (in particular, after checks, reviews, audits or investigations; see Article 25) — the granting authority rejects lump sum 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 contributions'.

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

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

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

{{total accepted EU contribution for the beneficiary

divided by

total accepted EU contribution for the action}

multiplied by

final grant amount for the action}.

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

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

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

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

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

22.4 Enforced recovery

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

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

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

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

(b) financial guarantee(s): not applicable

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

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

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

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

The amount to be recovered will be increased by **late-payment interest** at the rate set out in Article 23.5, 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[15] 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 reference rate applied by the European

[15] 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).

Central Bank (ECB) for its main refinancing operations in euros, plus the percentage specified in the Data Sheet (Point 4.2). The ECB reference rate to be used 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

Not applicable

ARTICLE 24 — CERTIFICATES

Not applicable

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 lump sum 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. 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, unless otherwise agreed with the granting authority (see Data Sheet, Point 4.2).

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, unless otherwise agreed with the granting authority (see Data Sheet, Point 4.2).

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[16] and No 2185/96[17]
- 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 findings

[16] 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).

[17] 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).

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

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

(a) the beneficiary concerned is found, in other EU grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — within the time-limit for audits set out in the Data Sheet (see Point 6).

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

If the extension concerns **rejections of lump sum 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, lump sum 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 CONTRIBUTIONS

27.1 Conditions

The granting authority will — at interim payment, final payment or afterwards — reject any lump sum 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 lump sum 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 lump sum contributions, it will deduct them from the lump sum 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 (extension of findings; see Article 25.5).

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 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 (extension of findings; see Article 25.5).

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. Moreover, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

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 (extension of findings; see Article 25.5)

(c) other:

(i) linked action issues: not applicable

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

31.2.2 Procedure

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

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

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

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

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

During the suspension, no prefinancing will be paid. Moreover, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

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 lump sum contributions for activities implemented before the end of work date (see Article 22). Partial lump sum contributions for work packages that were not completed (e.g. due to technical reasons) may exceptionally be taken into account.

If the granting authority does not receive the report within the deadline, only lump sum contributions which are included in an approved periodic report will be taken into account (no 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

(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 reports submitted in previous interim payments (i.e. beneficiary's lump sum contributions for completed and approved work packages).

Lump sum contributions for ongoing/not yet completed work packages will have to be included in the periodic report for the next reporting periods when those work packages have been completed.

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; see Article 25.5)

(l) despite a specific request by the granting authority, a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its

affiliated entities or associated partners that is in one of the situations under points (d), (f), (e), (g), (h), (i) or (j) and to reallocate its tasks, or

(m) other:

(i) linked action issues: not applicable

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

32.3.2 Procedure

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

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

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

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

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

32.3.3 Effects

(a) for **GA termination**:

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

The granting authority will calculate the final grant amount and final payment on the basis of the report submitted and taking into account the lump sum contributions for activities implemented before termination takes effect (see Article 22). Partial lump sum contributions for work packages that were not completed (e.g. due to technical reasons) may exceptionally be taken into account.

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 lump sum contributions which are included in an approved periodic report will be taken into account (no 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

(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 reports submitted in previous interim payments (i.e. beneficiary's lump sum contributions for completed and approved work packages).

Lump sum contributions for ongoing/not yet completed work packages will have to be included in the periodic report for the next reporting periods when those work packages have been completed.

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[18]).

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.

[18] 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).

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

CHAPTER 6 FINAL PROVISIONS

ARTICLE 36 — COMMUNICATION BETWEEN THE PARTIES

36.1 Forms and means of communication — Electronic management

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

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

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

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

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

36.2 Date of communication

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

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

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

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

36.3 Addresses for communication

The Portal can be accessed via the Europa website.

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

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

ARTICLE 37 — INTERPRETATION OF THE AGREEMENT

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

Annex 5 takes precedence over the Terms and Conditions.

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

Annex 2 takes precedence over Annex 1.

ARTICLE 38 — CALCULATION OF PERIODS AND DEADLINES

In accordance with Regulation No 1182/71[19], 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.

[19] 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).

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

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

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

ARTICLE 40 — ACCESSION AND ADDITION OF NEW BENEFICIARIES

40.1 Accession of the beneficiaries mentioned in the Preamble

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

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

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

40.2 Addition of new beneficiaries

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

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

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

Additions are also possible in mono-beneficiary grants.

ARTICLE 41 — TRANSFER OF THE AGREEMENT

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

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

- the reasons why
- the accession form (see Annex 3) signed by the new beneficiary directly in the Portal Amendment tool and

- additional supporting documents (if required by the granting authority).

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

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

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

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

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

ARTICLE 43 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

43.1 Applicable law

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

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

43.2 Dispute settlement

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

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

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

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

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

ARTICLE 44 — ENTRY INTO FORCE

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

SIGNATURES

For the coordinator

Giovanni ANTONINI with ECAS id nmitamdi signed in the Participant Portal on 26/09/2024 at 16:49:47 (transaction id SigId-24510-pQ5tzzU6NAozzzS6hM74mq3kzxtwUTEk1zztkAfgUVl4pkOeO8XPBEknLMWE2BWESPO6dNPfyzzGPUpyhq1jwDZCS-jpJZscgsw0KuLxFyEs36mK-dUAzmCWsuyzxdaAbb8R5BuSe9RACymzbAAN1GofANBpvcDvamffNKLcqCue2KqEzQnEzYSMxKA5ABSowiXzdBdS0). Timestamp by third party at 2024.09.26 16:49:52 CEST

For the granting authority

Signed by Anisoara ULCELUSE - PIRVAN with ECAS id ulcelan as an authorised representative on 07-10-2024 14:07:28 (transaction id SigId-102198-wrne3sedodqoqzwGaWEB9OFzWdDG5IKAQRccmkpuXKddYmzXt86AngYMJizscE5MrzxXTWIV8glvdvamooGT8jzm-jpJZscgsw0KuLxFyEs36mK-bs8VzMQSGp8CyYuBtSg9suGYInO3344vRPSV0cbsfqqu7hRziMbrpJQzVJwMsIGH72LpSxCTobOv8vW1xWwzLca) 2024.10.07 14:07:31 CEST

ANNEX 1

Horizon Europe (HORIZON)

Description of the action (DoA)

Part A

Part B

DESCRIPTION OF THE ACTION (PART A)

COVER PAGE

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

PROJECT *Grant Preparation (General Information screen) — Enter the info.*	
Project number:	101189340
Project name:	Enzyme-Linked DNA Displacement (ELIDIS) Assay as an innovative immunoassay platform
Project acronym:	ELIDIS
Call:	ERC-2024-POC
Topic:	ERC-2024-POC
Type of action:	HORIZON-ERC-POC
Service:	ERCEA/C/02
Project starting date:	first day of the month following the entry into force date
Project duration:	18 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.

Since its introduction more than 50 years ago, ELISA (Enzyme-Linked Immunosorbent Assay) remains one of the most widely used technologies for research, drug discovery and diagnosis. The reasons for this extraordinary longevity are manifold: ELISA combines the high specificity of antibody-antigen interactions with the high sensitivity of enzyme amplification. However, ELISA also has disadvantages: multiple washing steps and reagents are required and a specialized instrument is needed, which is not always available in all laboratories. An innovative immunoassay technology that can overcome the limitations of ELISA while retaining all of its best features would therefore represent a turning point in the global immunoassay market (> $35 billion in 2023).

Under the ERC Consolidator Grant PRO-TOOLKITS, we have developed a novel immunoassay, which we have named Enzyme-Linked DNA Displacement (ELIDIS), which has all the characteristics to meet this need and become an alternative to ELISA. In short, ELIDIS involves 2 steps and is based on the use of enzyme-conjugated DNA strands and disposable electrodes. ELIDIS retains the advantageous properties of ELISA (high sensitivity and specificity) but, unlike ELISA, is easier to perform, does not require enzyme-labeled antibodies and, more importantly, can be performed using portable electronic devices such as a laptop or smartphone without the need for additional instruments.

With these considerations in mind, in this PoC project we will validate the ELIDIS assay as a candidate to replace ELISA in any biotech and biopharma laboratory. To achieve the above goal, we will: 1) Validate the ELIDIS assay for the detection of two model targets (Trastuzumab and EGFR); 2) Develop two prototype kits using disposable sensor arrays and a portable device (or an app/software). 3) Create a “manufacturing plan” for assay production; 4) Develop an IP strategy for patent filing/maintenance; 5) Create a plan for business/commercialization.

LIST OF PARTICIPANTS

PARTICIPANTS

Grant Preparation (Beneficiaries screen) — Enter the info.

Number	Role	Short name	Legal name	Country	PIC
1	COO	INBB	ISTITUTO NAZIONALE DI BIOSTRUTTURE E BIOSISTEMI	IT	998052207

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	Proof of concept	1 - INBB	0.00	1	18	
WP2	Research Data Management	1 - INBB	0.00	1	18	D2.1 – Data Management Plan

Work package WP1 – Proof of concept

Work Package Number	WP1	Lead Beneficiary	1 - INBB
Work Package Name	Proof of concept		
Start Month	1	End Month	18

Objectives

Description
Proof of Concept

Work package WP2 – Research Data Management

Work Package Number	WP2	Lead Beneficiary	1 - INBB
Work Package Name	Research Data Management		
Start Month	1	End Month	18

Objectives

Description
Research Data Management

STAFF EFFORT

Staff effort per participant *Grant Preparation (Work packages - Effort screen) — Enter the info.*			
Participant	**WP1**	**WP2**	**Total Person-Months**
Total Person-Months	0.00	0.00	0.00

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)
D2.1	Data Management Plan	WP2	1 - INBB	DMP — Data Management Plan	PU - Public	6

Deliverable D2.1 – Data Management Plan

Deliverable Number	D2.1	**Lead Beneficiary**	1 - INBB
Deliverable Name	Data Management Plan		
Type	DMP — Data Management Plan	**Dissemination Level**	PU - Public
Due Date (month)	6	**Work Package No**	WP2

Description
Data Management Plan

LIST OF MILESTONES

(None)

LIST OF CRITICAL RISKS

(None)

ERC PI INFORMATION

PI personal information

PI No	Family Name	Birth Family Name	First Name	Gender	Title	Nationality	Date of Birth	Town of Birth	Country of Birth	Employer
PI-1	RICCI		francesco	Male	Prof.	Italy	1/Jan/77	Rome	Italy	University of Rome Tor Vergata

PI project-related information

PI No	As From Date	Until Date	Hosted and Engaged by	Coordinator Contact (Principal Investigator)	Time Commitment for the Action (%)	Time Commitment in a MS/AC (fixed %)
PI-1	1/10/2024		INBB	No	1	

ERC Proof of Concept Lump Sum Grant 2024-1 - Part B

Enzyme-Linked DNA Displacement (ELIDIS) Assay as an innovative immunoassay platform

ELIDIS at a glance: During the ERC Consolidator Grant PRO-TOOLKITS we have developed a new immunoassay based on the use of antigen-conjugated synthetic DNA strands and enzymatic amplification. The assay, named Enzyme-Linked DNA Displacement (ELIDIS), allows to achieve the detection of target molecules at pico-molar levels with high specificity and with low-cost reagents and minimal instrumentation. The goal of this project is to evaluate the commercial potential of this platform as an alternative to ELISA, the most used immunoassay in biopharma and biotech research.

SECTION 1A: THE IDEA – BREAKTHROUGH INNOVATION POTENTIAL

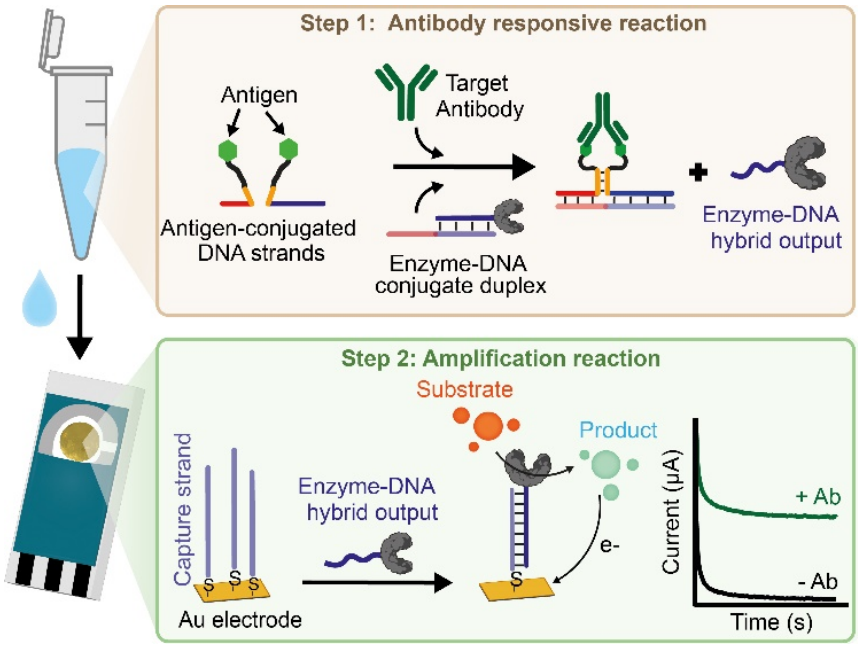
1a.i. Brief description of the idea to be taken to proof of concept.

- The problem: overcoming the limitations of immunoassays.

Since their introduction in the 1950s (1-3), immunoassays have remained one of the most widely used technologies in research, drug development and diagnosis. An immunoassay is a bioanalytical method that uses the reaction of an antigen with an antibody to obtain information about the presence and concentration (amount) of a specific target analyte. The binding between the antibody and the antigen is usually measured using labels that provide a measurable signal. Originally, radioactive labels were used (radioimmunoassay, RIA), but these had obvious contraindications in terms of user safety. In the 1970s, the ELISA (enzyme-linked immunosorbent assay) was introduced as a modification of the RIA by replacing the radioactive labels with enzymes. ELISA generally uses chromogenic enzymatic substrates that produce an observable color change in response to the presence of the enzyme label (4). Over the years, immunoassay technologies and formats have also evolved, resulting in a variety of immunoassay technology platforms that have different characteristics and advantages. However, despite the many attempts to replace this technology, ELISA remains the most widely used immunoassay approach for biomedical research and diagnostic purposes (5).

The reasons for the exceptional and unprecedented longevity of ELISA (more than 50 years!) are manifold: ELISA combines the extremely high specificity and selectivity of antibody-antigen interactions with the high sensitivity provided by enzyme amplification. It is safe and quite flexible in terms of the number of tests to be performed (when using 96-well plates or 384-well plates) (5). However, ELISA also has disadvantages, such as the need for multiple washing steps and reagents (which also increase the overall cost of the test). ELISA also requires different antibodies conjugated to enzymes, which not only increases the cost of the test, but also poses problems in terms of reagent instability (transportation and storage in cold environments are often required) (6). Finally, ELISA requires a specialized plate reader, which can be expensive and is not always available in all laboratories. Based on the above considerations and after a market analysis and interactions with R&D companies, we realized that the development of an alternative method that retains the same positive characteristics of ELISA but overcomes its main limitations would, without exaggeration, represent a turning point in the global immunoassay market.

- The solution. Under the ERC Consolidator Grant PRO-TOOLKITS, we have developed and optimized a novel immunoassay, which we have named Enzyme-Linked DNA Displacement (ELIDIS), that has all the features to meet this need and become an alternative to ELISA (7). In short, ELIDIS is an immunoassay that comprises 2 steps. In the first step (antibody reaction), antigen-conjugated DNA strands react with a specific target antibody and induce the release of an enzyme-DNA hybrid strand from a preformed duplex complex (Figure 1, top). In the second step (amplification



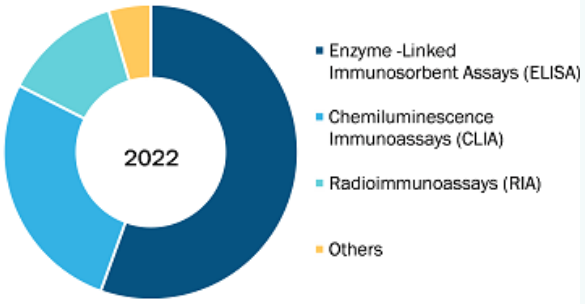
reaction), the reaction solution is transferred to an electrode surface so that the enzyme-DNA hybrid output strand can hybridize with a complementary strand immobilized on the electrode surface and provide a measurable current signal in the presence of the enzymatic substrate (Figure 1, bottom).

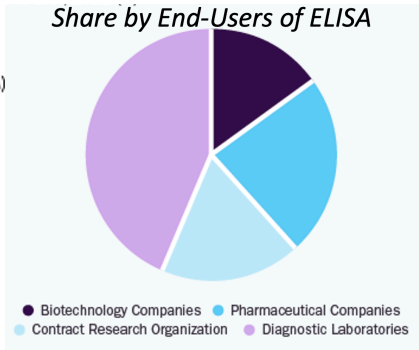
The ELIDIS assay can thus provide information on the presence and amount of a target antibody and can be used to detect potentially any biomarker through a competitive format. ELIDIS retains the advantageous characteristics of ELISA (high sensitivity and specificity) but, unlike ELISA, is easier to perform, does not require enzyme-labeled antibodies and, more importantly, can be performed using portable electronic devices such as a laptop or smartphone without the need for additional specialized instruments (7). The approach is also highly versatile and programmable and can be easily multiplexed or adapted for point-of-care and self-detection of different markers.
In light of the above considerations, in this PoC project we focus on validating the ELIDIS assay as a candidate to replace ELISA in any biotech and biopharma lab.

- The origin (and novelty compared to other sensors we developed so far). The ELIDIS assay was developed as part of the ERC Consolidator Grant PRO-TOOLKITS, which aims to develop responsive and programmable nucleic acid-based modules that can be used as diagnostic kits. As part of the project (and a previous ERC PoC), we have optimized various antibody-responsive DNA-based sensors that took advantage of the programmability and versatility of synthetic DNA (8-10). However, all previous technologies had the same limitation: they suffered from low sensitivity, which ultimately hindered their industrial application. ***With the ELIDIS assay, we are finally able to overcome this limitation. The crucial and novel aspect (compared to all our previously developed methods) is the use of an enzymatic amplification step (similar to ELISA) that allows to reach sensitivities that were not possible before.***

1a.ii. Demonstration of Breakthrough Innovation Potential

Immunoassays are routinely used in many areas of the biopharma and biotechnology industry (product development, quality control, etc.), in diagnostic laboratories and in research labs. In 2022, the global market for immunoassays was estimated at around 35 billion dollars and is expected to grow at an average growth rate of 6% until 2028. This increase is obviously the result of the increasing importance of biotechnology and the biopharmaceutical industry combined with the growing geriatric population and the increasing prevalence of chronic and infectious diseases. The increase in market value is also a result of the growth of the pharmaceutical industry in the Asia-Pacific region over the last 10 years.





ELISA has a very large share in this immunoassay market.
In 2022, the ELISA testing market reached a total value of 3.6 billion dollars, with a projected GACR of 5%. Global immunoassay companies include giants such as Roche, Abbott, ThermoFisher and Siemens as well as a large number of smaller companies. These companies may be interested in co-developing or licensing ELIDIS as a replacement for ELISA.

- Innovative aspects of the project outcomes
There is an urgent need for an innovative immunoassay that can overcome the limitations of ELISA while retaining all its best features. The ELIDIS assay could fulfil this need and therefore may have a very strong potential for an innovation breakthrough. The features of our platform are summarized below:

Value drivers **ADVANTAGES OF ELIDIS**
i) Sensitive and specific: our platform can detect antibodies and proteins at low picomolar concentrations (in some applications even lower than ELISA!). We have also shown that the ELIDIS assay can work without loss of sensitivity in complex samples such as blood serum.
ii) Stable: the synthetic DNA strands used in the ELIDIS assay are stable for months under dry conditions. We have also demonstrated a shelf life of the DNA strands under humid conditions (in a ready-to-use solution) of several weeks. The studies on storage stability will be continued as part of this grant.

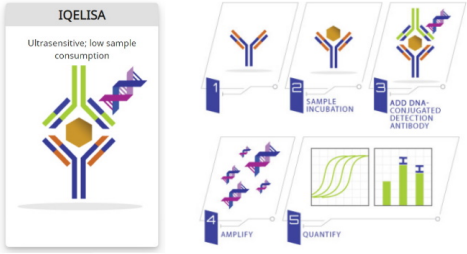
iii) Convenient and fast: our platform requires only 1 washing step after the reaction with the sample. This makes the platform particularly advantageous compared to ELISA.
iv) Low-cost: based on our initial experiments performed during the ERC grant, we calculated an average reagent cost of less than 0.2 €/assay.
v) Instrument-free: the entire technology is based on electrochemical measurements. More precisely, it is a simple chronoamperometric approach (applied potential and measurement of the current generated by the enzymatic product). In developing the ELIDIS test, we used a portable device (PalmSense) connected to a laptop. However, the electrochemical method we used is so simple that it will be possible to perform the assay using an app/software on a smartphone (or laptop) without the need for a dedicated device. The smartphone itself will apply the potential to the electrode (via the app) and measure the current. This will be possible thanks to a USB-C cable connecting the smartphone to a series of electrodes (similar to a 96-well plate) and a dedicated app. Note that as part of the PoC project, we will start developing the app/software with the help of an engineering company (possible identified companies: Labman Automation, Zimmer Peacock), but we will continue to use the portable instrument for the optimization of the detection kits.

- Value proposition

In view of the above characteristics, the ELIDIS test offers a number of advantages over ELISA and therefore seems particularly suitable for commercial use to replace this older technology. As far as we know, there are no comparable examples that offer the same sensitivity (comparable to ELISA) and the same simplicity and stability without the need for specialised instrumentation (see next point).

- Competing products

The most important benchmark for all our future optimization experiments will be ELISA. We will have to prove that ELIDIS has all the properties to replace ELISA, and for this we need specific comparative tests. However, ELISA is not the only immunoassay technology currently used in biopharma and biotech research, and several potential alternatives have been proposed so far by start-ups or established companies. These alternatives often focus on the ultra-sensitive detection of an analyte. Examples include:



(i) *Immuno-Quantitative ELISA* (IQELISA™), an assay based on real-time PCR (11)

ii) *Single Molecule Digital Array* (SIMOA™), a bead-based ELISA assay (12)

These new technologies are extremely sensitive but do not solve any of the problems that ELIDIS can solve (i.e. the cost of reagents and the complexity of the protocol). Furthermore, they require expensive (IQELISA) or very expensive (SIMOA) specialized instruments (a picture of the SIMOA instrument can be found here on the right).

1a.iii. Demonstration of the high-risk/high-gain idea

We want to create a valid alternative to ELISA that can replace this technology in the next 10 years. The idea, if successful, can lead to breakthrough innovations in the biopharma and biotech industry/research. This is of course a high-risk activity. We have identified several aspects (both scientific and non-scientific) that may not work and the possible countermeasures and remedies. These are listed in the table in section 2 (as requested in the submission template). More generally, we believe that the main obstacle to making the ELIDIS assay a competitive product is the possibility of making the assay "instrument-free". To achieve this, as explained above, a dedicated app/software must be developed that allows a fixed potential (approx. 0.6 V) to be applied to the electrode array and the generated current to be measured. This should be possible with a simple USB-C connection to a laptop or smartphone. There are already examples of similar apps (for completely different applications), but since we have no experience with similar projects, this could be a challenging task. For this purpose, we will work with an engineering company (we have already identified two that could be considered, see above) and outsource the production of the app. The sensor arrays, on the other hand, we will first manufacture in our lab (thanks to a semi-automatic screen printer we have) and then outsource this activity to scale production. In this case too, we have identified several companies (which we list in the next section).

SECTION 1B: APPROACH AND METHODOLOGY

1b.i. Approach and methodology to explore the innovation potential of ERC funded research

To realize the benefits described above and to ensure that the ELIDIS project is successful and progresses from Consolidator Grant ground breaking research to innovation, we divided the development into three phases.
1) The first phase consisted of the research conducted under the ERC Consolidator Grant PRO-TOOLKITS, which resulted in the idea presented in this project and early validation data (published and patented).
2) The second phase of development consists of the ERC PoC project ELIDIS, which will support us in the complete validation of the technology with a specific application focus (detection of an antibody drug, trastuzumab, and a protein, EGFR), the preparation of two prototype kits and the testing of the commercial feasibility of the product.
3) The third phase, which will be initiated after the PoC project, is the commercial exploitation of our innovation. This can be done in one of several business models. We have already taken all necessary steps to establish a start-up company (expected launch date April 2024). The name of the start-up will be **Fabrica Biosystems**. Prof. Ricci (65% share) will be the CEO of the company while Dr. Ranallo (30% share) will be involved with operating capacity. The HI (INBB) will be also part of the company with a 5% share. The start-up company will continue the work started with this PoC to produce prototype kits that can already be commercialized. This will generate revenue and also accelerate the development of new products (kits for new targets). The start-up will also seek the possibility to co-develop the technology with a large pharmaceutical company active in the field of immunoassays. Finally, the start-up will also license the technology to a third party. A final decision on the commercialization path will be made at the end of ELIDIS based on the commercial feasibility study (GO/NO-GO analysis point). This is based on the subsequent investment required to reach the market, the availability of personnel to run a start-up company and the interest of the market.

1b.ii Activities exploring the pathway from ground-breaking research towards innovation

The ERC Consolidator Grant PRO-TOOLKITS was the basis for the development of DNA-based responsive modules that can be used for various sensing applications. The general concept of ELIDIS was successfully implemented in WP2 of PRO-TOOLKITS (7). With ELIDIS we will now: i) validate the technology with a specific application focus (the detection of transtuzumab (Herceptin®) and EGFR), ii) develop two prototype kits and iii) test the commercial feasibility of the project.

Model targets: in this PoC we focus on the development of two prototype kits of the ELIDIS assay for the detection of two different analytes: transtuzumab (Herceptin®), a FDA-approved therapeutic antibody for HER2-positive breast cancer and the epidermal growth factor receptor (EGFR), a protein that is often overexpressed in tumor cells. These two target molecules will be detected using the ELIDIS assay in two different measurement formats (direct and competitive) and thus provide an important indication of the versatility of the assay.

The following activities are carried out as part of the ELIDIS project to explore the path from breakthrough research to innovation.

- Technical validation

The technical part of this PoC will address the following challenges: i) ensuring that the ELIDIS assay achieves the required sensitivity for the detection of transtuzumab and EGFR in clinical samples, ii) reducing potential interferences due to the use of clinical body fluid samples, iii) testing the performance of the platform in terms of transportation and storage conditions (lyophilized components), iv) creating a ready-to-use prototype kits.
We will also compare our system with possible competitors. In particular, we will compare the optimized ELIDIS prototype kits with commercially available ELISA kit products (detailed below).

- IPR position and strategy

A strong IP position is an important element for the successful commercialization of our project and would increase the chances of attracting additional funding and potential investors. A freedom-to-operate analysis will be the first task in this PoC project.
We have already filed a patent application to protect the ELIDIS assay (see details below). We will seek the advice of a patent attorney to clarify to what extent the previous patent protects new end products with innovative solutions (freeze-dried components, disposable electrodes, etc.) that could emerge from this PoC

project. This will be done at an early stage of the project so that we can (if necessary) file provisional patent applications with the data generated within ELIDIS. We will also involve the Innovation and Business Incubation Center of the host institution (INBB) from the beginning of the project. In order to convince commercial partners, we will also prepare a technical report, a manufacturing plan and a product portfolio describing the analytical features of our platform and highlighting the advantages compared to the tests currently offered commercially (long-term stability, specificity, cost, etc.).

- Industry/sector contacts

We have strategic partnerships with several companies that may be interested in this technology. The most important of these is the relationship with Merck, a multinational healthcare, life sciences and performance materials company based in Darmstadt, Germany. Prof. Ricci (PI) is already involved in two different research projects with Merck on the development of aptamer-based and DNA-based sensors for different applications (with non-overlapping technologies with ELIDIS). Given Merck's interest in immunoassays, this project could be the beginning of a very fruitful collaboration (Merck has already confirmed their interest). Prof. Ricci and the project team also have a broad network of industrial partners from previous EU and privately funded projects. Below we list a selection of these companies and their relationships with our group:

1) Dynamic Biosensors: based in Munich, Dynamic Biosensors is a provider of instruments, consumables and services in the field of analytical systems for the characterization of biomolecules and molecular interactions. Dynamic Biosensors is not only interested in the development of analytical platforms, but also distributes the Pro-Fire technology, a platform technology that enables easy conjugation between synthetic DNA and proteins (see letter of intent). Dynamic Biosensors could thus become an important partner for ELIDIS' activities, both by advising on the preparation of DNA-protein conjugates needed for the platform and by potentially licensing our technology once it is validated.

2) Ulisse Biomed: Ulisse BioMed is an Italian start-up company that develops diagnostic kits. We have been working with this company for more than 5 years on various projects. Ulisse Biomed has expressed its interest in working with us to validate our technology and compare it with ELISA (see letter of intent).

3) Biosearch Technology: This company specializes in DNA synthesis and DNA-based tests (such as real-time PCR and others). We are in close contact with the CEO of the company, Dr. Ron Cook, with whom we have already collaborated on a previous transcription factor detection project. The company could be a valuable business partner in several ways. They could help us with the development plan (after signing a commercial agreement) by providing the reagents needed to produce the assay kits. The company may also be interested in an exclusive license for the technology.

Finally, the HI (INBB) is an interuniversity consortium whose main objective is to build a bridge between academic research laboratories and industrial sectors, particularly in the clinical field. The INBB will therefore assist in the search for industrial and start-up companies for partnership licensing.

- Potential “end users” of the expected innovation

We envision two possible end users and different applications for our ELIDIS assay.

i) Pharmaceutical and biotechnology companies

The immunoassay market has experienced impressive growth and is expected to reach USD 46.7 billion by 2028. Global antibody giants such as Merck, Roche, Abbott, Johnson & Johnson and ThermoFisher are always on the lookout for potential new methods to replace ELISA. These efforts are often accompanied by similar research by smaller companies (spin-offs, start-ups, etc.). Pharmaceutical and biotech companies may therefore be interested in our ELIDIS assay, both as co-developers and as licensors.

ii) Academic institutions and research laboratoriess

Research laboratories at universities and research centers use ELISA and other immunoassays on a daily basis. These end users are of particular interest to us. They tend to be more flexible and innovative than big industry (as they tend to have fewer restrictions in terms of protocols). They may also be attracted (more than big industry) by the lower cost and greater versatility of the ELIDIS assay. Research labs can thus become the first users (and buyers) of ELIDIS prototype kits. This is a double opportunity for us: it provides us with the initial revenue to fund further research activities, and it also provides us with feedback from end users in academia that can help us improve our product.

1b.iii. Plan of the proof of concept - Description of the Action

- Description of the Action and timescale

We propose to investigate the commercial possibilities of the ELIDIS assay, which can be used for the detection of various proteins and markers. Our aim is to transform the results obtained within the ERC grant

PRO-TOOLKITS into a new immunoassay platform that can be used by the biotech and biopharma industry as well as research laboratories around the world as a valid alternative to ELISA. The aim of the PoC project is to provide a ready-to-use detection kit for immediate use in a portable electrochemical format with freeze-dried ready-to-use components.

To achieve the above goal, during this PoC we will: **1)** fully validate the ELIDIS assay for the detection of trastuzumab and EGFR; **2)** develop two prototype kits using disposable sensors and freeze-dried ready-to-use components with a portable device. **3)** Establish a "manufacturing plan" for production/testing of the sensor; **4)** Develop an IP strategy for patent filing and maintenance; **5)** Establish a business and commercialization plan.

The project duration is 18 months. The planned activities over time are shown below (Gannt diagram of the PoC project). A detailed description of our work and the allocation of resources can be found in the following sections.

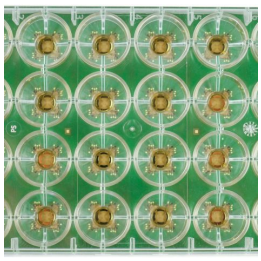
Gantt Chart of ELIDIS

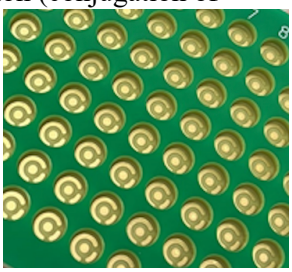
Activity	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18
WP1: Technical Validation												D.1						
Task 1a																		
Task 1b																		
Task 1c																		
WP2: Prototype design and manufactoring plan															D.2			
Task 2a																		
Task 2b																		
WP3: IP portfolio																		D.3
Task 3a																		
Task 3b																		
WP4: Market study and business planning																		D.4
Task 4a																		
Task 4b																		
Task 4c																		

WP 1: Technical Validation (month 0-12)

Summary: This activity focuses on the translation of our preliminary results on the ELIDIS assay into our new idea of an immunoassay kit for biomarker detection. During this work package we will characterize the ELIDIS assay so that its performance can be directly compared to commercial ELISA kits (see list above) and be ready for a marketing activity (product portfolio).

Task 1a: Analysis of targets, format optimization, use of disposable electrodes arrays, development of "instrument-free" app*/software *(month 0-4). We have already shown in our ERC Consolidator Grant that the ELIDIS assay can detect clinically relevant antibodies and proteins directly in 90% of serum with pico-molar detection limits and that can be competitive with ELISA (7). In the initial phase of this PoC grant (month 0-12), we will fully characterize the ELIDIS assay in terms of its analytical performance for the detection of trastuzumab and EGFR. We will conjugate the recognition elements and the enzyme glucose oxidase to synthetic DNA strands using a well standardized conjugation protocol. We will use click reactions and purification protocols (HPLC, gel electrophoresis, etc.). We will also use instruments (such as the ProFire, Dynamic Biosensors) specifically designed for this application (conjugation of proteins to synthetic DNA). We will then optimize the format assay. For trastuzumab we will follow a direct format assay while for EGFR we will use a competitive format. An important part of this task is the optimization/development of the array of disposable electrodes. We will start using 8- and 24-electrode arrays (similar to those represented on the right, example images taken from Macias Sensors company and NBT -New Biotechnology Ltd websites: https://maciassensors.com/and https://nbtltd.com/). The arrays will be produced with the screen printer we have in our lab (DEK 248). Once these arrays are optimized we will scale up to larger arrays (96-electrode). During this task we will also outsource the development of the app/software that will allow to control a 24-electrode array with a smartphone or a laptop without the need of additional instrument. This activity should not take more than 12 months.





Task 1b: Assay Kit validation (month 4-7). This activity will include extensive testing of the synthesized DNA strands to detect the two targets (EGFR and trastuzumab). We will begin testing with EGFR and trastuzumab spiked buffer solutions to validate the concentration range of our test system. Validation of the method will include characterization of accuracy, precision, selectivity, minimum required dilution, dilution linearity, short-term stability at room temperature, freeze–thaw stability and stability of the

process diluted sample. For this validation, we plan to use commercially available body fluids such as urine, blood plasma and serum samples.

Task 1c: Comparison study with standard method (ELISA kits) (month 8-12). We will directly compare the clinical sensitivity and specificity of our ELIDIS assay with those of the following commercially available ELISA kit products:

ELISA kits for the measurement of Herceptin/Trastuzumab:

1) Herceptin/Trastuzumab ELISA Kit from AbCam (13). Price 1.650 euros for 96 tests. Sample types: Plasma, Serum; Sensitivity = 11 ng/mL. Detection method: Colorimetric.

2) Human Herceptin ELISA Kit from Creative Diagnostics (14). Price 1.400 euros for 96 tests. Sample types: Plasma, Serum; Sensitivity = 0.24 ng/mL. Detection method: Colorimetric.

ELISA kits for the measurement of EGFR:

1) EGFR (Full-length) Human ELISA Kit from Thermo Fisher (15). Price 800 euros for 96 tests. Sample types: Plasma, Serum; Sensitivity = 0.2 ng/mL. Detection method:

2) Human EGFR ELISA Kit from AbCam (16). Price 760 euros for 96 tests. Sample types: Plasma, Serum; Sensitivity = 4 pg/mL. Detection method: colorimetric.

For this purpose, we will use serial dilutions of known standards (which also enable sensor calibration) in parallel tests of our platform and the commercial ELISA kits.

***Deliverable**:* Product portfolio with the following description: sensitivity, specificity, precision (relative standard deviations of repeat measurements), accuracy, stability of the ELIDIS assay for the detection of EGFR and trastuzumab and comparison table with the commercial ELISA kits.

Resources: Experienced personnel and consumables are required for technical validation. A postdoc will devote 100% of his/her working time to the project for 12 person-months (tasks 1a-c). For the first part of the project (task 1a), a PhD student will contribute to the project with his experience from the ERC grant PRO-TOOLKITS. Other members of the team described below will work for the project, but will be funded from other sources. Additional funding is foreseen for consumables (synthesis of DNA-protein conjugates, chemicals, reagents, materials).

WP 2: Prototype design and manufacturing plan (month 12-15)

Summary: Once the technical validation is completed, we intend to create a prototype to better highlight the benefits of the ELIDIS assay and to approach potential interested end users.

Task 2a: Design a prototype kit with freeze-dried components and a 24-electrode array (month 12-14). In this activity, we intend to develop a freeze-dried kit with a 24-electrode array for the detection of EGFR and trastuzumab with a portable electrochemical instrument. For this purpose, we will freeze-dry all components of the ELIDIS assay. This procedure should not pose any practical problems (both the synthetic DNA and the proteins and enzymes should be stable during freeze-drying). The components can be freeze-dried directly in a disposable Eppendorf tube. A drop of the sample to be analyzed is added to the disposable Eppendorf tube and dissolves the freeze-dried components. This triggers the target-responsive reactions that cause the release of a DNA sequence labeled with the enzyme (e.g. glucose oxidase). The solution is then transferred to an array of 24 electrodes and then measured with a portable instrument (e.g. PalmSense) using the chronoamperometry technique. The demonstration of this electrochemical array will illustrate the advantages of our platform over ELISA.

Task 2b: Manufacturing plan for the ELIDIS assay kit (month 14-15). In order to standardize the preparation and testing procedure of our ELIDIS assay, we will create a manufacturing plan that we will use for dissemination to interested companies. This will also aim to create an assay that is independent of the field of application and can be converted to other samples/media at a reasonable marginal cost.

Deliverables: Prototype of an ELIDIS assay kit in a disposable format.
A detailed manufacturing plan for ELIDIS assay kit production and testing.

Resources: To prepare a prototype, we reserve a part of the budget for material. The post-doc will be involved in this part of the project (together with technicians/post-doc lab assistants funded from other sources).

WP 3: IP portfolio (month 0-18)
***Summary**:* In parallel to the technical validation (WP1-2), we will also start working towards a strong IP position that would allow us to successfully commercialise our product and increase the chances of additional funding and potential investors.
Task 3a: Patent filing and maintenance (month 0-9). A first patent describing the general principle of our technology has already been filed (Italian patent application no. 102023000014028). In February 2024, we received the patent search report, which was very positive (proven innovations of the technology). We will now file an international extension of the patent (deadline 05/04/2025). We also plan to file a provisional patent describing the more specific protocol of the ELIDIS assay for multiplex detection. In addition to the further pursuit of this technology, new methods developed in WP1 or in the research supported by the ERC Consolidator Grant will also be protected by additional patent applications, if necessary. ***Task 3b: IP strategy (month 9-18).*** An IP strategy will be developed to guide future IP applications. This IP strategy will be based on the results of the market study in order to best support the commercial applications that have been identified as particularly attractive. In this respect, existing contacts with companies will provide valuable input for the strongest IP strategy.
Deliverables: IP strategy for idea and application protection.
Resources: The business developers of the HI will assist in this activity and will be supported by prof. A. Porchetta for the analyses of existing patents and the IP protection regarding the scientific details.

WP 4: Market study and business planning (month 6-18)
Summary: We will conduct an extensive market analysis including market size and growth rate, market trends and opportunities, the barrier to entry, competitive products and existing and emerging distribution channels.
Task 4a: Market analysis (month 6-12). A detailed market analysis will be performed to evaluate market size, volumes, price levels etc. We will approach possible commercial partners and we will better understand more qualitative market aspects such as market needs and new developments. ***Task 4b: Business proposition (month 12-15).*** Based also on the results from WP1-WP2 we will prepare a product portfolio where we highlight the features of our ELIDIS assay and the possible commercial applications (license, diagnostic, research labs, service). We will reach out to a wide range of different companies with the product portfolio for possible partnership and licensing. ***Task 4c: Business plan (month 15-18).*** The scenario with the most attractive effort/return ratio will be chosen and further developed into a full business plan. These considerations will not be limited to strictly financial considerations, but also include the potential for commercialization.
Deliverable: A market analysis and business plan.
Resources: The business developers of the HI will assist in this activity and will be supported by prof. A. Porchetta and Dr. Ranallo for the scientific details regarding the product portfolio.

- Description of the resources

i) Project staff: As PI I will spend 1% of my time to this project (this time will not be charged to the project.. This time will include the guidance of the post-doc and staff members, communication conferences and meetings with various external partners, coordination with team members to evaluate the progress of the project and develop a final business strategy. I will also hire 1.0 fte post-doc for 12 months. Team members experienced in diagnostic applications (funded by other sources) will also assist during the project (see below, description of the team). Finally, a business-developer of the INBB will work 15% of his time to this project.

ii) Consumables: A substantial amount of the budget is requested for consumables. These include costs for synthetic DNA strands, DNA modification and conjugation with proteins and enzymes, antibodies etc. Comparing our antibody-sensor to commercial ELISA kits will require the purchase of materials and lots (prices indicated above for each kit). We also plan to purchase and develop array of electrochemical sensors that will be used for measuring the ELIDIS signal.

iii) Equipment: We plan to purchase a plate reader (for ELISA comparison purposes).

iv) Travel requirements: We also expect to attend meetings with external evaluators, relevant conferences and workshops on immunotherapy and drug monitoring.

v) Other expenses: Market consultancy services to further guide the IP strategy will be also part of the budget.

vi) Other expenses: We plan to also purchase an app/software that will allow to control the electrode arrays using a simple USB-C connection with a smartphone or a laptop.
vii) Overhead: Overhead costs of 25% are justified, since the project will be supported by the host institution (Interuniversity Consortium, INBB, Biostructures and Biosystems National Institute) in the form of administrative support and the services offered by the business developers.

-Description of the team
The team participating in the ELIDIS project consists of the PI (Prof. Francesco Ricci), a postdoctoral researcher hired for 12 months, experienced researchers/technicians from Prof. Ricci's group (these team members salary will not be charged to the project). Prof. Ricci will coordinate the technical team. The postdoctoral researcher recruited for the project should have experience with DNA-based sensors for antibody detection and will perform and control the technical validation of the project (WP1-2). He/she will present the results at scientific conferences and at a later stage at industrial exhibitions. Dr. Ranallo (expert in antibody detection) will support the post-doctoral researcher in these activities. Prof. Alessandro Porchetta will supervise the activities related to intellectual property (WP3) and will be actively involved in the design of the knowledge transfer strategy towards the end of the project (WP4). The design and technical realization of the prototype kits will be supported by our technical staff (funded from other sources). The details of analyzing existing patents and IP protection for our invention will be outsourced, but the PI and collaborators will be involved in the scientific details.
The HI Innovation and Incubation Center will oversee the commercial activities (WP4) and provide support in preparing the business plan at the end of the project and in recruiting the right team for later exploitation if the spin-off route is chosen.
Designer: a free-lance graphic designer (Valentina Marchionni) will be also part of the team. The designer will be responsible to design the packaging of the prototype kits, the logo of the start-up and of the ELIDIS assay. The designer will also be responsible for the website of the start-up company (Fabrica Biosystems).

Strengths of the team:
Interdisciplinarity: mixed background, nanotech and analytical chemistry expertise combined in one team.
Availability: all team members are already employed and familiar with their assignments, the PoC project can start without any delay.
Experience: significant experience in the management of European projects and projects with industrial partners.
Network: the team is already collaborating with different pharmaceutical and diagnostic companies
Weakness of the team:
Industrial and regulatory issues: Our team has no experience with industrial assay protocols. However, within other funded projects we collaborate with different companies that will support us in the requirements needed by the assay protocols.
Engineering issues: Out team has no expertise in engineering activity and software development. For this reason we plan to outsource the development of the app/software that will allow to use the ELIDIS assay without a dedicated instrument.

Below are described the achievements and experience in relation to the approach taken during the project of each member of the team (PI will be described in the next section).

Dr. Simona Ranallo is a senior researcher expert in the development of novel DNA-based nanoswitches regulated by antibodies for diagnostic and drug-delivery applications. Simona spent more than 1 year during her PhD in international research contests (USA and Canada). She was also awarded with an individual postdoc fellowship by Fondazione Umberto Veronesi. Simona is the first author of several publications on peer-review journals (Nat. Commun., Angew. Chem. In. Ed., etc.) and she supervised PhD and master students. The salary of this team member will not be charged to the project.

Prof. Alessandro Porchetta is an associate professor and works in the group of Biosensors and Nanomachines since more than 8 years. He is an expert on DNA-based sensors and DNA nanodevices. Prof. Porchetta has a long-lasting experience on the design and characterization of DNA-based nanostructures, nanoswitches and nanodevices based on DNA. The salary of this team member will not be charged to the project.

Post-Doc + PhD student: A Post-Doc researcher (12 months) and a PhD student will be hired with experience in analytical biochemistry and diagnostic assay development, ideally someone with a background in an important application field such as infectious diseases. Important personal skills include a proven ability to manage projects, collaborate with a variety of external parties and be interested in further exploration of commercial applications.

SECTION 2: PRINCIPAL INVESTIGATOR- STRATEGIC LEAD AND PROJECT MANAGEMENT

Prof. Francesco Ricci – Principal Investigator (PI):
The Strategic Lead:
I am a full professor at the Chemistry Department of the University of Rome, Tor Vergata. My research activity is mainly devoted to the design, optimization and characterization of novel optical and electrochemical sensors and biosensors with emphasis on their possible practical applications in clinical analysis. I lead the group of Biosensors and Nanomachines hosted at the University of Rome Tor Vergata currently composed of 7 post-doc researchers and 6 graduate students. For more information visit the lab website: www.francescoriccilab.com. I will be responsible for the general strategic lead of the project in terms of the targets to be detected with ELIDIS, approaches and assay formats (direct or competitive) to be used and electrodes' arrays that will be more suitable for the ELIDIS assay (8- vs 24- vs 96-electrode arrays). I have all the expertise required to lead this project as demonstrated by similar complex projects in the same field.
Technical lead:
The technical lead will be shared between myself and Dr. Simona Ranallo (she will also be involved in the Fabrica Biosystems start-up company). Together we will be responsible for all the technical validation procedures. Dr. Ranallo will supervise the post-doc and PhD researchers and the other members of the group involved in this PoC project. This will be done by physical meetings every week in which the group members will update on the progresses.
Relationship lead:
I will be responsible for the contacts with possible diagnostic and pharma companies that could be interested in co-developing or licensing our technology. I have on-going and past collaborations with several diagnostic and pharmaceutical companies. Below are reported more details on these collaborations:
***Merck**:* 350 Research Challenges. Our 3-year project with Merck is focused on the development of novel DNA-switches for antibodies detection.
***Menarini**:* This is a multinational company based in Italy. We have been collaborating with this company since more than 10 years for the development of novel glucose continuous monitoring electrochemical sensors.
***Ulisse Biomed**:* We have collaborated with this Italian-based start-up for the development of DNA-based switches for diagnostic applications.

- The Project Management. The activities will be coordinated by myself as the Principal Investigator (PI) of the Biosensors and Nanomachines group. I will be responsible for the progress and the deliverable of the project. For the financial and administrative completion of the project I will be supported by the HI administrative personnel. For the team of the PoC project, monthly project meetings will be held additionally to the regular weekly team meetings to go over updates and enable promptly discussion about upcoming challenges. The new-business developer office of the HI will also provide support for market research, product portfolio, contacts with companies and IP related activities. The team consists of highly skilled professionals and is supported and surrounded by the research facilities of the Dep.nt of Chemistry of the University of Rome, Tor Vergata.

As this is a high-risk high-gain project we have identified a series of possible scientific risks and unforeseen events (non-scientific) that can slow down the progresses of the project. The table below describes these risks and the proposed counter-actions.

- Risk mitigation table

Description of the risk (likelihood to occur)	Proposed risk-mitigation measures
Difficulties due to low stability of glucose oxidase-DNA conjugate or to low turnover rate (medium/high)	Due to the modular approach we can easily change the enzyme used by the assay and rely on other enzymes (Horseradish peroxidase or Alkaline phosphatase) that are usually employed in ELISA and have already demonstrated a high turnover rate and high stability.
Difficulties in increasing the size of the electrode array (medium/high)	In case we found difficult to scale up the electrode arrays (from 8- or 24-electrode to 96-electrode) we will seek the help of specialized companies such as - Arrayjet Ltd, Inter-Array By FZMB Gmbh, Methrom, Multi Channel Systems, Macias Sensors.

Limitation of the platform's performance due to matrix effect (body fluid) (medium)	We will work with diluted samples or add filtration steps to remove or reduce the interferents.
Unforeseen event (likelihood to occur)	**Response**
The reagents cost is too high (low)	As our system does not require expensive instruments, the platform will remain competitive over laboratory-bound methods.
Regulatory hurdles (medium)	Since we first aim to develop a product for research-use, we expect the regulatory hurdles to be minimal and consist of only CE marking. During this PoC we will discuss what the specific requirements for CE-marking our product will be with the notified body and adjust our development strategy accordingly.
No personnel available to pursue the spin-off exploitation route / team member leaving (medium)	In case a team member leaves at the beginning of the project, we will advertise a job opening through the HI's network and social media (LinkedIn). If a team member leaves towards the end of the project, we will distribute their remaining work to other team members.

REFERENCES:

1. David W The immunoassay handbook, 3rd edn. (2005) Elsevier Ltd, Amsterdam
2. Davies C Principles of competitive and immunometric assays (including ELISA). (2013) *Immunoass Handbook* 29–59
3. Slage KM, Ghosn SJ Immunoassays. tools for sensitive, specific, and accurate test results. (1996) *Lab Med* 27(3), 117–83
4. Engvall E, Perlmann P. Enzyme-linked immunosorbent assay (ELISA) Quantitative Assay of Immunoglobulin g. *(*1971) *Immunochemistry* 8, 871–874
5. Ahsan H. Monoplex and multiplex immunoassays: approval, advancements, and alternatives (2022) *Comparative Clinical Pathology*, 31 (2), 333 - 345,
6. Tighe PJ, Ryder RR, Todd I, Fairclough LC. ELISA in the multiplex era: potentials and pitfalls. (2015) *Proteomics Clin Appl*. , 9, 406-22.
7. Díaz-Fernández, A., Ranallo, S., Ricci, F. Enzyme-Linked DNA Displacement (ELIDIS) Assay for Ultrasensitive Electrochemical Detection of Antibodies (2024) *Angewandte Chemie - International Edition*, 63 (1), e202314818,
8. Mariottini, D., Bracaglia, S., Barbero, L., Fuchs, S.W., Saal, C., Moniot, S., Knuehl, C., Baranda, L., Ranallo, S., Ricci, F. Bispecific Antibody Detection Using Antigen-Conjugated Synthetic Nucleic Acid Strands (2023) *ACS Sensors*, 8 (11), 4014-4019.
9. Ranallo, S., Bracaglia, S., Sorrentino, D., Ricci, F. Synthetic Antigen-Conjugated DNA Systems for Antibody Detection and Characterization(2023) *ACS Sensors*, 8 (7), pp. 2415-2426.
10. Bracaglia, S., Ranallo, S., Ricci, F. Electrochemical Cell-Free Biosensors for Antibody Detection (2023) *Angewandte Chemie - International Edition*, 62 (8), e202216512
11. Sano T., Smith C.L., Cantor C.R. Immuno-PCR: Very sensitive antigen detection by means of specific antibody-DNA conjugates. (1992) *Science*, 258 (5079), 120-122.
12. Cohen L., Walt D.R. Single-molecule arrays for protein and nucleic acid analysis (2017) *Annual Review of Analytical Chemistry*, 10, 345 – 363.
13. https://www.abcam.com/en-it/products/elisa-kits/her2-elisa-kit-ab237645#
14. https://www.creative-diagnostics.com/Herceptin-EIA-Kit-238306-499.htm
15. https://www.thermofisher.com/elisa/product/EGFR-Full-length-Human-ELISA-Kit/KHR9061
16. https://www.abcam.com/en-it/products/elisa-kits/human-egfr-elisa-kit-erbb-ab100505#

ANNEX 2

ESTIMATED BUDGET (LUMP SUM BREAKDOWN) FOR THE ACTION

	Estimated EU contribution		
	Estimated eligible lump sum contributions (per work package)		Maximum grant amount[1]
	WP1 Proof of concept	WP2 Research Data Management	
Forms of funding	Lump sum contribution	Lump sum contribution	
	a	b	c = a + b
1 - INBB	150 000.00	0.00	150 000.00

[1] The 'maximum grant amount' is the maximum grant amount fixed in the grant agreement (on the basis of the sum of the beneficiaries' lump sum shares for the work packages).

FINANCIAL STATEMENT FOR THE ACTION FOR REPORTING PERIOD [NUMBER]

	EU contribution											
	Eligible lump sum contributions (per work package)											Requested EU contribution
	WP1 [name]	WP2 [name]	WP3 [name]	WP4 [name]	WP5 [name]	WP6 [name]	WP7 [name]	WP8 [name]	WP9 [name]	WP10 [name]	WP [XX]	
Forms of funding	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	
Status of completion	**COMPLETED**	**COMPLETED**	**COMPLETED**	**COMPLETED**	**COMPLETED**	**COMPLETED**	**COMPLETED**	**PARTIALLY COMPLETED**	**PARTIALLY COMPLETED**	**COMPLETED**	**NOT COMPLETED**	
	a	b	c	d	e	f	g	h	i	j	k	l = a + b+ c + d+ e+ f+ g+ h+ i+ j+ k
1 – [short name beneficiary]												
1.1 – [short name affiliated entity]												
2 – [short name beneficiary]												
2.1 – [short name affiliated entity]												
X – [short name associated partner]												
Total consortium												

The consortium hereby confirms that:

The information provided is complete, reliable and true.

The lump sum contributions declared are eligible (in particular, the work packages have been completed and the work has been properly implemented and/or the results were achieved; see Article 6).

The proper implementation of the action/achievement of the results 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, 21 and 25).

ANNEX 5

SPECIFIC RULES

CONFIDENTIALITY AND SECURITY (— ARTICLE 13)

Sensitive information with security recommendation

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

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

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

EU classified information

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

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

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

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

ETHICS (— ARTICLE 14)

Ethics and research integrity

The beneficiaries must carry out the action in compliance with:

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

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

and

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

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

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

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

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

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

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

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

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

This implies compliance with the following principles:

- reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources
- honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way
- respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment

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

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

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

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

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

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

VALUES (— ARTICLE 14)

Gender mainstreaming

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

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

Definitions

Access rights — Rights to use results or background.

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

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

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

FAIR principles — ‘findability’, ‘accessibility’, ‘interoperability’ and ‘reusability’.

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

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

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

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

Scope of the obligations

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

Agreement on background — Background free from restrictions

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

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

Results free from restrictions

Where the call conditions restrict control due to strategic interests reasons, the beneficiaries must ensure that the results of the action are not subject to control or other restrictions by a country (or entity from a country) which is not one of the eligible countries or target countries set out in the call conditions — unless otherwise agreed with the granting authority.

Ownership of results

Results are owned by the beneficiaries that generate them.

However, two or more beneficiaries own results jointly if:

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

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

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

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

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

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

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

Protection of results

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

Exploitation of results

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

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

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

Additional exploitation obligations

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

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

Additional information obligation relating to standards

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

Transfer and licensing of results

Transfer of ownership

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

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

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

Granting licences

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

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

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

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

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

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

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

The granting authority may request additional information.

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

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

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

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

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

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

The request must:

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

The granting authority may request additional information.

Access rights to results and background

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

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

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

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

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

Access rights for implementing the action

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

- informed the other beneficiaries that access to its background is subject to restrictions, or

- agreed with the other beneficiaries that access would not be on a royalty-free basis.

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

Access rights for exploiting the results

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

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

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

Access rights for entities under the same control

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

- are established in an EU Member State or Horizon Europe associated country

- are under the direct or indirect control of another beneficiary, or under the same direct or indirect control as that beneficiary, or directly or indirectly controlling that beneficiary and

- need the access to exploit the results of that beneficiary.

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

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

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

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

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

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

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

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

Additional access rights

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

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

Dissemination

Dissemination of results

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

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

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

Additional dissemination obligations

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

Open Science

Open science: open access to scientific publications

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

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

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

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

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

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

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

Open science: research data management

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

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

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

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

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

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

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

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

Open science: additional practices

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

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

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

Plan for the exploitation and dissemination of results including communication activities

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

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

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

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

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

Recruitment and working conditions for researchers

The beneficiaries must take all measures to implement the principles set out in Annex II to the Council Recommendation on a European framework to attract and retain research, innovation and entrepreneurial talents in Europe[3] ('the European Charter for Researchers') in particular regarding:

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

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

Specific rules for ERC Grants

When implementing ERC Grants, the beneficiaries must ensure that the action tasks described in Annex 1 are performed under the guidance of the principal investigator.

In accordance with Article 21, beneficiaries must submit progress reports (scientific reports) and periodic reports according to the schedule and modalities set out in the Data Sheet (see Points 4.1 and 4.2). Reports must be prepared using the templates available in the Portal (ERC scientific and periodic reports).

The internal arrangements set out in Article 7 must cover the decision making procedures for scientific and grant management issues, the distribution of the EU contribution, internal dispute settlement and division of responsibilities for cases of rejection of costs or reduction of the grant.

In addition to the obligations set out in Article 17, communication and dissemination activities as well as infrastructure, equipment or major results funded by the grant must moreover display the following special logo:

[3] Council Recommendation C/2023/1640 of 18 December 2023 on a European framework to attract and retain research, innovation and entrepreneurial talents in Europe, Annex II (OJ C, C/2023/1640, 29.12.2023).

In addition, the beneficiaries must respect the following conditions for the principal investigator and their team:

- host and engage the principal investigator for the whole duration of the action
- take all measures to implement the principles set out in the European Charter for Researchers — in particular regarding working conditions, transparent recruitment processes based on merit and career development — and ensure that the principal investigator, researchers and third parties involved in the action are aware of them
- enter — before grant signature — into a Supplementary Agreement with the principal investigator, that specifies:
    - the obligation of the beneficiary to meet its obligations under the Grant Agreement
    - the obligation of the principal investigator to supervise the scientific and technological implementation of the action
    - the obligation of the principal investigator to assume the responsibility for the scientific reporting for the beneficiary and contribute to the periodic reporting
    - the obligation of the principal investigator to meet the time commitments for implementing the action and for working in an EU Member State or Horizon Europe associated country, as set out in Annex 1
    - the obligation of the principal investigator to apply the beneficiary's usual management practices
    - the obligation of the principal investigator to inform the beneficiary immediately of any events or circumstances likely to affect the Grant Agreement, such as:
        - a planned portability of the grant (or part of it) to a new beneficiary (see Articles 32.2, 39, 40, 41)
        - any personal grounds affecting the implementation of the action
        - any changes in the information that was used as a basis for signing the supplementary agreement
        - any changes in the information that was used as a basis for awarding the grant
    - the obligation of the principal investigator to ensure the visibility of EU funding in communications or publications and in applications for the protection of results (see Article 16 and 17)
    - the arrangements related to the intellectual property rights — during the implementation of the action and afterwards —, in particular, the obligation of the principal investigator to uphold the intellectual property rights of the beneficiary and full access — on a royalty-free basis — for the principal investigator to background and results needed for their activities under the action
    - the obligation of the principal investigator to maintain confidentiality (see Article 13)

- for portability of the grant to a new beneficiary (see Articles 32.2, 39, 40, 41):
    - the right of the principal investigator to request the portability of the grant, provided that the objectives of the action remain achievable
    - the obligation of the principal investigator to:
        - propose to the coordinator (in writing) to what extent the action will be transferred and the details of the transfer arrangement
        - provide a statement to the coordinator with the detailed results of the research up to the time of transfer
- the right of the bodies mentioned in Article 25 (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.) to exercise their rights also towards the principal investigator
- the applicable law and the dispute settlement forum

- provide the principal investigator with a copy of the signed Agreement
- guarantee the principal investigator scientific independence, in particular for the:
    - use of the budget to achieve the scientific objectives
    - authority to publish as senior author and invite as co-authors those who have contributed substantially to the work
    - preparation of scientific reports for the action
    - selection and supervision of the other team members, in line with the profiles needed to conduct the research and in accordance with the beneficiary's usual management practices
    - possibility to apply independently for funding
    - access to appropriate space and facilities for conducting the research
- provide — during the implementation of the action — research support to the principal investigator and the team members (regarding infrastructure, equipment, access rights, products and other services necessary for conducting the research)
- support the principal investigator and provide administrative assistance, in particular for the:
    - general management of the work and their team
    - scientific reporting, especially ensuring that the team members send their scientific results to the principal investigator
    - periodic reporting, especially providing timely and clear financial information (for actual cost grants)
    - application of the beneficiary's usual management practices
    - general logistics of the action

    - access to the electronic exchange system

- inform the principal investigator immediately (in writing) of any events or circumstances likely to affect the Agreement

- ensure that the principal investigator enjoys adequate:

    - conditions for annual, sickness and parental leave

    - occupational health and safety standards

    - insurance under the general social security scheme, such as pension rights

- allow (for both mono and multi-beneficiary actions) the portability of the grant to a new beneficiary, if requested by the principal investigator and provided that the objectives of the action remain achievable (see Articles 32.2, 39, 40, 41). The beneficiary may object only on the basis that the portability of the grant is not possible under national law. In particular, the beneficiary must:

    - agree with the principal investigator and the new beneficiary on a plan for the transfer of the intellectual property rights under the Agreement to the new beneficiary

    - transfer to the new beneficiary any part of the prefinancing received which is not covered by an approved periodic report, if requested by the granting authority

    - transfer to the new beneficiary the equipment purchased and used exclusively for the action — against reimbursement of the costs that have not yet been depreciated (for actual cost grants) or under fair and reasonable conditions agreed among the concerned beneficiaries (for lump sum grants) — if requested by the principal investigator and the granting authority, and unless the transfer is not possible under national law.

For ERC Grants with more than one principal investigator, the above-mentioned obligations must be ensured by each beneficiary towards their principal investigators and their teams (and by each principal investigator towards their beneficiary, the coordinator and the other principal investigators). Moreover, the following specificities must be observed:

- for the implementation of the action: the corresponding principal investigator bears the overall responsibility for the supervision of the scientific and technological implementation of the action, while the other principal investigators must contribute to the overall implementation and supervise each one their parts

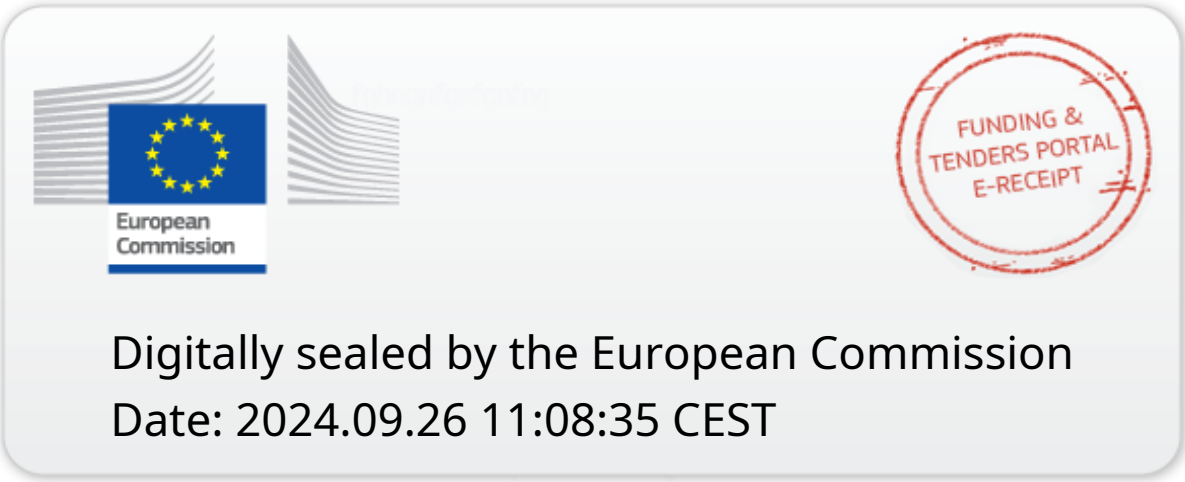
- for the reporting: the corresponding principal investigator assumes the primary responsibility for the scientific reporting and contribution to the periodic reporting, while the other principal investigators must contribute to both the scientific and periodic reporting

- for events or circumstances likely to affect the Agreement: each principal investigator must inform the coordinator, their beneficiary and the other principal investigators

- for portability of the grant by one of the principal investigators (Articles 32.2, 39, 40, 41):

  - the corresponding principal investigator must verify that the beneficiary of the principal investigator and the coordinator were informed
  - the principal investigator concerned must provide the coordinator and their beneficiary with a statement on the detailed results of the research up to the time of transfer
- for the internal arrangements (Article 7): they must also cover settlement of disputes between the principal investigators and between them and the beneficiaries).

For ERC Proof of Concept Grants, the specific rules on reporting (scientific and periodic reporting) and the special conditions for the principal investigator and their team do not apply.



This electronic receipt is a digitally signed version of the document submitted by your organisation. Both the content of the document and a set of metadata have been digitally sealed.

This digital signature mechanism, using a public-private key pair mechanism, uniquely binds this eReceipt to the modules of the Funding & Tenders Portal of the European Commission, to the transaction for which it was generated and ensures its full integrity. Therefore a complete digitally signed trail of the transaction is available both for your organisation and for the issuer of the eReceipt.

Any attempt to modify the content will lead to a break of the integrity of the electronic signature, which can be verified at any time by clicking on the eReceipt validation symbol.

More info about eReceipts can be found in the FAQ page of the Funding & Tenders Portal.

(https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/support/faq)