

# **Fast Track – EP PerMed Financial Support Agreement**



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This Financial Support Agreement, hereinafter the “**Agreement**”, shall have retroactive effect as of **1<sup>st</sup> June 2025** and is entered into by and between:

**Legal Entity of Knowledge and Innovation Community EIT Health:** EIT Health e.V., with registered office at Mies-van-der-Rohe-Straße 1C, 80807 München, Germany, hereinafter referred to as “KIC LE”;

and

[Recipient of subgrant],

[Recipient of subgrant],

Hereinafter, jointly or individually, referred to as the “Recipients” or “Recipient”;

KIC LE and the Recipients hereinafter, jointly or individually, referred to as “Parties” or “Party”;

#### **WHEREAS:**

The KIC LE, together with other entities, having considerable experience in the field concerned, have submitted a proposal for the **Project 101137129 – European Partnership for Personalised Medicine (“EP PerMed”)** to the granting authority, the European Health and Digital Executive Agency (“HADEA”) as part of Horizon Europe – the Framework Programme for Research and Innovation (2021-2027) (the “Action”).

The KIC LE, together with the other entities (together referred to as the “Beneficiaries”), have been awarded a grant for the Action and have entered into a Grant Agreement with the European Health and Digital Executive Agency (HADEA) (the “GA”), with effective date of 1 November 2023, setting out the rights and obligations and terms and conditions applicable to the grant awarded for the implementation of the Action.

Under Work Package 3 – Task 3.2 EP PerMed Accelerator of the GA, the KIC LE facilitates open calls for validation projects with the aim to select a team of researchers or a start-up to carry out a fast track – validation study, which studies will be matched with pre-selected and vetted (translational) infrastructures (WP5), and allows the KIC LE to provide financial support to third parties, in the form of lump sum funding for such projects (the “**Financial Support to Third Parties**”).

The KIC LE, subject to its selection procedure and criteria, has selected the proposal of the Recipients (the “**Project**”).

The Recipients will be involved in the Project as a **Third Parties Receiving Financial Support**.

The KIC LE, in its capacity of beneficiary under the GA must respect certain conditions in terms of transparency, non-discrimination, sound financial management and no conflict of interest. The KIC LE must further ensure that other conditions in terms of eligibility of costs, financial control and audit mechanism, IPR rules and communication, dissemination and visibility rules, standards for monitoring and reporting and rights for i.e. EIT, OLAF and Court of Auditors as provided for in the GA are put in place with the Recipient.

In this Agreement the Parties wish to lay down the contractual arrangements between them regarding their respective rights and obligations for the implementation by the Recipients of the Project, transposing to the extent needed the provisions of the GA.

**NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:**

## **Article 1: Definitions**

### **1.1 Definitions**

Words beginning with a capital letter shall have the meaning defined either herein or in the Horizon Europe Programme or Grant Agreement, including its Annexes.

### **1.2 Additional Definitions**

**“Authorised Representative”** shall mean the person or persons duly authorised to sign this Agreement, including its Annexes, on behalf of a Party.

**“Effective Date”** shall mean the date first referenced above.

**“Force Majeure”** shall mean any situation or event that:

- prevents either Party from fulfilling their obligations under this Agreement,
- was unforeseeable, exceptional situation and beyond the Parties’s 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.

**“Grant Agreement” or “GA”** shall mean the agreement signed by HADEA and the Beneficiaries, setting out the rights and obligations and terms and conditions applicable to the HADEA grant awarded for the implementation of the Action.

**“Grant Management System”** shall mean the official grant management system of KIC EIT Health.

**“Horizon Europe Programme”** shall mean Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013.

**“Final Activity Report”** shall mean a written report issued by each Recipient providing information to enable the verification of the completion of the tasks and the achievement of the Project’s objectives.

**“IP Policy”** shall mean the EIT Health’s IP Policy as available on EIT Health’s website.

**“Lump Sum Contribution”** shall mean the amount awarded to each Recipient as stated in the Project Plan in Annex 2.

**“Project”** shall mean the Recipients’ project selected by KIC LE under the Accelerator call under the Action, which the Recipients shall implement, as described in the Project Plan, as further described in Annex 2 to this Agreement.

**“Third Party Receiving Financial Support”** shall mean a recipient of financial support to third parties, (in the form of grants, prizes or similar forms of support as described in Article 9.4 and Annex V of the GA).

## Article 2: Purpose

The purpose of this Agreement is to lay down the contractual arrangements between the Parties regarding their respective rights and obligations pertaining to the implementation by the Recipients of the Project. For the implementation of the Project the Recipients will act as a Third Parties Receiving Financial Support from KIC LE.

The contractual arrangements will in particular pertain to monitoring and reporting, IPR rules, communication, dissemination and visibility rules, information obligations, checks, reviews, audits and investigations, financial provisions (including eligibility rules for KAVAs/projects), division of roles and responsibility, inter alia liability, non-disclosure of information and dispute resolution.

The Recipients acknowledge and agree that in this Agreement, the conditions of the GA are transposed in the legal arrangement between the KIC LE and the Recipients, in order to ensure that the KIC LE shall meet its obligations and exercise its rights (including those towards the HADEA) under the GA.

## Article 3: Entry into force, duration, and termination

### 3.1 Entry into force and duration

This Agreement shall have effect from the Effective Date and shall apply for the duration of the Project (the “**Project Period**”) as further described in the Project Plan. During the Project Period, the Recipients agree to complete the work in accordance with the specifications and timelines set forth in the Project Plan.

Recipients may apply for an extension of the Project Period if there are objective conditions that prevent its implementation in time. The Recipients’ request should indicate the circumstances justifying the extension and the period for which the Project and this Agreement should be extended.

The circumstances of an extension will be assessed and may be accepted by the KIC LE.

This Agreement may be terminated in accordance with Article 3.2 of this Agreement.

### 3.2 Termination

#### 3.2.1. *Breach by KIC LE Termination by the Recipients*

**3.2.1.1.** In the event that the KIC LE is in breach of its obligations under this Agreement, the Recipients may give formal notice to the KIC LE requiring that such breach will be remedied within 90 calendar days of this formal notice, unless such breach cannot be remedied.

If such breach is substantial and is not remedied within that period of 90 calendar days or, is not capable of remedy, the Recipients may decide to terminate the Agreement upon notice.

**3.2.1.2.** The Recipients may terminate this Agreement with immediate effect through written notice to the KIC LE, if the KIC LE is subject to an event of Force Majeure, which prevents the KIC LE from



correct performance of its obligations hereunder and such circumstances have lasted, or can reasonably be expected to last more than 120 calendar days.

### **3.2.2. Breach by one of the Recipients - Termination by the KIC LE**

**3.2.2.1.** In the event that one of the Recipients is in breach of its obligations under this Agreement, the KIC LE may give formal notice to such Recipient requiring that such breach will be remedied within 14 calendar days of this formal notice, unless such breach cannot be remedied.

If such breach is substantial and is not remedied within that period or, is not capable of remedy, the KIC LE may decide to declare such Recipient to be a defaulting Party and to decide on the consequences thereof which may include termination of this Agreement upon notice and other measures (see Article 3.3.2 of this Agreement). Such serious breaches are for example improper implementation of the Project, non-compliance with the call conditions, submission of false information or incomplete information, failure to provide required information, breach of ethics or security rules (if applicable). For the avoidance of doubt, when one of the Recipients is in breach and a defaulting Party, the decision of KIC LE to terminate this Agreement will also affect the other Recipient, notwithstanding the right of the non-defaulting Recipient to take actions against the defaulting Recipient in accordance with the provisions of their own agreement or applicable law.

**3.2.2.2.** The KIC LE may terminate this Agreement with immediate effect through written notice to the Recipients, if one of the Recipients is subject to an event of Force Majeure, which prevents such Recipient from correct performance of its obligations hereunder and such circumstances have lasted, or can reasonably be expected to last more than 120 calendar days.

**3.2.2.3.** If the GA is terminated by the HADEA or the KIC LE, the KIC LE shall have right to terminate this Agreement upon notice to the Recipients, subject to the provisions surviving the expiration of termination under Article 3.3.1 of this Agreement.

**3.2.2.4.** The KIC LE may at any time terminate this Agreement immediately upon notice if one of the following events occurs:

- a change to the legal, financial, technical, organisational or ownership situation of one of the Recipients is likely to substantially affect or delay the implementation of the Project or calls into question the decision to select the Project (including changes linked to one of the exclusion grounds listed in the declaration of honour, signed by the time of the signature of this Agreement);
- one of the Recipients 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.);
- one of the Recipients is in breach of social security or tax obligations;
- one of the Recipients (or person having powers of representation, decision-making or control, or person essential for the implementation of the Project) has been found guilty of grave professional misconduct;
- one of the Recipients (or a person having powers of representation, decision-making or control, or person essential for the implementation of the Project) has committed fraud, corruption, or is involved in a criminal organisation, money laundering, terrorism related crimes (including terrorism financing), child labour or human trafficking;
- one of the Recipient (or a person having powers of representation, decision-making or control, or person essential for the implementation of the Project) 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);



- one of the Recipients (or person having powers of representation, decision-making or control, or person essential for the implementation of the Project) has committed substantial errors, irregularities or fraud.

### **3.3 Effects of termination**

#### **3.3.1. Survival of rights and obligations**

After termination, the Recipients' obligations (in particular Articles 17 (Non-disclosure of information), 10 (IPR), 16 (Liability), 11 (Communication, dissemination and visibility rules), 6.3 (Reporting), 13 (Checks, reviews, audits and investigations), and 19.7 (Applicable law) of this Agreement, and Articles 26 (Impact evaluation), 27 (Rejections), 28 (Grant reduction) and 42 (Assignment of claims) of the GA continue to apply.

Termination shall not affect any rights or obligations of the Parties incurred prior to the date of termination, unless otherwise stipulated herein or agreed between the Parties. This includes the obligation to provide all input, deliverables, and documents for the period that the Agreement was still in force and effect.

#### **3.3.2. Measures towards defaulting Recipient**

KIC LE shall have the right to stop or reorient the scope of the Project. KIC LE shall also have the right to suspend any payment towards the defaulting Recipient and to request the defaulting Recipient to return the funds received (recovery or withdrawal of funds) without prejudice to its right to claim compensation for damages caused by Recipient's breach.

For the avoidance of doubt, KIC LE may decide to recover funds if and to the extent the Project implemented so far has not started or rendered, in the reasonable discretion of the KIC LE, any substantial innovation or other benefit, or in the situations referred to in Article 7.4.1 of this Agreement.

#### **3.3.3. Termination report**

The Recipients must – within the next reporting cycle from when termination takes effect – submit a termination report, for the open reporting period under the Project until termination, containing an overview of the progress of the work and the explanation on the use of resources.

The KIC LE will calculate the amount that might be due to the Recipients on the basis of the report submitted.

For the avoidance of doubt, after termination, the Recipients shall also be obliged to provide further information, records and supporting documents in the context of checks, reviews, audits or investigations.

## **Article 4: Project**

### **4.1 General Principles**

Each Recipient is fully responsible towards the KIC LE for implementing its tasks in the Project.

Each Recipient must:

- implement this Agreement to the best of its abilities, in good faith and in accordance with all the obligations and terms and conditions it sets out.
- have the appropriate resources to implement the Project under its own responsibility. If a Recipient relies on its affiliated entities or other third parties (see Article 4.4 of this Agreement), such Recipient retains sole responsibility towards HADEA, the KIC LE and the other Recipient involved in the Project. If the KIC LE requires joint and several liability of affiliated entities they must sign the declaration set out in Annex 5 and may be held liable in case of enforced recoveries against their Recipients (see Article 22.2 and 22.4 of the GA).
- remain eligible under the Horizon Europe programme funding for the entire duration of this Agreement. Costs and contributions will be eligible only as long as the Recipient and the Project is eligible.
- promptly notify to the KIC LE any significant information, fact, problem or delay likely to affect its participation in the Project, especially relating to the events mentioned in Article 3.2.5.5 of this Agreement.
- promptly provide all information reasonably required by the KIC LE for the implementation of the Project.

#### **4.2 Proper implementation of the Project**

The Recipients must implement the Project as described in the “Project Plan” and according the “Project Period” as available in the Grant Management System.

#### **4.3 Consequences of not properly implementing the Project**

In the event of an improper implementation of the Project by a Recipient in accordance with the Project Plan and the Project Period, the KIC LE may:

- re-orient the scope of the Project,
- reduce the amount of financial support and/or

#### **4.4 Involvement of third parties (including affiliated entities, subcontractors)**

4.4.1 The third parties which will participate in a Project are further described in the “Project Plan” .

##### **4.4.2 Subcontracting**

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

Recipients that are ‘contracting authorities/entities’ within the meaning of the EU Directives on public procurement must also comply with the applicable national law on public procurement. The tasks to be subcontracted, the estimated cost for each subcontract and the total estimated costs of subcontracting per Recipient must be set out in the “Project Plan” and according the “Project Period” .

4.4.3 The Recipients must ensure that their contractual obligations under Articles 4.2 (Proper implementation of the Project), 14 (Conflict of interest), 17 (non-disclosure of information), 12

(Information, record keeping), 15 (Ethics), 11 (Visibility rules) of this Agreement and any other specific rules for carrying out Project as described in the “Project Plan” and according to the “Project Period”, also apply to the involved subcontractors.

The Recipients must ensure that the KIC LE, the HADEA, and/or the European Commission, the European Anti-Fraud Office (OLAF), European Public Prosecutor’s Office (EPPO) and the European Court of Auditors (ECA), can exercise their rights also towards the involved third parties (see Article 13 of this Agreement).

## **Article 5: Monitoring and reporting**

### **5.1 Specific responsibilities regarding reporting and implementation**

#### **5.1.1 Final Activity Report**

The Recipients commit to continuously provide information on the progress of the implementation of the tasks. Recipients shall issue a Final Activity Report at the completion of the tasks, as outlined in the 7.1 Payment Schedule and the Project Plan in Annex 2. The Final Activity Report provided should enable the verification of the completion of the tasks and the achievement of the Project’s objectives.

#### **5.1.2 Termination reports**

When the Project is terminated before the foreseen end date of the Project Period, each Recipient shall issue a termination report in accordance with Article 3.3.3 of this Agreement.

#### **5.1.3 Proper implementation**

Each Recipient shall perform its tasks in accordance with the Project Plan and the conditions set in section 7.1 and contribute to the completion of the Project.

## **Article 6: Financial provisions**

### **6.1. Distribution of the Lump Sum Contributions**

The maximum financial support for the activities under the Project (as set out in the Project Plan) amounts to 80,000 EUR. This financial support is intended to cover validation services.

The direct and indirect eligible costs eligible for financial support for the tasks properly carried out in accordance with the Project Plan and Project Period, are further described in Annex 1 to this Agreement.

The financial support of the KIC LE to the Project shall be distributed by the KIC LE as a Lump Sum to each Recipient according to:

- the Project Plan
- the Project Period
- the approval of the Final Activity Reports by the KIC LE, and
- the provisions of payment in Section 7.

Furthermore, the Lump Sum shall only be distributed after validation of the Project Plan, in accordance with the following criteria:

- a. Feasibility and Comprehensiveness of the Plan
- b. Suitability of the Validation Centre
- c. Adequacy of Resource Allocation
- d. Readiness of the Project Team

Each Recipient is entitled to its Lump Sum Contribution as approved by the KIC LE after completion of the respective tasks, in accordance with the Project Plan and Project Period. For tasks not completed at the end of the Project, the KIC LE distributes to each Recipient only the share of Lump Sum Contribution as approved by the KIC LE based on the Payment Schedule and HADEA at final payment.

## 6.2 Justifying Lump Sum Contributions

Each Recipient contributes with complete, reliable and true information to all reporting requirements regarding the completion of the Project and proper implementation. Moreover, adequate records and supporting documents must be provided by the Recipients concerned upon request of the KIC LE or HADEA in line with the GA. Each Recipient is solely liable for justifying its Lump Sum Contribution or share.

The Recipients shall use the financial support transferred by the KIC LE only for the implementation and execution of the Project as reflected in the Project Plan.

## 6.3 Excess payments

A Recipient has received excess payment if the KIC LE assessed that the performance of a Recipient regarding the completion of one or several tasks is significantly lower than foreseen in the Project Plan and that the Recipient received more funding than approved by the KIC LE.

In case a Recipient has received excess payment, the provisions of Section 7.4.1 shall apply.

## Article 6: Payments

### 7.1 Payment Schedule

The payment will be distributed by KIC LE to each Recipient in two instalments, after receipt of payment from HADEA:

Amount to be paid	Payment tranche	Initiated
50 % of the Lump Sum Contribution	Pre-financing	Within 45 days after signature of this Agreement
50 % of the Lump Sum Contribution	Final payment	Within 45 days after approval by the KIC LE of the Recipient's Final Activity Report which allows for an assessment of the completion of the task and the Project's objectives.

The KIC LE is entitled to withhold any payments due to a Recipient identified to be in breach of its obligations under this Agreement.

The KIC LE is entitled to recover any payments already paid to a defaulting party except its Lump Sum Contributions already accepted by the KIC LE.

The first instalment, amounting to 50% of the grant, shall be paid upon the successful validation of the Project Plan as set out in Section 6.1.

The second instalment shall be paid subject to the condition of validation of the Final Activity Report by the KIC LE and the Recipients as outlined in the Project Plan in Annex 2.

## **7.2 Eligibility for funding**

The Recipients are eligible for any financial support from HADEA if all the following provisions are complied with on a continuous basis during the term of this Agreement:

- All relevant eligibility criteria under the Agreement are fulfilled;
- the Recipient is not in default under this Agreement;
- The KIC LE has received the relevant payments from HADEA.

## **7.3 Payments**

Payment by the KIC LE to the Recipients hereunder, shall be made to the bank account indicated for the Recipient in the Grant Management System.

## **7.4 Recovery – Setoff**

### 7.4.1. Recovery by KIC LE

In the event a Recipient did not use the financial support from KIC LE for the purpose of the Project or not in accordance with the terms and conditions of this Agreement, it is under the obligation to return the unused or unjustified amounts within 30 calendar days upon notification from the KIC LE. Upon non-compliance by the Recipient with this obligation, it is in substantial breach of this Agreement.

The KIC LE shall have the right to recover any undue financial support of KIC LE, if the eligibility rules of Article 6 of the GA are not complied with, or if a Recipient has not fulfilled all its other obligations pertaining to the implementation of Project under this Agreement.

### 7.4.2. Setoff

KIC LE shall have the right to setoff payments for any present or future claims KIC LE may have against a Recipient.

## **Article 9: Liability**



9.1. Each Party shall comply with its obligations towards the other Parties under this Agreement and its Annexes.

9.2. The Recipients have individual financial responsibility for their own financial obligations under this Agreement agreed upon ("**financial liability**").

9.3. The Recipients acknowledge the joint and several liability for the technical implementation of the Project ("**technical liability**"), therefore it applies at the level of the Project, even though the Recipients may agree to differently distribute the liability amongst them in a separate agreement.

If a Recipient fails to implement its part of the Project or in case it withdraws from the Project, the other Recipient becomes responsible for implementing this part or completing the Project, without being entitled to any additional funding at Project level for doing so, unless the KIC LE expressly relieves them of this obligation or unless the failure to implement the part of the Project is due to gross negligence of the KIC LE. For the avoidance of doubt, the remaining budget share of the failing or withdrawing Recipient may be reallocated to the remaining Recipient to enable them to complete the failing or withdrawing Recipient's part of the Project.

The Recipients may supplement the liability provisions of this Article 9 in a separate agreement, but cannot deviate from the provisions of this Agreement.

For the avoidance of doubt, when executing coordination or monitoring tasks as required by the GA, for example, coordinating of reporting (i.e. final reporting, progress monitoring, ...), the KIC LE is not deemed to be jointly and severally liable for the technical implementation of the Project.

#### **Article 10: IPR rules**

Under this Agreement, the IPR rules as provided for in Section 1 of Annex 3 to this Agreement apply.

The Recipients acknowledge and agree that it should also comply with EIT Health's IP Policy, as available on EIT Health website, drafted in accordance with the IPR rules as set out in Section 1 of Annex 3 to this Agreement.

Moreover, the IPR provisions of Section 1 of Annex 3 to this Agreement and the EIT Health's IP Policy may be supplemented further in a separate agreement between the Recipients.

#### **Article 11: Communication, dissemination and visibility rules**

Under this Agreement, the Communication, dissemination and visibility rules as provided for in Section 2 of Annex 3 to this Agreement apply.

This obligation shall last during the execution of the Project and for a period of one year from the end of the GA under which the financial support has been awarded to the Recipients.

#### **Article 12: Information obligations – record keeping**

##### **12.1 General information obligations**



#### 12.1.1. Information requests

The Recipients must provide — during the Project(s) or afterwards — any information requested, including Sensitive Information if necessary, in order to verify eligibility of the costs or contributions declared, proper implementation of the Project and compliance with the other obligations under this Agreement. The information provided must be accurate, precise and complete and in the format requested, including electronic format.

#### 12.1.2. Participant Register data updates

The Recipients must keep — at all times, during the Project or afterwards — their information stored in the Portal Participant Register and the Grant Management System up to date, in particular, their name, address, legal representatives, legal form and organization.

#### 12.1.3. Information about events and circumstances which impact the Project

The Recipients must immediately inform the KIC LE of any of the following:

- (a) events which are likely to affect or delay the implementation of the Project or affect the EU's financial interests, in particular 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 the signature of this Agreement); and/or
- (b) circumstances affecting: (i) the decision to select the Project or (ii) compliance with requirements under the Agreement.

### **12.2 Record keeping**

#### 12.2.1. Keeping records and supporting documents

The Recipients must — at least until the time-limit of the Project — keep records and other supporting documents to prove the proper implementation of the Project in line with the accepted standards in the respective field (if any).

Further details are set out in Section 3 of Annex 3 to this Agreement.

### **Article 13: Checks, reviews, audits and investigations**

The Recipients acknowledge and agree that enabling checks, reviews, audits and investigations is of the essence for the KIC system. As a consequence thereof, the Recipients shall allow and support any checks, reviews, audits and investigations during the implementation of the Project and afterwards, by the KIC LE, the HADEA, and/or the European Commission, the European Anti-Fraud Office (OLAF), European Public Prosecutor's Office (EPPO) and the European Court of Auditors (ECA), deemed necessary by the foregoing in their reasonable discretion to satisfy themselves of the compliance with the obligations under the Agreement, including the proper use of the HADEA funding.

Further details are set out in Section 4 of Annex 3 to this Agreement.

### **Article 14: Conflict of interest**

**14.1** The Recipients acknowledge and agree:

- to 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').
- to avoid any conflict of interest in the purchase of services and goods in pursuit of the Project.

They must formally notify the KIC LE 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 KIC LE may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

**14.2** The Recipients acknowledge and agree to comply with the principles of transparency, non-discrimination and sound financial management.

### **Article 15: Ethics and values**

The Project must be carried out in line with the ethics and values requirements further described in Section 5 of Annex 3 to this Agreement.

### **Article 16: Liability towards each other**

#### **16.1 Limitations of contractual liability**

The Parties shall take all the necessary steps to limit or mitigate any damage.

No Party shall be responsible to the other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, provided such damage was not caused by a wilful act, gross negligence or by a breach of confidentiality.

The terms of this Agreement shall not be construed to amend or limit either Party's statutory liability.

#### **16.2 Damage caused to third parties**

Each Party shall be solely liable for any loss, damage or injury to third parties resulting from the performance of the said Party's obligations by it or on its behalf under this Agreement.

#### **16.3 Hold harmless**

The Recipients shall hold the KIC LE and its respective assigns and employees, officers and directors harmless from and against all losses, costs, liabilities, claims, damages and expenses, resulting from or relating to or arising out of the breach or default in the performance of any obligation on the Recipients' part under this Agreement through a legal action, including any counterclaim, that has proceeded to final judgment by a court of competent jurisdiction, in either case to the extent it determined a breach or default by the Recipients in the performance of this Agreement, provided it is not caused by the KIC LE's wilful act or gross negligence. The Recipients will be entitled to make observations towards the KIC LE, regarding the Recipients' obligation to hold the KIC LE harmless and the KIC LE shall reasonably consider such observations by the Recipients. The KIC LE shall take into account the reasonable requests of the Recipients with regard to the defence and the settlement of

such claims, including the selection of counsels, and it is understood that KIC LE shall not settle any claim without the consent of the the Recipients.

#### **16.4 Force Majeure**

No Party shall be considered to be in breach of the Agreement if it is prevented from fulfilling its obligations under the Agreement by Force Majeure.

Each Party will notify the other Party of any Force Majeure without undue delay.

#### **Article 17: Confidentiality**

The Parties must keep confidential any data, documents or other material (in any form) that is identified as sensitive in writing, or when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the disclosing Party, is “Sensitive Information”. Unless otherwise agreed between the Parties, they may use Sensitive Information only to implement the Agreement.

The Parties may disclose Sensitive Information to its personnel or other participants in the Project only if they:

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

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 receiving parties 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 or permitted by EU, international or national law.
- (d) A time period of five years after the disclosure of the Sensitive Information has passed, unless otherwise agreed upon between the Parties
- (e) The Sensitive Information is subsequently independently developed by or on behalf of the receiving Party without use of the disclosing Party’s Sensitive Information.

If and when the confidentiality obligations no longer apply, the receiving party of the information undertakes to return to the disclosing Party, or to destroy, on request all Sensitive Information that has been disclosed to the receiving parties including all copies thereof and to delete all information stored in a machine readable form to the extent practically possible. The receiving parties may keep a copy to the extent it is required to keep, archive or store such Sensitive Information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided that the receiving party comply with the confidentiality obligations herein contained with respect to such copy.

If a Party becomes aware that it will be required, or is likely to be required, to disclose Sensitive Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure

- notify the disclosing Party, and
- comply with the disclosing Party's reasonable instructions to protect the confidentiality of the information.

## **Article 18: Miscellaneous**

### **18.1 Inconsistencies and severability**

Should any provision of this Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Agreement. In such a case, the Parties shall be entitled to request that a valid and practicable provision be negotiated which fulfils the purpose of the original provision.

### **18.2 No representation, partnership or agency**

No Party shall be entitled to act or to make legally binding declarations on behalf of the other Parties.

Nothing in this Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

### **18.3 Notices and other communication**

Any notice to be given under this Agreement shall be in writing to the addresses and recipients as listed below.

Formal notices:

If it is required in this Agreement that a formal notice, consent or approval shall be given, such notice shall be signed by a Party's Authorised Representative(s) and shall either be served personally or sent by mail with recorded delivery or e-mail with receipt acknowledgement.

Other communication:

Other communication between the Parties may also be affected by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of written form.

Any change of persons or contact details shall be notified immediately by the respective Party to the other Party.

### **18.4 Assignment and amendments**

No rights or obligations of the Parties arising from this Agreement may be assigned or transferred, in whole or in part, to any third party without the other Party's prior formal approval.

Amendments and modifications to the text of this Agreement require a separate written agreement to be signed by Authorized Representatives of both Parties.

### **18.5 Language**

This Agreement is drawn up in English, which language shall govern all documents, notices, meetings, arbitral proceedings and processes relative thereto.

### **18.6 Mandatory national law**

Nothing in this Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

### **18.7 Applicable law**

This Agreement shall be construed in accordance with and governed by the laws of Belgium.

### **18.8 Settlement of disputes**

The Parties shall endeavour to settle their disputes amicably.

All disputes arising out of or in connection with this Agreement, which cannot be solved amicably, shall be finally settled before the courts of Brussels.

### **18.9 Data Protection**

The Recipients ensure that any processing of personal data shall be performed in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

The collected personal data will be used solely for the implementation, follow-up, reporting and management of this Agreement by the Recipients and their subsidiaries and for dissemination of information and communication purposes foreseen for this Agreement. Data subjects have the right to access, rectify or delete their personal data. Data subjects can also object to its processing. To exercise these rights, data subjects can contact Recipient as stated on the EIT Health website.

### **Article 19: Annexes<sup>1</sup>**

The following annexes are attached to this Agreement:

Annex 1 – Cost eligibility rules

Annex 2 – Project Plan

Annex 3 – General provisions of the Grant Agreement

Annex 4 – Declaration of honour

Annex 5 – Declaration on joint and several liability of affiliated entities

In case of conflict between the provisions of this Agreement and its Annexes, the provisions of this Agreement will prevail.

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<sup>1</sup> Annexe 1 and 2 will be provided in due time

## Signatures

The Parties have caused this Agreement to be duly signed by the undersigned Authorised Representatives.

The signature of each Party that will be completed via the Grant Management System (an electronic signature), counts as an original signature with the same validity, enforceability and permissibility. Each Party receives a fully signed copy of the Agreement. The transfer of this copy by e-mail or via an electronic signature system will have the same legal force and legal effect as the transfer of the original copy of the Agreement

**For KIC LE**

Name: Jean Marc Bourez

Title : CEO

In : Munich

On :

Signature \_\_\_\_\_

**Recipient:**

Name:

Title:

In:

On:

Signature \_\_\_\_\_

**Recipient:**

Name:

Title:

In:

On:

Signature \_\_\_\_\_



## Annex 2 - Project Plan

Annex 2 of the Financial Support agreement will be made available as a separate document.



## Annex 3 – General provisions of the Grant Agreement

### Annex 3 - Section 1: IPR rules

#### 1.1 General

Further to Article 10 of the Agreement, the following IPR rules apply:

The Recipient acknowledges and agrees that it should also comply with EIT Health's IP Policy, as available on the EIT Health website, drafted in accordance with the IPR rules as set out in Article 1.2 of this Section 1 of this Annex 3.

Further specific IPR rules for the Project(s) may be set out in the relevant Project Agreement.

Moreover, the Recipients involved in the same Project may supplement the provisions of Article 1.2 of this Section 1 of this Annex 3 and the IP Policy in a consortium agreement.

#### 1.2. IPR rules

##### 1.2.1. Definitions

Under this Article 1.2.1 of Section 1 and Article 2.2. of Section 2 of this Annex 3, the following definitions apply.

“Access rights” shall mean the rights to use results or background.

“Dissemination” shall mean 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)” shall mean the use of results in further research and innovation activities other than those covered by the Project 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” shall mean 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” shall mean ‘findability’, ‘accessibility’, ‘interoperability’ and ‘reusability’.

“Open access” shall mean online access to research outputs provided free of charge to the end-user.

“Open science” shall mean an approach to the scientific process based on open cooperative work, tools and diffusing knowledge.

“Research data management” shall mean 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” shall mean 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.

#### 1.2.2. Scope of the obligations

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

#### 1.2.3. Agreement on background — Background free from restrictions

The Recipient together with the other Recipients involved in the same Project must identify in a written agreement the background as needed for implementing the Project 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 KIC LE.

#### 1.2.4. Results free from restrictions

Where the call conditions restrict control due to strategic interests reasons, the Recipients must ensure that the results of the Project 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 KIC LE.

#### 1.2.5. Ownership of results

Results are owned by the Recipient that generates them. However, two or more Recipients own results jointly if they have jointly generated them and - it is not possible to:

- establish the respective contribution of each Recipient, 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 the 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 Recipient must ensure that those rights can be exercised in a manner compatible with its obligations under the Agreement. The Recipient must indicate the owner(s) of the results (results ownership list) in the final periodic report.

#### 1.2.6. Protection of results

The Recipient which has received EIT funding must adequately protect its 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 Recipients in the same Project and any other legitimate interests.

#### 1.2.7. Exploitation of results

The Recipient [which has received EIT funding under the grant] must — up to four years after the end of the Project — use its best efforts to exploit its results directly or to have them exploited indirectly by another entity, in particular through transfer or licensing. If, despite the Recipient's best efforts, the results are not exploited within one year after the end of the Project, the Recipient must (unless otherwise agreed in writing with the KIC LE) use the Horizon Results Platform to find interested parties to exploit the results. If results are incorporated in a standard, the Recipient must (unless otherwise agreed with the KIC LE or unless it is impossible) ask the standardisation body to include the funding statement (see Article 2.3.1. of Section 2 of this Annex 3) in (information related to) the standard.

##### 1.2.7.1. 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 Recipients must comply with them — up to four years after the end of the Project. Where the call conditions impose additional exploitation obligations in case of a public emergency, the Recipients must (if requested by the KIC LE) 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 Project.

##### 1.2.7.2. Additional information obligation relating to standards

Where the call conditions impose additional information obligations relating to possible standardisation, the Recipients must — up to four years after the end of the Project — inform the KIC LE, if the results could reasonably be expected to contribute to European or international standards.

#### 1.2.8. Transfer and licensing of results

##### 1.2.8.1. Transfer of ownership

The Recipient may transfer ownership of its results, provided this does not affect compliance with its obligations under the Agreement. The Recipient must ensure that its obligations under the Agreement regarding its 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, it must inform the other Recipients involved in the same Project 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 other Recipients involved in the same Project to assess the effects on their access rights. The Recipients involved in the same Project 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 Recipients concerned.

#### 1.2.8.2. Granting licences

The Recipient may grant licences to its 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 Recipients involved in the same Project concerned have waived their access rights.

#### 1.2.8.3. KIC LE right to object to transfers or licensing

Where the call conditions provide for the right to object to transfers or licensing, the KIC LE may — up to four years after the end of the action — object to a transfer of ownership or the exclusive licensing of results, if:

- the Recipients 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 KIC LE considers that the transfer or licence is not in line with EU interests.

The Recipients that intend to transfer ownership or grant an exclusive licence must formally notify the KIC LE 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 KIC LE may request additional information.

If the KIC LE decides to object to a transfer or exclusive licence, it must formally notify the Recipient 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 KIC LE objects
- until the conditions are complied with, if the KIC LE objection comes with conditions.

A Recipient 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 KIC LE agrees, it will formally notify the Recipient concerned within 60 days of receiving notification (or any additional information requested).

#### 12.8.4. 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 Recipients 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 KIC LE.

The request must:

- identify the specific results concerned
- describe in detail the new owner and the planned or potential exploitation of the results, and



- include a reasoned assessment of the likely impact of the transfer or license on the strategic assets, interests, autonomy or security of the EU and its Member States.

The KIC LE may request additional information.

#### 1.2.9. Access rights to results and background

##### 1.2.9.1. 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 Recipient granting access, access rights do not include the right to sub-license. If a Recipient is no longer involved in the Project, this does not affect its obligations to grant access. If the Recipient defaults on its obligations, the other Recipients involved in the same Project may agree that that Recipient no longer has access rights

##### 1.2.9.2. Access rights for implementing the action

The Recipient must grant to the other Recipients involved in the same Project access — on a royalty-free basis — to background needed to implement its own tasks under the Project, unless the Recipient that holds the background has — before acceding to the Project Agreement —:

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

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

##### 1.2.9.3. Access rights for exploiting the results

The Recipient must grant to the other Recipients in the same Project access — under fair and reasonable conditions — to results needed for exploiting their results. The Recipient must grant to the other Recipients in the same Project access — under fair and reasonable conditions — to background needed for exploiting their results, unless the Recipient that holds the background has — before acceding to the Project Agreement — informed the other Recipients in the same Project 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 Project.

##### 1.2.9.4. Access rights for entities under the same control

Unless agreed otherwise in writing by the Recipients involved in the same Project, 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 Recipient, or under the same direct or indirect control as that Recipient or directly or indirectly controlling that Recipient and
- need the access to exploit the results of that Recipient.

Unless agreed otherwise in writing, such requests for access must be made by the entity directly to the Recipient concerned. Requests for access must be made — unless agreed otherwise in writing — up to one year after the end of the Project.



#### 1.2.9.5. 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 Recipient which have received funding under the grant must grant access to its results — on a royalty-free basis — to the KIC LE, the EIT, EU institutions, bodies, offices or agencies for developing, implementing and monitoring EU policies or programmes. Such access rights do not extend to the Recipients' background. Such access rights are limited to non-commercial and non-competitive use.

For Projects 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.

#### 1.2.9.6. Additional access rights

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

## **Annex 3 - Section 2: Communication, dissemination and visibility rules**

### **2.1 General**

Further to Article 11 of the Agreement, the following communication, dissemination and visibility rules as provided in this Section 2 of this Annex 3 apply.

Further specific communication, dissemination and visibility rules for the Project(s) may be set out in the relevant Project Agreement.

### **2.2 Communication and dissemination**

#### **2.2.1. Dissemination**

##### **2.2.1.1. Dissemination of results**

The Recipient must disseminate its 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. If Recipient intends to disseminate its results, it must give at least 15 days advance notice to KIC LE and the other Recipients involved in the same Project (unless agreed otherwise), together with sufficient information on the results it will disseminate.

The KIC LE or another Recipient involved in the same Project 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.

##### **2.2.1.2. Additional dissemination obligations**

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

#### **2.2.2. Open Science**

##### **2.2.2.1. Open science: open access to scientific publications**

The Recipient must ensure open access to peer-reviewed scientific publications relating to its results. In particular, it 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.

The Recipient must retain sufficient intellectual property rights to comply with the open access requirements.

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

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

#### 2.2.2.2. Open science: research data management

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

- establish a data management plan ('DMP') (and regularly update it);
- as soon as possible and within the deadlines set out in the DMP, deposit the data in a trusted repository; if required in the call conditions, this repository must be federated in the EOSC in compliance with EOSC requirements;
- as soon as possible and within the deadlines set out in the DMP, ensure open access — via the repository — to the deposited data, under the latest available version of the Creative Commons Attribution International Public License (CC BY) or Creative Commons Public Domain Dedication (CC 0) or a licence with equivalent rights, following the principle 'as open as possible as closed as necessary', unless providing open access would in particular:
  - o be against the Recipient's legitimate interests, including regarding commercial exploitation, or
  - o be contrary to any other constraints, in particular the EU competitive interests or the Recipient's obligations under this Agreement; if open access is not provided (to some or all data), this must be justified in the DMP
- provide information via the repository about any research output or any other tools and instruments needed to re-use or validate the data.

Metadata of deposited data must be open under a Creative Common Public Domain Dedication (CC 0) or equivalent (to the extent legitimate interests or constraints are safeguarded), in line with the FAIR principles (in particular machine-actionable) and provide information at least about the following: datasets (description, date of deposit, author(s), venue and embargo); Horizon Europe or Euratom funding; 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.

#### 2.2.2.3. Open science: additional practices

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

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

Where the call conditions impose additional open science obligations in case of a public emergency, the Recipient must (if requested by the granting authority) immediately deposit any research output in a repository and provide open access to it under a CC BY licence, a Public Domain Dedication (CC 0) or equivalent. As an exception, if the access would be against the Recipient’s legitimate interests, the Recipient must grant nonexclusive 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.

**2.2.3. Plan for the exploitation and dissemination of results including communication activities**

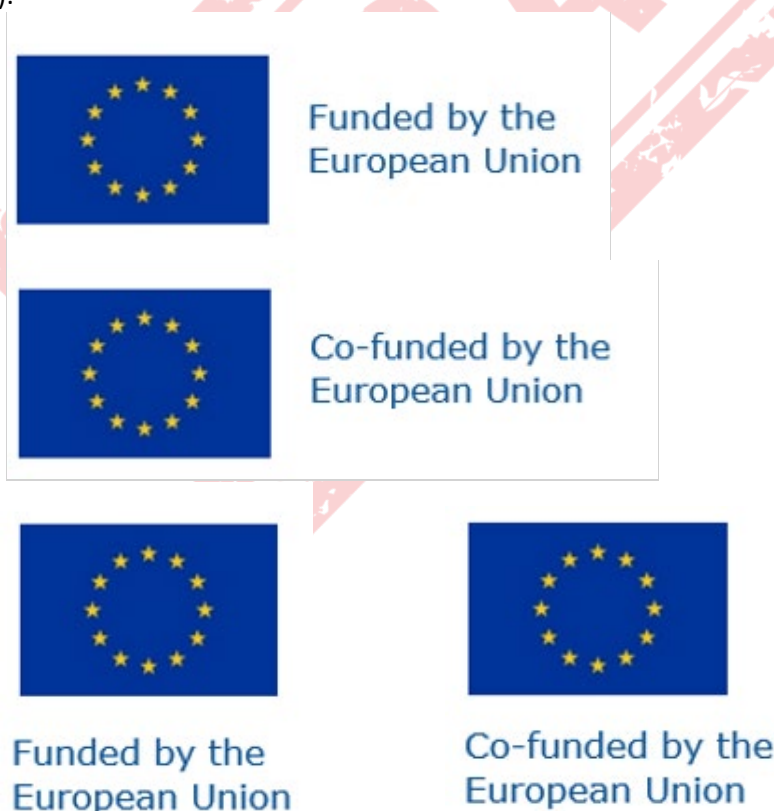
Unless excluded by the call conditions, the beneficiaries must provide and regularly update a plan for the exploitation and dissemination of results including communication activities.

**2.3 Visibility rules**

**2.3.1. European flag and funding statement**

When engaging in communication and promotion activities, the Recipient must follow the logos and guidelines provided in the EIT Community Brand Book published on the EIT website.

In particular, activities funded through EIT grants must follow the grant agreement and must display the European flag (emblem) and funding statement (translated into local languages, where appropriate):



and the special logo of EIT Health:



and the following text:

“EIT Health is supported by the European Institute of Innovation and Technology (EIT), a body of the European Union”

for all communication activities and infrastructure, equipment or major results.

In addition, the Recipient shall take into account and respect any co-branding guidelines and requirements provided and set by EIT Health. For clarification purposes, specific guidelines and requirements may be set for different kind of activities and results, such as KAVA and start-ups created.

The Recipient shall comply with these co-branding obligations in accordance with the monitoring processes as provided for by EIT Health.

### 2.3.2. Quality of information - disclaimer

Any communication or dissemination activity related to the Project(s) 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 the EIT. Neither the European Union nor the granting authority can be held responsible for them.”

### 2.3.3. Use of names, logos or trademarks

Nothing in this Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the KIC LE and other Recipients or any of their logos or trademarks without their prior written approval.

### Annex 3 - Section 3: Record keeping

In addition to the provisions of Article 12.2.1 of the Agreement, the Recipient must — for the same period — keep the following to justify the amounts declared:

- (a) for actual costs: adequate records and supporting documents to prove the costs declared (such as contracts, subcontracts, invoices and accounting records); in addition, the Recipient's usual accounting and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documents;
- (b) for flat-rate costs and contributions (if any): adequate records and supporting documents to prove the eligibility of the costs or contributions to which the flat-rate is applied;
- (c) for the following simplified costs and contributions: the Recipient does not need to keep specific records on the actual costs incurred, but must keep:
  - for unit costs and contributions (if any): adequate records and supporting documents to prove the number of units declared;
  - (ii) for lump sum costs and contributions (if any): adequate records and supporting documents to prove proper implementation of the work as described in the relevant Project Agreement;
  - for financing not linked to costs (if any): adequate records and supporting documents to prove the achievement of the results or the fulfilment of the conditions as described in the relevant Project Agreement;
- (d) for unit, flat-rate and lump sum costs and contributions according to usual cost accounting practices (if any): the Recipient must keep any adequate records and supporting documents to prove that its cost accounting practices have been applied in a consistent manner, based on objective criteria, regardless of the source of funding, and that they comply with the eligibility conditions set out in Article 5.3 of the Agreement.
- (e) the following is needed for personnel costs: time worked for the Recipient under the Project must be supported by declarations signed monthly by the person and their supervisor, unless another reliable time-record system is in place; the granting authority may accept alternative evidence supporting the time worked for the action declared, if it considers that it offers an adequate level of assurance.

The records and supporting documents must be made available upon request (see Article 12.1 of the Agreement) or in the context of checks, reviews, audits or investigations (see Article 13 of the Agreement). 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 13 of the Agreement), the Recipient must keep these records and other supporting documentation until the end of these procedures. The Recipient must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The KIC LE may accept non-original documents if they offer a comparable level of assurance.



### **Annex 3 - Section 4: Checks, reviews, audits and investigations**

Further to Article 13 of the Agreement, the following shall apply:

**4.1.** The Recipient expressly agrees to cooperate diligently and provide all information requested (in addition to deliverables and reports already submitted, including information on the use of resources), concerning the compliance with its obligations under the Agreement, including the proper use of the Confirmed EIT Funding. The foregoing including the obligation to provide access to its sites, and premises (including to outside experts) and must ensure that information requested is readily available. Information provided must be accurate, precise, and provided in a complete manner and in the format requested including electronic format. The Recipient will also give access to data processing systems, bodies, staff and external persons or bodies.

**4.2.** The checks, reviews, audits and investigations pertain to:

- Project reviews: reviews on the proper implementation of the Project(s) and compliance with the obligations under the Agreement. Such Project reviews may be started during the implementation of the Project(s) and until the time-limit] set out in the GA.
- Audits: on the proper implementation of the Project(s) and compliance with the obligations under the Agreement. Such Project reviews may be started during the implementation of the Project(s) and until the time-limit set out in the GA.

**4.3.** The Recipient must keep all relevant information relating to the Project(s), at least the amount of time specified in the GA.

## Annex 3 - Section 5: Ethics and values

Further to Article 15 of the Agreement, the following shall apply:

### 5.1. Ethics

#### Ethics and research integrity

The Recipient must carry out the Projects in compliance with:

- ethical principles (including the highest standards of research integrity) and
- applicable EU, international and national law, including the Charter of Fundamental Rights of the European Union and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Supplementary Protocols.

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

The Recipient 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 Recipient must ensure that the KAVA(s)/Project(s) have an exclusive focus on civil applications.

The Recipient must ensure that the activities under the Projects 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).

KAVA(s)/Project(s) involving research on human embryos or human embryonic stem cells may be carried out only if KIC LE has obtained explicit approval (in writing) from the EIT.

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

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
- 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 the Recipient 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.

Projects raising ethical issues must comply with the additional requirements formulated by the ethics panels (including after checks, reviews or audits; see Article 13 of the Agreement).

Before starting a KAVA/Project task raising ethical issues, the Recipient must have obtained all approvals or other mandatory documents needed for implementing the KAVA/Project, 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 KIC LE to the EIT. 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).

## **5.2. Values**

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

## **5.3 Gender mainstreaming**

The Recipient must take all measures to promote equal opportunities between men and women in the implementation of the KAVA(s)/Project(s) 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 KAVA(s)/Project(s), including at supervisory and managerial level.

**Annex 4 – Declaration of honour**

## Declaration on honour

**Ref: EIT Health**

**GA 2023/2025**

The undersigned [type person here], representing:

<i>(only for natural persons)</i> himself or herself:	<i>(for legal persons and entities without legal personality )</i> the following entity:
ID or passport number:  (‘the person’)	Full official name: Official legal form: Statutory registration number: Full official address: VAT registration number: (‘the person’)

The person is not required to submit the declaration on exclusion criteria if the same declaration has already been submitted for the purposes of another award procedure of the same Agency, provided the situation has not changed, and that the time that has elapsed since the issuing date of the declaration does not exceed one year.

In this case, the signatory declares that the person has already provided the same declaration on exclusion criteria for a previous procedure and confirms that there has been no change in its situation:

Date of the declaration	Full reference to previous procedure and the institution/body that launched it

which has been authorised to sign the present declaration on behalf of the following other persons<sup>2</sup>:

(1) declares that the person is eligible in accordance with the criteria set out in the specific call for proposals;
(2) declares that the person has the required financial and operational capacity as set out in the specific call for proposals <sup>3</sup> ;

<sup>2</sup> Please also consult the call for proposals in case specific options are defined to sign the declaration

<sup>3</sup> This does not apply to affiliated entities except if their financial capacity and operational capacity is necessary due to the fact that the beneficiary composed of these affiliated entities does not have the required capacity itself.

- (3) declares that the person has not received any other Union funding to carry out the action subject of this grant application and commits to declare immediately to the Agency any other such Union funding it would receive until the end of the action.

**IF ANY OF THE ABOVE REQUIREMENTS IS NOT SATISFIED, PLEASE INDICATE in annex to this declaration which and THE NAME OF THE CONCERNED PERSON WITH A BRIEF EXPLANATION.**

**I – Situations of exclusion concerning the person**

<p>(4) declares that the person is <b>not</b> in one of the following situations. <b><i>If yes, please indicate in annex to this declaration which situation and the name(s) of the concerned person with a brief explanation.</i></b></p>
<p>a) it is bankrupt, subject to insolvency or winding-up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under Union or national law;</p>
<p>b) it has been established by a final judgement or a final administrative decision that it is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the applicable law;</p>
<p>c) it has been established by a final judgement or a final administrative decision that it is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:</p> <ul style="list-style-type: none"> <li>(i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of eligibility and selection criteria or in the performance of a contract, an agreement or a grant decision;</li> <li>(ii) entering into agreement with other persons with the aim of distorting competition;</li> <li>(iii) violating intellectual property rights;</li> <li>(iv) attempting to influence the decision-making process of the Agency during the award procedure;</li> <li>(v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;</li> </ul>
<p>d) it has been established by a final judgement that it is guilty of any of the following:</p>
<p>(i) fraud, within the meaning of Article 3 of Directive (EU) 2017/1371 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;</p>
<p>(ii) corruption, as defined in Article 4(2) of Directive (EU) 2017/1371 or active corruption within the meaning of Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997, or conduct referred to in Article 2(1) of Council Framework Decision 2003/568/JHA, or corruption as defined in other applicable laws;</p>
<p>(iii) conduct related to a criminal organisation, as referred to in Article 2 of Council Framework Decision 2008/841/JHA;</p>



(iv) money laundering or terrorist financing within the meaning of Article 1(3), (4) and (5) of Directive (EU) 2015/849 of the European Parliament and of the Council;
(v) terrorist offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;
(vi) child labour or other offences concerning trafficking in human beings as referred to in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;
e) it has shown significant deficiencies in complying with the main obligations in the performance of a contract, an agreement or a grant decision financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an Authorising Officer, OLAF or the Court of Auditors;
f) it has been established by a final judgment or final administrative decision that it has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;
g) it has been established by a final judgment or final administrative decision that the person has created an entity under a different jurisdiction with the intent to circumvent fiscal, social or any other legal obligations of mandatory application in the jurisdiction of its registered office, central administration or principal place of business;
h) ( <i>only for legal persons and entities without legal personality</i> ) it has been established by a final judgment or final administrative decision that the person has been created with the intent provided for in point (g);
i) for the situations referred to in points (c) to (h) above the person is subject to: <ul style="list-style-type: none"> <li>i. facts established in the context of audits or investigations carried out by the European Public Prosecutor's Office after its establishment, the Court of Auditors, the European Anti-Fraud Office or internal auditor, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body;</li> <li>ii. non-final judgments or non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics;</li> <li>iii. facts referred to in decisions of entities or persons being entrusted with EU budget implementation tasks;</li> <li>iv. information transmitted by Member States implementing Union funds;</li> <li>v. decisions of the Commission relating to the infringement of Union competition law or of a national competent authority relating to the infringement of Union or national competition law; or</li> <li>vi. decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.</li> </ul>

**II – situations of exclusion concerning a natural person who is essential for the award or the implementation of the action or work programme subject to the grant application<sup>4</sup>**

<sup>4</sup> Where the natural person has been defined in the grant application as essential for the award or for implementation of the legal commitment in the meaning of Article 136(4)(c) Financial Regulation (e.g. principal investigator in a research project)



(5) declares that a natural person who is essential for the award or for the implementation of the [action] [work programme] subject to the grant application is <b>not</b> in one of the following situations <b><i>If yes, please indicate in annex to this declaration which situation and the name(s) of the concerned person(s) with a brief explanation:</i></b>
Situation (c) above (grave professional misconduct)
Situation (d) above (fraud, corruption or other criminal offence)
Situation (e) above (significant deficiencies in performance of a contract )
Situation (f) above (irregularity)
Situation (g) above (creation of an entity with the intent to circumvent legal obligations)
Situation (i) above

**III – Situations of exclusion concerning beneficial owners and natural or legal persons with power of representation, decision-making or control**

***Not applicable to natural persons, Member States and local authorities***

(6) declares that a natural or legal person who is a member of the administrative, management or supervisory body of the above-mentioned person(s), or who has powers of representation, decision or control with regard to the above-mentioned person(s) (this covers e.g. company directors, members of management or supervisory bodies, and cases where one natural or legal person holds a majority of shares), or a beneficial owner of the person(s) (as referred to in point 6 of article 3 of Directive (EU) No 2015/849) is <b>not</b> in one of the following situations. <b><i>If yes, please indicate in annex to this declaration which situation and the name(s) of the concerned person(s) with a brief explanation.</i></b>
- situation (c) above (grave professional misconduct)
- situation (d) above (fraud, corruption or other criminal offence)
- situation (e) above (significant deficiencies in performance of a contract)
- situation (f) above (irregularity)
- situation (g) above (creation of an entity with the intent to circumvent legal obligations)
- situation (h) above (person created with the intent to circumvent legal obligations)
- situation (i) above

**IV – Situations of exclusion concerning natural or legal persons assuming unlimited liability for the debts of the person**

***This section applies only to declarations that include a person for which a natural or legal person assumes unlimited liability for debts***

(7) declares that a natural or legal person that assumes unlimited liability for the debts of the above-mentioned person(s) is <b>not</b> in one of the following situations. <b><i>If yes, please indicate in annex to this declaration which situation and the name(s) of the concerned person(s) with a brief explanation .</i></b>
- situation (a) above (bankruptcy)

- situation (b) above (breach in payment of taxes or social security contributions)

**V – Grounds for rejection from this procedure**

(8) declares that the person:

was **not** previously involved in the preparation of documents used in this award procedure, where this entailed a breach of the principle of equality of treatment including distortion of competition that cannot be remedied otherwise. ***If yes, please indicate in annex to this declaration the name(s) of the concerned person(s) with a brief explanation .***

**VI – Remedial measures**

If the person(s) declare one of the situations of exclusion listed above, it/they must indicate measures it/they has/have taken to remedy the exclusion situation, thus demonstrating its/their reliability. This may include e.g. technical, organisational and personnel measures to prevent further occurrence, compensation of damage or payment of fines or of any taxes or social security contributions. The relevant documentary evidence which illustrates the remedial measures taken must be provided in annex to this declaration. This does not apply for situations referred in point (d) of this declaration.

**VII – Evidence upon request**

The Agency may request any person subject to this declaration to provide information and the applicable evidence on any natural or legal person that is member of an administrative, management or supervisory body or that have powers of representation, decision or control, including legal and natural persons within the ownership and control structure and beneficial owners, as well as on a natural persons who are essential for the award or for the implementation of the action or work programme subject to the grant application.

The Agency may request any person subject to this declaration to provide the applicable evidence concerning the person itself and the natural or legal persons which assume unlimited liability for the debts of the person.

Evidence may be requested as follows:

For situations described in (a), (c), (d),(f), (g) and (h) production of a recent extract from the judicial record is required or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of establishment of the entity showing that those requirements are satisfied.

For the situation described in point (b), production of recent certificates issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the entity is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions. Where any document described above is not issued in the country concerned, it may be replaced by a sworn statement made before a judicial authority or notary or, failing that, a solemn statement made before an administrative authority or a qualified professional body in its country of establishment.

If a person has already submitted such evidence for the purpose of another award procedure of the same Agency the documents must have been issued no more than one year before the date of their request and must still be valid at that date.

If selected to be awarded a grant, the person subject to this declaration accept(s) the terms and conditions laid down in the grant agreement.

The above-mentioned person must immediately inform the Agency of any changes in the situations as declared.

The person subject to this declaration may be subject to rejection from this procedure and to administrative sanctions (exclusion) if any of the declarations or information provided as a condition for participating in this procedure prove to be false.

Full name

Date

Signature



## Annex 5 – Declaration on joint and several liability of affiliated entities<sup>5</sup>

Annex 5 of the Financial Support agreement will be made available as a separate document.



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<sup>5</sup> HE template: see Annex 3a of the GA under the following link: [https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/temp-form/gap/declaration-joint-and-several-liability-affiliated-entities\\_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/temp-form/gap/declaration-joint-and-several-liability-affiliated-entities_en.pdf)