SUBGRANTING AGREEMENT

This Subgranting Agreement, hereinafter the "**Subgranting Agreement**", is made on 12.05.2020

BETWEEN:

EIT Health InnoStars e.V.
Having its registered seat at Garching b. München Germany, 85748, Lichtenbergstr. 2a
Registration number: VR 206595
VAT number DE308252541
Represented by XXX, managing director
(hereinafter referred to as: "**InnoStars**")

And
Project leader: InoCure s.r.o.
Having its registered seat at Politických veznů 13, 110 00 Praha 1
Registration number: 03835243
VAT number: CZ03835243
Represented by XXX
(hereinafter referred to as: "Project leader or generally Subgrantee")

Project partner: Charles University, Faculty of Pharmacy in Hradec Králové
Having its registered seat at Akademika Heyrovského 1203, 500 05 Hradec Králové, the Czech Republic
Registration number:00216208
VAT number:CZ00216208
Represented by prof. PharmDr. Tomáš Šimůnek, Ph.D., acting as the dean of the Faculty of Pharmacy
(hereinafter referred to as: "Project leader or generally Subgrantee")

Hereinanfeter the project partners referred to as: "Project consortium"

Hereinafter, jointly or individually, referred to as "Parties" or "Party";

WHEREAS:

EIT Health e.V. has entered into the Framework Partnership Agreement ("FPA") with the European Institute of Innovation and Technology ("EIT") with an effective date of January 1, 2016 establishing a long-term cooperation ('framework partnership'), and setting out its terms and conditions and the general terms and conditions and rights and obligations applicable to the Specific Grants that may be awarded by the EIT for specific actions under the framework partnership;

EIT Health e.V. has entered into the Specific Grant Agreement ("SGA") with EIT; by virtue of

which EIT has awarded a Specific Grant to EIT Health e.V., in accordance with and subject to the terms and conditions of the FPA and SGA;

Within the framework of the FPA and the SGA, EIT Health e.V. has entered into a Project Grant Agreement ("PGA") and has set up KAVA activities, being "RIS – Improving ecosystem development".

Subgrantee submitted an application for the RIS Innovation call 2020. After the review of the submitted applications Subgrantee has been provided grant to implement the project detailed in Annex 2.

InnoStars is a Party of the PGA for the "KAVA activitiy" to be implemented from 1 January 2020 to 31 December 2020. Whereas EIT Health will provide financial support through InnoStars to the Subgrantees as a so-called third party receiving financial support;

Whereas in this Subgranting Agreement the Parties wish to lay down the contractual arrangements between them regarding their respective rights and obligations.

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 Rules of Participation for Horizon 2020 or in the FPA or SGA, including their respective Annexes.

1.2 Additional Definitions

"EIT" shall mean the European Institute of Innovation and Technology.

"EIT Health e.V." or **"KIC LE"** shall mean the legal entity under German law, with registered office at Mies-van-der-Rohe-Straße 1, 80807 München, Germany.

"**KIC EIT Health"** shall mean the autonomous partnership of higher education institutions, research organisations, companies and other stakeholders in the innovation process in the form of a strategic network based on joint mid-to long-term innovation planning to achieve the EIT challenges, in the field of health, comprising EIT Health e.V. and the KIC EIT Health Partners (the latter are identified in the Project Agreement, for the purposes of said agreement, as the "**KIC Partners**").

"Affiliated Entity" shall mean a legal entity that is directly or indirectly Controlled by, or under common Control with or Controlling a Party, where "**Control**" means the direct or indirect

- ownership of more than 50% of the issued share capital of the entity or of more than 50% of the issued share capital entitling the holders to vote for the election of directors or persons performing similar functions in such entity, or

- right by any other means to elect or appoint managing board members of the entity (or persons performing similar functions) who together have a majority vote, while the status of Affiliated Entity lasts only as long as such Control exists, it being understood that common Control through government does not, in itself, create Affiliated Entity status.

"Articles of Association" shall mean the Articles of Association of EIT Health e.V.

"By-Laws" shall mean the By-Laws of EIT Health e.V.

"Framework Partnership Agreement" or "FPA" shall mean the agreement establishing the long-term cooperation ('framework partnership') between the EIT and the EIT Health e.V and the KIC EIT Health Partners, with the effective date as of 1 January 2016.

"Specific Agreement" or "SGA" shall mean the agreement concluded between the EIT and EIT Health e.V., if the EIT has decided to award a grant for a given year to the KIC EIT Health.

"Authorized Representative" shall mean the person or persons duly authorized to sign this Subgranting Agreement on behalf of a Party.

"Effective Date" shall mean the date first referenced above.

"Business Plan" shall mean the yearly business plan as approved by the Partner Assembly of the KIC EIT Health including short, mid and long-term objectives and targets, key performance indicators, and describing the KIC activities which consist of KIC Added Value Activities to be supported by the Specific Grant and KIC Complementary Activities having a clear link with at least one KIC Added Value Activity and not financed by the Specific Grant.

"Management Board "of EIT Health e.V. shall mean the management body of EIT Health e.V. as referred to in Article 7.1.2 of the Articles of Association of KIC LE.

"**Project"** shall mean the Project as described in annexed Project Plan

Article 2: Purpose

The purpose of this Subgranting Agreement is to lay down the contractual arrangements between the Parties regarding the participation of the Subgrantee in the Project.

Article 3: Entry into force, duration and termination

3.1 Entry into force

This Subgranting Agreement shall have effect from the Effective Date identified at the beginning of this Subgranting Agreement.

3.2 Duration and termination

This Subgranting Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Subgrantee for the Project under this Subgranting

Agreement. The expected end date of the Project is 31.12.2020.

However, this Subgranting Agreement may be terminated in accordance with the terms of this Subgranting Agreement. The InnoStars may at any time terminate this Subgranting Agreement upon notice if an SGA is terminated or not concluded for a given year.

3.3 Survival of rights and obligations

The provisions relating to Access Rights (Article 9), non-disclosure of information (Article 10), for the time period mentioned therein, as well as for liability (Article 5), applicable law (Article 11.7) and settlement of disputes (Article 11.8) shall survive the expiration or termination of this Subgranting Agreement.

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 Subgranting Agreement was still in force and effect.

Article 4: Responsibilities of Parties

4.1 General Principles

The Subgrantee acknowledges and agrees that the InnoStars must be able to comply with its obligations under the Framework Partnership Agreement and the Specific Agreement and therefore Subgrantee agrees to provide, when relevant, the rights necessary to KIC LE to ensure compliance.

The Subgrantee acknowledges and agrees that the EIT, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 28 and 29 of the FPA also towards it as if the Subgrantee was a KIC Partner. The Subgrantee acknowledges and agrees that the InnoStars' obligations under Articles 41, 42, 44 and 52 of the FPA also apply to the Subgrantee as if the Subgrantee was a KIC Partner. Furthermore, the Subgrantee acknowledges and agrees that it shall have no rights or claims to be enforced against EIT. The articles 28, 29, 41, 42, 44 and 52 of the FPA are attached in Annex 1 to this Subgranting Agreement.

The Subgrantee undertakes to take part in the efficient implementation of the Project as described in the Project Plan, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under this Subgranting Agreement as may be reasonably required from it and in a manner of good faith as prescribed by Belgian law.

The Subgrantee undertakes to notify promptly to InnoStars any significant information, fact, problem or delay likely to affect its participation in the Project.

The Subgrantee shall promptly provide all information reasonably required by InnoStars. InnoStars will take care to inform the respective CLC and is entitled to do so.

4.2 Breach

In the event that a Party is in breach of its obligations under this Subgranting Agreement, the non-defaulting Party will give formal notice to such Party requiring that such breach will be remedied within 30 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 non-defaulting Party may decide to declare the Party to be a defaulting Party and to decide on the consequences thereof which may include termination upon notice.

4.3 Involvement of third parties

The Subgrantee only have the right to subcontract or assign its work or rights and obligations under this Subgranting Agreement to third party if explicitly mentioned and approved by the InnoStars in the annexed Project Plan.

Article 5: Governance structure

5.1 Set-up of governance

The Project Partners shall set up an efficient internal project organization and governance structure for the Project. At the latest at the Effective Date, the Project Leader shall notify InnoStars of the structures and processes agreed upon between the Project Partners, and the Project Leader shall notify InnoStars of any changes thereto immediately.

5.2 Project leader

The Project Leader is the legal entity acting as the intermediary between the Project Partners and InnoStars and is the first point of contact for InnoStars regarding the Project, its progress and its participants.

The Project Leader shall, in addition to its responsibilities as a Party, perform the following tasks:

- monitoring compliance by the Project Partners with their obligations under this Project Agreement; and in particular
- monitoring overall project performance and the execution of decisions taken by the governance bodies of the Project;
- monitoring compliance of the Project Partners with the guidelines issued by InnoStars to provide reports and regular updates on the reports;
- collecting from the Project Partners:
  - information on technical progress; and
  - an explanation of the use of recourses and the use of subcontracting services and in-kind contributions by third parties and from each linked third party,
- monitoring the effective and efficient implementation of the Project;
- submitting reports (in particular technical progress reports) and specific requested documents to InnoStars.

5.3 Project Partners

The Project Partners is responsible for implementing the tasks set out in the project plan. The Project Partners shall co-operate with the Project Leader and with InnoStars to provide all information as is required to fulfil the reporting obligations towards InnoStrars and EIT Health. The Project Partners and the Project Leader shall further comply with the guidelines issued by InnoStars to provide reports and shall provide regular updates on the reports regarding technical progress and financial aspects in accordance with these guidelines.

5.4 RIS Hub

The RIS hub as the first contact point of InnoStars in the RIS region perform as coordinator of the implementation and provide support for the Project Partners and ensures the proper implementation complying with EIT Health rules, regulations and guidelines.

Article 6: Liability towards each other

6.1 Limitations of contractual liability

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 or by a breach of confidentiality.

Each Party's aggregate liability towards the other Party shall be limited to the amounts due to be paid under this Subgranting Agreement, provided such damage was not caused by a wilful act or gross negligence.

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

6.2 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 Subgranting Agreement.

6.3 Force Majeure

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

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

If the consequences of Force Majeure are not overcome within 12 weeks after such notification, either Party shall have the right to terminate this Subgranting Agreement upon notification.

Article 7: Reporting

The Project leader shall co-operate with InnoStars to provide all information as is required to fulfil the reporting obligations towards InnoStars, the KIC LE and the EIT. The Subgrantee shall further comply with the applicable guidelines issued by the KIC LE's Management Board to provide reports regarding technical progress and financial aspects.

It is the Project leader who shall submit the report in the name of the project consortium after implementing the tasks set out in the Project plan. In this context the project leader is responsible to collect and provide all the information and supporting documents that necessary to meet the requirements of the reporting process. The reporting template and the required supporting documents is Annexed to the Agreement.

Article 8: Financial provisions

8.1 General Principles

The Project consortium shall receive financial contribution from the KIC LE through InnoStars only for its tasks in the Project, carried out in accordance with Article 4.1. Each Subgrantee shall receive financial contribution for its personnel costs, costs for travel, accommodation and subsistence allowances, sub-contracting, consumables and supplies incurred for the execution of its work for the Project under this Subgranting Agreement The expected costs are outlined in the annexed Project Plan.

The costs are eligible from the effective date of this contract.In exceptional cases costs incurred earlier than the effective date (but no later than the award notification letter) can be eligible if the reason for starting the project earlier is duly justified and approved by InnoStars.

The maximum amount of financial contribution from the EIT funding is in total not more than EUR 75.000, and the maximum amount provided to one Supgrantee is not more than 50.000 EUR. Furthermore, the Subgrantee must keep the records and the original documents supporting the costs declared.

If the Project Agreement is terminated before the completion of the Project, each Subgrantee shall refund all payments it has received except the amount corresponding to the costs already incurred and accepted by InnoStars.

8.2 Payments

Each Subgrantee is entitled to one pre-financing payment within 15 days from the signature of the Agreement and a final payment that can be requested (as part of the final report) after completing of the project as follows:

Payment #1: After signing the Agreement InnoStars provide 50% pre-finanincing payment of the grant to each Subgrantee.

Payment #2: The project leader shall submit the final report on behalf of the consortium to the KIC LE latest by 5th January 2021. The project consortium shall report on all work

performed in connection with the Project in 2020 as well as on all results achieved in line with the Project workplan. The report shall also contain a financial statement on the amount spent by each partner during 2020. The KIC LE transfer the amount indicated and properly justified in the report to the respective Subgrantee after the approval of the final report but latest on 31st January 2021.

The InnoStars shall notify the Subgrantee concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references.

Payment by the InnoStars to the Subgrantee hereunder, shall be made to the following bank account:

Company Name: InoCure s.r.o.
Bank: Raiffeisenbank s.r.o.
Account Name: InoCure s.r.o.
IBAN: XXX
SWIFT Code: XXX
With reference: EIT Health InnoStars RIS Innovation project funding

Company Name: Charles University, Faculty of Pharmacy in Hradec Králové
Bank: Československá obchodní banka, a.s., Radlická 333/150, 150 57 Praha 5
Account Name: 166595745/0300
IBAN: XXX
SWIFT Code: XXX
With reference: EIT Health InnoStars RIS Innovation project funding

or any other bank account details as may be provided by the Subgrantee to InnoStars after the execution of this Subgranting Agreement, which new details shall only be effective five working days after receipt by InnoStars of written notice from the Subgrantee in that respect.

Article 9: Results

9.1 Ownership of Results

Results generated by the Subgrantee in the execution of the work under this Subgranting Agreement are owned by the Subgrantee.

9.2 Dissemination

Any dissemination of Results by the Subgrantee shall be subject to the prior written approval of the InnoStars, such approval not be unreasonably withheld or delayed.

9.3 Use of names, logos or trademarks

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

The Subgrantee shall have the right to use the EIT Brand and the EIT Health logo, in accordance with the instructions from KIC LE.

Article 10: Access Rights

No Access Rights to Background and Results are needed in view of the Workplan.

Article 11: Non-disclosure of information

11.1 All information in whatever form or mode of communication, which is disclosed by a Party (the "Disclosing Party") to the other Party (the "Recipient") in connection with the Project during its implementation and which has been explicitly marked as "confidential" at the time of disclosure, or when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within thirty (30) calendar days from oral disclosure at the latest as confidential information by the Disclosing Party, is "Confidential Information".

11.2 The Recipients hereby undertake in addition and without prejudice to any commitment of non-disclosure under the SGA, for a period of 4 years after the end of the Project:

- not to use Confidential Information otherwise than for the purpose for which it was disclosed;
- not to disclose Confidential Information to any third party without the prior written consent by the Disclosing Party;
- to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
- to return to the Disclosing Party on demand all Confidential Information which has been supplied to or acquired by the Recipients including all copies thereof and to delete all information stored in a machine-readable form. The Recipients may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations.

11.3 The Recipient shall be responsible for the fulfilment of the above obligations on the part of their employees or third parties involved in the Project and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of the contractual relationship with the employee or third party.

11.4 The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

- the Confidential Information becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
- the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;

- the Confidential Information is communicated to the Recipient without any obligation of confidence by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidence to the Disclosing Party;

- the disclosure or communication of the Confidential Information is foreseen by provisions of this Subgranting Agreement, the Project Agreement, FPA or SGA;

- the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party; or

- the Confidential Information was already known to the Recipient prior to disclosure; or

- the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Article 10.7 hereunder.

11.5 The Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care.

11.6 Each Party shall promptly advise the other Party in writing of any unauthorized disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorized disclosure, misappropriation or misuse.

11.7 If either Party becomes aware that it will be required, or is likely to be required, to disclose Confidential 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 12: Miscellaneous

12.1 Inconsistencies and severability

Should any provision of this Subgranting Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Subgranting 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.

12.2 No representation, partnership or agency

No Party shall be entitled to act or to make legally binding declarations on behalf of the other Party. Nothing in this Subgranting 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.

12.3 Notices and other communication

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

Formal notices:
If it is required in this Subgranting Agreement (that a formal notice, consent or approval shall be given, such notice shall be signed by an Authorised Representative of a Party and shall either be served personally or sent by mail with recorded delivery or telefax with receipt acknowledgement.

Other communication:
Other communication between the Parties may also be effected 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.

12.4 Assignment and amendments

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

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

12.5 Mandatory national law

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

12.6 Language

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

12.7 Applicable law

This Subgranting Agreement shall be construed in accordance with and governed by the laws of Belgium excluding its conflict of law provisions.

12.8 Settlement of disputes

The parties shall endeavor to settle their disputes amicably.

All disputes arising out of or in connection with this Subgranting Agreement, which cannot be

solved amicably, shall be finally settled before the courts of Brussels.

Nothing in this Subgranting Agreement shall limit the Parties' right to seek injunctive relief in any applicable competent court.

Article 13: Signatures

AS WITNESS:

The Parties have caused this Project Agreement to be duly signed by the undersigned authorised representatives in separate signature pages the day and year first above written.

The signature of a Party by means of a scan or digitization of the original signature (e.g. a scan in PDF format) or an electronic signature (e.g. via AdobeSign), 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.

EIT Health InnoStars e.V.

Signature:

Name: XXX
Title: Managing director
Date: 11. 6. 2020

InoCure s.r.o

Signature:

Name(s):
Title(s):
Date: 12.5.2020

Charles University

Signature:

Name(s): Prof. PharmDr. Tomáš Šimůnek, Ph.D.
Title(s): Dean of the faculty

Date: 12. 5. 2020

Annex 1

Article 28: Checks, reviews, audits and investigations – extension of findings

28.1 Checks, reviews and audits by the EIT and the Commission

28.1.1 Right to carry out checks

The EIT will – during the implementation of a specific action or afterwards – check the proper implementation of the specific action and compliance with the obligations under the Framework Partnership Agreement and the Specific Agreement, including assessing deliverables and reports.

For this purpose, the EIT may be assisted by external persons or bodies.

The EIT may also request additional information in accordance with Article 23. The EIT may request KIC Partners to provide such information to it directly.

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

28.1.2 Right to carry out reviews

The EIT may – during the implementation of a specific action or afterwards – carry out reviews on the proper implementation of the specific action (including assessment of deliverables and reports), compliance with the obligations under the Framework Partnership Agreement and the Specific Agreement.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the KIC LE or KIC Partner concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 15 to 22), the KIC Partner concerned must inform the third party.

The EIT may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the KIC LE or the KIC Partner concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The KIC LE or KIC Partner concerned must provide – within the deadline requested – any information and data in addition to deliverables and reports already submitted (including information on the use of resources).

The KIC LE or KIC Partner concerned may be requested to participate in meetings, including with external experts. For on-the-spot reviews, the KIC Partners must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available. Information provided must be accurate, precise and complete

and in the format requested, including electronic format.

On the basis of the review findings, a 'review report' will be drawn up. The EIT will formally notify the review report to the KIC LE or KIC Partner concerned, which has 30 days to formally notify observations ('contradictory review procedure'). Reviews (including review reports) are in English.

28.1.3 Right to carry out audits

The EIT or the Commission may – during the implementation of a specific action or afterwards – carry out audits on the proper implementation of the specific action and compliance with the obligations under the Framework Partnership Agreement and the Specific Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the KIC LE or KIC Partner concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 15 to 22), the KIC Partner concerned must inform the third party.

The EIT or the Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the KIC LE or the KIC Partner concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The KIC LE or the KIC Partner concerned must provide – within the deadline requested – any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Framework Partnership Agreement and Specific Agreements. The EIT or the Commission may request KIC Partners to provide such information to it directly.

For on-the-spot audits, the KIC Partners must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available. Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a 'draft audit report' will be drawn up. The EIT or the Commission will formally notify the draft audit report to the KIC LE or the KIC Partner concerned, which has 30 days to formally notify observations ('contradictory audit procedure'). This period may be extended by the EIT or the Commission in justified cases.

The 'final audit report' will take into account observations by the KIC LE or KIC Partner concerned. The report will be formally notified to it. Audits (including audit reports) are in English.

The EIT or the Commission may also access the KIC Partners' statutory records for the periodical assessment of unit costs, flat-rate amounts or lump sums.

28.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013 and No 2185/96 (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may – at any moment during implementation of a specific action or afterwards – carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity under the Framework Partnership Agreement or Specific Agreement affecting the financial interests of the EU.

28.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 111 of the EIT Financial Regulation, the European Court of Auditors (ECA) may – at any moment during implementation of a specific action or afterwards – carry out audits. The ECA has the right of access for the purpose of checks and audits.

28.4 Checks, reviews, audits and investigations for international organisations

Not applicable

28.5 Consequences of findings in checks, reviews, audits and investigations – Extension of findings

28.5.1 Findings in a specific grant

Findings in checks, reviews, audits or investigations carried out in the context of a specific grant may lead to the rejection of ineligible costs (see Article 48), reduction of the specific grant (see Article 49), recovery of undue amounts (see Article 50) or to any of the other measures described in Section 5.

Rejection of costs or reduction of the specific grant after the payment of the balance will lead to a revised final grant amount (see Article 4 SGA).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 to the Specific Agreement (see Article 61).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EIT, EU or Euratom grants awarded under similar conditions ('extension of findings from the specific grant to other grants'). Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

28.5.2 Findings in other grants

The EIT or the Commission may extend findings from other grants to a specific grant ('extension of findings from other grants to a specific grant'), if:

the KIC Partner concerned is found, in other EIT, EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on the specific grant and

those findings are formally notified to the KIC Partner concerned – together with the list of grants affected by the findings – no later than two years after the payment of the balance of the specific grant.

The extension of findings may lead to the rejection of costs (see Article 48) reduction of the specific grant (see Article 49), recovery of undue amounts (see Article 50), suspension of the action implementation (see Article 55) or termination of the specific grant (see Article 56).

28.5.3 Procedure

The EIT or the Commission will formally notify the KIC Partner concerned the systemic or recurrent errors, and its intention to extend these audit findings together with the list of grants affected.

28.5.3.1 If the findings concern eligibility of costs: the formal notification will include:

- an invitation to submit observations on the list of grants affected by the findings;

the request to submit revised financial statements for all grants affected;

the correction rate for extrapolation established by the EIT or the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the KIC Partner concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The KIC Partner concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated alternative correction method. This period may be extended by the EIT or the Commission in justified cases.

The amounts to be rejected will be determined on the basis of the revised financial statements, subject to their approval.

If the EIT or the Commission does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify to the KIC Partner concerned the application of the initially notified correction rate for extrapolation.

If the EIT or the Commission accepts the alternative correction method proposed by the KIC Partner concerned, it will formally notify to the KIC Partner concerned the application of the accepted alternative correction method.

28.5.3.2 If the findings concern improper implementation or breach of other obligations, the formal notification will include:

- an invitation to submit observations on the list of grants affected by the findings and

the flat-rate the EIT or the Commission intends to apply according to the principle of proportionality.

The KIC Partner concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the EIT or the Commission does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify to the KIC Partner concerned the application of the initially notified flat-rate.

If the EIT or the Commission accepts the alternative flat-rate proposed by the KIC Partner, it will formally notify the KIC Partner concerned the application of the accepted alternative flat-rate.

28.6 Consequences of non-compliance

If a KIC Partner breaches any of its obligations under this Article, any insufficiently substantiated costs of specific actions will be ineligible (see Article 5 SGA) and will be rejected (see Article 48).

Such breaches may also lead to any of the other measures described in Section 5.

Article 29: Monitoring and external evaluation of the KIC

29.1 Right to monitor and evaluate the KIC

The EIT or the Commission may carry out interim and final evaluations of the output, results and impact of the KIC.

Evaluations may be started during implementation of a specific action and up to a period of five years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the KIC LE or KIC Partners.

The EIT or the Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The KIC LE and KIC Partners must provide any information requested to evaluate its impact, including information in electronic format.

29.2 Consequences of non-compliance

If a KIC Partner breaches any of its obligations under this Article, the EIT may apply the measures described in Section 5.

ARTICLE 29a: Management of intellectual property

29a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

KIC Partners that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities.

This does not change the obligations set out in Subsubsections 2 and 3 of this Subsection. The KIC Partners must ensure that researchers and third parties involved in the specific actions are aware of them.

29a.2 Consequences of non-compliance

If a KIC Partner breaches its obligations under this Article, the EIT may apply any of the measures described in Section 5.

Article 41: Conflict of interests

41.1 Obligation to avoid a conflict of interests

The KIC Partners must take all measures to prevent any situation where the impartial and objective implementation of the specific actions is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('conflict of interests').

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

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

41.2 Consequences of non-compliance

If a KIC Partner breaches any of its obligations under this Article, the grant may be reduced (see Article 49) and the Specific Agreement or participation of the KIC Partner may be terminated (see Article 56).

Such breaches may also lead to any of the other measures described in Section 5.

Article 42: Confidentiality

42.1 General obligation to maintain confidentiality

During implementation of the specific action and for four years after the period set out in Article 3 of the Specific Agreement, the parties must keep confidential any data, documents

or other material (in any form) that is identified as confidential at the time it is disclosed ('confidential information').

If a KIC Partner requests, the EIT may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Framework Partnership Agreement or Specific Agreement.

The KIC Partners may disclose confidential information to their personnel or third parties involved in the specific action only if they:

- need to know to implement the Framework Partnership Agreement or Specific Agreements and

are bound by an obligation of confidentiality.

This does not change the security obligations in Article 43, which still apply.

The EIT may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

- this is necessary to implement the Framework Partnership Agreement or Specific Agreement or safeguard the EIT's financial interests and

the recipients of the information are bound by an obligation of confidentiality.

The confidentiality obligations no longer apply if:

- the disclosing party agrees to release the other party;

the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

the recipient proves that the information was developed without the use of confidential information;

the information becomes generally and publicly available, without breaching any confidentiality obligation, or

the disclosure of the information is required by EU or national law.

42.2 Consequences of non-compliance

If a KIC Partner breaches any of its obligations under this Article, the specific grant may be reduced (see Article 49).

Such breaches may also lead to any of the other measures described in Section 5.

Article 44: Promoting the KIC – visibility of the EIT and EU funding

44.1 Communication activities by the KIC Partners

44.1.1 Obligation to promote the specific action and its results

The KIC Partners must promote the specific action and its results by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the specific dissemination obligations in Article 35, the confidentiality obligations in Article 42 or the security obligations in Article 43, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the KIC Partners must inform the EIT (see Article 58).

44.1.2 Information on EIT and EU funding – Obligation and right to use the EIT KIC logo and the EU emblem

Unless the EIT requests or agrees otherwise or unless it is impossible, any communication activity related to the specific action (including in electronic form, via social media, etc.) as well as any infrastructure, equipment and major results funded by the specific grants must:

- display the EIT KIC logo as adopted by the EIT;

display the EU emblem;

follow the brand guidelines outlined in the EIT Community Brand Book as adopted by the EIT; and

include the following text:

For communication activities: 'This activity has received funding from the European Institute of Innovation and Technology (EIT). This body of the European Union receives support from the European Union's Horizon 2020 research and innovation programme.'

For infrastructure, equipment and major results: 'This *[infrastructure] [equipment] [insert type of result]* is part of an activity that has received funding from the European Institute of Innovation and Technology (EIT). This body of the European Union receives support from the European Union's Horizon 2020 research and innovation programme.'

When displayed together with another logo, the EIT KIC logo and the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the KIC Partners may use the EIT KIC logo and the EU emblem without prior approval from the EIT. This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EIT KIC logo or the EU emblem (or any similar trademark or logo), either by registration or by any other means.

44.1.3 Disclaimer excluding EIT responsibility

Any communication activity related to the specific action must indicate that it reflects only the author's view and that the EIT is not responsible for any use that may be made of the information it contains.

44.2 Communication activities by the EIT

44.2.1 Right to use KIC's materials, documents or information

The EIT may use, for its communication and dissemination activities, information relating to the specific action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any KIC Partner (including in electronic form).

This does not change the confidentiality obligations in Article 42 and the security obligations in Article 43, all of which still apply.

However, if the EIT's use of these materials, documents or information would risk compromising legitimate interests, the KIC Partner concerned may request the EIT not to use it (see Article 58).

The right to use a KIC Partner's materials, documents and information includes:

- use for its own purposes (in particular, making them available to persons working for the EIT or any other EU institution, agency or body, or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

distribution to the public (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

editing or redrafting for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

translation;

giving access in response to individual requests under Regulation No 1049/2001, without the right to reproduce or exploit;

storage in paper, electronic or other form;

archiving, in line with applicable document-management rules, and

the right to authorise third parties to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties, if needed for the communication and publicising activities of the EIT.

If the right of use is subject to rights of a third party (including personnel of the KIC Partner), the KIC Partner must ensure that it complies with its obligations under the Framework Partnership Agreement and the Specific Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the KIC Partners), the EIT will insert the following information:
"© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the European Institute of Innovation and Technology (EIT) under conditions."

44.3 Consequences of non-compliance

If a KIC Partner breaches any of its obligations under this Article, the specific grant may be reduced (see Article 49).

Such breaches may also lead to any of the other measures described in Section 5.

Article 52: Liability for damages

52.1 Liability of the EIT

The EIT cannot be held liable for any damage caused to the KIC Partners or to third parties as a consequence of implementing the Framework Partnership Agreement or a Specific Agreement, including for gross negligence.

The EIT cannot be held liable for any damage caused by any of the KIC Partners or third parties involved in the specific action, as a consequence of implementing the Framework Partnership Agreement or a Specific Agreement.

52.2 Liability of the KIC Partners

52.2.1 Conditions

Except in case of force majeure (see Article 57), the KIC Partners must compensate the EIT for any damage the EIT sustains as a result of the implementation of a specific action or because a specific action was not implemented in full compliance with the Framework Partnership Agreement or a Specific Agreement.

Each KIC Partner is responsible for paying the damages claimed from it.

52.2.2 Amount of damages – Calculation

The amount the EIT can claim from a KIC Partner will correspond to the damage caused by that KIC Partner.

52.2.3 Procedure

Before claiming damages, the EIT will formally notify the KIC Partner concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the EIT does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify confirmation of the claim for damages and a debit note, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the EIT may recover the amount:

- by offsetting it – without the KIC Partner's consent – against any amounts owed to the KIC Partner concerned by the EIT.

In exceptional circumstances, to safeguard its financial interests, the EIT may offset before the payment date in the debit note;

by taking legal action (see Article 63).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by late-payment interest at the rate set out in Article 17 SGA, from the day following the payment date in the debit note, up to and including the date the EIT receives full payment of the amount.

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

Bank charges incurred in the recovery process will be borne by the KIC Partner, unless Directive 2007/64/EC applies.

Annex2
EIT Health InnoStars RIS innovation project plan

Contact

Award holder (project leader company):	InoCure s.r.o.		
Project title:	HepaMATRIX - Active 3D cell culture system for primary hepatocytes		
Name of contact person:	XXX		
Email:	XXX	**Mobile:**	
Innostars contact:	XXX, XXX		
Email:	XXX		

Project team

Name of the Partner	Role	Tasks
InoCure s.r.o.	Project leader	• Works-Like prototypes: Development of 2 sets of DifMATRIX Hepato (HepaMATRIX): Iteration 1 – effect of matrix additives (chitosan-lactobionic acid, gelatine-lactobionic acid, PEI-lactobionic acid). Iteration 2 – effect of HGF concentration on best formulation from Iteration 1. • Killer experiment: Molecular biology and functional validation on model of human primary hepatocytes. • Personal: 3 PM total: 0,5 person FTE x 6 months x 3000 EUR/month • Material: Material for HepaMATRIX membranes; Polymers – PCL, gelatin, lactobionic acid, PEI, chitosan – 1000 EUR; Growth factors – HGF – 3000 EUR; Detection kits (i.e. ELISA kits, metabolic kits, antibodies, fluorophores) – 3000 EUR; In-house cell culture tests – 1000 EUR • Works-like/Looks-like prototypes: Validation of resulting HepaMATRIX kit on model drugs (4 drugs). • BOM: Manufacturing plan (SOP determination) and costing determination.

		• Killer technical experiment: Molecular biology and functional validation on model of human primary hepatocytes with 4 model drugs. • Personal: 1,5 PM total; 0,5 FTE x 3 months x 3000 EUR • Material: Polymers – PCL, gelatin, lactobionic acid, PEI, chitosan – 1000 EUR; Growth factors – HGF – 2000 EUR; Detection kits (i.e. ELISA kits, metabolic kits, antibodies, fluorophores) – 1000 EUR • Business plan development based on consulting of coach and DEX-IC experts. • Investor-ready business plan including workflow description, impact plan, draft IFU developed, IRB submission, data requirement determination. • Feedback from clinicians and economic buyers (>20) • Set-up of Advisory board, key management team • Personal:0,9 PM total;0,1 FTE x 9 months x 3000 EUR • Subcontracting: Coaching services • Presence on networking events (EIT Health events, BioEurope 2020) • Gathering partners/customers. • Feedback from >20 clinicians, feedback from > 20 economic buyers. • Consulting with regulators for IRB, need/workflow plan inputs, data requirements.
Charles University	Project partner	• Works-Like prototypes: Development of 2 sets of DifMATRIX Hepato (HepaMATRIX): Iteration 1 – effect of matrix additives (chitosan-lactobionic acid, gelatine-lactobionic acid, PEI-lactobionic acid). Iteration 2 – effect of HGF concentration on best formulation from Iteration 1. • Killer experiment: Molecular biology and functional validation on model of human primary hepatocytes. • Personal;2 PM total:0,4 person FTE x 6 months x 3000 EUR/month • Material: Cryopreserved Primary human hepatocytes, culture media, supplements – 8 000 EUR; Model drugs, qPCR reagents, ATP assay – 2300 EUR

		• Works-like/Looks-like prototypes: Validation of resulting HepaMATRIX kit on model drugs (4 drugs). • BOM: Manufacturing plan (SOP determination) and costing determination. • Killer technical experiment: Molecular biology and functional validation on model of human primary hepatocytes with 4 model drugs. • Personal:2 PM total;0,4 person FTE x 6 months x 3000 EUR/month • Material: Cryopreserved Primary human hepatocytes, culture media, supplements – 8 000 EUR;Model drugs, qPCR reagents, ATP assay – 2300 EUR
DEX	RIS Hub	• Supporting, monitoring and supervising the implementation of the project

Work plan

Start date:	12.05.2020	**End date:**	31.12.2020
Project description *(max 500 words)*:	Drug effect on liver tissue is among the primary tests used in early phases of drug development and toxicological screening. Today, the hepatotoxicity is tested either on cell lines (in vitro) or experimental animals (> 10 million animals/year). In vitro cultured cells are rapidly losing their physiological properties (about 72 hours) resulting in poor correlation to results in human. New cell culture models – such as 3D cell culture are needed to solve this problem. However, state-of-the-art in vitro models are not mimicking cell-to-cell communication and does not replicate behavior in humans. Therefore, there lack of proper models of liver tissue delivering relevant, high-throughput and ethical preclinical drug testing is of high demand. InoCure in 2016 introduced InoMATRIX – a 3D cell culture system. In order to address the disadvantage from lack of signaling regulation we created HepaMATRIX: the first active 3D cell culture system combining both mimicking of 3D environment and gradients of signaling molecules by their controlled release ("talking-to-cells"). The system enables stimulation of cells by physiological doses of growth factors and other signaling molecules mimicking the situation in real tissue. The active HepaMATRIX membranes are coming as ready to use kit designed for cultivation of primary hepatocytes and leading to formation of cell culture niche enabling more precise drug testing		

Deliverables

Name of the deliverable	Description	Target value

DEL1: SOP for HepaMATRIX 3D cell culture kit manufacturing (12/2020)	SOP for manufacturing of HepaMATRIX including technological protocol, protocol for packaging/sterilization, instructions for use (IFU) and pricing/cost analysis.	1
DEL2: Report from validation of HepaMATRIX 3D cell culture kit	Report about testing of different versions of HepaMATRIX (from Charles University).	1
DEL3: Investor Business plan for HepaMATRIX (12/2020)	Investor ready business plan containing i.e. updated need/workflow description, market/competitor landscape, USP/value proposition, feedback from >20 clinical/>20 economic buyers and needs for clinical/regulatory approvals.	1

Schedule

Milestone/Output	When?
MS1: PoF iteration 1 performed and reported (link to DEL2)	7/2020
MS2: Pof iteration 2 performed and reported (link to DEL2 and OUT1	10/2020
MS3: PoV validation of technology performed (link to DEL1, DEL2 and OUT1)	12/2020
MS4: SOP for HepaMATRIX (link to DEL1, OUT1)	12/2020
MS5: Networking events finished and reported (DEL3)	11/2020
MS6: Coaching performed and business plan drafted (DEL3	9/2020
MS7: Investor ready business plan prepared and reviewed (DEL3	12/2020
OUT1: HepaMATRIX 3D cell culture kit – validated kit for hepatic cell culture achieved	12/2020.

Indicative budget

Total Budget	Indicative cost	Funding from EIT Health	Contribution from other sources*
Personnel	30 600,00 €	30 600,00 €	0 €
Travel and subsistence	5 800,00 €	5 800,00 €	0 €
Consumables and equipment	0 €	0 €	0 €
Services and sub-contracting	6 000,00 €	6 000,00 €	0 €
Other goods and servicews	32 600,00 €	32 600,00 €	0 €

Total	**75 000,00 €**	**75 000,00 €**	**0 €**

Budget of project leader	Indicative cost	Funding from EIT Health	Contribution from other sources*
Personnel	16 200,00 €	16 200,00 €	0 €
Travel and subsistence	5 800,00 €	5 800,00 €	0 €
Consumables and equipment	0 €	0 €	0 €
Services and sub-contracting	6 000,00 €	6 000,00 €	0 €
Other goods and servicews	12 000,00 €	12 000,00 €	0 €
Total	**40 000,00 €**	**40 000,00 €**	**0 €**

Budget of project partner 1	Indicative cost	Funding from EIT Health	Contribution from other sources*
Personnel	14 400,00 €	14 400,00 €	0 €
Travel and subsistence	0 €	0 €	0 €
Consumables and equipment	0 €	0 €	0 €
Services and sub-contracting	0 €	0 €	0 €
Other goods and servicews	20 600,00 €	20 600,00 €	0 €
Total	**35 000,00 €**	**35 000,00 €**	**0 €**

* The budget breakdown may be adjusted by transfer of amounts between budget categories if all the activities are implemented as described in the Work plan and in line with the Schedule.

Funding profile

Trigger for release of funding?		Amount
Payment 1	50% pre-financing payment after the signature of the subgranting agreement	37500 €
Payment 2	After completing the project tasks and submitting the financial statement with supporting evidencies: invoices, bank statements, completion certificate of the mentoring services (see Annex 4), booking confirmatiom/tickets for travel and acommodation	37500 €

Reporting

Reporting requirements	Due
Concise final report that contains: - Description of the completed activities - Assessment of the progess (to be compiled with the support of the mentor) - Financial Statement on the amount spent (in line with the Funding) - Supporting documents justifying the spending as set out in Funding profile	05.01.2021