# EIT Health Call Document Transformative Health Instrument Call 2025

7 November 2024

## Change Log

| ID | Date | Document | Page | Description |
|---|---|---|---|---|
| **1** | 11/11/2024 | Call document | 5,13,15 and 18 | Corrected the number of SMEs to be selected for potential funding. |
| **2** | 11/11/2024 | Call document | 13 and 16 | Removed footnote 9 and 10 |
| **3** | 28/11/2024 | Call document | 22 | Updated the date of last drop-in session to Tuesday, 7 January, 2025 |
| **4** | 28/11/2024 | Call document | Footnote 6 | Clarified the situation with Swiss entities |
| **5** | 28/11/2024 | Call document | 18 - 19 | Final Notification - Clarification on funding being contingent on signing of all legal agreements. |

# Introduction

Europe is facing a turning point in healthcare. From an increase in infectious diseases, pandemic threats, antimicrobial resistance, to the rising costs of healthcare delivery, and social and healthcare systems typically slow to change and adapt, the time to act is now.

At the same time, the European private investment market backing innovation development has been significanty reduced after the investment frenzy observed in 2020 and 2021 in response to the Covid threat and global focus on Health. During 2023, private equity deal activity in Europe declined. Both the number of transactions and total transaction value dropped by 32% compared to 2022[1]. This downturn was largely attributed to economic uncertainty, persistently high interest rates, and ongoing geopolitical tensions. But there are indications that this decline is turning around. Quarter four of 2023 saw the highest transaction value compared to the previous 18 months, and the ecosystem continued to show signs of recovery in early 2024. But the landscape remains complex and competitive, particularly for companies seeking funding, many of which struggle to close funding rounds.

Europe has a unique opportunity to strengthen its early-stage innovation investment, which can help close the gap with its global competitors. By enhancing support and creating incentives, the European startup ecosystem can thrive, fostering greater innovation and competitiveness. This approach aligns with recent high-level recommendations for boosting the EU's economic performance, which emphasize the critical role of innovation in maintaining Europe's global competitiveness, particularly in advanced technologies and emerging sectors[2].

In response, EIT Health is strengthening its support for high-potential, Micro, Small and Medium-sized enterprises (SME's) by providing targeted funding through the Transformative Health Instrument (THI). The THI is designed to support high-potential European SMEs that aim to create significant impact in healthcare.

The THI offers up to €500,000 in grant funding in 2025 to SMEs, with the possibility of additional funding in 2026-28 for future research and development (R&D) projects that are co-funded through private capital investments in future equity rounds.

Beneficiaries of the THI are required to co-fund a minimum of 30% of the 2025 project. For subsequent projects in 2026-28, co-funding requirements will continue to apply, with rates varying based on each project's start date. With this opportunity, EIT Health aims to support SMEs to activate private capital and propel their venture's acceleration.

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[1] https://www.pwc.de/en/private-equity/private-equity-trend-report.html
https://www.investeurope.eu/media/i4zpjz1m/20240507_invest-europe_pe-activity-data-2023-report.pdf
[2] Draghi, M. (2024). Report on European Competitiveness. European Commission.

# Objectives and Scope

With the ambition to contribute to some of the top health priorities that have been identified at the EU level and aligned with our Flagships strategy, EIT Health is calling for projects that are driving Innovation and Transformation in Healthcare.

## Transformative Health Instrument

The Transformative Health Instrument (THI) seeks to advance healthcare innovation by supporting state-of-the-art technologies and data-driven approaches to create transformative solutions for a healthier Europe. By leveraging recent breakthroughs in science and technology, the instrument aims to support the evolution of healthcare systems across the continent. It focuses on supporting innovation that leads to improvement of healthcare outcomes, enhancement of efficiency of clinical and operational processes, and ensuring that healthcare systems are better prepared to address emerging challenges. Through these efforts, EIT Health seeks to foster a forward-thinking healthcare landscape that is adaptable, patient-centred towards delivering more sustainable and effective care. Ultimately, it aims to drive long-term improvements in public health, ensuring that European healthcare remains at the forefront of global innovation.

The THI is tailored to provide access to funding and EIT Health's network of expertise and partnerships for companies that have moved beyond the advanced proof-of-concept stage. Its primary goal is to support these businesses with funding to further validate their innovations and accelerating their readiness for market entry. By offering financial support, the instrument enables SMEs to conduct additional testing, validation, and development work that is crucial for navigating the complex transition from concept to commercialization.

The THI acts as a gateway to EIT Health's expansive network of industry experts, mentors, and potential collaborators, to leverage critical support to enhance product development, meet regulatory requirements, and refine go-to-market strategies. This network allows companies to seek expert advice, form strategic partnerships, and collaborate with other innovators, helping them overcome technical challenges and operational barriers. By facilitating these connections, EIT Health empowers companies to advance their innovations and better position themselves for successful market adoption.

## In a nutshell

The THI Call 2025 aims at funding up to 12 Innovative Companies with up to €500,000 of funding for a project in 2025. The overall financial amount of this call is up to €6,000,000 subject to available EIT funding.

# Conditions to receive funding

This call follows the principle of equal opportunity and is open to applications for funding from both EIT Health association members and applicants outside of the EIT Health Partnership.

## General conditions

To be eligible for funding, all applicants must be established in one of the Member States (MS) including their outermost regions, the Overseas Countries and Territories linked to the Member States[3] or in countries associated to Horizon Europe as well as certain low- and middle-income countries [4] [5].

Individuals cannot apply for funding under this call.

The provisions of the Articles of Association and By-Laws of the EIT Health association (EIT Health e.V) will apply to SMEs of selected activity who will only be eligible to receive funding after they have acceded to the relevant EIT Health legal framework.

The European Commission is committed to promoting gender equality in innovation and technology. The EIT, as a body of the European Union and an integral part of Horizon Europe, plays a vital role in supporting the EU's objectives of creating sustainable economic growth and jobs by enabling entrepreneurs and innovators to turn their best ideas into products and services for Europe. EIT Health shares the EIT KIC gender diversity value statement through supporting well-being at work, compliance with domestic and EU regulations, attracting and retaining talents, economic benefits, excellence and quality, effectiveness and efficiency of innovations and technology and as a leverage for organisational change. Consequently, the gender requirements in Horizon Europe are of significant importance for all EIT Health-supported and funded activities.

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[3] Entities from Overseas Countries and Territories (OCT) are eligible for funding under the same conditions as entities from the Member States to which the OCT in question is linked.

[4] UK entities will now be eligible to directly receive EIT funding, if selected as a part of a granted project and will be treated as all other participants from Horizon Europe participating and associated countries. UK entities selected as part of prior calls for proposals (2023 and prior) will continue to be covered by the local UK reimbursement scheme. Further information on this topic can be found on the UK Research and Innovation website or by reaching out to the EIT Health Ireland-UK Co-location Centre.

[5] Switzerland and the European Commission are negotiating a transitional arrangement for the 2025 Horizon Europe programme. As a result, Swiss SMEs can prepare applications for Horizon Europe funding as potential beneficiaries. In the context of this call, if an association agreement between Switzerland and the European Commission is signed before the notification of final results is sent, Swiss SMEs that pass the selection phase will be eligible for funding. However, if no agreement is in place the time the final results notification is sent, applications from Swiss SMEs will be considered ineligible and will not be considered for grant awards. Further information is available from the State Secretariat for Education, Research and Innovation (SERI) of Switzerland, on the call FAQs page, or by reaching out to the EIT Health Germany-Switzerland Co-location Centre.

EIT Health encourages the participation of entities from the EIT Regional Innovation Scheme (EIT RIS Regions) with the goal of improving the Knowledge Triangle integration, the innovation capacity of local ecosystems in RIS countries and regions, and attract new RIS Partners.

The grant period for this call ends on 31 December 2025 and beneficiaries of THI are expected to co-fund at least 30% of the total costs for the 2025 project as part of this call.

The maximum amount of financial support provided to individual entities within the 3-year duration of the Grant Agreement between EIT Health and EIT, namely 2023-2025 should not exceed €6,000,000.

Applicants should carefully review the specified terms before submitting their applications to ensure compliance with this fundamental aspect of the funding agreement. Companies unable to accept the Grant to Options to Equity terms, as detailed in the Financial Sustainability Model section of this document, are ineligible for this call.

Above and beyond the specific EIT Health rules of participation, all activities must comply with the relevant Horizon Europe and EIT financial and legal framework considerations. EIT Health monitoring principles and obligations are governed by the Horizon Europe MGA, Annex 5 general-mga_horizon-euratom_en.pdf (europa.eu).

In case of questions regarding eligibility please reach out to flagships@eithealth.eu.

# Activity description

## Activity summary

| | Description |
|---|---|
| **Goal** | The THI call seeks SMEs developing innovative solutions in Biotech, MedTech, Digital Health, and Biomarker/Diagnostics sectors. These solutions should aim to transform European healthcare by driving innovation in technology and data-driven solutions, enabling the advancement of healthcare systems to improve outcomes, increase efficiency, tackle emerging challenges, and build a more sustainable, patient-focused, and globally competitive healthcare environment. |
| **Product Requirements** | Below listed are starting IMLs for the lead product of applying companies:<br>• IML ≥ 5 for Biotech (Safety Tox study stage)<br>• IML≥ 6 in Medtech (Initial clinical Proof of Concept)<br>• IML ≥ 7 for Digital (Market validation)<br>• IML ≥ 7 for Biomarker Diagnostics<br>(more on IMLs here) |
| **Activity Examples**[6] | Study design and execution for evidence generation<br>Training for Healthcare professionals<br>Patient Engagement<br>Activities to include the innovation into clinical workflows<br>Compliance with Regulatory Requirements<br>Pricing and Business Model<br>Go-to-market Strategy |
| **Duration** | From notification date until 31 December 2025 at latest. |
| **Funding** | Max. €500,000 grant may be requested by the company for the 2025 project<br>Min. 30% co-funding required. |

## Detailed activity description

Through this call, EIT Health aims to support the transformation and strengthening European healthcare systems. We are calling for SMEs in the healthcare sector, with focus on Biotech, Medtech, Digital Health, Biomarker Diagnostics or a combination of those, that are actively working on cutting-edge solutions designed to address the evolving needs of the industry. These SMEs should be focused on creating adaptable innovations that place patients at the core of their efforts, ensuring that healthcare delivery becomes more personalised, sustainable, and effective. By targeting forward-thinking enterprises that prioritise both

[6] The list is exemplary only. For further details on eligible cost please refer to the MGA, Article 6.

innovation and patient outcomes, we aim to foster advancements that not only improve care but also promote long-term sustainability within healthcare systems. These solutions should be scalable and capable of responding to future challenges, contributing to a more resilient and efficient healthcare landscape.

The proposed innovative solutions must be at an Innovation Maturity Level (IML) of the following categories at the time of the application submission.

- IML ≥ 5 for Biotech (Safety/Tox study stage)
- IML ≥ 7 for Biomarker Diagnostics (Clinical validation)
- IML ≥ 6 in Medtech (Initial clinical Proof of Concept)
- IML ≥ 7 for Digital (Market validation)

### Exclusion criteria

In this call, EIT Health is **not** supporting the funding of:

- Non-medical devices and applications:
  - Products primarily designed for wellness or lifestyle purposes
  - Solutions that do not directly address medical conditions or treatments
- Consumer-oriented products:
  - Items intended for direct consumer use without professional medical oversight
  - Over-the-counter solutions that are not aimed at regulatory approval and prescription for personal use
- Healthcare management software solutions that do not directly impact patient diagnosis, treatment, or care

### SME Eligibility

EIT Health staff will conduct a formal eligibility check after reviewing all applications, considering completeness and compliance with all requirements specified in the application platform. Applications that do not fulfil eligibility criteria will be rejected from the selection process.

The following requirements and definitions shall apply to all applicants:

- The entity is a for-profit micro, small or medium enterprise according to the European Commission SME definition
- The entity was established in one of the Member States (MS) including their outermost regions, the Overseas Countries and Territories linked to the Member States or in countries associated to Horizon Europe as well as certain low- and middle-income countries The entity must be a privately held company that has not issued any publicly traded securities or initiated any public offering process.

- The company must have successfully closed an equity funding round in 2023 or 2024 that meets all of the following conditions: Hereafter referred to as a Qualified Investment Round:
    - A minimum total investment of €4,000,000 within a 12-month period, with at least one new investor contributing.
    - At least one of the new investors must be a professional investor in Europe, investing from a fund regulated under either the Alternative Investment Fund Managers Directive (AIFMD), the European Venture Capital Funds (EuVECA) Regulation or similar regulatory framework under national law, or at least one corporate venture capital (CVC) arms[7]. The round must be a priced round with a set valuation. Funding rounds via a convertible note or Simple Agreement for Future Equity (SAFE) do not qualify.

### Budget

- The maximum grant that can be requested from EIT Health is €500,000 for the total duration of the 2025 Project.
- The minimum grant that shall be requested from EIT Health is €400,000 for the total duration of the 2025 Project.
- The Company is requested to co-fund at least 30% of the 2025 project.

### Additional funding in 2026-28

Dependent on the successful implementation of the 2025 project and contingent on EIT funding, EIT Health may consider deploying additional grant funding towards a future project proposed by the SME, that is aligned with the objectives of the 2025 project.

Successful implementation of the 2025 project is defined as the achievement of all milestones, timely submission of all milestone reports, and efficient and compliant cost reporting. To qualify for additional funding, the SME must not only meet these implementation criteria for the 2025 project, but also close a Qualified Investment Round between (see above) 2026-2028 and successfully pass an updated due diligence process (see due diligence section for details).

[7] Corporate venture capital (CVC) arms are defined as investment entities directly affiliated with and funded by established corporations. These can be structured as dedicated investment funds, limited partnerships, investment divisions, subsidiaries, or fully integrated programs within the corporate structure. They must be registered and compliant with relevant regulations, which may include the AIFMD or EuVECA in the EU, or Investment Company Act exemptions and Regulation D in the US.

### Duration of the Project

- The starting date of the project (date from which grant support applies) is the day of selection notification (see Activity timeline).
- The grant covers the activity until 31 December 2025, at the latest. Selected companies must commit to the timelines as outlined in this document and the application form. There will be no possibility of extension of the activity beyond 31 December 2025.

### Financial Sustainability Model

To uphold the principles of EIT Health financial sustainability, all activities selected in EIT Health's portfolio and receiving funding must commit to contributing to the long-term financial sustainability targets of EIT Health. To that end, SMEs awarded under this call will be required to enter into a Financial Sustainability agreement that establishes a contractual framework for responsible financial management and commitment to adhere to the specified EIT Health financial model and practices ( see appendix on Grant to Options to Equity).

The feasibility of implementing the financial sustainability model with the SME of the project will be assessed in the selection phase, and the final agreement must be signed at the time of project contracting and before project commencement. Failure to execute the financial sustainability agreement will result in the revocation of the grant award.

### Impact

The following key performance indicators (KPIs) are mandatory [8]:

| Key performance Indicators | Description |
|---|---|
| **EITHE01.1** | The activity must aim at protecting innovative solutions through filing of patents, trademarks, registered designs, copyrights, etc. |
| **EITHE02.4** | The company must aim at introducing and scaling its innovative products to the market within 3 years after completion of the activity with a sales revenue of at least €10,000 documented. |
| **EITHE06.1** | The company must aim to raise at least €5,000,000 of private and public capital within three years after completion of the project to secure the continued development of its innovative solutions. |

[8] EITHE2.4 is mandatory for all companies except biotech firms, who are exempt due to their longer developmental timelines.

| Key performance Indicators | Description |
|---|---|
| **KIC13** | Number of citizens/patients that benefitted from solutions developed or implemented in KAVAs |
| **Custom KPI** | Each company must contribute to the European Green Deal and the Sustainable Development Goals (SDGs). Therefore, at least one customised KPI should be added that proves how the project will contribute to the reduction of the environmental impact of its activity. |
| **Custom KPI** | Each company must contribute to promoting gender equality and inclusivity in healthcare innovation and technology. Therefore, at least one customised KPI should be added that proves how the project intends to do this. |

### General conditions

- Each SME must contribute to the European Green Deal and the Sustainable Development Goals (SDGs). Therefore, they should add at least one customised KPI that proves how they contribute to the reduction of the environmental impact of their activity and select at least two SDGs that the activity will contribute to.
- Each SME must contribute to the EIT and EIT Health Dissemination and Promotion, and must follow the communication, dissemination, open science and visibility rules, including branding guidelines and obligations (set out in MGA Article 17).
- The final recipients of funding must comply with the Intellectual Property Right (IPR) rules under the MGA Article 16

### Ethics

- Each SME must complete the mandatory Ethical, Legal and Social Implications self-assessment checklist related to Horizon Europe in the EIT Health application system. Please see Horizon Europe guidance here, if needed.

All points described above are expected to be demonstrated through dedicated KPIs, milestones and/or deliverables at the application stage and shall be documented by the end of the project. Please find here the list of KPIs available and the reporting requirements.

# Application Process

## How to apply

The application will be made through the EIT Health Application Platform. New applicants will need to register on the Application Platform here.

If the applicant is already an EIT Health member or has registered as an External Project Partner in a previous call or calls on the previous EIT Health application platform PLAZA, the corresponding data for the organisation will be available in the current Application Platform. However, the applicant will still need to create a new account as an organisation representative and link themselves to their organisation.

The approval of this link might take up to 48 hours and extra information on the organisation profile might be requested.

As part of overall EU programmes, Applicant organisations are required to be registered and have a 9-digit Participant Identification Code (PIC) from the EU Funding & Tenders Portal. Please check whether your organisation has already been registered. If so, no need to register it again.

Application Submission deadline is set for **7 January 2025 4pm CET**.

To ensure a smooth application process, we strongly advise applicants to familiarize themselves with the EIT Health Application Platform before beginning their submission. We recommend starting the application well in advance of the deadline to allow ample time for addressing any potential technical issues or last-minute questions.

All applications must be in English.

The application process timeline is detailed in the table below.

## Timeline

| Evaluation Process step | START DATE | END DATE |
|---|---|---|
| **Call open** | 7 November 2024 | |
| **Call closed** | **7 January 2025, 4 pm CET** | |
| **Eligibility check** | 7 January 2025 | 10 January 2025 |
| **Eligibility check outcome notification** | 10 January 2025 | |
| **Remote evaluation** | 10 January 2025 | 24 January 2025 |

| Evaluation Process step | START DATE | END DATE |
|---|---|---|
| **Remote evaluation outcome notification** | 27 January 2025 | |
| **Due diligence document upload** | 27 January 2025 | 3 February 2025 |
| **Due diligence** | 3 February 2025 | 26 February 2025 |
| **ELSI Evaluation** | 19 February 2025 | 26 February 2025 |
| **Final selection outcome notification** | 28 February 2025 | |
| **Stand Still period** | 28 February 2025 | 28 March 2025 |
| **Contracting** | | 31 May 2025 |
| **Project cost eligibility period** | 28 February 2025 | 31 December 2025 |

## Evaluation process overview

Following submission, all applications will undergo an initial eligibility check. All applications must satisfy the eligibility requirements before proceeding to the next step. Please see the relevant section for the general and specific conditions.

All applications that pass the initial eligibility check will be assessed by external experts commissioned by EIT Health for a quality review. This quality review will be carried out remotely. Once the remote quality review is completed, applications will be ranked by the final score achieved at remote review. Up to the top 25 applications will then be selected to move on to the due diligence stage of the evaluation process. To progress to the due diligence process applications must score at least 70 /100 at the remote review stage.

The final evaluation stage is the due diligence process. The due diligence process assesses the SME potential, financials, and sustainability.

As applications progress through the evaluation process notifications for all applications will be sent to applicants by email from the EIT Health Application Platform.

# Selection process in detail

## Eligibility

SMEs are to submit an application form (accessible through EIT Health's Application Platform). The application form requests the general information of the proposed activity, as well as the SME background information.

The minimum requirements for applying, including eligibility criteria, are specified section on Activity description. The following documentation must be provided in the application:

- Business plan (including, but not limited to, product/technology description, IP strategy, clinical/regulatory strategy, market analysis, business strategy, competitive analysis, value creation plan to exit, team and track record)
- Non-confidential investor pitch deck
- Financial projection in the form of a PnL.
    - Please use the tab '(1) P&L & CF' in the template Excel file 'THI25_FinancialTemplateSME' that is available to download in the application platform.
- CVs of the founder, managerial team and board members
- Business supporting documents:
    - Legal Self-Assessment Certificate and documentation and if applicable lists of commercial agreements signed with third parties.
    - Board resolution approving the Qualified Investment Round or similar documentation as proof.
    - Amended and restated Certificate of Incorporation to document the capital increase.
    - Capitalisation Table showing the pre-money and post-money ownership structures before and after the Qualifying Investment Round. If the qualifying equity financing round was not the last financing round, please provide also the most current cap table.
        - Please use the tab '(2) Cap_Table' in the template Excel file 'THI25_FinancialTemplateSME' that is available to download in the application platform.

An eligibility check will be performed against the relevant general and specific conditions stated in the General Conditions and the Activity Description sections to validate the

application's compliance with the requirements outlined in this Call. This will yield a yes/no decision on the progression of the applications in the evaluation process.

## Remote Evaluation

Eligible applications will be evaluated by external evaluators, commissioned by EIT Health, based on the below criteria. Evaluators are contracted under strict conflict of interest policies and are obligated to inform EIT Health of any potential conflicts before proceeding with the application evaluation.

For all eligible applications, the external evaluation will be based on the following criteria:

| **Remote Evaluation Criteria** |
|---|
| **Activity Excellence and Strategic Fit (40%)**<br><br>Disruptiveness and description of the solution: Clarity and pertinence of the solution's objectives, and the extent to which the proposed work plan is ambitious and goes beyond the state-of-the-art. Companies must propose breakthrough solutions with unique selling points capable of significantly altering market dynamics and create new paradigms with the final goal of improving patient's lives.<br><br>Innovativeness: The proposed solution demonstrates a novel approach or technology that addresses a critical industry challenge and has the potential to significantly transform or disrupt current practices, leading to substantial improvements in efficiency, sustainability, or value creation within the sector.<br><br>Unmet need: The application is aligned with the company's mission to solve unmet clinical and/or business needs in the healthcare sector.<br><br>Strategic Fit: The application is aligned with EIT Health's ambition and strategy. |
| **Impact and Sustainability (30%)**<br><br>Credibility and potential of the Company to achieve the expected outcomes and impacts specified in the work plan, and the likely scale and significance of the contributions of the application. |
| **Implementation and Feasibility (30%)**<br><br>Quality and effectiveness of the work plan, assessment of risks, and appropriateness of the effort assigned to work packages, the resource need overall and the feasibility of projected costs within the specified timeframe. |

Once applications have been reviewed by external experts, applications will be ranked by their final quality score. A maximum of 100 points can be awarded by each evaluator during the remote evaluation. The final remote evaluation score will be the average of all remote evaluators' scores. EIT Health will rank all applications and select up to the top 25 applications

to proceed to the due diligence process. Only applications that score at least 70 / 100 may be invited to the due diligence stage.

The results of the remote evaluations will be communicated to applicants by email through the EIT Health Application Platform.

## Due diligence

The second step of the evaluation is the due diligence step. This process will assess the proposed project's financial viability and fit with the requirements of the relevant financial sustainability model (Grant to Option to Equity ).

To be considered for the due diligence process, projects must score at least 70/100 during the remote evaluation stage.

The due diligence process involves an assessment conducted by both internal EIT Health investment specialists and external experts. The due diligence results in a go / no-go decision. Should more than 12 companies score 70 /100 or more and receive a 'go' decision from the due diligence process, companies will be ranked by their remote evaluation score, and up to 12 will be selected to proceed.

EIT Health may communicate directly with SMEs during this process. The aim of the due diligence process is for EIT Health to gain a comprehensive understanding of each applicant to assess its potential to scale and to drive disruption in their respective sector.

Successful applicants that pass the remote evaluation stage must upload the requested documentation from their Qualified Investment Round (see below) to validate their eligibility. Submitted documents will be treated as confidential. Provided documentation will only be accessible to relevant EIT Health staff and/or independent third parties bound by confidentiality provisions. It is expected that companies will collaborate with EIT Health by providing relevant information and documentation in a timely fashion to facilitate the due diligence, documentation must be submitted by 3 February 2025. Failing to provide the documentation within this deadline will result in disqualification and exclude the application from progressing further in the process.

Documentation is expected to be in English (except for the registration certificate and the Share Purchase Agreement if only available in local language). The below list explains the documents that will be requested during the due diligence stage.

- If applicable: executed agreements regarding IP, technology ownership, partnerships, exclusivity rights, regulatory approvals.
- Financing documents from the Qualified Investment Round, including but not limited to executed Share Purchase Agreement, Subscription Agreement, Investment Agreement, Shareholders' Agreement, or any other legally binding document that governs the acquisition of shares, equity, or equity-like instruments by new investors in the Company.

The evaluation criteria for the due diligence process are in the table below. These criteria are designed to align with the financial sustainability requirements of the EIT Health.

| Due Diligence criteria |
| --- |
| **1. Company Potential**<br>• Management team: Experience and capability. The management team should possess relevant experience and demonstrated capability to support the Company's future growth.<br>• Governance and ownership structure. Clear and effective governance and ownership structures should be in place that will not pose a risk to realising the EIT Health financial sustainability mechanism.<br>• Legal. Based on the legal self-assessment, the Company should indicate no significant issues or concerns, ensuring compliance and minimizing potential legal risks.<br>• Professional investor commitment as a proxy of market affirmation. |
| **2. Financials and Sustainability**<br>• Financial Projections. The Profit and Loss (P&L) statement should demonstrate a healthy and realistic financial performance, with a clear trend of revenue growth and profitability. It should reflect efficient cost management and provide evidence of sustainable financial practices that support the Company's long-term viability and growth objectives.<br>• Potential to realise the EIT Health financial sustainability mechanism. Due diligence will look for a realistic value creation plan for the Company factoring terms of investment. |

## Ethical Legal and Social Issues (ELSI) review

The ELSI review will aim to ensure that all elements in the application linked to critical ethical, legal and social considerations are well defined and addressed throughout the application, thereby helping to de-risk the EIT Health portfolio. All applications short listed for potential EIT Health funding will undergo an ELSI review.

## Final notification

Following the due diligence process, all applications that successfully pass the due diligence process will be ranked by their quality evaluation score and up to the top 12 applications will be selected for potential funding and invited to proceed to contracting. Once all stages are complete, a notification of the final results will be sent to all applicants informing them of the results and sharing the reviewer feedback and scores via the EIT Health application platform.

## Contracting

Applications that are accepted for funding must execute a set of legal agreements (see the list below).

The contracting phase must be completed within the first three months after notification date. Release of funding is contingent on the execution of all agreements and will follow the rates and timing outlined in the Implementation Handbook.

## Monitoring

All funded applications are subject to a regular formal review.

The process serves to either fast-track, support, redirect, or stop the activity in cases of improper implementation or severe underperformance.

The review is a go/no-go point for the continuation of the activity and its EIT funding.

Post-funding monitoring will also be required for up to five years after activity closure to capture impact which exceeds the activity lifetime and contributes to the EIT Health Strategic Agenda and Horizon Europe indicators.

Post-funding monitoring will, in most cases, be in a light format. However, capture of EIT Core KPIs in post-funding years is given special attention. Additionally, post-funding monitoring will help to identify potential success stories and capture key learnings to be shared with the wider community.

EIT Health monitoring principles and obligations are governed by the Horizon Europe MGA, Annex 5 general-mga_horizon-euratom_en.pdf (europa.eu).

## Selection process for additional funding in 2026-28

The selection process for additional funding for projects in 2026-28 will adhere to principles similar to those of the due diligence process explained above. Only projects funded for this call will be considered for funding in 2026 - 28. To be considered for additional funding, companies will have to submit updated documentation from their most recent Qualified Investment Round, comparable to that outlined in the Remote Evaluation and Due diligence.

Submitted documents will be treated as confidential. Provided documentation will only be accessible to relevant EIT Health staff and/or independent third parties bound by confidentiality provisions. It is expected that Companies will collaborate with EIT Health by providing relevant information and documentation in a timely fashion to facilitate the due diligence.

# Confidentiality and conflict of interest

All applications submitted through the application platform are accessible only to EIT Health staff members for the processing of the application, as well as the persons designated during the application phase.

During the selection process, applications and its attached contents are shared with assigned external evaluators, who are contractually bound to confidentiality. Additionally, EIT Health may give access to documentation provided during the due diligence phase to external advisors to support the assessment.

Furthermore, EIT Health may give access to the submitted data to sub-contractors who are tasked with maintaining the application platform and the grant management system.

All such third parties are also bound by confidentiality provisions.

EIT Health staff are bound by the policy on conflicts of interest.

Staff of EIT Health Partners are not involved in the evaluation process of the applications. Furthermore, members of the EIT Health Managing Boards (Supervisory Board) cannot be involved in activities.

Applicants and potential beneficiaries of the EIT grant in selected activities must avoid any conflict of interest and comply with the principles of transparency, non-discrimination, and sound financial management. (Régulation EU 2021/695) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0695

# Grounds for appeal and appeal procedure

The appeal process can be publicly found here: https://eithealth.eu/appeals-procedure/

Applicants may appeal the process for the selection of their own application(s).The only grounds for appeal are:

- Process errors
- Technical problems beyond the control of applicants, e.g., the technical failure of the electronic submission system
- Human/technical errors made by EIT Health staff
- If you consider that you have been adversely affected by a particular decision not following EIT Health's Code of Conduct.

What does not constitute grounds for appeal:

- Scores awarded in the course of the evaluation process, unless if these go against EIT Health's Code of Conduct

Appeal process:

- Applicants should send their appeals in writing to appeals@eithealth.eu as soon as they identify an error, but no later than 21 days after the error occurred,
- EIT Health assesses the claim and deliver a first response,
- If there are grounds for appeal, the staff will attempt to remedy the consequences, e.g., if a technical error of EIT Health prevented the submission of an application, a late submission may still be accepted as eligible,
- The Head of Compliance, and where applicable, Supervisory Board is notified about the matter if:
    - the applicant does not accept a rejection of the appeal, or
    - there are grounds for appeal, but the problem cannot be remedied any more without disrupting the process.

# Where to get help

Prospective applicants are invited to attend an online webinar on **22 November 2024** to hear more about the call and ask questions. Access the webinar by this registration link.

EIT Health is also offering a bi-weekly opportunity to clarify open questions. Please use this link to directly join any of the open sessions at the times and dates below:

| Date | Time |
|---|---|
| **Friday, 8 November, 2024** | 12:00-12:30 pm, CET |
| **Friday, 6 December, 2024** | 12:00-12:30 pm, CET |
| **Friday, 20 December, 2024** | 12:00-12:30 pm, CET |
| **Tuesday, 7 January, 2025** | 12:00-12:30 pm, CET |

Applicants will be informed of any call updates by a change log that will be added to this document when needed.

EIT Health has pan-EU representation via eight Co-Location Centers (CLCs), and an InnoStars office, all of which operate as strong clusters of relevant actors, collaborating in a thriving ecosystem. For support in the preparation and submission of applications, or to find out how to participate, please contact your Co-Location Center (CLC) / InnoStars.

More information here: https://eithealth.eu/in-your-region/

Please contact support in the regions according to the table below:

| CLC | Affiliated Countries |
|---|---|
| **Austria** | Austria |
| **Belgium-Netherlands** | Belgium, Luxembourg, Netherlands, Israel |
| **France** | France |
| **Germany-Switzerland** | Germany, Switzerland |

| CLC | Affiliated Countries |
|---|---|
| **InnoStars** | Italy, Bulgaria, Croatia, Cyprus, Malta, Czechia, Poland, Portugal, Romania, Slovakia, Slovenia, Greece, Hungary, Albania, Bosnia and Herzegovina, North Macedonia, Montenegro, Serbia, Turkey, Moldova, Ukraine, Georgia, Armenia, Latvia, Lithuania |
| **Scandinavia** | Denmark, Estonia, Finland, Sweden, Iceland, Norway, Faroe Islands |
| **Spain** | Spain |
| **Ireland-UK** | Ireland, United Kingdom |

For further support, please refer to our **Frequently Asked Questions** document.

# Appendices

# Appendix I – Grant to Options to Equity Term Sheet

## Grant to Option to Equity Model Description

EIT Health is committing to support the development of the selected SMEs by granting funds to support innovation activities of a project. In return, EIT Health shall participate in the enterprise by way of receiving options that convert to equity at 25 January 2027 (the Maturation Date) following the principle of a standard convertible note, but without any interest accruing. The total value of EIT Health`s investment shall be the total amount of the grant paid to the enterprise. Further details can be found in the template Term Sheet below.

## Grant to Options to Equity Term Sheet

### Participation of EIT Health e.V. (hereinafter "KIC LE") in Company

This term sheet (**"Term Sheet"**) summarizes the principal terms of a potential participation of EIT Health e.V. in the Company (as defined below). It is for information purposes only, and there is no legally binding obligation on the part of any negotiating party until definitive agreements are signed and delivered by all parties. This Term Sheet does not constitute an offer to sell nor an offer to purchase securities in the Company.

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| **Preamble** | The Company (in the following the "**Company**"; KIC LE and Company jointly the "**Parties**" and each a "**Party**") has been accepted as a participating company to KIC LE´s THI Instrument ("**THI**"). THI is an instrument which aims at boosting the European healthcare ecosystem by enabling breakthrough projects that can significantly transform health and care in Europe.<br><br>Within THI KIC LE is committing to support the development of the Company by granting funds that shall be spend towards an innovation project (the **"Project"**), in accordance with terms and conditions of the |

EIT Grant Agreement and the Project Grant Agreement. The Project shall be completed by December 31st, 2025 at the latest.

In return for the support of the Project, KIC LE shall be entitled to participate in the Company on the terms and conditions set out in this Term Sheet.

Based on this Term Sheet, the Parties and the shareholders of the Company intend to enter into binding agreements (the **"Binding Agreements"**).

**Current Valuation**

Prior to the conclusion of this Term Sheet the Company raised a financing round (the **"Current Financing Round"**) with a post money valuation of EUR [●] (the **"Post Money Valuation"**).

The current valuation of the Company (the **"Current Valuation"**) shall be:

- The Post Money Valuation if the Current Financing Round was concluded after 01 April 2024
- The Post Money Valuation plus a premium of 10%, if the Current Financing Round was concluded after 30 September 2023 and before 01 April 2024
- The Post Money Valuation plus a premium of 15%, if the Current Financing Round was concluded after 1 January 2023 and before 30 September 2023.

**Investment**

KIC LE is committed to support the Project by granting funds to the Project in the total amount of up to EUR 500,000.00 (the **"Investment"**). The payout mechanism will be regulated by separate agreements (such as the Project Grant Agreement and the Financial Support Agreement).

The grants shall be paid out in tranches according to the agreed timetable and, further, according to annual plans to be agreed prior to the respective year and annual reports to be reviewed after the respective year.

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| **Participation of EIT Health** | In return for the Investment KIC LE shall get an option, which is convertible into shares of the Company upon the occurrence of certain triggering events as further set forth in this Term Sheet (the "**Option**"). |
| **Term** | The Options shall mature on 15 January 2027 (the **"Maturity Date"**). |
| **Mandatory Conversion** | **1. Upon Qualified Equity Financing Round**<br>If the Company consummates a Qualified Equity Financing Round (as defined below), then the Investment will be mandatorily converted into the highest category of shares of the Company at the conversion price which is equal to the lower of:<br>- the price obtained by dividing the Current Valuation by the Company's Fully Diluted Shares immediately prior to the relevant Qualified Equity Financing Round, and<br>- 100% of the subscription price paid (and not set off) by the investors in such Qualified Equity Financing Round if completed within 6 months from the date of the conclusion of Binding Agreements or 80% if completed thereafter;<br>A "**Qualified Equity Financing Round**" shall mean the next *bona fide* share capital increase during which new shares of the Company are issued against cash in an overall amount equal to or exceeding EUR 4.000.000,00 (including agio) to existing or new investors, excluding any and all indebtedness that is converted (such as convertible loans).<br>"**Fully Diluted Shares**" shall mean all issued shares of the Company together with all option or conversion rights of any kind (whether vested or not and including any authorized but unallocated rights) on an as-converted-basis (but excluding the effects of the conversion of the Option.<br>2. **Upon Change of Control**<br>If the Company consummates a Change of Control (as defined below), then the Investment will be mandatorily converted into the highest category of shares of the Company at the conversion price which is equal to the lower of: |

- the price obtained by dividing the Current Valuation by the Company's Fully Diluted Shares immediately prior to the Change of Control event, and
- 100% of the price per share agreed upon in the context of the Change of Control event if completed within 6 months from the date of the conclusion of Binding Agreements or 80% if completed thereafter

**"Change of Control"** means:

a) the acquisition of more than 50% of the Company's outstanding Shares by any person or entity in any transaction or series of related transactions (other than as a result of bona fide equity financing purposes (including, but not limited to a Qualified Equity Financing Round or Non-Qualified Equity Financing Round); or

b) a merger, spin-off or other type of restructuring in which the holders of the voting securities of the Company outstanding immediately prior to such transaction retain less than the majority of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such transaction; or

c) a sale, lease, transfer, exclusive license or other conveyance of all or substantially all of the assets of the Company in an arms' length transaction (other than to a wholly owned subsidiary of the Company or to a parent of the Company).

**Voluntary Conversion**

**1. Upon a Non-Qualified Equity Financing Round**

If, prior to the Maturity Date, the Company consummates an equity financing round that does not qualify as a Qualified Equity Financing Round (a "**Non-Qualified Financing Round**"), then KIC LE may request a conversion at the conversion price as applicable to a Qualified Equity Financing Round (however with the valuation of the Non-Qualified Financing Round).

**2. Upon Maturity Date**

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| | Upon Maturity Date the Investment may be converted within 60 calendar days of the Maturity Date if such conversion is requested by KIC LE. The conversion price shall be the lower of<br>d) the price obtained by dividing the Current Valuation by the Company's Fully Diluted Shares immediately prior to the conversion, or<br>e) the price obtained by dividing the valuation of the last Non-Qualifying Financing Round by the Company's Fully Diluted Shares immediately prior to the conversion. |
| **Implementation of Conversion** | The mandatory or voluntary conversion shall be implemented at the Maturity Date at the earliest, i.e. KIC LE becoming a shareholder of the Company at this date at the earliest, except upon a Change of Control where the Investment shall convert immediately prior to the event. |
| **Financing Right** | KIC LE shall have the right to invest in one of the next financing rounds of the Company up to an additional EUR 500,000.00 at the conditions of the respective financing round. |
| **Compensation Right** | Prior to the conversion of the Option, the Company is entitled but not obligated to settle all claims of KIC LE by paying the Investment Amounts multiplied by 4.0 to KIC LE. |
| **Representations and Warranties** | Customary representations and warranties of the Company to KIC KLE. |
| **Information and Reporting Rights** | KIIC LE shall get standard information rights of an investor and in addition reporting rights required for the controlling of the grants. |
| **Indicative Timeline** | Binding Agreements shall be signed by [●].<br>First payout shall be [●]. |
| **Confidentiality** | This Term Sheet is confidential and may not be disclosed to any party other than a party to this Term Sheet and its employees and legal advisors. |
| **Definitive Agreement** | The KIC LE will provide the Company with the first draft of the Binding Agreements in the English language upon selection. The Binding |

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| | Agreements will be modified to comply with the local law governing the contract. The Binding Agreements shall be signed by the Company, the Founders and all other shareholders of the Company. |
| **Governing Law** | The definitive documentation relating to the participation of KIC LE shall be governed by the laws of [the country the Company is incorporated in]. |
| **Most Favored Nation** | If the Company previously or subsequently to the Option has granted or grants terms to another investor that are more favorable for the respective investor than the ones agreed with KIC LE, such more favorable terms shall equally apply to KIC LE, unless such equal treatment is explicitly waived by KIC LE. |
| **Legal Fees and Expenses** | Each Party shall bear its own costs and expenses arising out of or incurred, and any taxes and fees imposed on it, in connection with the Binding Agreements and all transactions contemplated thereby. |