EIT Health Call Document

IPCEI Med4Cure: The Re-Industrialisation of Europe Flagship Call 2025 (EIT Health Support to IPCEI Med4Cure)

14 August 2024

Change log

ID	Date	Document	Page	Description
1	17/09/2024	Grant to Options	Whole document	The provisional Grant to Options agreement removed from annexes. All hyperlinks now point to the final Grant to Option agreement.
2	27/09/2024	Call document	13 - 14	**Conditions to receive funding**. Membership requirements receive funding updated.
3	27/09/2024	Supporting documents Financial templates		Financial templates updated and support video updated.

Introduction

As an external contributor to Important Projects of Common European Interest (IPCEI) with a mandate to accelerate and provide complementary support to projects supported by Med4Cure, **EIT Health** is pleased to announce the launch of the "**The Re-Industrialisation of Europe" Flagship call**.

This Flagship aims at:

i. equipping Europe with a strong, innovative, and export-friendly healthcare industry that can meet the challenges posed by the future of medical care and

ii. developing lasting and innovative European manufacturing capabilities regarding critical products, notably pharmaceuticals.

This funding opportunity is designed to provide short term support to the ongoing workstreams and projects of IPCEI Med4Cure, with activities that can lay the groundwork for their long-term success, impact, and sustainability.

EIT Health seek proposals that demonstrate a clear plan for implementation within **one year**, with measurable outcomes that will significantly contribute to the main objectives of Med4Cure projects. Selected proposals will receive financial support to undertake activities that are complementary and integrated with the Med4Cure projects and will be evaluated based on their alignment with Med4Cure's strategic goals, their feasibility, and their potential impact in the short term.

This document and the supporting documents provide the necessary information about the objectives and scope, eligibility criteria, submission guidelines and evaluation process.

About Important Projects of Common European Interest (IPCEI)

Important Projects of Common European Interest (IPCEI) are based on Article 107(3)(b) of the Treaty on the Functioning of the European Union (TFEU). This legislation allows EU Member States to collaboratively fund and implement an important project of common European interest, or to remedy a serious disturbance in an economy of a Member State that may be considered compatible with the internal market.

IPCEIs are Member State-led, cross-border programmes that work on innovation and infrastructure projects that can contribute significantly to the achievement of EU strategies and generate positive spill-over effects benefiting the EU economy and its citizens at large beyond the participating Member States.

IPCEIs are funded from national budgets. Therefore, Member States are responsible for identifying the scope of the project, to select participating companies (preferably following open calls), and to

agree on project governance. The public support by Member States to the projects and companies participating under an IPCEI, which constitutes State aid under EU rules, must be notified to the Commission for assessment and approval. Once formally notified, the Commission assesses proposed projects for support under the IPCEI legislation. To qualify a project must:

- provide an important contribution to EU objectives;
- demonstrably overcome important market failures;
- involve at least four Member States, unless a smaller number is exceptionally justified by the nature of the project;
- be designed in a transparent and inclusive manner, providing all Member States a genuine opportunity to participate in an emerging project;
- deliver concrete positive spill-over effects benefiting the EU economy and society, beyond the participating Member States and companies;
- involve important co-financing by the companies that will receive State aid; and
- avoid negative environmental impacts due to failure to comply with the principle of 'do no significant harm' that are unlikely to be outweighed by sufficient positive effects.

Since 2018, the Commission has approved State aid for at least one integrated Important Project of Common European Interest (IPCEI) each year. There are ten IPCEIs approved so far, nine of these IPCEIs concern predominantly research and development as well as projects of first industrial deployment.

About IPCEI Med4Cure

In March 2022, 16 Member States signed a joint Manifesto towards a health IPCEI, in which they stated their support for an IPCEI concerning innovation in production technologies of medicines, tackling antimicrobial resistance, rare diseases and emerging health threats, and the development of cell and gene therapies. In May 2024, the European Commission approved **IPCEI Med4Cure**. This is the latest IPCEI to be approved, and the first IPCEI to support research, innovation and the industrial deployment of healthcare products and innovative production processes for pharmaceuticals.

IPCEI Med4Cure aims to accelerate medical advancement and foster the resilience of the EU health industry by enhancing drug discovery. The project focusses on unmet medical needs such as rare diseases and developing innovative and more sustainable production processes for pharmaceuticals. These developments will improve the quality of healthcare and increase the EU's preparedness for emerging health threats while contributing to the green transition.

Med4Cure was initiated by six Member States: Belgium, France, Hungary, Italy, Slovakia, and Spain. These Member States will collectively provide up to €1 billion in public funding, which is expected to unlock an additional €5.9 billion in private investments.

Thirteen companies, including nine small and medium-sized enterprises (SMEs), will undertake **14 highly innovative projects as part of this IPCEI**. The 14 projects are part of the wider IPCEI Med4Cure ecosystem, which also involves **11 associated partners.** These projects **aim to develop technologies that go beyond what the market currently offers** and allow major improvements in diagnosing and managing rare diseases, antimicrobial resistance, and cancers. The companies carrying out these projects span the entire pharmaceutical value chain, from the collection and study of cells, tissues, and other biological samples to the development of sustainable production technologies for breakthrough therapies, including personalised treatments. The application of advanced digital technologies will also be a key component of these projects. **Figure 1** below provides a graphical representation of the Med4Cure structure.

IPCEI Med4Cure will complete in 2036, with timelines varying based on the individual projects and companies involved. According to the participating Member States, around 6,000 direct and indirect jobs are expected to be created through this initiative.

Each of the 14 projects approved by IPCEI Med4Cure encompasses activities spanning one or several defined workstreams with clearly pre-defined goals. Details on the defined workstreams and activities can be found below in this document.

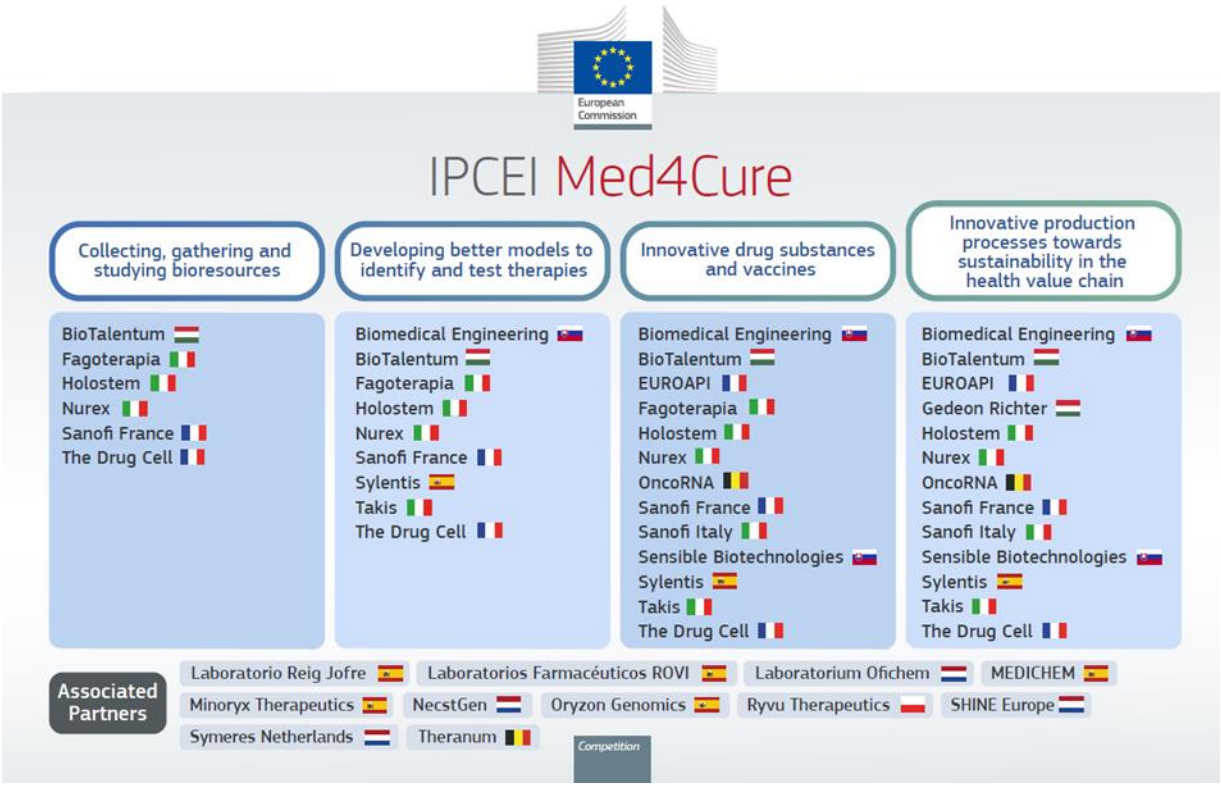

Figure 1. IPCEI Med4Cure Structure

About EIT Health

EIT Health is one of the Knowledge Innovation Communities (KICs) of the European Institute of Innovation and technology (EIT). EIT Health a community with a unique complementarity of public, private, academic and innovation partners alongside private investors, combining their strengths and assets to drive higher quality healthcare solutions for all and support the transformation of the health economy in Europe.

EIT Health's focus on innovation, entrepreneurship, and the education of future healthcare professionals, combined with substantive investments from our partners, uniquely positions us to catalyse the development and implementation of transformative solutions[1].

EIT Health's areas of expertise strongly support and complement the ambitions of the IPCEI namely through:

- Accelerating needs-based health innovations to achieve wide market uptake in Europe.
- Increasing the value and impact of EU-based SMEs in the health and healthcare sector to compete at global level.
- Supporting health care providers and professionals to transform care towards outcomes that have the highest impact and are of most importance to patients.
- Impacting and driving healthcare innovation policy in Europe based on evidence, learnings, and experience from EIT Health activities.

EIT Health provides a European network of partners across business, academia and research (the Knowledge triangle), and a proven delivery mechanism to support competitiveness and innovation in the health care sector.

[1] https://eithealth.eu/who-we-are/

Objectives and Scope

The selected projects will deliver innovative solutions that provide immediate, tangible benefits and foundational support to the IPCEI Med4Cure workstreams, setting the stage for continued progress beyond the initial grant period of one year.

In alignment with EIT Health's goal of supporting and accelerating the market uptake of healthcare innovations, we will be looking to support up to 8 proposals. Proposals are to be submitted by a consortium built between **IPCEI Med4Cure Direct or Associated Partners**, **academia or healthcare providers** and **micro-small enterprises**.[2] Submissions should demonstrate how they support the different workstreams of the selected IPCEI Med4Cure projects. EIT Health will be looking to fund innovative solutions and technologies in the areas of digital tools, personalised medicine, and green manufacturing.

Selected projects will receive a **grant of up to € 1million per project** and must utilise the financial resources by **31 December 2025**. The funding rate for the call is set at **50%**. The co-funding structure is designed to ensure commitment and investment from the participants, thereby fostering a more substantial and engaged partnership in achieving the objectives of the IPCEI Med4Cure initiative.

Project consortia should consist of one IPCEI Med4Cure direct partner or associated partner, one micro or small enterprise, and at least one academic organisation (research institute, university, hospital) or healthcare service provider. See the eligibility criteria for further details.

The funded activities are expected to result into B2B partnerships between selected IPCEI Med4Cure partners and micro/small enterprises that foster the launch to market of technologies and solutions that enhance the competitiveness of industrial processes in the health and pharmaceutical industries. It is expected that these partnerships lead to a successful market commercialisation of the proposed solutions no later than one year after the end of the EIT Health grant period. Projects must be prepared to work with this short timeline.

[2] The companies leading the 14 projects already approved into Med4Cure are referred to as IPCEI Direct Partners or Associated Partners.

Specific Activities

There are four IPCEI Med4Cure workstreams:

A. **Collecting, gathering and studying bio-resources.**
B. **Tools for better understanding disease biology and increasing medical translatability.**
C. **Processing innovations through enhanced, drug discovery, preclinical and clinical procedures.**
D. **Innovative production processes and tools towards sustainability and resilience across the health value chain.**

EIT Health invites applicants to submit proposals for innovative solutions that complement the activities of the IPCEI Med4Cure projects in the above workstreams. Proposed solutions can be in the areas of **digital tools, personalised medicine, and green manufacturing.** These categories have been selected to address the diverse and critical needs of Med4Cure projects and partners, ensuring a comprehensive approach to innovation and development.

The table below highlights the types of activities that align with EIT Health strategic objectives and requirements, providing some specific examples of activities within each thematic area as guidance. However, EIT Health **remains open to receiving proposals for other complementary and integrated activities** that meet established criteria and are aligned with the four IPCEI Med4Cure workstreams.

EIT Health encourages submissions for robust, innovative and validated solutions that demonstrate a strong market uptake potential, relevant fit with the IPCEI Med4Cure projects. By welcoming a broad range of activities, we aim to foster a collaborative environment that advances the IPCEI Med4Cure collective goals.

EIT Health Thematic areas	IPCEI Med4Cure Workstreams matching	Example Complementary Activities.
DIGITAL TOOLS: **Databases, tools to facilitate the use of clinical data, predictive model, federated data, in silico tools, etc.**	A. COLLECTING, GATHERING AND STUDYING BIO-RESOURCES. B. TOOLS FOR BETTER UNDERSTANDING DISEASE BIOLOGY AND INCREASING MEDICAL TRANSLATABILITY.	*Bioinformatics and Data Analytics Platforms: Pilot a bioinformatics tool to manage and analyse initial datasets from biobanks, ensuring early functionality and usability.*
		In-Silico Drug Discovery: Develop computational models and simulations to predict the efficacy and safety of drug candidates, reducing the need for extensive laboratory testing.
		(…)

EIT Health Thematic areas	IPCEI Med4Cure Workstreams matching	Example Complementary Activities.
PERSONALISED MEDICINE: **Diagnostic and early diagnostic, tools to facilitate improvements on current practices, AMR monitoring, genetic diversity, etc.**	B. TOOLS FOR BETTER UNDERSTANDING DISEASE BIOLOGY AND INCREASING MEDICAL TRANSLATABILITY. C. PROCESSING INNOVATIONS THROUGH ENHANCED, DRUG DISCOVERY, PRECLINICAL AND CLINICAL PROCEDURES.	*Translational Research Models: Develop new organ-on-chip technologies to better replicate human disease conditions and improve the predictability of pre-clinical studies.*
		High-Throughput Screening Technologies: Develop/setup of high-throughput screening equipment. Provide training for researchers on using this equipment effectively to test a large number of compounds rapidly.
		(…)
GREEN MANUFACTURING: **Bioproduction tools, innovative production, digitalisation of production lines, etc.**	D. INNOVATIVE PRODUCTION PROCESSES AND TOOLS TOWARDS SUSTAINABILITY AND RESILIENCE ACROSS THE HEALTH VALUE CHAIN.	*Sustainable Manufacturing Innovations: Feasibility study or pilot project to explore and implement sustainable practices/tools in pharmaceutical production, such as energy-efficient processes or water recycling systems.*
		Green Chemistry Initiatives: Develop and implement green chemistry protocols/tools to minimise the environmental impact of pharmaceutical manufacturing processes, including the reduction of hazardous waste and the use of renewable resources.

Table 1. Examples of complementary and integrated activities (non-exhaustive list) that could be supported by this call for proposals.

Activities that are outside the scope of this call

While EIT Health welcomes innovative and strategic proposals that align with the IPCEI Med4Cure workstreams, certain activities are out of scope for this call due to their complexity and the limited timeframe of a one-year grant.

Therefore, **projects that involve long-term clinical trials, extensive regulatory approval processes, large-scale manufacturing setups or molecule development will not be funded**. This is because significant value creation milestones on such projects cannot be achieved within the timeframes of this call.

Purely administration software development is out of scope.

Software development projects will be considered only in the following two development cases:

- Software with a direct medical application and patient focus, to enhance data collection, improve patient engagement or facilitate adjustments in Med4Cure clinical trials or effectiveness and safety studies.
- Non-clinical software playing critical role in the improvement of drug discovery, development and manufacturing context, facilitating and sharing clinical data for secondary use which are integral to the healthcare sector but may not directly interact with patients.

Call summary

IPCEI Med4Cure Complementary activities	
Goal	Financing complementary and integrated activities that support and enhance the main workstreams of the 14 Med4Cure approved projects.
Description	Complementary and integrated activities that can provide significant impact within a short timeframe (**one-year grant period**) while still supporting the main workstreams of Med4Cure, providing substantial support and progress, laying the groundwork for long-term success and impact (Med4Cure projects will last around 5-7 years). To be considered for this call, proposed solutions **must have a minimum Innovation Maturity Level IML 7 (Validation of Solution)** and demonstrate how the funding will be utilised to reach the market within 1 year after the end of the project.
KPIs	Mandatory: • **KPI EITHE01.1** The activity must aim at protecting innovative solutions through filing of patents, trademarks, registered designs, copyrights, etc. • **KPI EITHE02.4** The activity must aim at introducing and scaling products to the market during the activity duration or within one year after the EIT Health financial support ends with a minimum of 10K€ revenues. The activity must prioritise EU markets over other markets. • **At least one CUST KPI** *(*See IMPACT section)*
Consortium	The project consortia **must include**: One IPCEI direct partner/associated partner, one micro or small enterprise, and at least one academic organisation (research institute, university, hospital) or healthcare service provider.
Financial Sustainability	The micro or small enterprise **must sign a financial sustainability agreement** based on the "Grant to Option" financial model if the project is granted.
Reimbursement rate	• A **50% co-funding rate per project** is required. • It is expected -but not required- that the 50% co-funding is brought by the IPCEI direct partner/associated partner involved in the consortium, coming from activities already funded in the 14 approved Med4Cure projects and assigned to the IPCEI direct partner/associate partner.
Grant period	Eligibility of costs timeline: **1 January 2025 - 31 December 2025**
Indicative Grant Amount	A maximum grant of up to **1 M EUR** per project is available. The micro or small enterprise's grant is of a minimum of 400K€ and a maximum of 500K€.

Eligibility Criteria

General conditions to receive funding

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

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] [6].

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 partners of selected activity consortiums who will only be eligible to receive fundingafter 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 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-

[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 consortia 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 is currently not an associated country of the Horizon Europe programme. As such, Swiss entities are not directly eligible to receive EIT funding, when part of a selected project consortia. Entities can receive up to €60,000 in EIT funding within the EIT Health Business Plan 2023-2025. However, for funding above €60,000 organisations need to refer to the Swiss national reimbursement scheme. In the current non-associated third country mode, researchers and innovators in Switzerland are funded directly by the Swiss Confederation if the complete project proposal has been positively evaluated. Further information is available on the State Secretariat for Education, Research and Innovation (SERI) of Switzerland or by reaching out to the EIT Health Germany-Switzerland Co-location Centre.

[6] Due to a decision by the Council of the European Union, published on and effective as of 15 December 2022, certain Hungarian "public trust foundations" are currently not eligible to receive funding under the Horizon Europe and Erasmus programmes. These Hungarian entities can still participate without receiving EIT funding, as an Associated partner, if allowed by the call conditions. Further information can be found on the EU Commission Funding and Tenders FAQ website. EU Commission Funding and Tenders FAQ website.

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.

EIT Health encourages the participation of entities from the EIT Regional Innovation Scheme 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 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 EUR 6,000,000.

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.

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

General conditions to participate in the call

- Each consortium must include participants residing in at least **two eligible countries**, participating through **two different Co-Location Centres** (CLCs)[5].
- Each consortium must involve organisations from **two sides of the Knowledge Triangle**, e.g., industry and healthcare provider, higher education institution and industry, etc.
- Each consortium 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). A communication, dissemination and outreach plan is required for each activity, including those providing financial support to third parties.
- Each consortium 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.
- The final recipients of funding must comply with the **IPR rules** under the MGA Article 16.

Consortia conditions

Proposals applying to this call must be led by a **consortium that includes an IPCEI Med4Cure direct partner or associated partner**. This ensures that the proposed activities are well-integrated with the existing projects and contribute effectively to the overall goals of IPCEI Med4Cure. The IPCEI Med4Cure direct partner or associated partner will not receive funding from EIT Health.

Project consortia must be structured to include a diverse range of participants to ensure a comprehensive and multidisciplinary approach to the objectives of the call, ensuring representation

from all sides of the knowledge triangle (business, education and research). The consortia must include:

- **One IPCEI Med4Cure direct partner or associated partner**: This inclusion is crucial for aligning the consortium's efforts with the overarching goals and strategic directions set forth by the IPCEI Med4Cure project. The IPCEI Med4Cure Direct Partners and Associated Partners can be found listed below.
- **One Micro or Small Enterprise,** that will be responsible for bringing and integrating the innovative solution or technology with the IPCEI Med4Cure project (see thematic areas outlined below) and will lead the commercialisation of the solution in the market. The enterprise will be granted with a minimum of 400K€ and a maximum of 500K€.

  The following requirements shall apply to micro and small enterprises applying as a commercialisation entity:

  - The entity is a for-profit micro or small enterprise according to the EU definition
  - The entity must bring a relevant, validated and market-ready technology or solution to the Med4Cure project at an IML 7 or 8 (Innovation Maturity Levels: IML 7 – Validation of Solution, IML 8 – Approval and Launch). If applicable, Phase 3 clinical trials should be completed and/or CE mark should be granted.
  - The entity must have at least 4 paid FTEs (Full Time Equivalent) working at the time of the proposal submission. The entity must have a CEO working full-time in the small and micro enterprise at the time of the proposal submission, where full-time refers to the legally mandated number of hours for a full-time occupation in the country where the entity is incorporated.
  - The entity cannot have publicly traded shares or gone through an IPO.
- **At least one academic organisation (research institute, university, hospital) or healthcare service provider**: The involvement of these organisations ensures that the initiatives maintain a strong focus on public interest, social impact, and community engagement.

By mandating the inclusion of these three types of participants, each element of the Knowledge Triangle (business, education and research) is included and creates a balanced and effective consortium.

Co-Funding conditions

A **50% co-funding rate per project** is required. Any co-funding for the EIT funded project must not be sourced from European Commission funds and must come from other sources, such as Member State funds, or other funds. EIT Health funding for this call comes from the European Commission and this approach is **necessary to avoid double funding.** Both the associate partner and the consortium must ensure that co-funding meets this key eligibility requirement. See **Figure 2** below for a graphical description.

For the above-mentioned reason, we are encouraging co-funding by the **IPCEI Med4Cure direct partner or associated partner** mainly, but other sources of co-funding are welcomed, as long as double funding is avoided.

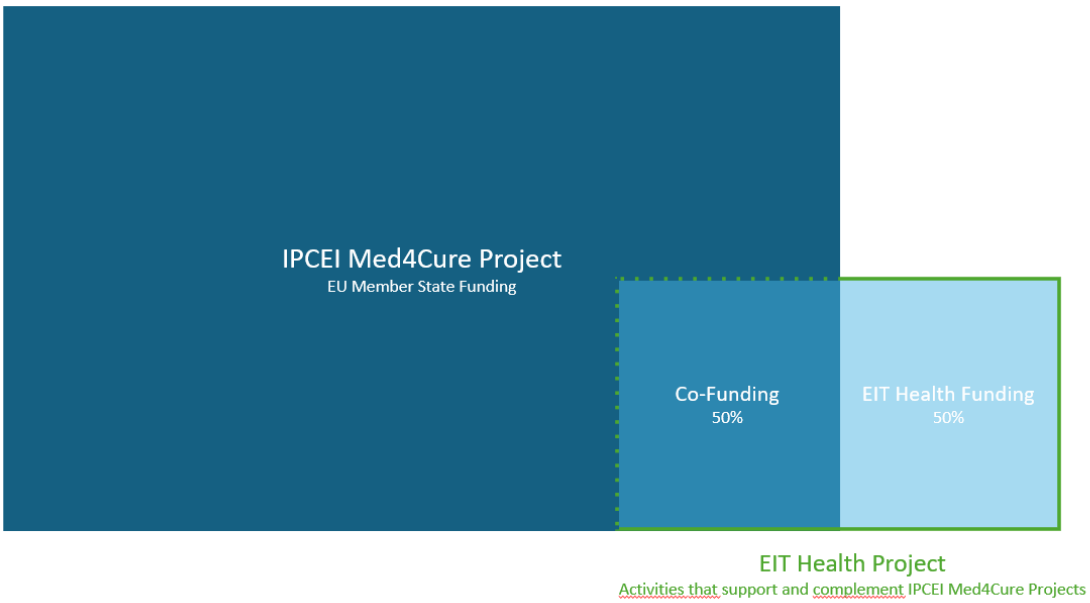

Figure 2. Co-funding representation for the activities supported in this call.

Project expected impact (key performance indicators)

The funded activities are expected to result into B2B partnerships between selected IPCEI Med4Cure partners and micro/small enterprises that foster the launch to market of technologies and solutions that enhance the competitiveness of industrial processes in the health and pharmaceutical industries. It is expected that these partnerships lead to a successful market commercialisation of the proposed solutions no later than one year after the end of the EIT Health grant period. Projects must be prepared to work with this short timeline.

The following key performance indicators (KPIs) are mandatory:

- The activity must aim at protecting innovative solutions through filing of patents, trademarks, registered designs, copyrights, etc. **(KPI EITHE01.1)**
- The activity must aim at introducing and scaling products to the market during the activity duration or within one year after the EIT Health financial support ends with a minimum of 10K€ revenues. The activity must prioritise EU markets over other markets. **(KPI EITHE02.4)**
- Each consortium 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 and at least two SDGs that the activity will contribute to.

- Each consortium must contribute to the promote gender equality in innovation and technology. Therefore, at least one customised KPI should be added that proves how the project will contribute to it.

All points described above are expected to be demonstrated through dedicated KPIs (core KPI, EIT Health KPI, or custom KPIs), milestones and/or deliverables at the proposal submission stage and shall be documented by annual reporting. Please see the supporting documents for the full list of EIT Health KPIs and the reporting requirements.

Financial sustainability and revenue generation

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 and will be required to enter into a Financial Sustainability agreement. This agreement establishes a framework for responsible financial management, where beneficiaries are obligated to sign the Financial Sustainability agreement, acknowledging their commitment to adhere to the specified EIT Health financial model.

The "Grant to Option" model is designated as the financial sustainable model for micro and small enterprises responsible for introducing the product or service to the market. Please find further information about the "Grant to Option" model in the supporting documents.

EIT Health does not claim ownership of the intellectual property (IP) generated in the funded projects. The ownership of IP remains with the beneficiaries who create the results, in accordance with the guidelines established by Horizon Europe.

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 **individual** 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.

Proposal Submission deadline is set for **15 October 2024**, **4 pm CEST**.

Evaluation process overview

The selection process for this call will involve a single proposal submission, followed by two critical stages. The first stage entails an invitation to hearings, contingent upon passing the eligibility checks. Please refer to the eligibility criteria detailed above. The first stage considers the quality of the project. Successful applications will proceed to the second stage, which involves a due diligence evaluation. This process considers the investment potential in the small and micro enterprise (aka 'the start-up') exclusively. This evaluation is carried out by senior leadership experts in EIT Health and external experts and consultants.

Proposals that successfully navigate these two critical stages will be the only ones considered for funding. To go through the critical stages a minimum score of 70 / 100 is required to pass through to each stage, and to be considered for funding.

Evaluation Process step	START DATE	END DATE
Call document published	14 August 2024	
Call webinar Q&A	4 September 2024, **11.00 CEST**	
Call open	14 August 2024	15 October 2024
Matchmaking platform open	14 August 2024	15 October 2024

Evaluation Process step	START DATE	END DATE
Matchmaking event, Online pitching session	5 September 2024, **13.00 – 14.00 CEST**	
Matchmaking event, Online pitching session	6 September 2024 **13.00 – 14.00 CEST**	
Matchmaking event, Brussels	12 September 2024, **13.30 - 17.30 CEST**	
Call closed	15 October 2024, **16.00 CEST**	
Eligibility check notification and invitation to Hearings (if applicable)	18 October 2024	
Due Diligence Documentation presentation period	18 October 2024	28 October 2024
Hearings	28 October 2024	30 October 2024
Hearings notification	4 November 2024	
Due diligence process begins	4 November 2024	
Selection notification	19 December 2024	
Project start	19 January 2025	

Table 2. Timeline

Matchmaking

To facilitate consortium composition, networking, and ensure the highest quality of proposals, EIT Health will offer a free online matchmaking platform service. This service will open at the same time as the call publication date and close at the call deadline date. If you would like to participate, please register on the match making platform.

Register on the match making platform here

Call webinar Q&A – 4 September 2024, 11 am – 12pm

Prospective applicants are invited to attend an online webinar Q&A to hear more about the call and to ask any questions you may have. You can access the webinar by clicking on the below link:

Attend the webinar

Meeting ID: 381 456 393 347

Passcode: xUaBnJ

Online pitching sessions – 5 to 6 September 2024
The Med4Cure Direct and Associated partners will be invited to present their projects, to allow the community to get to know their projects.

The relevant startups will also have the opportunity to pitch during these online sessions. If you would like to participate, please register on the match making platform.

Register on the match making platform here

Face to Face Event – 12 September 2024

To support the kick-off of the "The Re-Industrialisation of Europe flagship 2024" matchmaking, an onsite event is organised to present the objectives of Med4Cure, explain the related call for projects and bring a 360° perspective on the initiatives related to biomanufacturing that could leverage on the IPCEI on health. All the IPCEI participants will be invited to attend the event, thus the sessions will be broadcast to allow wider participation and dissemination.

Date: 12 September 2024

Venue: EIT House, Rue Guimard 7 – 4th floor, Brussels, Belgium

If you wish to participate, please register on the match making platform

Register on the match making platform here

Eligibility check

Consortiums will be invited to submit a single proposal form (accessible through EIT Health's application platform).

All project details are expected at the submission date. The minimum requirements for applying (including eligibility criteria) are specified in the Eligibility Criteria section.

All eligibility criteria will need to be met for an application to progress to the application evaluation stage. Upon completion of the eligibility check, observations on the project and consortium partners may be communicated to the Hearings evaluators.

Hearings

Once an application has passed all eligibility checks, applicants will be invited to an online hearing which will take place between 28 and 30 October 2024. Details on the specific date and time of the Hearings will be timely communicated to shortlisted applicants.

Applicants will be asked to present their application to a panel of experts, who will then evaluate the application and proposal. The evaluation criteria and the relative weighting is detailed in the table below.

Projects will be scored out of 100. In order to proceed to the next stage, projects will need to score at least 70/100. If more than 16 projects score 70/100 or more, applications will be ranked by score, and up to the top 16 will be selected to move to the due diligence stage (see section below).

Final funding decisions will be based on the score at the hearings and passing the due diligence stage. Up to the top 8 applications that achieve 70/100 or more at the hearings, and also pass the due diligence stage will be selected for funding.

Evaluation criteria
1. EXCELLENCE AND STRATEGIC FIT (30%) • **Relevance and strategic fit with Med4Cure Objectives:** Proposals must clearly demonstrate alignment with the Med4Cure strategic goals and specific workstreams. • **Innovation novelty:** The proposed solution addresses a clear market need, backed by sound evidence and data, and brings a high degree of innovation and differentiation to the market compared to existing solutions
2. IMPACT AND SUSTAINABILITY (40%) • **Expected outcomes and impact:** Projects should clearly state their expected outcomes and explain how these will be measured. The potential for lasting benefits in the healthcare and pharmaceutical industries should be central to the project's intended impacts. • **Scalability potential and broader application:** There is a clear potential for future scalability and broader applications beyond the initial implementation. Projects that can easily integrate with existing healthcare/pharmaceutical systems or platforms, or projects that can be replicated or scaled up efficiently in different settings or geographies will be prioritised. • **Maturity level and market readiness:** Proposals must **demonstrate** the **sufficient maturity and market readiness levels to enable the product or service to reach the market within maximum one year after the project end.** T**he regulatory pathway to market and** required **certification(s)** are thoroughly explained**.** • **Commercial growth strategy:** The proposal must outline a credible growth strategy to ensure and increase market traction with a sustainable commercialization path. Business model aspects, financial projections and commercial strategy will be evaluated.

3. IMPLEMENTATION AND FEASIBILITY (30%)

- **Implementation Plan**: The proposed activities must be practical, with a clear and realistic implementation plan. The timeline should be detailed, indicating how objectives will be met within the one-year grant period.
- **Consortium Strength:** The consortium should include committed partners with relevant and complementary expertise, ensuring strong collaboration and effective execution of the project.
- **Budget and Resource Allocation:** The budget should be well-justified, showing efficient use of resources. A commitment to co-funding and effective resource allocation will be assessed.

Table 3. Quality evaluation criteria

Due Diligence

All micro and small enterprises acting as commercialising entities and applying to this call must go through a due diligence process to assess the small and micro enterprise's potential. EIT Health will select **up to 16 commercialising entities** associated with projects to undergo due diligence. To be considered for the due diligence process, projects must score a minimum of 70/100 at the Hearings evaluation stage. If more than 16 projects score 70/100 or more, EIT Health will rank projects by their evaluation score and select the top 16 to pass through to the due diligence stage. Companies that fail to pass due diligence will be removed from the selection process.

The due diligence process comprises of a review by external due diligence consultants, and a review by investment specialists within EIT Health and external specialists. The process involves the following activities:

- Additional document request
- Team interviews
- Review by external consultants
- Review by EIT Health investment specialists
- Alignment meetings between EIT Health senior management and external consultants.

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. The documentation will be requested during the period from 18 - 28 October 2024. Failing to provide the documentation after the given 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). The below list explains which documents must be included. The EIT Health application platform provides further details on what is required.

- 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)
- CVs of the founder, managerial team and board members
- Business supporting documents:
  - Legal Self-Assessment Certificate and documentation upon request
  - Supporting documents regarding IP, technology ownership, partnerships, exclusivity rights, regulatory approvals
- Financial supporting documents:
  - Historic financial information
  - Financial projections, ownership structure and value creation plan, in one Excel, with the financial summary using a specific template, see the supporting documents for the template.
  - Explanations to the projections and year-to-date financial traction
  - Financial agreements, historical changes of cap table and valuation calculations
  - Governance structure

Submitted documents will be treated as confidential. They will only be accessible to relevant EIT Health staff and/or independent third parties bound by confidentiality provisions (see paragraph below).

It is expected that EIT Health and the independent third party contracted by EIT Health will communicate directly with the micro and small enterprises during this process aiming to gain a comprehensive understanding of the small and micro enterprise and to finalize the due diligence.

The evaluative criteria of the due diligence is based on the financial sustainability requirements of EIT Health. The table below provides further detail on the evaluative criteria on which the due diligence conclusions will be drawn.

The outcome of the due diligence evaluation will be a score out of 100. Only applications that achieve a due diligence score of 70 or more will be considered for selection for EIT Health funding and to progress to the contracting stage.

Due Diligence criteria
1. Product • **Product scalability.** The product must be scalable in an economically viable manner. • **Technology maturity.** The technology used must be of sufficient maturity to be applied to a commercial product within a reasonable timescale. • **Regulation strategy.** A clear and realistic strategy must be in place to ensure the product is compliant with all required regulations. • **Product commercialisation strategy.** The small and micro enterprise must have a clear and feasible strategy to commercialise its product. • **Product design.** The product design must be innovative, with features that enhance functionality and usability. It must add significant value to the healthcare system and/or patients by addressing gaps and improving efficiency. • **Product portfolio strategy.** The small and micro enterprise must have a promising and feasible strategy to expand its portfolio, demonstrating plans for growth and diversification.
2. Market assessment • **Market competition.** The small and micro enterprise and product must have a reasonable lead on the relevant competition in the market to as part of its commercialisation strategy. • **Market demand.** There must be a clearly identified demand from the market for the product. • **Market size and growth.** There must be a considerable growing market for the small and micro enterprise to service and operate in.
3. Management team. • **Experience and capability.** The management team should possess relevant experience and demonstrated capability to support the small and micro enterprise's future growth.
4. Business model • **Revenue model.** The small and micro enterprise should plan for a feasible revenue model that is scalable, realistic and sustainable. • **Partnerships.** Partnerships or validated partnership opportunities validated by qualified documentation

Due Diligence criteria
• **Business milestones.** Milestones planned should provide added value to the small and micro enterprise and its current and future shareholders. • **Risk assessment.** Due diligence will look for an effective risk assessment, and effective risk mitigation strategies.
5. Governance • **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. • **Legal.** The small and micro enterprise's legal self-assessment should indicate no significant issues or concerns, ensuring compliance and minimizing potential legal risks.
6. Financials and Sustainability • **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 small and micro enterprise's long-term viability and growth objectives. • **Potential to realise the EIT Health financial sustainability mechanism.** Due diligence will look for a realistic value creation plan for the small and micro enterprise factoring in investor/commercial appetite.

Table 4. Due diligence evaluation criteria

Ethical, Legal, and Social Issues (ELSI) review

To de-risk the EIT Health portfolio, selected applications will be submitted for a review of an ethical, legal, or social issues (ELSI review) to ensure that any such considerations are clearly identified in the application and addressed. The feedback from the ELSI review will be shared with the selected candidates to ensure that can be incorporated in their project execution.

Final notification

Once all review stages are completed, applicants will be notified of the final result by e-mail. After final notification, a one month stand-still period will apply.

Projects will start 19 January 2025 and will be able to retroactively claim costs from 1 January 2025 and until 31 December 2025.

Contracting

Activities that are accepted for funding must execute a set of legal agreements (see the list below). Finalisation of the terms and conditions of such agreements will commence immediately after notification. It is expected that the contracting phase will last approximately three months. Release of funding is contingent on execution of all agreements, but activities will be able to claim costs retroactively from the notification date which is the earliest date that activities can start.

The legal documents that will need to be signed are the following:

- **Internal Agreement (IA)** which is transposing the provisions of the Partnership agreement between EIT and EIT Health and the **Financial Support Agreement (FSA)** which is outlining the conditions for receiving financial support from EIT Health.
- **Project Grant Agreement (PGA)** which is the basis to govern the relationship between the EIT Health and the consortium in one specific activity as well as the relationship amongst the parties in this activity.
- **Financial sustainability agreement** is the agreement between EIT Health and the commercialising entity that governs the financial sustainability model - Grant to Options - implemented in the activity. See the supporting documents.

Further information on contracting as well as pre-financing rates and timing of (balance) payments can be found in the Implementation Handbook in the supporting documents.

Monitoring and reporting

All activities are subject to a formal review once a year. This review is a go/no-go point for the continuation of the activity and its EIT funding. The annual review aims to either fast-track, support, redirect, or stop the activity in cases of improper implementation or severe underperformance.

Post-funding monitoring will also be required for up to five years after activity closure to capture impact that exceeds the activity lifetime and contributes to the EIT Health Strategic Agenda and Horizon Europe indicators. Post-funding monitoring will, in most cases, be light touch. 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 General Model Grant Agreement.

Confidentiality and conflict of interest

All proposals submitted through the application platform are accessible only to EIT Health staff members for the processing of the application, and the Master Contact of each Partner, as well as the persons designated during the proposal phase.

During the selection process, proposals 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.

In addition, EIT Health may give access to the submitted data to sub-contractors who are tasked with maintaining the application platform and the Plaza system.

All such third parties are also bound by confidentiality provisions.

EIT Health staff are bound by the policy on conflicts of interest which is part of EIT Health's Code of Conduct.

Staff of EIT Health Partners are not involved in the evaluation process of the proposals. Furthermore, members of the EIT Health Supervisory Board may be involved in proposals and activities, but this must be declared in the EIT Health Supervisory Board annual Conflict of Interest Declaration. EIT Health Supervisory Board members must not lead on any proposal or activity, in accordance with EIT Health's Conflict of Interest policy

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 proposal(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 during 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 a proposal or 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

EIT Health has pan-EU representation via eight Co-Location Centres (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 proposals, or to find out how to participate, please contact your Co-Location Centre (CLC) / InnoStars.

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

For applications by non-Partners without CLC affiliation, please contact support in the regions according to the table below:

Hub	Affiliated countries
Austria	Austria
Belgium-Netherlands	Belgium, Luxembourg, Netherlands, Israel
France	France
Germany-Switzerland	Germany, Switzerland
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 in the supporting documents.