EIT Health Flagships Call 2025

Frequently Asked Questions (FAQs)

eit Health

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In this document you will find the most common questions answered relating to the EIT Health Flagships Call 2025. For your ease we have grouped these around common themes – if you have a question that is not covered here, please don't hesitate to reach out to your regional **Co-Location Centre**.

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GENERAL QUESTIONS

ELIGIBILITY

1. Are there any restrictions regarding resubmissions from previous calls? How many times can a project be resubmitted?

There are no restrictions for re-submissions.

2. There has been a development regarding the UK´s association to the Horizon Europe programme. Does this change UK Partners´ eligibility to receive funding from EIT Health in the Flagship Call 2025?

Yes, 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.

3. Are entities based in Switzerland eligible to receive EIT funding following a successful application to the Flagship Call 2024?

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.

4. Are all Hungarian entities eligible to receive EIT funding following a successful application to the Flagship Call 2024?

Due to a decision by the Council of the European Union, published on and effective as of 15 December 2022, certain Hungarian institutions designated as “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**.

FINANCIAL SUSTAINABILITY CONTRIBUTION

5. What are the different financial sustainability models, and how do you choose which financial sustainability model to apply?

There are two financial sustainability models used – the "Grant to Options" and the "Revenue Sharing" models. The choice on which model to apply depends on the size of the commercialising entity of the project.
The "Grant to Options" model is designated for micro and small enterprises, while the "Revenue Sharing" model is intended for medium enterprises, large companies, or any organisational entity responsible for introducing the product to the market that does not fall under the definition of a micro and small enterprise (SME).

All micro and small enterprises must go through a Due Diligence process to assess the company's potential and fit with the requirements of the "Grant to Options" model (please refer to page 36 of the Call Document) and the feasibility of implementing the "Grant to Options" agreement with the SME is evaluated by EIT Health's Investment Committee. The approval of the project is conditional on the approval by the Investment Committee. The Investment Committee is composed of selected senior leaders from EIT Health and externally recruited members who are selected based on their experience and track record in health innovation investment.

In the case of the "Revenue Sharing" model, commercial entities are required to include a revenue sharing financial proposal at the time of submission of their full proposal. Guidelines are provided to ensure the financial proposal is aligned with EIT Health's financial sustainability requirements. The proposal is reviewed during the selection process by EIT Health's Asset Management team.

MEMBERSHIP / CONSORTIUM

ELIGIBILITY

6. Can a proposal only be made with non-members of the EIT Health partnership?

No. Each consortium must have at least one EIT Health member (Core or Associate Partner) as part of the consortium at the time of submitting their application.

However, those activities requesting less than 50,000 EUR are exempt from this requirement.

7. For the evaluation process, does it make any difference if the application is submitted by an applicant outside of the EIT Health community?

The evaluation process is the same for all applications within the same activity type, regardless of whether they are members from within or outside the EIT Health community. There are eligibility rules on the overall consortium at proposal submission stage. A minimum of one EIT Health member, core or associate, is required, with the exception for applicants of activities requesting less than 50,000 EUR. It is highly recommended to contact various EIT Health members as early as possible to foresee what is feasible, secure their participation and construct solid consortia.

8. The call is now open to the participation of all entities (external EIT Health partners). Will external partners be able to lead projects?

Yes, non-EIT Health members can lead projects.

9. Can non-members of the EIT Health community secure as much funding as EIT Health Core/Associate Partners?

With the new regulation of Horizon Europe, non-members do not have a funding cap but must become members of the association if the proposal is selected and they apply to receive more than 50,000 EUR per year.

10. Does the minimum one EIT Health Partner mandatory per consortium also include external or network partners or must they be EIT Health Associate or Premium (core) partners?

Where applicable, the requirement of minimum one EIT Health partner refers to EIT Health Associate or Premium (core) partners. Therefore, each consortium must contain at least one EIT Health Association or Premium partner.

11. Can a research centre be the coordinator of a project proposal? Do you expect an industry Partner to coordinate the project, or it is sufficient for an industry Partner to be strongly involved and another partner to coordinate?

There are no rules on who should be the activity leader. It can be any member of the consortium. Usually, the activity leader is the member at the centre of the project, the member that is driving it. However, it is important to keep in mind that in all innovation projects, a product or service should be launched on the market. Therefore, if a research centre is the activity leader because it's driving the development of the solution, the role of the industry or of the commercialisation partner is crucial and should be clearly identified. The commercialising entity of the project must be included and clearly outlines in the proposal , regardless of who is the coordinator of the project.

12. Can a Swiss start-up apply and lead a project, especially if they are teaming up with other existing EIT Health Partners who do not want to lead?

Yes, Swiss entities can lead projects and are eligible to participate to the Flagship programme and receive funding from EIT Health up to 60,000 EUR over the 3 years' grant duration. If they wish to receive more than 60,000 EUR, they must either cover the cost themselves or take advantage of the Swiss Government financial guarantee and seek reimbursement from the Swiss State Secretariat for Education, Research and Innovation (SERI). Please see full details in the call document or reach out to the EIT Health Germany-Switzerland Hub for support.

13. Regarding Swiss entities, what happens to the option agreement?

There is no issue with entities adhering to the "Revenue Sharing" model. However, the "Grant to Option" model suited for micro and small enterprises is not feasible as EIT Health cannot take options for a grant that EIT has not provided (in this case, it would be SERI that would provide the funds).

In any case, the commercialising entity of the project must be identified at proposal stage, regardless of whether they come from the EIT Health community or not.

CALL BUDGET

GENERAL QUESTIONS

14. How many projects per Flagship and cut-off will be funded?

The number of potential funded activities is outlined in the call document. The concrete number of selected activities will depend on the quality of proposals received and the final available budget.

15. Are all funded projects able to request the same budget?

No. Budget specifics for each activity are detailed in the specific section of the call document.

ELIGIBILITY

16. Will projects have indirect costs? If so, what percentage?

Yes, the same percentage as in Horizon Europe - 25%.

17. Where can information be found regarding eligible costs for each call within the Flagship?

We follow Horizon Europe cost eligibility rules for all our programmes and activities. The Annotated Model Grant Agreement or AMGA is the backbone of all Horizon Europe grant agreements. Visit: **https://connections.eithealth.eu/guidance/financial-guidance** to download the AMGA, which provides the description of eligible costs for Horizon Europe projects.

18. If we wish to submit a proposal video to complement our application, can it be uploaded to the application platform?

It must be in English, a maximum duration of 5 minutes, mp4 format and a maximum size of 2GB.

INNOVATION TO MARKET & DIGINNOVATION PROGRAMME RELATED QUESTIONS

ELIGIBILITY

19. For innovation activities, the solution must be CE-marked, or be in the process of receiving the CE-mark at the time of proposal submission – what does this mean?

For Innovation to Market projects, the solution must either already have been granted CE-approval or be able to demonstrate that they have submitted their CE-mark dossier to a notified body at least 6 months prior to the proposal submission. This is to ensure the timely delivery of the solution to the market with the timeframe imposed by the Call. Applicants must upload proof of their regulatory approval status in the application platform.

For DiGinnovation projects, the solution is required to already have the CE-mark at the time of proposal submission.

More information about CE-marking can be found on the European Commission website here - **https://single-market-economy.ec.europa.eu/single-market/ce-marking_en**.

20. Regarding rare diseases, projects might have difficulties in achieving the number of patients involved set out in the criteria. How is this going to be handled?

The request that the final impact must reach 150,000 citizens/patients is mandatory but does not mean that it must be achieved during the first year of the project. High-impact achievement is a requirement for our project portfolio, so a solution must meet the requirement to achieve a specific and measurable impact.

For rare diseases, initiatives that can cover several conditions could potentially reach the target number three years after the project ends.

FINANCIAL AGREEMENT

21. Is the "Revenue Sharing" model a repayable loan?

No, it is not a repayable loan. EIT Health is supporting the innovation of the projects and taking on the risk that the solution may not be commercialised or the commercialisation takes place later than planned. Partners are committed to return the grant assigned to the project only if the commercialisation is successful. For Innovation to Market projects, the conditions of the "Revenue Sharing" model are defined by the consortium according to their plan, within the boundaries explained in the call proposal.

22. When the project ends, how will invoices be issued to the company once the payments are installed?

The exact mechanism of payment (invoice amounts, instalments) will be defined with EIT Health during the contracting phase (for projects accepted into the portfolio). Invoicing will be triggered accordingly following successful commercialisation of the project. The mechanism of invoicing (i.e., how exactly EIT Health will issue the invoices) is provided as grant funding - not a loan. Payments are returned on successful commercialisation only, and the terms of payment are defined and agreed by the consortium.

23. Is the revenue sharing model applicable to academic Partners?

The "Revenue Sharing" model is applied to the commercialising entity of the solution in Innovation-to-Market projects. This could be an academic or service provider too, if they are the Partner commercialising the product or service developed in those projects.

For education programmes, a specific revenue sharing agreement is defined and led by EIT Health where the common interest is also successful commercialisation. EIT Health will share the revenues at a fixed percentage agreed with the consortium once the full grant is returned to EIT Health for future reinvestment in other activities.

24. The call document states that micro and small enterprises applying as a commercialising entity must have at least 4 paid FTEs working in the company at the time of submission and CEO working full-time in the company. What does this mean?

It means that for micro and small enterprises applying, the company CEO must be fully dedicated to the company and working full-time in the company. The entity must have four full-time equivalent (FTE) paid employees working at the time of proposal submission.

25. When will the Due Diligence for micro and small enterprises take place?

The Due Diligence process will begin on 02 December 2024 for those applications that score 70/100 or more. It will only take place if you are invited to Hearings. Entities who can provide results of a recent Due Diligence process that EIT Health deems sufficient may be exempt from undertaking the EIT Health Due Diligence process. However, the exemption is fully at EIT Health's discretion.

26. Can Small Enterprises choose the "Revenue Sharing" model as a return mechanism?

No. The only available model for small enterprises is "Grant to Options".

FLAGSHIP SPECIFIC

Digital Transformation of Healthcare

27. Must Digital Medical Devices (DMD) be CE-marked at the time of application?

For the DiGinnovation programme, Digital Medical Devices must be CE-marked at the time of the proposal submission. For Innovation to Market activities, Digital Medical Devices must be CE-marked at the time of the proposal submission or in the process of getting CE marked. This can be evidenced by showing that a CE-mark dossier has been submitted to a notified body at least 6 months prior to application submission. This is to ensure that approval is achieved in time to reach the market within 1 year of EIT Health funding ending.

28. In the call document, what is meant by the phrase, "... focus on new market entry and commercial piloting activities for patient-centred DMDs to facilitate and accelerate their implementation and wider adoption across EU markets"?

For the DiGinnovation programme, Digital Medical Devices must fulfil the specific requirements of reimbursement of the selected target market. Proposals will not be eligible for funding if they fail to fulfil the reimbursement requirements of their selected target market(s), such as achieving the required risk classification of the digital medical device for the selected target market.

For Innovation to Market projects, your proposal must define how you plan to enter the market, and, if applicable, specify the reimbursement model you are applying for.

29. Is DiGinnovation only focused on countries that already have a reimbursement pathway, such as Germany, France, Belgium? Or can proposals target other countries if they find a reimbursement partner (e.g., private insurance, specific hospital, etc.)?

Proposals must target at least one European country market(s) with a fast-track reimbursement scheme. Where a proposal is also targeting a country that has no fast-

track reimbursement scheme, proposals must provide a clear plan on rapid market entry. This may involve a private payor, but is not an explicit requirement. This area is changing very fast, and we will evaluate each proposal on a case-by-case basis.

30. When should Innovation projects start?

Work will start one month after selection notification, allowing for a one month stand still period. However, costs for work carried out from 1 March 2025 are eligible as part of the grant award. Work must be completed by 31 December 2025. There will be no extension possibility.

31. What is the definition of "patient-centred" when referring to Digital Medical Device solutions?

With a primary focus on meeting the needs, preferences, and circumstances of patients, Digital Medical Devices (DMD) are health technologies falling into the definition of medical devices as outlined in the Regulation (EU) 2017/74511, whereby the main function is based on digital technologies intended to support one or more of the following medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability.
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state.
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

A patient-centred device will leverage digital tools and data to enhance patient care, improve health outcomes, and facilitate a more personalized healthcare experience. It could include software intended to be used alone or in combination with hardware (e.g., scanners, sensors, monitors, etc.), and include static and self-learning algorithms (e.g., Artificial Intelligence, Machine Learning).

DMDs can be used by patients, caregivers, healthcare professionals and health system users in the broadest sense.

Devices that are not intended to support medical purposes (e.g., wellness apps), software qualified as an accessory for a hardware, and administrative software are not considered patient-centred DMDs and are not eligible for the call.

32. Is the call limited to micro and small enterprises or can medium enterprises, large companies and other organisational entities participate ?

All organisational entities can participate, but the financial mechanism applied is different depending on the maturity and size of the commercial entity. For micro and small enterprises, the mechanism used is the "Grant to Options" agreement, while for medium enterprises, big industry and others it is the "Revenue Sharing" model.

33. For Innovation to Market activities in Digital Transformation of Healthcare (DTH), does the funded solution have to be a Digital Medical Device or could it be a digital platform to support patient-centred DMDs today and in the future in their validation, certification and market access processes?

It must be a Digital Medical Device according to the definition provided in the Call document, page 23.

EDUCATION PROGRAMMES RELATED QUESTIONS

34. Who will support the delivery of making developed modules part of the EIT Health Academy?

The EIT Health Academy is the platform where all educational modules developed by selected consortia will be hosted and delivered. The Academy team supports and guides the different steps to count with the modules in the portfolio.

35. Who will be responsible for maintenance and update of the modules in the EIT Health Academy?

The EIT Health Academy is a service offered to selected consortia that will collaborate with EIT Health to upload and update modules on the platform. At the end of the activity funding period, content will remain in the EIT Health Academy, and the intellectual property will be owned by the consortium.

36. Can a Master that doesn't fall under national quality agencies because of the faculty configuration, still qualify despite not being able to provide ECTS?

No. The EIT Label only considers fully nationally accredited Masters and is an essential requirement.

37. How is the grant for the Fellowship modules divided between year 1 and 2?

It also depends on the consortium and how the work is planned. Though we expect that most of the grant would come in year 1, as the repurposing task is the biggest. The remaining amounts would come in year 2 for the assessment task.

REIMBURSEMENT RATE

38. How is the IP managed for funded Education programmes?

In the Flagship Call 2025, all the education activities are led and administered by EIT Health. Therefore, EIT Health will be a member of the Consortium overseeing the programmes. A dedicated agreement including EIT Health and selected consortia will be signed. The **Consortium** Agreement will address the topic of IP. The Education programmes in the Flagship Call 2025 are a collaborative effort between the selected consortia and EIT Health to exploit the results.

39. Regarding co-funding, can funds come from other grants, or does it need to be from private investment?

Co-funding can come from different sources, private funding, own resources and other grants. However, additional EU funding is not allowed in terms of co-funding for a given cost within the same activity. This is known as double funding and is not permitted. EIT Health expect applicants to ensure that they are compliant with the relevant funding and audit requirements.

In any case, 30% own co-funding is mandatory to demonstrate Partners' co-investment commitment in Innovation to Market projects and the DiGinnovation programme.

40. Regarding co-funding, should the company have capability to co-finance at the time of submission or at the actual start date of the project?

EIT Health will not audit the financial status of an applicant at proposal stage. Projects should have sufficient funding until pre-financing is launched. This could take between 3 - 6 months following award notification depending on how fast contracts can be signed.

41. In the call for educational modules, is co-funding mandatory?

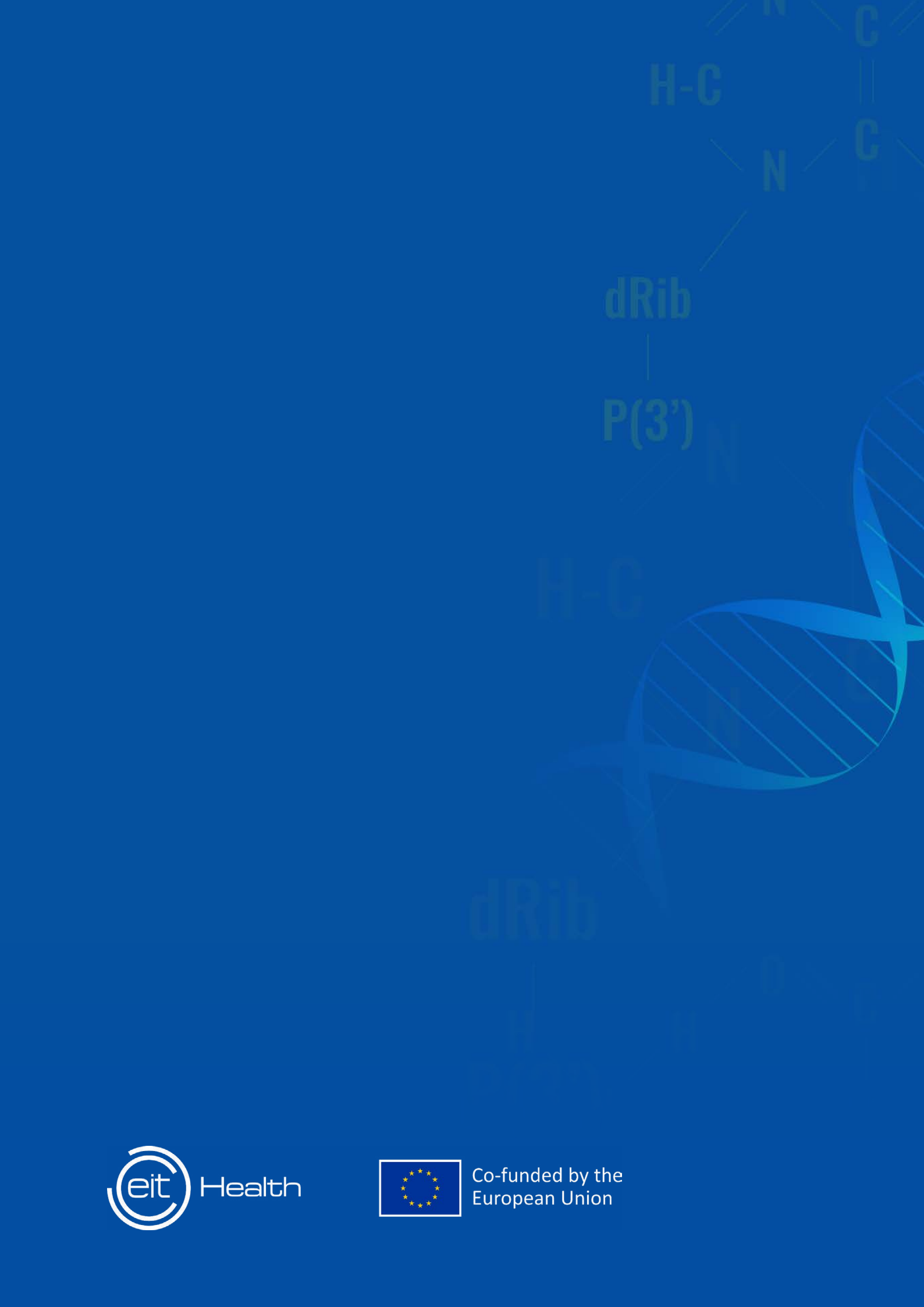
No. The EIT Label only considers fully nationally accredited Masters and is an essential requirement.

42. How can we have synergies with other EU funding without falling in the double funding trap?

If the funding is not supporting the same cost of the project, it will not be considered as double funding.

43. Are co-funding percentages (own resources and other non-EIT programmes) applied per project or per Partner?

Co-funding percentages are applied per project and not by partner.



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