EIT Health Flagships Call 2024

Frequently Asked Questions (FAQs)

eit Health

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In this document you will find answers to the most common questions we get asked, relating to the EIT Health Flagship Call 2024. We have grouped queries around common themes. If a question you have isn't covered here, please feel free 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 cut-offs? 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, which will likely come into effect on 1 January 2024. Does this change UK Partners´ eligibility to receive funding from EIT Health in the Flagship Call 2024?

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 “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.

FINANCIAL SUSTAINABILITY CONTRIBUTION

5. Is the revenue sharing contribution from the projects to EIT Health evaluated during short proposal phase?

No, it will only be evaluated in the full proposal, to be submitted at the end of the support programme. The party or parties that will act as the commercialising entities will need to be identified in the system at the short proposal stage. Please consider that single step submissions will need to include all the information at the single stage submission.

MEMBERSHIP / CONSORTIUM

ELIGIBILITY

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

At the short proposal stage yes, but at the full proposal stage there must be at least one current EIT Health member. Exceptions apply only for applicants of the following activities: i-Days and Masters.

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 single/short and full proposal submission stage. A minimum of one EIT Health member, core or associate, is required, with the exception for applicants of these activities: i-Days and master's degrees. For the other activities, 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 partners secure as much funding as EIT Health Partners?

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

10. 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 about 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 identified at the short proposal stage, regardless of who is the coordinator of the project.

11. Can a Swiss start-up apply and lead a project in a start-up driven 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 over the 3 years' grant duration. If they wish to receive more than €60,000, 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.

12. 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 Small and Medium Enterprises (SMEs) 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 short proposal stage, regardless of whether they come from the EIT Health community or not.

CALL BUDGET

GENERAL QUESTIONS

13. 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.

14. What is the budget distribution between cut-offs?

Most of the budget is planned for the first cut-off, to allow projects more time until the end of the BP in December 2025. We are calling only for the shorter DiGinnovation projects during the second cut off.

ELIGIBILITY

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

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

16. 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.

17. What are the requirements/format of the proposal video that can 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.

SUPPORT PROGRAMME

18. Will Partners be paid during the support programme?

Partners do not receive payments in the support programme. It is a support phase and is designed to help strengthen your proposal. The engagement expected from Partners is comparable to assembling the proposal on their own, but with the support of EIT Health and mentors.

19. Who is expected to participate in the support programme, is it just the project Partner leader or more Partners of the consortium?

There may be a limited number of places per consortium. Participation in the support programme is mandatory, and involvement of the project leader involvement is expected. Depending also on the type of experience being provided, a few different Partners may also be needed and not just the project leader. We will give a lot of flexibility to the consortium on who they would like to invite to participate, but with a limited number of places. The only exception is for those teams who have participated

with the same proposal in previous submissions. This will be considered in a case-by-case scenario – please get in touch if this applies to you.

EVALUATION

20. How will the pre-evaluations (filtering) phase occur?

Filtering is an internally assessed remote check for eligibility and preliminary screening for strategic fit, potential future impact, and project feasibility.

21. Who will perform the filtering?

A multidisciplinary, pan-European team of EIT Health staff is assessing the proposals against first eligibility and then strategic fit, potential future impact, and project feasibility.

22. Can you provide more detail on the specific criteria and the shortlisting stage?

The criteria on which the filtering will be based are outlined in the call document and included here: strategic fit, potential future impact, and project feasibility.

The short and single proposal information provided with the application will be used to perform this assessment but questions in the proposal template also follow this structure.

For example, for strategic fit we will look at how innovative the proposed solution/service/programme is and if it solves a clearly defined need that falls within the flagship areas. For potential future impact, we are interested in filtering those proposals for which the impact generated by the project is clearly described with realistic and achievable target values. Finally, regarding feasibility, for innovation projects we will be looking at the preliminary evidence, to see whether the project will be able to achieve the expected markets goals 1 year after the end of the EIT Health funding period.

For education programmes, we will be evaluating whether there is already subject matter expertise linked to the proposed flagship areas, convincing elements of expertise of instructional design, and either understanding of the use of EIT Health Academy Platform or validated experience running similar programmes/education. **Please see our executive summary for more information on what makes a winning proposal.**

23. How is EIT Health ensuring neutrality in the shortlisting stage for short proposals?

Each proposal is assessed by more than one individual during this stage therefore preventing any potential conflict of interest. The final pool of invited projects to the pre-selection stage will be decided at a consensus meeting where all regions will be represented. The outcome of the evaluation process will be always validated by the EIT Health Management Board.

SERVICE AND TECHNOLOGY DEVELOPMENT ACTIVITIES & DIGINNOVATION PROGRAMME RELATED QUESTIONS

ELIGIBILITY

24. For technology and service projects, ethical approval is required before the project start: does this mean before the start of the clinical trial or before the start of the project? If there are delays obtaining the approval of the ethics committees - how is this going to be handled?

In the past too many projects suffered delays, negative reviews and ultimately budget reductions because ethical approvals were not sufficiently planned or started late. As a result, we have improved our support programme and are now offering help and guidance preparing the clinical dossier required, in line with other Horizon Europe programmes.

The final approval will not be requested at hearings but, if selected, the project will need to provide proof of submission in all sites involved, a maximum of one month after the notification date. As soon as the first site is approved, it will trigger the eligibility of the costs in general that will be retroactive to the notification date.

In the case of delays by the ethics committee, EIT Health will be flexible. Normally the validations happen across several touchpoints, so we understand that certain special circumstances can occur, but it is rare that it happens in all places of the project in which the validation is being carried out. After one validation is ready, eligibility of the costs in general can be triggered that will be retroactive to the notification date. This first validation must come a maximum of four months after the notification date.

25. 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 SUSTAINABILITY RETURN TO EIT HEALTH

26. 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 the risks in case the solution is not commercialised or the commercialisation takes place at lower speed than planned. Partners are committed to return the grant assigned to the project, if the commercialisation is successful, which is of interest to us all, our Partners and EIT Health. For technology and service development 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.

27. 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 by the project during the support programme and confirmed with EIT Health during the subsequent 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.

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

The revenue sharing model is applied to the commercialising entity of the solution in technology and service development 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.

29. Can you provide any clarification about the following phrase in the call document regarding the start-up: "Have at least 2 paid FTEs working in the start-up at the time of submission and CEO working full-time in the company".

It means that for SMEs applying, the company CEO must be fully dedicated to the company and working full-time in the company. The entity must have two full time equivalent (FTE) paid employees working at the time of submission of the Short Proposal stage.

30. When will the due diligence for start-ups take place?

If you are applying with the "grant to option" model, the due diligence process will start in parallel to the support programme, so will only take place if you are selected to enter the support programme. Entities who can provide results of a recent due diligence process may be exempt from undertaking another due diligence process.

FLAGSHIP SPECIFIC

New Models to Deliver Healthcare (NMDH)

31. Do we need to provide letters of commitment for service development projects from the involved payors as was requested in previous EIT Health calls?

Letters of commitment from payors are no longer a mandatory requirement. Of course, should a consortium have such a commitment letter it should absolutely be provided to strengthen their proposal and showcase the link that exists between the payors and healthcare providers.

32. With respect for service development activities in NMDH, can the commercialising entity be non-EU?

The rules to receive funding are defined in the call text. Exceptions and details are clarified for UK/Swiss/Hungary specificities.

33. Can the payors be public payors or only private payors?

Payors can be public and/or private.

34. Is platform development mandatory to capture patient data? Is an existing platform eligible to be used?

There needs to be a platform to capture the data to build the analytics. The requirements come from what the payor will need to trust the evidence generated for the payor. If the platform is ready and can be repurposed, even better.

Digital Transformation of Healthcare

35. Does this requirement, "The prescription and reimbursement in EU countries for already certified medical devices" mean that the digital medical device (DMD) must be CE marked at the time of application?

For the DiGinnovation programme: CE marked at the time of the application is required.

For technology development activities: CE marked at the time of the application is not required but must be planned during the project timeline or immediately afterwards to ensure timely required launch to market.

36. What is the exact meaning of "...the focus will be primarily put on patient centred DMDs that fall under the reimbursement requirements"?

For the DiGinnovation programme: the DMD must fulfil the requirements of reimbursement of the selected target market. Failing to fulfil these requirements will make a proposal non eligible. i.e. medical device certification obtained risk classification.

For longer projects in technology development: The proposal must define how you plan to enter the system and the reimbursement model you are looking for.

37. When should the the longer projects (technology and service development) start?

In the current call, technology and service development projects will only have one cut-off. The communication date of the final results will be the starting date of the project if granted.

38. Why are there shorter projects in this Flagship Call 2024?

EIT Health's business plan is ending in 2025 and the current call is designed with this in mind. Once the rules for 2025 onwards are defined, a new call will be considered.

39. What is the definition of "patient centred" when referring to DMD solutions?

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.

These devices could include software intended to be used alone or in combination with hardware (e.g. scanners, sensors, monitors...), and include static and self-learning algorithms (e.g. Artificial Intelligence, Machine Learning). (**Call Outlines document, page 21**)

40. Is the call limited to micro enterprises or can SMEs participate?

They can both participate, but the financial mechanism allowed is different depending on the maturity, so for micro and small enterprises the mechanism is "grant to options", while for medium enterprises and big industry it is revenue sharing.

41. For technology development 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 21.

EDUCATION PROGRAMMES RELATED QUESTIONS

42. Developed modules will become part of an academy. Who will support the delivery of this?

The EIT Health Academy Platform is the platform where all educational modules developed by selected consortia will be hosted and delivered. The EIT Health Academy team will support selected consortia to validate the learner journey through curriculum development workshops, ensuring an optimal instructional design and learning experience on the platform.

43. 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 who will collaborate with EIT Health to upload/update modules on the platform. At the end of the activity funding, when the content will remain in the EIT Health Academy, the IP will be the property of the consortia.

REIMBURSEMENT RATE

44. Regarding co-funding, can the 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. To note, double funding is not permitted – additional EU funding is not allowed in terms of co-funding for a given cost within the same activity. This will be an issue on the applicant's side in case of an audit.

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

45. 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 is not auditing the financial status of an applicant at proposal stage.

The project should be able to be financed until the pre-financing will be launched. This could mean between 3 -6 months depending on how fast the contracts can be signed.

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

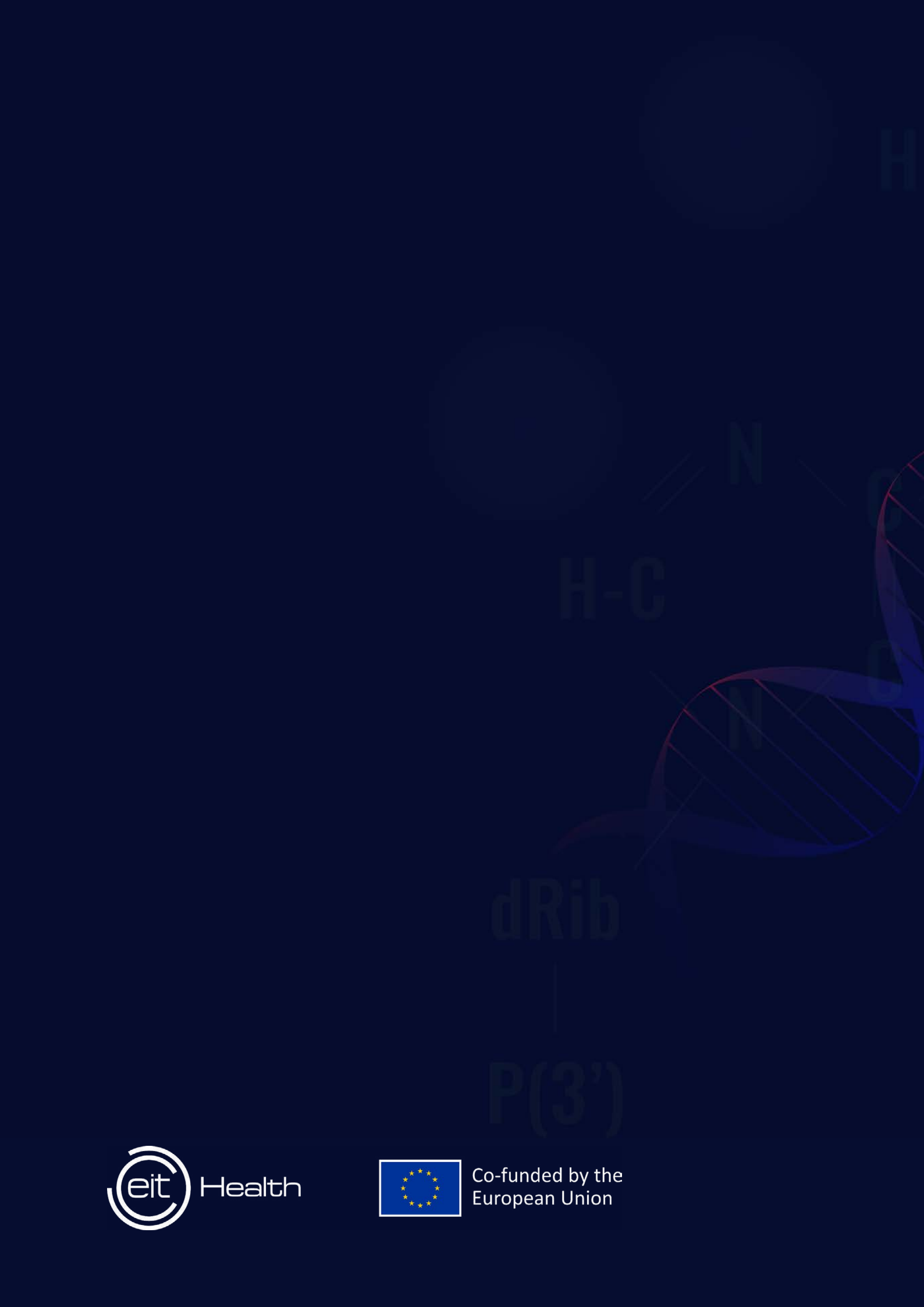
No, it's not mandatory. But in the spirit and the strategic direction of EIT Health, providing co-funding is evaluated favourably.

47. 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.

48. 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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