

Frequently asked questions RIS 2020 Innovation Call

Table of content

Application criteria	2
Project elements	
Funding	
Reporting, cost eligibility	



Original text

Updated text

Application criteria

1. Where can I find RIS Innovation project calls and announcements?

The aim of the programme is to develop the local innovation ecosystems in the regions where RIS Hubs are located and it targets local innovators, however the programme is managed centrally by EIT Health InnoStars. The Call and related announcements can be found on the website of EIT Health: https://eithealth.eu/get-involved/live-opportunities/

2. How can I apply?

The proposals shall be submitted via Optimy online electronic system. You can submit your proposal after registration using the link provided in the announcement.

3. Who can submit an application?

The Call is open for all legal entities, however at least two legal entities' collaboration is expected, where both academic and non-academic partners are represented. Natural persons are not eligible. The application should be submitted by the project leader who must have an established and registered representation/branch in the NUT2 region where one of EIT Health Hubs is located in the corresponding RIS country.

4. Should we mark to the Members of the partnership table also the RIS HUB?

Yes

5. Can we have images in the template form?

No

6. We would like to write more than 750 characters. Is that possible?

We would write an addition if that would be excepted. No annexes are accepted. The limit of characters can be seen under each text box in the Call application form



7. How can someone submit with the proposal letters of intent or support? Does the submission platform provide this option?

In this stage, it is not mandatory, you should sigh partnership agreement if you got selected. In the proposal you should indicate the partners involved in the partnership.

8. Can a natural person apply?

No, natural persons are not eligible.

9. What is an academic institution?

Academic institutions as an educational institution dedicated to education and research, which grants academic degrees.

10. What is a non-academic institution?

Non-academic institutions include local hospitals, SMEs, healthcare industry, start-ups, research institutes, local/regional government and other NGOs.

11. Who can participate in RIS innovation project calls?

At least two legal entities' collaboration from the same RIS regions can apply in partnership where at least one academic and one non-academic partner participate. The local RIS hub, as the EIT Health coordinator in the given region must be involved in the project as supervisor/coordinator.

12. Does a college that issue associate degrees qualify as an academic institution that can be a lead partner in the project call?

Yes, it can, but please note that there should be at least one academic and one non-academic partner in the partnership.

13. Is research institution eligible to be the project leader?

Yes.

14. The leading partner does not have to be the academic one, right?

Not necessarily.

15. To whom may the HUB should promote the project call and who may participate in the webinar?

Possible academic and non-academic partners.



16. Can a RIS hub's affiliate participate in the RIS innovation project calls?

If a project partner is affiliated to the RIS hub (e.g. two units of the same university), it can participate in the project only as project supporter without receiving fund from the project.

17. Who is the project leader?

The project leader is the project partner responsible for the project and for the whole team. Members of the partnership has the decision who will lead the project. The application should be submitted by the project leader who must have an established and registered representation/branch in the NUT2 region where one of EIT Health Hubs is located in the corresponding RIS country.

18. What are the conditions/form on how the established and registered representation/branch should be proved in the manner that it meets the eligibility criteria?

The existence and the location of an established and registered representation/branch should be based on self-declaration at application phase, however selected projects will have to provide company's registration document before signing the sub-granting agreement.

19. Can an individual company submit a proposal?

No, there must be at least two partners (one academic and one non-academic) in the project partnership. Therefore, an individual company cannot apply.

20. What kind of relations can the applicant company have with a full member of EIT Health? Can they have a contract-based relationship? Can a full member own shares in the company that applies?

Other commercial/ professional relationships that do not interfere directly with this call is not considered.

21. What are the eligible RIS countries?

Eligible RIS countries are Croatia, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, Slovenia.

22. What are the eligible NUT2 regions and EIT HealthRIS Hubs?

	Eligible NUT2 regions:	EIT Health RIS Hubs
1	Continental Croatia Region,	University of Zagreb
	Croatia	http://cirtt.unizg.hr/en/about-us/projekti/eit-health/

DEX Innovation Centre North East Region, Czech http://dex-ic.com/ Republic 3 Estonia Tartu Biotechnoloogia Park http://biopark.ee/ National Documentation Centre Attica, Greece 4 http://www.ekt.gr/en 5 South Transdanubia Region, Institute of Transdisciplinary Discoveries Hungary http://itdweb.hu/hu/kezdolap/ Sicily, Italy Consortium ARCA 6 http://www.consorzioarca.it/index.php/en/ 7 Latvia Rīga Stradiņš University https://www.rsu.lv/starptautiska-sadarbiba/eitnealth-ris-centrs Kaunas University of Technology 8 North East Region, Lithuania https://en.ktu.edu/ or Lithuanian University of Health Sciences http://www.lsmuni.lt/en/ Medical University of Gdańsk Pomeranian Region, Poland https://mug.edu.pl University of Évora 10 Alentejo, Portugal https://www.uevora.pt/ 11 North Portugal Region, Portugal University of Porto https://upin.up.pt/en/content/projects Associatia INIT & Freshblood HealthTech 12 North West Region, Romania freshblood.ro 13 Eastern Slovakia Region, Slovakia T-Svstems https://myt-systems.sk/en/home/ 14 Western Slovenia Region, jubljana University Incubatorhttps://lui.si/ Slovenia

Health

23. Can one of the partners be from another country that is classified as an EIT Health RIS country or Horizon 2020 associated country?

No, since we aim for the funding of local projects. Each partner must be established in the same RIS country.

24. The partners should all be located in the same country or one of them could be in another part of the country or in another European country?

Each partner must be established in the same RIS country. The leader legal entity of the partnership must have an established and registered representation/branch in the NUT2 region where one of EIT Health Hubs is located in the corresponding RIS country.

25. Is there a criterion for the numbers of partners in RIS innovation project proposals?

There is no limitation in the number of partners, however the participating countries and



types of participants are regulated. Project partnerships will be funded to a maximum of EUR 75.000 (even if there are more than 2 partners).

26. Is there a possibility to become a non-funded partner at the contracting stage?

There is the possibility to become a non-funded partner, but only in case when this partner is also involved in the project and contributes to the project.

27. Can a research institute (besides the Hub) qualify as an academic partner for the purposes of this project application? Or is every unit within the University considered to be part of RIS Hub?

Yes, if the research institute is a separate legal entity (i.e. has independent tax number from the university)

28. What if the education institution issues academic degrees but is not necessarily dedicated to both education and research, ie. its primarily an education institution. How do you assess that they are dedicated to research?

According to the definition in the Call document, an academic institution is an educational institution dedicated to education and research, which grants academic degrees. Therefore, there need to have research activities at the institution beside education

29. Is an academic institution (medical school of a university) and a research center eligible for submitting a proposal? I.e. without an SME?

Yes, if the research center fulfills the requirements of being a non-academic partner in the collaboration.

30. Is it advantageous to have two academic partners (from the same country, within the region)?

There is no advantage, or extra score in our evaluation system.

31. Is it possible to include as a partner a company specialized in market analysis and market strategy?

Yes, there is no requirement for the type/industry of an additional (besides an academic and a non-academic) partner, as long as you are targeting EIT Health's six Focus Areas to be developed by local actors including both academic and non-academic partners in collaboration with EIT RIS hubs.

32. Is it possible to apply with two projects?

It is possible, but in case the applicant wins more than one project (and so exceeds the 50k



limit), it has the right to decide which project they want to deliver.

33. Can last year's winner apply again for a call?

Proposals which have received funding in the EIT Health InnoStars RIS Innovation Call 2019 are excluded from receiving funding for the same project." – Therefore, the answer is yes, they can apply with a new project.

34. Can non-public partners be part of the partnership?

The call does not differentiate between public, private or semi-private academic institutions. Point 4 of the Call document states: "Academic institution is an educational institution dedicated to education and research, which grants academic degrees."

35. Can the business partner be part of a multinational company?

Yes, but only SMEs can be granted, the big companies can be project supporters.

36. Is a consortium formed by a university, start-up and regional public hospital eligible for the project?

Yes, if at least one academic and one non-academic partners are there.

- 37. How those who are not EIT Health Partners can participate in the BP 2022 Calls for Proposals?
- Non-members can participate in partnership as "External Project Partners" in projects that are led by Core or Associate Partners.
- Innovative start-ups now have the possibility to become the project leads, even if they
 are not EIT Health Partners. <u>The EIT Health Amplifier</u> allows start-ups to drive
 Innovation Projects and receive up to €500 000 in support, in exchange for giving EIT
 Health options that can be sold or converted into equity.

More information can be found here.

38. Where can I find information on the different aspects of the implementation?

InnoStars will share the <u>Guidance&Templates</u> folder with the project teams, which contains all the information and templates needed during the implementation. You can learn the funding principals from the <u>Annotated Model Grant Agreement</u>.

39. What is an Affiliated Entity?

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



indirect ownership of more than 50% of the issued share capital of the entity or of more than 50% of the issued share capital entitling the holders to vote for the election of directors or persons performing similar functions in such entity, or right by any other means to elect or appoint managing board members of the entity (or persons performing similar functions) who together have a majority vote, while the status of Affiliated Entity lasts only as long as such Control exists, it being understood that common Control through government does not, in itself, create Affiliated Entity status.

40. What is the difference between a subcontractor and a partner?

Partner: A project partner is a legal entity who has signed a partnership agreement with other legal entities to participate in EIT Health RIS Innovation project Call(s). Any legal entity (academic or non-academic) can be a partner, provided that all partners are established in the same RIS country, they are financially viable and qualified to perform the tasks specified in the project proposal.

Subcontractor: A subcontract can only cover part of the work to be done by any partner and the partner remains fully responsible for the work done by the subcontractor. The task defined in the project description is carried out by the subcontractor independently rather than by the project participant. The respective costs have to be indicated specifically in the project budget as "subcontracting". The price of subcontracts usually includes a profit margin for the contractors. EIT Health RIS Innovation participants therefore have to choose such contractors on the basis of best value for money.

There is no restriction regarding the maximum amount for subcontracting however we prefer not to exceed 25% subcontracting in order to utilize the funding mainly by the subgrantees instead of outsourcing the implementation of the project.

41. Do the project applications need to be of commercial nature? What is meant by "system and organizational" types of projects

We are supporting need-based innovations, either of commercial nature or other projects with business value (system and organizational efficiency is considered business value).

42. Please clarify, at what degree is it mandatory to include new developed technology as a final product? My understanding right now is that it could be a new service or a new process and new technology is not necessarily critical. Is that correct?

EIT Health RIS 2020 innovation call aims at funding high-quality, strong, balanced projects, targeting EIT Health's six Focus Areas to be developed by local actors including both academic and non-academic partners in collaboration with EIT RIS hubs. The innovation does not necessarily have to be a product, it can be a technology or service or process as



well. The level/necessity/merit of the innovation will be evaluated by the independent experts.

43. Is it necessary to have CE certificate for medical device when applying for this call?

The requirements for medical devices in the EU have consisted of three directives:

- <u>Directive 90/385/EEC</u> regarding active implantable medical devices (AIMD)
- <u>Directive 93/42/EEC</u> regarding medical devices (MDD)
- <u>Directive 98/79/EC</u> regarding in vitro diagnostic medical devices (IVDD)

These Directives are being replaced by the new Medical Devices Regulation (MDR 2017/745) and IVD Regulation, entering into force in May 2020.

Please also see in the Directives list of harmonized

standards (https://ec.europa.eu/growth/single-market/european-standards/harmonisedstandards/medical-devices/).

There are exceptions for CE marking drawn up in the legislation, also CE Marking usually comes after clinical validation, because for obtaining CE marking you need to prepare a Clinical Evaluation Report (CER). Therefore, obtaining CE marking is usually in a later stage of product development than CIMIT IML 2. Therefore having in place a CE certificate for the medical device is not a requirement when applying for this Call.

44. Can you provide an example of a project that has "started IML3", e.g. in the clinical domain?

We cannot provide any example because the principle of equal treatment would be harmed.

45. The call funds projects that are beyond the idea stage and have already some tangible results to demonstrate. Is that correct?

Yes, selected projects will have completed IML 2 (Idea) AND has started IML 3 (Proof of Concept) at least in 2 of the 4 domains.

46. Does the project MUST start on the end of phase 2 of Cimit Maturity Innovation Template or it can start later in the process? How much later?

The maturity level expectations are minimum requirements. The project can be more advanced, however based on research, the RIS region lacks funding for completing 'Proof



of concept'. It will be the responsibilities of the evaluators to evaluate the necessity of the funding for the project.

47. How does one determine his finish point? Which phase in CIMIT Maturity Innovation Template should be applied on the end of the year?

Funded projects' finish point will depend on the sector (BioTech, MedTech, Digital Health), and complexity of the project.

48. How are RIS Innovation Call 2019 and RIS Innovation call 2020 different? please respond with example?

RIS Innovation Call 2019 and RIS Innovation Call 2020 are different calls, not different cutoff dates of the same call. Therefore, they are different. Please use the Call 2020 only as a reference.

Project elements

49. What is the purpose of the mentoring and what tasks are to be done?

The goal of the mentoring is twofold. On one hand InnoStars aims to provide project teams with expert support to be able to successfully implement their project and reach the expected level of development. To reach this goal the mentor is expected to share her or his expert opinion on how to implement a project efficiently, what are the tools, techniques to be used to ensure the achievement of the KPI-s, how to overcome the difficulties and how to handle risks, etc. Mentor is requested to supervise the Work plan and the reports on implementation in order to justify the sufficient progress of the project towards InnoStars.

Secondly, InnoStars intends to provide the project teams all support to negotiate successfully with potential partners resulting long term cooperation(s). Therefore the mentor is requested to help the teams to identify the selling point of their solution and articulate a clear value proposition to potentially engage new partners and/or create the opportunity for the project teams to be involved in further EIT Health activities (e.g. participation in BP 2022 innovation calls). In this context – based on mentor's judgement – sharing tools for pitching, techniques of negotiation are welcome.

50. How the mentors for the teams will be selected?

The mentors will be provided by InnoStars based on the mentor's field of experience and the focus area of the proposal.



51. Can we select the mentor?

No, InnoStars team will allocate the mentor on the proposals based on the projects 'focus area.

52. How much it will cost, 9h with your mentor?

The cost of the mentoring is included in the funding, last year it was approximately 9*150 EUR = 1350 EUR. Please note that this is an estimated amount, so the price can change later.

53. How can I participate in matchmaking events?

Participation in EIT Health matchmaking events is not automatic since the seats in the events are limited. InnoStars maps the opportunities and negotiates on the conditions with the organizers. After agreeing on the details InnoStars will invite the project teams to take part in such events. Only the invited teams can participate.

The purpose of these events to introduce the teams to EIT Health network in order to create the opportunity for further cooperation with partners operating in the field of interests of the project team. The cooperation can result either in joint actions or in joining project partnership participating in EIT Health Business plan innovation projects.

The event organizers provide matchmaking platforms where beneficiaries can identify potential partners and invite them to short one-on-one meetings during the matchmaking session of these events.

Funding

54. What type of funding is the RIS innovation projects programme?

The RIS innovation projects programme provides funding for innovators from the RIS regions¹ to develop their projects to the maturity level that creates the opportunity to join EIT Health partners applying for EIT Health Business Plan innovation calls. The programme is funded by EIT Health InnoStars as part of Horizon 2020, the EU's Research and Innovation framework programme.

55. What is the maximum amount and the reimbursement rate of the funding?

One project (the project partnership together) can be funded up to 75.000 EUR. At the same time, the requested funding per partner may not exceed 50.000 EUR. The 50.000 EUR threshold is an aggregated amount. If an organization participates in more projects, the

¹ For more details please see: <u>https://eit.europa.eu/our-activities/outreach/eit-regional-innovation-scheme-ris</u>



total amount of the funding must not be higher than 50.000 EUR.

For non-profit organizations and micro and small enterprises the projects are funded for 100%. Medium enterprise will only be funded up to 70%, large enterprises cannot receive funding but can be part of a partnership applying for funding and they can benefit from the networking opportunities.

56. Is the RIS Innovation project counted to the 50k EUR limit per SME? Does it prohibit application to Headstart? Can RIS Innovation (50k EUR) project holder apply for Headstart (50 k EUR) - if successful in both then will receive 100k EUR - but this is more than maximum for all EIT Health funding opportunities for partner per year?

One project partner can be granted with max 50k, maximum grant is EUR 50k in total. (by all RIS funding schemes together) and the total RIS Innovation project budget of the project is 75k.

57. Does each partner included in the partnership directly receive the amount of funding that is designated for its activities?

Yes.

58. What is the funding in case of the Hub?

The Hub cannot participate in the budget and cannot profit from this funding scheme, the funding will go to the local actors. (academic and non-academic partners)

59. When can we expect the payments?

There is one pre-financing payment after signing the subgranting agreement and one after the completion of the tasks and the approval of the (final) report by InnoStars. The second payment will be transferred by 10.02.2021.

60. What kind of activities are supported?

The cost of those activities can be reimbursed that contributes to the development of the project to a maturity level that enables the beneficiaries to negotiate with EIT Health partners about the participation in EIT Health BP22 Innovation calls. Only those activities can be funded which are listed in the proposal and approved by the funding activities.

Beside the project implementation there are further compulsory activities to be done by the beneficiaries.

• The beneficiary will be connected with a mentor from EIT Health InnoStars mentor pool, who will support the implementation of the project throughout the project lifecycle. At least 9 hours of mentoring is obligatory.



- With the support of the mentor from EIT Health InnoStars mentor pool, a project development plan is to be compiled summarizing the actions to be taken for the innovative solution to reach the market.
- The beneficiaries shall take part in matchmaking events and organize meetings where the possibilities of taking part in 2022 EIT Health Business Plan proposals can be negotiated.

61. How many projects will be supported (total amount of grants)?

We are planning to grant the best 12 projects, but the exact number of selected proposals depends on our budget.

Reporting, cost eligibility

62. How can I report on the progress and claim for funding?

The final report must be compiled using the template attached to the subgranting agreement (annex 3) in which the technical progress and the use of resources (financial performance) must be explained. This will serve as the basis for the payment of the fund. The financial report must detail the costs incurred in connection with the action implemented and must be justified by supporting documents. Only the appropriately justified cost items can be reimbursed.

63. Which costs are eligible?

Only direct costs are eligible and thus can be declared. Direct costs are the costs which are directly required for the management and implementation of the project, such as equipment, personnel, travel, subcontracting. Indirect (overhead) costs are costs which cannot be evidently linked to the management and implementation of the project, but rather supplementary costs such as rent, heating, electricity, equipment maintenance and postage.

64. What are the eligible cost categories?

- Direct personnel costs
 - o costs for employees (salary including all social contributions, taxes, etc)
 - o costs for natural persons working under a direct contract
 - o costs of personnel seconded by a third party against payment
 - o costs for SME owners without salary
 - o costs for beneficiaries that are natural persons without salary
 - o personnel costs for providing trans-national access to research infrastructure



- Direct costs of subcontracting
- Other direct costs
 - travel costs and related subsistence allowances
 - o equipment costs
 - o costs of other goods and services

For details please see the Financial guidelines provided by InnoStars.

- 65. What are the supporting documents that justify the use of the funding?
- Personnel costs:
 - Contracts,
 - Payrolls,
 - Time sheets (template is provided by InnoStars),
 - Tax returns (the declaration forms of taxes and social contributions),
 - Bank statements that justify the settlement of the salaries and taxes/contributions.
- Services:
 - Procurement documents (if applicable),
 - o Contract,
 - o Invoice,
 - Bank statement,
- Consumables/equipments/other goods and services
 - Procurement documents (if applicable)
 - Purchase order/contract (if applicable),
 - o Invoice,
 - Bank statement.
- Travel:
 - o Invoice,
 - Booking confirmation,
 - Bank statement,
 - If the travel cost was paid by on the company's employee you need to submit the reimbursement request of the employee, and the bank statement that your company paid the amount to its employee.

For details please see the H2020 Annotated Model Grant Agreement and the Financial guidelines provided by InnoStars.

66. The costs incurred by the startup after the presentation of the project but before knowing the outcome are eligible?

Yes, this cost is eligible.



67. Are actual product R&D activities eligible?

Please see the definition of optional eligible activities and eligible costs and cost categories in the Call document. If your planned activities comply with those, then they are eligible. Please also see the Financial Guideline for further information.

68. Are product development activities eligible?

Please see the definition of optional eligible activities and eligible costs and cost categories in the Call document. If your planned activities comply with those, then they are eligible.

69. Can salary be paid from the project budget and what can be the maximum hourly rate?

Yes, salary can be paid from the project budget (with all the taxes and social contributions) and the hourly rate must be the same what the employee normally gets from its employer.

70. What happens if I spend less than the grant I received?

The surplus that you cannot cover with invoices/mentoring contract will be withdrawn and the total amount of the grant will be reduced.

71. What happens if I spend more than the grant I received?

There is no possibility to increase the grant. You will have to cover the extra spending from your own financial resources.

72. What happens if I cannot fulfill a task set out in the sub-granting agreement?

The original budget of this task will be completely withdrawn, and the total grant amount will be reduced with this amount.

73. What happens if I can only partially fulfill a task?

The proportional part of the original budget allocated to this task will be withdrawn and the total grant amount will be reduced with this amount. (e.g. if you conclude only half of the required interviews, half of the original budget – allocated for interviews – will be withdrawn from you).

74. Can I shift between the budget lines of the subgranting agreement?

Yes, this is possible. You can shift amounts between the different budget lines (e.g. spend more on mentoring and less on travels) and between partners as well. But, please note that you have to fulfill all your contractual obligations, tasks and deliverables set out in the



75. Can I implement the project in 2021 as well?

No. The project ends in 2020, only those costs are eligible that incur in 2020, no cost can be funded that incurs after 31 December 2020.