

EIT Health Business Plan Calls 2021

Innovation Projects

ANNEX 2:

Start-up Amplifier Instrument

A new instrument in the BP 2021 Innovation Call for Proposals

Amended 14 April 2020



About the amendments

The document was updated on 22 November 2019, based on the feedback and questions from the partners and start-ups during the CLC webinars. The following is a summary of the changes:

| PAGE, SECTION | EXPLANATION OF THE CHANGES |
|--|--|
| Page 3: Which type of external project partner can apply within the Start-up Amplifier? | <ul style="list-style-type: none"> Link to the EU definition of a start-up is added, as well as link to the self-assessment questionnaire. Clarification is provided on the incorporation date of a start-up. |
| Page 3: Rules of participation | <ul style="list-style-type: none"> Clarification is provided on the requirement for a start-up to be operational. Clarification is provided regarding the process of start-up registration on Plaza and its accession to the Framework Partnership Agreement. Other requirements from the Call document are now all collected in one place for simplification. |
| Page 4: Main Principles | <ul style="list-style-type: none"> Clarification is provided on the EIT Health's and start-up's rights during certain financial events (eg.: share deal exit). Link to the Term Sheet is added. |
| Page 5: Options definition | <ul style="list-style-type: none"> Clarification is provided on how the pre-money valuation will be decided upon and when it will be communicated to a start-up. List of financial events that allow EIT Health to convert Options into equity is clarified. Merger is no longer a such financial event. Clarification is provided on the EIT Health's and start-up's rights during financial events. |
| Page 6: Due Diligence Documents requested | <ul style="list-style-type: none"> List of documents requested for Due Diligence was complemented. Clarification is provided on the Due Diligence process and confidentiality. |
| Pages 7-11: FAQs | <ul style="list-style-type: none"> FAQs were enhanced to take into account the questions asked during CLC webinars. |

The document was updated on 23 February 2020 with the following changes:

| PAGE, SECTION | EXPLANATION OF THE CHANGES |
|---------------|---|
| Page 4 | <ul style="list-style-type: none"> Text that was added is in red: <i>Have at least 2 (full-time) employees with the start of the preparatory work of the project by 1 September 2020 at the latest. Founders can also count as employees in this case</i> |
| Page 5 | <ul style="list-style-type: none"> Text that was added is in red: <i>Start-up Amplifier is mandatory for the Innovation proposals where</i> |

| | |
|----------------|--|
| | <ul style="list-style-type: none"> • <i>the start-up is the main driver of the project:</i> • The two paragraphs were deleted: <i>Start-up Amplifier is an optional instrument embedded in Innovation project call: Consortia involving start-ups that apply for the Innovation call in BP2021, can choose whether to use the instrument or not. This decision should be made in a unanimous way within the consortium. Full consortium needs to agree with the participation in the new instrument and notify it in the Stage 0 Expression of Interest as well as final proposal.</i> |
| Page 8 | <ul style="list-style-type: none"> • Answer to the question: <i>Is participation in Start-up Amplifier mandatory for all Innovation Projects where Start-up is involved?</i> updated |
| Page 10 | <ul style="list-style-type: none"> • Question: <i>Can running Innovation Projects that were selected in previous calls apply for Start-up Amplifier retroactively?</i> Deleted. |

The document was updated on 14 April 2020 with the following changes:

| PAGE | EXPLANATION OF THE CHANGES |
|---------------|--|
| Page 4 | <ul style="list-style-type: none"> • Adding “Be a for-profit SME” |
| Page 4 | <ul style="list-style-type: none"> • Change date of final application in rules of application |
| Page 5 | <ul style="list-style-type: none"> • Access to FPA timeline changed |
| Page 8 | <ul style="list-style-type: none"> • Updating important deadline section |

I. Why add a new instrument?

In a number of Innovation Projects, external project partners play a vital role, being the driving force of the product development and market entry. At the same time, EIT Health's support to these companies was limited, maximum of €50,000 per year. With introduction of the Start-up Amplifier, EIT Health provides opportunity for start-ups at the core of an Innovation project to benefit from extended funding in Innovation projects in return for Options. This instrument contributes to EIT Health's sustainability strategy and makes EIT Health a magnet for healthcare and life science Start-ups in Europe for the benefit of our Partners.

What is the Start-up Amplifier?

Start-up Amplifier is a new instrument offered to the Innovation projects during the proposal submission, focused on elevating the role of top start-ups in Innovation projects by increasing their involvement and available funding in return for the Options.

Which type of external project partner can apply within the Start-up Amplifier?

Only external project partner defined as start-up¹ could apply to the Start-up Amplifier:

- Be a for-profit SME
- Be an SME according to [EU definition](#): enterprise which employs fewer than 250 persons and which has an annual turnover not exceeding 50 million euro, and/or an annual balance sheet total not exceeding 43 million euro. By the link [here](#) is the self-assessment questionnaire that allows to see if a start-up fits under the EU definition of SME.
- Be registered in one of the EU Member States or [countries associated to Horizon 2020](#).
- Be incorporated on or later than January 1, 2013. Be incorporated at the time of the proposal submission.
- Have at least 2 (full-time) employees latest with the start of the preparatory work of the project by 1 September 2020. Founders can also count as employees in this case.

Rules of participation

- Start-up brings the innovation which is in the core of the Innovation Project: without start-up, there is no Innovation Project.
- The start-up is already operational (i.e. has full time employees, pays taxes and establishes processes for increasing its efficiency) and has a capacity to scale operations. Start-up does not necessarily need to have a product / service on the market at the application stage.
- An external project partner can **only apply to one Innovation Project as a participant in the Start-up Amplifier**. The external project partner **must be linked to a CLC** before the submission deadline (email contacts are given [here](#), page 14 of the call document).
- The application of an external project partner into the Start-up Amplifier **prevents its application in any other projects or programs** from EIT Health where it could receive grant.
- If an external project partner **is granted through the Start-up Amplifier, that partner cannot apply to any other project or program** from EIT Health as long as the granted project is running.
- One start-up can't receive funding in more than one Innovation Project at the same time.
- Start-ups that intend to participate in the Start-up Amplifier **need to be registered in the Plaza before the final date of submission (8 July 2020)**. Please reach out to the Project Management Office for more information on the registration process (email:

¹ All start-ups are SMEs, however not all SMEs are start-ups. Based on the generalized definition, **start-up** is an innovative company younger than 5-10 years that searches for a repeatable and scalable business model

partnershipmanager@eithealth.eu). If the project is granted, Start-ups will need to have submitted the registration documentation required to accede to the Framework Partnership Agreement by the 18 December 2020, at the very latest.

Main Principles

- Start-up Amplifier is mandatory for the Innovation proposals where the start-up is the main driver of the project: “Without the start-up, there is no innovation project”.
- For successful projects with core start-up having applied to the instrument, EIT Health will grant start-up up to €500,000 in a 3-year project (capped at €250,000 per year) within the 3M€ maximum grant and in return will take Options. Options will be based on a market standard valuation of the start-up and the financial contributions of EIT Health. In certain financial events (eg.: share deal exit), EIT Health has the right to convert options into equity. Instead of giving equity to EIT Health, the Start-up may decide to make a compensation payment. Please see more details on options below.
- In the evaluation process, EIT Health will evaluate the proposal itself (as it currently does) and the start-up through a due diligence. Both elements will be taken into account to define the level of success of an Innovation project.
- EIT Health will not have any claims to start-up’s IP. Existing IP agreements between start-up and other Partners will not be affected.
- In addition to the Project Grant Agreement (PGA) signed by all EIT Health partners in the consortium of funded Innovation project, start-up will additionally sign [Term sheet](#) and Option agreement with EIT Health.
- **Specific monitoring rules** will be added to assess **start-up performance** in funded projects.

How to apply?

- Innovation projects that apply with Start-up Amplifier go through the general application process.
- Start-up needs to provide additional information and documentation during the proposal submission phase to enable due diligence (cf 3.)

II. Options Definition

With Start-up Amplifier, EIT Health will invest in selected start-ups up to €500,000. In return, EIT Health shall participate in the economic success of the start-up and will assume Options. This participation is part of EIT Health's sustainability strategy: If EIT Health gets remunerations, these funds shall be re-invested by EIT Health. Thus, the sustainability strategy aims at vitalizing the European start-up scene and at establishing EIT Health as an independent player in the European start-up market. The sustainability strategy of EIT Health aims at minimizing the dependence on public funds.

Main principles:

- By using Options, EIT Health intends to be treated economically comparable to a shareholder and to participate in the financial success of the start-up without assuming equity.
- Options are **internationally known**, are **accepted** and **do not include debt-elements**.
- Options shall be **exercised in certain financial events**. Thus, EIT Health will only participate in the upside of the start-ups if start-ups are successful.
- The number of Options EIT Health shall subscribe, **depends on the pre-money valuation**. The pre-money valuation shall be either (i) the post-money valuation of the last financing round if the financing round was concluded no more than one year prior to application or (ii) the pre-money valuation obtained as a part of valuation analysis during due diligence. Individual valuation will be communicated to the start-up before the hearings. The individual valuation of the Start-up will be part of the [Term Sheet](#) and the definite agreements with a start-up.
- Options will **dilute in financing rounds** in the same ratio as equity-shares.
- EIT Health will participate in the following financial events:
 - Sale of more than 50% of the shares in the Company;
 - Sale of more than 50% of the assets as well as the licensing of substantial IP rights of the Company;
 - IPO;
 - Liquidation.
- In these financial events, **EIT Health has the right, not the obligation**, to exercise the Option agreement, which EIT Health can do in two ways:
 - Converting Options into equity
 - Receiving the compensation payment (if decided so by a Start-up)
- In **the event of a merger**, the options of EIT Health shall be converted into new options or similar instruments on the level of the new entity. The conversion shall occur on the same economic conditions as agreed for the shareholders.
- As long as Options are not yet exercised, EIT Health does **not hold equity** in the start-up and will not have rights of a shareholder.
- EIT Health gets the right to decide whether it wants to take a seat on **the Advisory Board or, if applicable, the Supervisory Board** of the start-up as long as EIT Health holds at least 8% of participation.
- EIT Health does **not seek IP ownership** in the start-up.

III. Due Diligence Documents requested

Start-up needs to provide additional information and documentation during the proposal submission phase to enable due diligence:

- Start-up website
- Pitching deck
- One-pager about a start-up
- Registration certificate
- Organizational structure and number of employees
- Structure of ownership (cap table)
- Business Plan
- Articles of Association
- Financials (i.e. Financial plan, balance sheet and where available results of the financial audit not older than 1 year from the application, revenue projections etc.)
- List of all IPR items owned – specifically any IPR connected to the innovation at the core of the project
- Information on participation (including information on coordination/reporting experience) and/or grant received in EIT Health programmes and other publicly funded programmes, including EU-funded ones (SME Instrument, etc.)
- If the start-up plans to lead the project in Amplifier, they must present proofs of expertise in project management and reporting of EU grants and coordination of international consortium. Alternatively, the task should be given to partner with the skills.

Submitted documents will be treated as confidential. A firm performing due diligence might contact a start-up to have a call in the framework of due diligence process and /or ask for additional documents.

IV. Frequently Asked Questions

Is participation in Start-up Amplifier mandatory for all Innovation Projects where Start-up is involved?

The instrument is mandatory for all Innovation projects where the start-up is in the core of the project and brings the product/service on the market. External project partners that are not playing the commercialization role can still take part in Innovation projects without using this instrument, with a maximum funding of €50 000 in EIT funding per year.

What are the metrics of success for this instrument?

Among others, we see the following metrics of success:

- Follow-up funds secured as an investment by the start-up during the project or a maximum of 2 years after the funding ends (KPI EITN06)
- Product launched on the market (KPI EITN03)
- Jobs creation (KPI OUTKPI62)

We expect Innovation projects applying with Start-up Amplifier to include KPI EITN03 as mandatory, and EITN06 and OUTKPI62 as recommended.

What are the main deadlines to keep in mind?

Innovation Projects that apply with Start-up Amplifier go through the general application process:

- Deadline for the submission of the Expression of Interest (Eoi) is 11 December 2019, 16:00 CET (Munich time).
- Deadline for the submission of Expression of Interest linked to pandemics stream is 27 May 2020, 16:00 CEST (Munich time)
- Final submission deadline for the full proposal is 8 July 2020, 16:00 CEST (Munich time).
- Start-ups that intend to participate in the Instrument need to be registered on the Plaza platform before the final date of submission (8 July 2020). Please reach out to the Project Management Office for more information on the registration process (email: partnershipmanager@eithealth.eu). If the project is granted, Start-ups will need to have submitted the registration documentation required to accede to the Framework Partnership Agreement by 18th December 2020, at the very latest.

Is it true that a Start-up cannot send any Expression of Interest?

A Start-up can send an Expression of Interest but needs first to be linked to a CLC and to have contact with EIT Health partners as Innovation projects are collaborative projects and need to be submitted with a consortium of partners.

Can a Start-up lead Innovation Project?

Yes, however they need to understand what the Lead partner role entails. A dedicated project manager should be hired for this role (within the €500,000 grant). At the proposal stage, the proofs should be provided that a Start-up has previous grant management experience.

Can a Start-up from non-EU countries participate in Start-up Amplifier?

Start-up registered in one of the EU Member States or [countries associated to Horizon 2020](#) can participate.

Can a Start-up that was not previously a part of EIT Health network participate?

Yes, EIT Health is interested in engaging the best start-ups from EU/H2020 associated countries, even if they have not previously been a part of EIT Health network.

What will be the official status of a Start-up participating in Start-up Amplifier in EIT Health network?

External Project Partner

Does a Start-up applying within Start-up Amplifier count in the eligibility criteria of “partners coming from at least 2 CLCs/InnoStars”?

Yes.

Will Start-ups pay fees?

No, they will not. They do not make a commitment in the present (paying fees initially) but they make a commitment in the future (they exchange the grant for an Option in their company).

What happens with the IP?

The instrument does not affect the existing IP structure.

Will Start-ups need to contribute with KCA?

We are looking for top Start-ups, already advanced in their development. In most cases, we expect that they have received grants, maybe investments, etc. They should be able to contribute with KCA.

However, we aim to maintain the KCA rule at the project level. It is possible that some Partners cover the larger part of the expected KCA contribution than others.

Will Start-ups need to contribute with co-funding?

The general rules of co-funding in EIT Health apply to the Start-up. If Start-up fits under the definition of small and micro enterprise, it can have up to 100% reimbursement rate. If it's a medium sized SME, it has reimbursement rate up to 70%. More details [by the link](#). EIT Health always welcomes the co-funding contribution from the partners.

Why do Start-ups incorporated more than 7 years ago cannot participate in Start-up Amplifier?

We aim to engage Start-ups that are not too old, but still in more advanced stage of development.

Why do we need start-up due diligence?

Due diligence is put in place to make sure that:

- The start-up is a solid partner that can contribute to the partnership
- The numbers provided are valid, claims are real and there are no legal issues
- The start-up team has core competencies for performing the planned work.

A valuation analysis will be performed in the framework of due diligence.

How will the valuation of a Start-up be decided upon?

The pre-money valuation shall be either (i) the post-money valuation of the last financing round if the financing round was concluded no more than one year prior to application or (ii) the pre-money valuation obtained as a part of valuation analysis during due diligence.

Individual valuation will be communicated to the start-up before the hearings. The individual valuation of the Start-up will be part of the Term Sheet and the definite agreements with a Start-up.

How do the results of start-up due diligence impact the funding decision?

Due diligence will be done only for the start-ups that participate in the hearings. As a result of due diligence, one of the following scenarios will be possible:

- Start-up passes the due diligence (none or minor issues identified during due diligence) and will be considered for EIT funding as a part of an Innovation proposal.
- Start-up does not pass the due diligence (major issues identified during due diligence) and Innovation proposal will not be considered for EIT funding.

To be noted that there is no option to change the Innovation project with Start-up Amplifier to ordinary Innovation Project, if start-up fails in due diligence.

Is a letter of support required from existing EIT Health partners during the application process?

We do not require a formal letter of support. For EIT Health the best show of support is the proposal developed by the full consortium with an active participation of a Start-up.

When can EIT Health convert Options into equity or receive a compensation payment from the start-up?

EIT Health can convert Options into equity or receive a compensation payment from the start-up in the following financial events:

- Sale of more than 50% of the shares in the Company;
- Sale of more than 50% of assets as well as the licensing of substantial IP rights of the Company;
- IPO;
- Liquidation.

In the event of a merger, the options of EIT Health shall be converted into new options or similar instruments on the level of the new entity. The conversion shall occur on the same economic conditions as agreed for the shareholders.

Will EIT Health be involved in future financing rounds?

By assuming Options, EIT Health will not become a shareholder and will not become a party of a shareholders' agreement. Thus, provided that the future investors confirm *vis-à-vis* EIT Health their acceptance of the terms of the Options, EIT Health does not need to be involved in financing rounds as long as EIT Health's Options are not converted into equity.

Will EIT Health be involved in the decision making of the start-up?

Unless EIT Health's Options are converted, there is no need to involve EIT Health in shareholders' resolutions. The start-up and its shareholders stay free in their decision-making process.

Will a licensing deal of a start-up will be triggering payments to EIT Health?

In general, a licensing deal over a substantial part of the Company's IP will be triggering payments for EIT Health in cases where shareholders get returns.

What happens if the start-up will be wound-up without distributing proceeds to shareholders?

Then the Options of EIT Health will terminate.

What happens if the start-up does not ask for the full €500,000 in 3 years?

This is possible. Number of Options that EIT Health will obtain will be based on the amount of funding provided.

What happens with Options if the project is terminated?

The number of Options is re-calculated based on the amount of EIT funding provided prior to the termination.

Will the participation of EIT Health be the same in every European country or will there be differences?

Economically EIT Health's Options will be implemented at the same conditions all over Europe. However, the legal implementation will take into account different legal jurisdictions.

Can the economic conditions be negotiated?

The economic conditions are the same for all teams and will not be negotiated.

How will EIT Health's Options be implemented?

The following example illustrates the participation of EIT Health:

- The Company has a share capital of 25,000 EUR.
- 25,000 shares are held by the Founders. Thus, no external investor is a shareholder and no financing round has taken place.
- No other options have been granted. There is no Employee Stock Ownership Plans (ESOP) or a similar scheme in place.
- In the Due Diligence phase a pre-money valuation of 2,000,000 EUR has been determined.
- EIT Health invests the full amount of 500,000 EUR into the Company. The price per option is EUR 80.00 ($2,000,000.00 / 25,000.00 = 80.00$)
- In this situation EIT Health assumes on a pre-money valuation of EUR 2,000,000 in total 6,250 options corresponding to a participation of 20% of the increased share capital of the Company.

What agreements does a Start-up need to sign when Innovation Project is funded?

Start-up needs to sign the following agreements: (1) Term Sheet that sets out the process (2) Project Grant Agreement that regulates the work of the full consortium, (3) Option Agreement.