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2022 Business Plan Call

Annex 3: Innovation projects

- Start-up-driven projects
- High Value Care project features
- CIMIT Healthcare Innovation Cycle
- Milestones Framework
- HVC Implementation Framework
- Impact and Financial Sustainability Check

Amended 11 March 2021

Contents

1. Start-up Amplifier instrument in Start-up-driven projects 3
1.1 About the Start-up Amplifier instrument 3
1.2 Start-up Amplifier instrument option definition 5
1.3. Start-up Amplifier instrument due diligence and valuation analysis 6
1.4. Start-up Amplifier instrument Frequently Asked Questions 8
2. High Value Care project features 18
2.1 What is High Value Care? 18
2.2 What is EIT Health looking for in High Value Care innovation projects? 18
2.3 Which type of project partner can apply to HVC Innovation projects? 19
2.4 What will an HVC Innovation project look like? 20
2.5 What will success look like for High Value Care innovation projects? 21
2.6 How will the HVC Pilot Selection Process work? 22
3. CIMIT Healthcare Innovation Cycle 24
4. Milestones Framework 26
Biomarkers Diagnostics Milestones 27
Medtech Milestones 29
Digital Health Milestones 31
5. High Value Care Implementation Framework 33
6. Impact and Financial Sustainability Check 34
6.1 Main Principles of the impact and Financial Sustainability Check 34
6.3 How the Impact and Financial Sustainability Check is implemented 35
6.4 KPIs and metrics of Impact and Financial Sustainability Check 35
6.5 An Illustrative Example of Impact and Financial Sustainability Check implementation 37
6.6 Frequently Asked Questions 39
Amendments 42

1. Start-up Amplifier instrument in Start-up-driven projects

1.1 About the Start-up Amplifier instrument

What is the Start-up Amplifier Instrument?

Start-up Amplifier instrument is a grant-for-option instrument offered to Start-up-driven 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 option to assume shares in the start-up when certain "financial events" occur. 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.

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

Only external project partners defined as a start-up can apply to the Start-up Amplifier instrument. The start-up must:

- Be a **for-profit** SME according to the EU definition: an enterprise that employs fewer than 250 persons and has an annual turnover not exceeding €50 million, and/or an annual balance sheet total not exceeding €43 million. Follow this link for the self-assessment questionnaire used to check 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 1 January 2014.
- Have at least two (full-time) employees at the time of the proposal submission (for start-up driven projects that apply with already incorporated start-up) or by 1 October 2021 (for start-up driven projects that apply with the non-incorporated start-up). Founders can also count as employees in this case.

For a specific case where a start-up will be not incorporated at the time of the proposal submission, the start-up should be incorporated by 1 October 2021 at the latest. By this date, the start-up should meet all other criteria listed in 1.1.

Rules of participation of Start-up Amplifier applicant into Start-up-driven projects

- The start-up brings the innovation that is the core of the Start-up driven project: without the 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. The start-up does not necessarily need to have a product or service on the market at the application stage.
- The minimum total grant for which the start-up can apply is €300,000. The maximum is €500,000.
- An external project partner applicant to the Start-up Amplifier instrument can apply to only one Innovation project. A start-up granted through the Start-up Amplifier instrument can't receive

funding in more than one Innovation activity at the same time.

- The application of an external project partner into the Start-up Amplifier instrument prevents its application in any other projects or programmes from EIT Health where it could receive grant simultaneously as in the Innovation project in case this would be granted.
- If an external project partner is granted through the Start-up Amplifier instrument, that partner cannot apply to any other project or programme from EIT Health (where it would get funded) for the duration of the project.
- Start-ups that intend to apply to the Start-up Amplifier instrument need to be registered in the Plaza system before the final date of submission and linked to the appropriate EIT Health regional Innovation Hub. 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 mid-August.

Main Principles of the Start-up Amplifier Instrument

- The Start-up Amplifier instrument is mandatory for Start-up-driven proposals i.e., where the start-up is the main driver of the Innovation project: without the start-up, there is no innovation project.
- For activities with a core start-up accepted to the instrument, EIT Health will grant the start-up up to €500,000 for a three-year project (capped at €250,000 per year) within a maximum €2.5 million grant, and in return will take the option to assume shares in the start-up when certain "financial events" occur. EIT Health's option 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 the option into equity. Instead of giving equity to EIT Health, the start-up may decide to make a compensation payment. Please see more details on EIT Health's option below.
- In the evaluation process, EIT Health will evaluate the proposal itself and also evaluate the start-up, through a due diligence process. Both elements will be taken into account to define the level of success of an Innovation project.
- Valuation analysis will be performed in the framework of a due diligence process. The valuation results will be communicated to the start-up prior to the hearings (for start-up driven projects with already incorporated start-up) or prior to the project start (for start-up driven projects with non-incorporated start-up). Should the valuation not be accepted by the start-up, the full Innovation project will not participate in the hearings (in the first case) and will not be considered for funding (in both cases).
- Results of the due diligence assessment will be considered in the final funding decision. There are two alternatives possible:
    - Start-up passes the due diligence (no, 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.
- 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 the funded Innovation project, the start-up will additionally sign a 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?

- Start-up-driven projects go through the general application process.
- Participation in Start-up Amplifier instrument needs to be noted in the Expression of Interest (EOI) as well as in final proposal.
- Before submitting an EOI, a start-up must have already identified at least one EIT Health Core or Associate partner with whom to collaborate, and they must be included in the EOI.
- Start-up needs to register on the submission system (Plaza) and be connected to a regional Innovation Hub.
- Start-up needs to provide additional information and documentation during the proposal submission phase to enable due diligence. All the documentation needs to be submitted in English (except the registration certificate).

1.2 Start-up Amplifier instrument option definition

With Start-up Amplifier instrument, 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 via an option to assume shares in the start-up in the case of certain "financial events". This participation is part of EIT Health's sustainability strategy: if EIT Health receives remuneration, these funds shall be reinvested by EIT Health. Thus, the sustainability strategy aims at strengthening 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 minimising dependence on public funds.

Main principles:

- By using the option instrument, EIT Health intends to receive treatment comparable to a shareholder, and to participate in the financial success of the start-up without assuming equity at the moment when EIT Health signs the Option Agreement with the start-up.
- The instrument of an option is internationally known, is accepted and does not include debt-elements.
- The option will 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 shares EIT Health is entitled to subscribe in the financial event depends on the pre-money valuation. The pre-money valuation will 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 for approval (for start-up driven projects with incorporated start-up) or prior to the project start (for start-up driven

projects with non-incorporated start-up). Should the valuation not be accepted by the start-up, the full Innovation project will not participate in the hearings (in the first case) and will not be considered for funding (in both cases). The individual valuation of the start-up will be part of the Term Sheet and Option Agreement with a start-up.

- The option 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 assets as well as licensing of substantial IP rights of company.
    - Initial Public Offering (IPO).
    - Liquidation.
- In these financial events, EIT Health has the right, but no obligation, to exercise the option agreement, which EIT Health can do in two ways:
    - Assuming equity.
    - receiving the compensation payment (if decided so by a Start-up).
- In the event of a merger, the option of EIT Health shall be converted into new option on the level of the new entity. The conversion shall occur under the same economic conditions agreed upon for the shareholders.
- As long as the option is 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 of the start-up as long as EIT Health holds at least a participation equivalent to 8% on a fully diluted basis.
- EIT Health does not seek IP ownership in the start-up.

1.3. Start-up Amplifier instrument due diligence and valuation analysis

Should a start-up driven project with an incorporated start-up be invited to the hearings, the start-up at core of the project will go through due diligence and valuation analysis.

The start-up needs to provide additional information and documentation in English (except for the registration certificate) during the proposal submission phase, to enable due diligence and valuation analysis. Documentation includes:

- Registration certificate
- Start-up website
- Pitch deck
- Business plan
- Historic financials
- Financial projections
- List of shareholders
- If the start-up plans to lead the project in the Start-up-driven project, they must present proof of

expertise in project management, reporting of EU grants and coordination of an international consortium. Alternatively, the task of activity lead should be given to the partner with these skills.

- Letters of intent, pre-order agreements, order agreements (optional)

Submitted documents will be treated as confidential. An Independent third party performing due diligence and valuation analysis will have calls with start-ups in the framework of this process. EIT Health or an independent third party performing due diligence and valuation analysis may reach out to the Start-up in case more information is required to finalise the due diligence and/or valuation analysis.

Individual valuation will be communicated to the start-up before the hearings for approval. Should the valuation not be accepted by the start-up, the full Innovation project will not participate in the hearings and will not be considered for funding. The individual valuation of the start-up will be part of the specific agreement with the start-up.

It is possible to reconsider the valuation of a start-up during the project lifetime, though this step is not required. Therefore, two alternative approaches to valuation evolution are made available in the Option Agreement:

- Alternative 1: The valuation is fixed at the time of the Option Agreement signature and no valuation increase is foreseen.
- Alternative 2: The increase in valuation is foreseen and agreed upon if certain defined milestones that significantly de-risk the project and start-up are achieved (e.g. endpoints achieved in pivotal clinical trials, CE mark obtained etc.). In this case, these milestones (up to 2) should be selected from the Milestone framework linked to the CIMIT Healthcare Innovation Cycle and communicated to EIT Health during the hearings. Should the Innovation proposal be funded, we will have additional round of valuation prior to the Option Agreement signature to define the valuation increase associated with the achievement of these milestones. The list of milestones, achievement deadlines, valuation associated with the timely achievement of these milestones and the tranches of funding per milestone will be defined before the project start and included in the Option Agreement.

Please note that in alternative 2, the calculation of the number of shares EIT Health is entitled to when converting its option following the valuation increase will only consider the grant distributed to the start-up after the milestone achievement.

The start-up can select the Alternative they prefer.

As a result of due diligence, one of the following scenarios will be possible:

1. 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.
2. Start-up does not pass the due diligence (major issues identified during due diligence) and Innovation proposal will not be considered for EIT funding.

In the specific case where the start-up will be not incorporated before March 24, 2021 (Call deadline), the start-up should be incorporated by October 1, 2021 and will go through valuation analysis and due diligence right after the incorporation. Should the start-up not accept the valuation and/or not pass due diligence, the Innovation proposal will not be funded as a part of Business Plan 2022.

1.4. Start-up Amplifier instrument Frequently Asked Questions

General Questions

Is participation in Start-up Amplifier instrument mandatory for all Innovation projects where a start-up is in the core of a project?

Yes, Start-up Amplifier is mandatory for all Innovation projects where the External project partner (start-up) is at the core of the project and/or brings the product/service on the market. External project partners that are not playing the commercialisation role can still take part in Innovation projects without using this instrument, with a maximum funding of €50 000 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 EITHE06.1)
- Product launched on the market (KPI EITHE02.1)
- Jobs creation (KPI 02)

We expect Start-up-driven projects to include KPI EITHE02.1 as mandatory, and EITHE06.1 and KPI02 as recommended.

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 option in their company).

What happens with the start-up's IP?

The instrument does not affect the existing intellectual property structure.

Can a start-up lead an Innovation project?

Yes, however it is important 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.

To be an activity lead, we need to provide proof of project management and grant management experience. What does this entail exactly?

Leading a project means, among other responsibilities, coordinating the work on the full consortium and being the main contact point for EIT Health in terms of monitoring and reporting. You can use the Grant Management Template to summarize your project and grant management experience for the proposal submission.

Can a start-up from a non-EU country apply to the Start-up Amplifier instrument?

Start-ups 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 the 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 the EIT Health network.

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

External Project Partner**.**

Does a start-up applying to the Start-up Amplifier instrument count in the eligibility criteria of "partners coming from at least 2 regional Innovation Hubs"?

Yes.

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 active participation of a start-up.

What agreements does a start-up need to sign when Innovation project is funded?

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

Why can Start-ups incorporated more than seven years not participate in the Start-up Amplifier instrument?

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

Will a start-up need to contribute with co-funding?

The general rules of co-funding in EIT Health apply to the start-up.

Can a start-up apply alone, without any partners?

No. Innovation projects are collaborative projects that are submitted by a consortium of partners. Innovation projects with or without Start-up Amplifier instrument need to meet the eligibility criteria outlined in the Call for proposals.

We applied to previous EIT Health programmes through Optimy and stayed connected with Living Labs through Chronos. Do we need to register again with the Plaza interface or can we use the same credentials?

Start-up representatives should register as individuals on Plaza. In addition, a start-up needs to be added in Plaza as a company to be selectable in the proposal's partner drop-down list. Please reach out to the Project Management Office for more information on the registration process (email: partnershipmanager@eithealth.eu).

What is the grant limit for a start-up?

The overall grant limit for all partners in an Innovation project is €2.5 million. A start-up can ask between €300,000-€500,000 in a three-year Innovation project (and no more than €250,000 per year).

How does a start-up protect its intellectual property (IP) during proposal preparation and application? Can this be done through non-disclosure agreements (NDAs) with other project partners?

EIT Health does not require an official agreement between partners at the EOI stage. Partners by their own initiative can decide on a case-by-case basis to sign a letter of intent or any other relevant document to officialise their relationship at the proposal preparation stage. If an activity is funded, IP protection will be regulated through the consortium agreement or other agreements that the project deems relevant. It is recommended to clarify the IP situation at the application stage, determining how the IP rights will be distributed for any IP generated throughout an Innovation project.

Who will own IP in an Innovation project?

If start-up owns IP before applying for an Innovation project, this IP normally should stay in the start-up's ownership. If new IP is generated as a part of an Innovation project, there should be an agreement reached and signed between consortium partners as to who will own the IP. Many scenarios of IP distribution are possible here. The most common case is when IP rights are shared between the consortium partners. All these questions will be regulated in the consortium agreement. EIT Health will not have any claims to a start-up's IP.

Can the start-up use the (maximum) €500,000 funding as they wish, or are there restrictions about the types of expenditures?

All partners in EIT-funded projects, including a start-up, should comply with Horizon2020/Horizon Europe cost eligibility criteria outlined in the Annotated Model Grant Agreement.

How will the payments be made to the funded start-up?

Payments will follow a regular EIT Health's payment schedule. A start-up will receive a pre-financing at the beginning of the year N (given that necessary agreements are signed). The final payout will take place in Q3 of year N+1, when the final progress and cost reports are approved by EIT. This means that a start-up needs to have enough funds to sustain itself until the final payout. The exact payment schedule might be adjusted from year to year and will be confirmed with the funded start-up prior to the signature of the Option Agreement.

Can two start-ups from one start-up driven project both apply to the Start-up Amplifier instrument?

Yes, however, if several start-ups are funded through the Start-up Amplifier instrument in the same Start-up driven project, the maximum grant amount of €500,000 must be split between them. In addition, both start-ups will go through due diligence and valuation analysis, and if one of the start-ups does not accept valuation or does not pass due diligence, the full Start-up-driven project will not be considered for funding.

Can other External Project Partners, not applicant to the Start-up Amplifier instrument, participate in a Start-up-driven project?

Yes, given that Innovation project still meets eligibility criteria i.e. those External Projects Partners are not at the core of the activity

Are spin-offs considered start-ups?

If they meet eligibility criteria outlined in the Call document, on top of meeting the EU requirements of being a for-profit SME, they can be considered start-ups.

Does a start-up applicant to the Start-up Amplifier instrument need to become an EIT Health partner or can it remain an External Project Partner?

The start-up will stay an External Project Partner (EPP). If their Innovation proposal application is successful and accepted for funding, the start-up will have to submit specific documentation to be registered as a direct beneficiary of an EIT grant.

Can non-profit SMEs apply to the Start-up Amplifier instrument?

Non-profit organisations are not suited for the Start-up Amplifier instrument. Only for-profit SMEs are eligible for the Start-up Amplifier instrument.

Can an existing start-up create a new start-up to specifically participate in the Start-up Amplifier instrument?

Usually this type of consortium set-up is perceived as artificial and cannot be expected to increase the chances for the solution's successful market launch. Therefore, EIT Health does not encourage such a set-up.

Can full-time employees in the start-up be unpaid?

Yes, the founders or other people who work full time on the start-up (40 hours per week or other full-time equivalent depending on the country's labour legislation) are eligible, even if they are not receiving salaries.

Due Diligence and valuation analysis

Why do we need due diligence of start-ups?

Due diligence is put in place to make sure that:

- The start-up is a solid partner that can contribute to the partnership and commercialise the product/service.
- 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 do the results of start-up due diligence impact the funding decision?

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

- The 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.
- The start-up does not pass the due diligence (major issues identified during due diligence) and the Innovation proposal will not be considered for EIT funding.

How will the valuation of a start-up be decided?

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.

Valuation analysis will be performed as a part of the due diligence process for incorporated start-ups that are invited to the hearings. It will be performed by an Independent third party selected in the European tender. Valuation analysis will be based on market-accepted methods. Specific approach and models used for the valuation will depend on the maturity of a start-up.

Individual valuation will be communicated to the incorporated start-up before the hearings. Should the valuation not be accepted by the start-up, the full Innovation project will not participate in the hearings and will not be considered for funding. The individual valuation of the start-up will be part of the Term Sheet and the specific agreements with a start-up.

In a case where the start-up will be not incorporated before 24 March 2021 (the Call deadline), the start-up should be incorporated by 1 October 2021 and will go through valuation analysis and due diligence right after the incorporation. Should the start-up not accept the valuation and/or not pass due diligence, the Innovation proposal will not be funded in Business Plan 2022.

Is there a lower limit of the pre-money valuation?

No, there is none. However, we expect mature and ambitious start-ups to apply.

What if the value of the company grows with time, will its valuation be re-assessed?

It is possible to increase the valuation of a start-up during the project lifetime, though this step is not required. Therefore, two alternative approaches to valuation evolution are made available in the Option Agreement:

- Alternative 1: The valuation is fixed at the time of the Option Agreement signature and no valuation increase is foreseen.
- Alternative 2: The increase in valuation is foreseen and agreed upon if certain defined milestones that significantly de-risk the start-up are achieved (e.g. endpoints achieved in pivotal clinical trials, CE mark obtained etc.). In this case, these milestones (up to 2) should be selected from the Milestone Framework linked to the CIMIT Healthcare Innovation Cycle and communicated to EIT Health during the hearings. Should the Innovation proposal be funded, we will have an additional round of valuation prior to the Option Agreement signature to define the valuation increase associated with the achievement of these milestones. The list of milestones, achievement deadlines, valuation associated with the timely achievement of these milestones and the tranches of funding per milestone will be defined before the project start and included in the Option Agreement.

Please note that in Alternative 2, the calculation of shares following the valuation increase (and upon conversion of the option) will only consider the grant distributed to the start-up after the milestone achievement.

The start-up can select the Alternative they prefer.

Is it mandatory to have milestone-related valuation increase as a part of the Option Agreement?

It is not mandatory. This is an optional alternative available to start-ups. Based on our experience, most start-ups prefer this alternative as it gives them the chance to increase their valuation during the Start-up Amplifier instrument-supported activity, which means they give away a lower participation.

Do milestones that lead to the valuation increase need to be achieved during the Innovation project?

Yes, the milestones should take place in the timeframe of an Innovation project.

How many milestones that lead to the valuation increase can a start-up have?

A maximum of two maximum (you can also have zero or one).

How do we select milestones that lead to the valuation increase? Can we suggest our own or do we need to select from the list?

The start-ups should select the milestones that lead to the valuation increase from the Milestones Framework linked to the CIMIT Healthcare Innovation Cycle (in the document, these milestones are shown in red). Please adjust these milestones to your concrete project (e.g. add the product name, type of registration planned – CE mark/FDA, type of clinical trials, size of the investment round etc.)

Do the milestones need to be connected to the Innovation project, or can they be only connected to the start-up?

Because EIT Health funds the start-up in the framework of an Innovation project, in general both milestones shall be connected to the Innovation project, so that EIT Health can see progress in the project. However, as each milestone needs to contribute to a valuation increase, not only the success within the Innovation project (e.g. CE mark/FDA approval of the product in the core of an Innovation project) will be reflected, but also the overall progress of the start-up (e.g. key patents issued). Thus, in certain cases, and upon approval from EIT Health, it can be sufficient that only one milestone is directly connected to the Innovation project while the second milestone is only indirectly related to the Innovation project.

The selection and definition of the milestones will be done on a case-by-case basis by the start-up and reviewed and confirmed by EIT Health. It is possible that the milestones list presented during the hearings will need to be adjusted based on the feedback received from the review experts. The approved milestones will be incorporated into the Option Agreement (defining the "Option Price") and project plan in the grant management system in Plaza.

Should the calculations in the financial documents submitted by the start-up at the proposals stage already take into account the potential EIT Health contribution?

The start-up should model its case as if it is able to get the support / funding of EIT Health, since it is the norm that start-ups will get support along the way to be able to reach their goals. Looking at a case that does not consider such a support or something similar would not reflect the reality of the start-up's development process.

EIT Health's participation (Option Agreement)

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

EIT Health can convert its Option 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 licensing of substantial IP rights of the company; IPO; or liquidation. In the event of a merger, the option of EIT Health shall be converted into a new option on the level of the new entity. The conversion shall occur under the same economic conditions as agreed upon for shareholders.

Will EIT Health be involved in future financing rounds?

By entering into the Option Agreement, 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 Option Agreement, EIT Health does not need to be involved in financing rounds as long as EIT Health's option is not converted into equity.

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

Unless EIT Health´s option is converted into equity, 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 trigger payments to EIT Health?

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

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

Then the option of EIT Health will terminate.

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

This is possible. The entitlement of EIT Health to assume shares under the Option Agreement will be based on the amount of funding provided. Please note that the minimum grant amount the start-up can request in a Start-up-driven project is € 300,000 for the full project lifetime.

What happens with EIT Health´s option if the project is terminated?

The number of shares EIT Health is entitled to when exercising the option 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 option will be implemented under 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 companies and will not be negotiated.

How will EIT Health's Option be implemented?

The following example illustrates the participation of EIT Health:

- The company has a share capital of €25,000.
- A total of 25,000 shares are held by the founders. Thus, no external investor is a shareholder, and

no financing round has taken place.

- No other option(s) has/have been granted. These is no Employee Stock Ownership Plans (ESOP) or similar scheme in place.
- In the Due Diligence phase, a pre-money valuation of €2,000,000 has been determined.
- EIT Health invests the full amount of €500,000 into the Company. The price per share is €80.00 (€2,000,000.00/€25,000.00 = €80.00) so EIT Health will assume 6,250 shares if the option converts (€500,000/80 = 6,250)**.**
- On a fully diluted basis, the option corresponds to a participation of 20% of the virtually increased share capital of the Company (20%*(25,000+6,250) = 6,250)**.**

Is there a maximal cap for the percentage of stock ownership assumed by EIT Health? In case of a valuation of €100,000, would EIT really assume ~80% of ownership?

EIT Health does not assume a percentage of ownership; it assumes the right for conversion into a certain number of shares in the case of a financial event. There is no cap. However, the option dilutes in financing rounds in the same ratio as equity-shares. In addition, a pre-money valuation of €100,000 is not realistic, as EIT Health intends to cooperate with ambitious and promising start-ups. Thus, realistically the valuation will be higher.

Why should EIT Health take part in a liquidation process (when the company shuts down) as it is not a success for a start-up?

This is a very rare case, but in order to have a full picture, liquidation was added to the list of financial events. In case the start-up was successful in the last years before the liquidation, and there are proceeds in the company that will be distributed to the shareholders, EIT Health will participate as well. If the company is not successful, EIT Health will not receive anything.

Can you provide an example of a Compensation payment calculation? Will it always be equal to the amount invested by EIT Health?

The amount of the Compensation payment can differ and will not always be equal to the amount invested by EIT Health. The examples and formula for calculating the compensation payment can be found in the Option agreement (please reach out to your EIT Health regional Innovation Hub for it), a simplified example is provided in the Term Sheet.

Is there any attached interest rate linked to the Option Agreement? Is there a deadline for transformation of the option or is it an indefinite right?

There is no interest linked to the Option Agreement and no deadline for executing the option.

Can the option be repurchased by the company with a premium predefined beforehand?

No, there is no opportunity to re-purchase the option at a certain defined price. However, if a success event happens, the start-up has the right to buy out EIT Health, on the conditions of the success event. Before the success event, there is no way to re-purchase the option.

What if the funded project is not successful, but the start-up is successful as the result of its other activities?

In this case, EIT Health participation still holds. EIT Health will participate in the success events of a start-up.

Will EIT Health seek a board seat?

EIT Health will not seek a seat in the management board. However, if an advisory board is established, EIT Health will be entitled to appoint one member of the advisory board, as long as EIT Health hold the ption or shares which - on a fully diluted basis – correspond to at least 8.00 % of the share capital.

Where can I find the Term Sheet implemented in Start-up Amplifier instrument?

You can find the Term Sheet here.

Can EIT Health sell the option (to the start-up's competitors, for example)?

This is regulated by the Option Agreement. EIT Health may sell or transfer its option to entities that are controlled by EIT Health in the meaning of Sect. 17 German Stock Corporation Act without restrictions, provided, however, that: (i) the relevant transferee shall at any time be and remain controlled by EIT Health in the meaning of Sect. 17 German Stock Corporation Act; and (ii) in the event that the transferee ceases to be controlled by EIT Health in the meaning of Sect. 17 German Stock Corporation Act, then the option shall be re-transferred to an entity controlled by EIT Health in the meaning of Sect. 17 German Stock Corporation Act. In addition, sale or transfer of the option requires prior approval of the company.

Does EIT Health take the option in a start-up or in a project?

EIT Health will perform valuation and will take the option in a start-up, not in a project.

What is the duration of the Option Agreement?

The Option Agreement is signed initially for 15 years. After 15 years, if not terminated, is it automatically renewed every year.

Participation of Start-up Amplifier instrument applicants in other EIT Health programmes[1]

Can start-ups applying to the Start-up Amplifier instrument participate in EIT Health Business Creation programmes in 2021?

Yes. Start-ups that apply to the Start-up Amplifier instrument (starting in BP 2022), but also wish to participate in Business Creation programmes in 2021, should seek to ensure that their registration as External Project Partners (EPPs) is effective from 1 January 2022. This would enable the start-ups to receive funding (sub-grants) from Business Creation programmes until the end of 2021. The Partnership Manager will send a communication to all successful Innovation projects involving EPPs with specific instructions on how to complete this process once the Call 2022 selection process has concluded.

What happens when funding though Start-up Amplifier instrument begins on 1 January 2022?

When the funding period starts, 1 January 2022, registered EPPs will no longer be eligible to receive sub-grants from EIT Health. However, other forms of non-monetary support – such as free mentorship and

[1] This information also applies to start-ups applying as "normal" External Project Partners in Innovation and Campus proposals.

support via Gold Track, the Investor Network and the Crowdfunding Platform – will remain open to start-ups.

How can EPPs terminate their status and thus become eligible for financial (sub-granting) support again?

Following the conclusion of the start-up's involvement as an EPP, the start-up can terminate its EPP status by sending a letter to the Partnership Manager. This letter should include information about the desired membership end date. Only once the EPP status has been confirmed as terminated will the start-up again be eligible to receive sub-grants (i.e. from Business Creation programmes).

What happens if a Business Creation programme (e.g. Headstart or Bridgehead) has not concluded before the Start-up-driven project starts?

Start-up Amplifier instrument grantees involved in Business Creation programmes in 2021 that go beyond 31 December 2021, will need to have been paid in full and having spent the sub-grant by the end of 2021 using Business Plan 2021 funds. December 31, 2021 needs to appear as the latest end date of the grant agreement signed with the start-up.

The reason for the above is that, once registered as an EPP, start-ups cannot receive sub-granting, as per the financial guidelines that stipulate that sub-grantees (receiving what is known as "financial support to third parties") cannot be beneficiaries (i.e. an EPP). This means that later payments in 2022 (e.g. 80% at project start in 2021 and 20% after the final report in 2022) are not possible. Follow up vouchers (e.g. for MCN) would also not be possible to obtain in 2022.

Start-ups involved in Accelerator programmes in 2021 must be aware that in case of a successful Start-up-driven application they will have to flag this to the Partnership Manager when completing the EPP registration process.

2. High Value Care project features

2.1 What is High Value Care?

High Value Care (HVC) is the "result" we are striving towards when implementing Value-Based Health Care.

The concept of Value-Based Health Care (VBHC) was introduced by Michael Porter (Harvard Business School) and Elizabeth Teisberg (Value Institute for Health and Care, a joint endeavor of the Dell Medical School and McCombs School of Business at the University of Texas at Austin): first, in an article in the Harvard Business Review "Redefining Competition in Health Care" (June 2004); then, as a book, with the title "Redefining Health Care" (April 2006).

The concept gained wide acceptance as a growing body of thinking focused on how to restructure health care delivery around value for patients, where value is defined as "the health outcomes achieved per euro spent".

Value-based health care delivery concepts start with providers but encompass new strategies for payors (national/regional health systems; private medical insurers), technology providers (pharma, medtech, digital health), and governments.

Based on the research of Professor Michael Porter, value is being defined as the outcomes that matter most to individuals and families over the resources spent to achieve those outcomes. As living in good health is less expensive than living in poor health, better outcomes often reduce spending as well, thereby creating further value.

Value-Based Health Care is the "process", being described in detail in EIT Health's recently published report, "Implementing Value-Based Health Care in Europe: Handbook for Pioneers". High Value Care is the "result" of that implementation.

The High Value Care Implementation Framework is the guiding template for new High Value Care projects. For those new to the field, the framework will serve as the basis on how to start and for those ready to scale will ensure the successful deployment in different settings or countries.

2.2 What is EIT Health looking for in High Value Care innovation projects?

High Value Care projects are a new type of Innovation projects aimed to create value by improving the health outcomes that matter most to patients.

The focus of those projects should be on implementation, rather than in technology development, and they could cover any part from prevention to long-term follow-up, anything from therapy optimization to integrated care, while having outcomes that matter to patients at its centre.

The selected cases compiled in "Implementing Value-Based Health Care in Europe: Handbook for Pioneers" are highlighted for their work in one or more of the building blocks, and they are meant to serve as inspiration regarding EIT Health objectives.

2.3 Which type of project partner can apply to HVC Innovation projects?

All partners are welcome to apply to HVC Innovation projects. EIT Health will be looking for a specific balance within the consortium configuration. A key component of HVC projects is that they are pan-European in nature. Each HVC project should be implemented in at least two different countries and should also aim to replicate the project in other regions beyond the two initial ones, if the project is successful.

The suggested consortium configuration is as follows:

- Healthcare providers coming from two different countries.
- Payors coming from the same country as the HCP.
- One or more technology providers (industry and/or start-ups).
- One knowledge sharing or academic (university) partner. (These partners are not mandatory but including them might be encouraged.)
- One patient representative association. (While patient associations participation in the consortia is not mandatory, including them might be encouraged, and patient engagement activities are a mandatory requirement for all EIT health innovation projects.)

In order to ensure a lasting transformation and high impact on the Healthcare system, two points have to be fulfilled:

- The healthcare provider and the payor should come from the same country: one should provide the healthcare services that the other will purchase.
- The healthcare provider and the payor must work on having a preliminary agreement on the changes needed before the start of the project, to make sure that can be in place and executed at the end of the EIT Health funding.

A payor is the stakeholder who can decide to change their current means of financing a healthcare service. Nowadays, most payors are financing healthcare services by the activity performed, ie. consultations, tests performed, visits to the emergency room, etc. This can be referred to as "fee-for-service" or "pay-for-volume".

EIT Health High Value Care projects aim to transform the way to finance healthcare services. This can involve a variety of models; to give some examples:

- Bundled payment
- Capitation
- Pay for performance
- Pay for outcomes
- Risk sharing

Payors are the only ones who also can force the necessary changes from industry, which will need to sell will need to sell results (outcomes) instead of selling devices (volume).

If the healthcare provider (i.e. a hospital) will pay the industry by outcomes but get paid by the payor (i.e. national or regional government) by volume, the equation will not work; the hospital will lose money and the healthcare system transformation will not be achieved fully.

2.4 What will an HVC Innovation project look like?

In terms of project maturity, EIT Health is looking for projects that have already started their High Value Care journey and are looking for financial and network support to bring them one step further. Before entering the portfolio, the project should already began assembling the following mandatory building blocks mentioned in the HVC Implementation Framework:

- **People with a health condition:** the proposal needs to be defined around a specific patient group or a specific condition, also applicable to the prevention of the condition.
- **Internal forces:** a minimum alignment of expertise is expected: clinical champions, data/IT team and finance team representatives should be involved in the project.
- **Scorecard:** a minimally defined set of outcomes to be measured needs to be already identified.
- **Data platform:** it is expected that some platform is set up to ensure systematic data storage and analysis.
- **Investment:** the consortia is expected to co-fund and invest in the project implementation.

Within the proposal evaluation process, those elements will be considered as minimum entrance requirements. We encourage the teams to detail their previous experience and improvements achieved in these domains to facilitate the understanding of the project maturity.

In terms of project structure, the following work package distribution is encouraged, to support the partners in clustering the different activities foreseen in HVC Innovation projects. Please use them as a reference for the task allocation during the project timeframe.

- WP1: Coordination.
- WP2: Implementation design – Design the new method to measure outcomes and to deliver healthcare to specific patients' group(s) targeted by the project.
- WP3: Implementation – Determine the outcomes baseline in each setting where the innovation is expected to be implemented and execute the new method of operations in both regions simultaneously, while measuring new outcomes.
- WP4: Evaluation – Analyze the data gathered (outcomes measured) and suggest improvements. Evaluate the impact generated with the new method to provide healthcare in socio-economic terms.
- WP5: Replicating – Look for new countries outside the consortium to replicate the process and/or develop new use cases in current settings. This work package should contain an exploitation plan.
- WP6: Communication and Dissemination – Develop training or educational programs and support communication activities around the project.

In terms of project budget, EIT Health will finance the transformation of the health service, not the technology solution. The main budget allocation should therefore be focused on the following types of costs:

- **Personnel costs** to manage the transformation from the current situation (ie. process reengineering).
- **Legal support** to create new procurement/purchasing contracts.
- **IT costs** linked to data capturing (PROMs and PREMs), data storing, data analysis, dashboards for managers, dashboard to support the use in clinical setting between healthcare professional and patient/citizen, etc.
- **Health economics analysis costs**, to demonstrate the impact of different diagnostic or treatment interventions.

2.5 What will success look like for High Value Care innovation projects?

Each HVC project should always **create value for all**: patients, providers, payor ("system" or "insurer") and industry. Success is achieved for EIT Health when:

- Transformation is adopted and sustained in the region → *Sustainable health system*
- Value is proven by socioeconomic impact studies → *Sustainable health economy*
- Improved outcomes are reported by patients → *Better health*

The expected transformation as a result of successful implementation of an HVC Innovation project is multidimensional and is likely to mostly involve change in the mindset of people. This includes, but is not limited to: understanding who the customers are and why; agreeing on the purchase of value-oriented projects taking place through regular purchasing instruments; transitioning the role of the industry from "technology provider" to "health and diseases manager"; providing healthcare professionals access to a set of technologies to adapt to the needs of the patient; helping patients understand and deciding together with their doctors their treatment options, depending on their potential expected outcomes. Considering the diversity of EIT Health's network, success could look differently depending on individual points of view. All in all, HVC innovation projects should aim to drive better health outcomes for European citizens. Possible measures of success could include:

For patients:

- Identify and act upon real needs of citizens and patients.
- Deliver and measure outcomes that matter to citizens and patients.
- Meaningfully involve citizens and patients across all our communities**.**

For academia:

- Improve the way healthcare providers are trained.
- Help patients and carers become co-responsible for the medical decisions
- Educate policy-makers in governments and C-level executives in value-based procurement, purchasing and decision making.

For healthcare systems:

- Cost reduction to systems, payors and government.
- Transform the way healthcare is delivered.

For industry:

- Access to providers and regional health systems**.**
- Speed – to scale faster**.**

2.6 How will the HVC Pilot Selection Process work?

An HVC Pilot Project will be selected in June 2021. The main reason to have a pilot project is to **test the process and the support needed** from the partners to build strong HVC Innovation Proposals.

The entry point for proposals will be the BP 2022 Expression of Interest (EOI). These EOIs will be submitted through Plaza, so there is no dedicated call for projects for the pilot. The EOI template will have a dedicated button to ask partners if they are willing to participate in HVC Pilot Selection Process.

All eligible HVC EOIs will be invited to participate in the Pilot Selection Process. While teams will be invited to join the parallel process of the pilot, they will still be requested to submit their full proposals to participate in the BP 2022 Call.

The EOI forms will be reviewed by externals, who will provide feedback in a short time frame. That feedback will come on time for partners to include it in their proposals, as the BP 2022 call will still be open.

After the call deadline, all projects should comply with the rules on the maximum number of innovation proposals that can be submitted by a partner, by which the Pilot Selection Process is also limited. This means that partners involved in HVC proposals submitted after the 24 March 2021 deadline and invited into the workshops process must adhere to these limits:

- Involvement in no more than seven proposals for Core Partners,
- Involvement in no more than four proposals for Associate Partners
- Involvement in no more than one proposal for External Project Partners.

See section 3.4.1 of the Call Document for details.

Up to 10 projects will be invited to participate in the process's intensive feedback segment, which will consist of a series of three afternoon workshops focused on Outcomes, Reward Systems and Culture, followed by a pitch competition session. This will support the teams in the refinement of their projects and create a community of HVC EIT Health pioneers. The 10 projects entering this part of the process will be able to remain in the BP 2022 process, so the BP 2022 Call remote review phase will take place for them. Regardless of their results in the BP 2022 process, projects will be able to continue participating in the pilot if they make it through the different evaluation steps. The same applies in reverse: their continuation in the BP2022 call selection process will not be influenced by the results of the PILOT Selection Process evaluation.

Up to five teams will be invited to the final pitching stage, happening in June (hearings week), They will be encouraged to meet with experts during "office hours", to prepare and refine the projects before the final

pitching stage. The experts engaged, and the office hours, taking place during May, will be tailored to the needs of each of the five final projects.

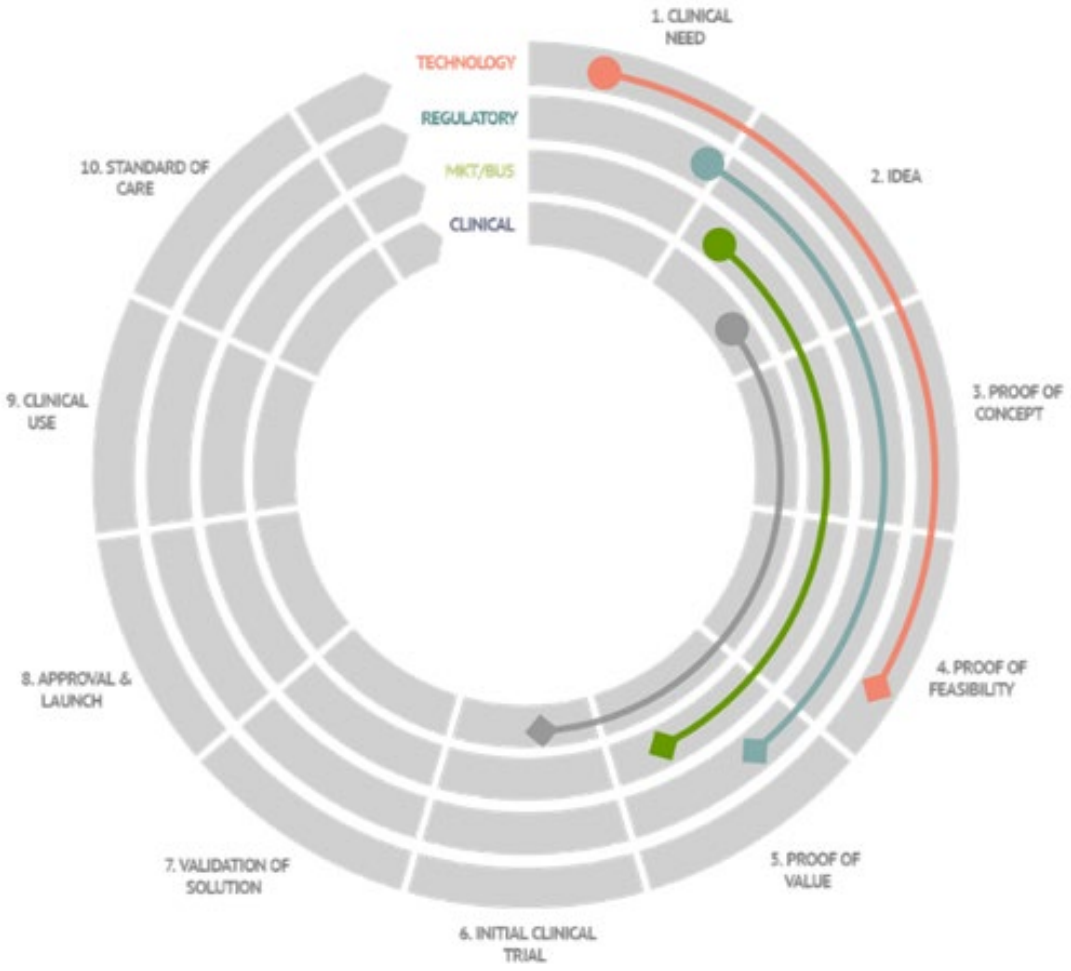
The selected Pilot Project will start after the notification in July, six months earlier than any other EIT Health HVC project. It will become the EIT Health HVC Pioneer, receiving extensive feedback and dedicated support and follow-up.

After the HVC Pilot Selection Process:

- **All teams** get remote **feedback.**
- Up to 10 teams have **additional co-creation workshops.**

  Up to five final teams get **additional one-to-one feedback** .
- **One HVC Pilot Project** is selected and can **start already in 2021.**

3. CIMIT Healthcare Innovation Cycle



Partner-driven and Start-up-driven projects will need to use the CIMIT Healthcare Innovation Cycle when defining their project.

Both type of projects will need to start at a minimum level of IML 3 (Proof of Concept). The level projects are expected to achieve by the time EIT Health support is finished will depend on the sector (BioPharma, MedTech, Digital Health). For the complete definition of Innovation Maturity Levels please the following section, Milestones Framework.

Innovation Maturity Levels (IML) have been defined by CIMIT, so that they can be applied as a matrix system to measure the maturity of a project in four different domains: Technology, Regulatory, Marketing/Business, and Clinical.

This is a different concept from the concept of TRL (technology readiness level), which focuses only on

technology maturity.

The use of the CIMIT Healthcare Innovation Cycle in the proposal process will allow us to develop an understanding of:

- Where projects start (to ensure they are at the right maturity level and thus have a reasonable chance of "success")**.**
- Where they will be at the end of EIT Health intervention (with the support of funds, value-added services, etc.)**.**

4. Milestones Framework

EIT Health Innovation Pillar aims to use the following Milestone Framework Checklist to track maturity of the projects that aim to reach the market by commercializing their solutions and support them in their steps along the journey.

Please use this framework to complete your hearings slides, match the Critical Milestones selected in your proposal (if possible) with the available Milestone Framework and the Corresponding Innovation Maturity Level. Milestones highlighted in red bold have been identified as those steps that would lead to a start-up valuation increase.

For Start-up Amplifier Instrument proposals only: you can select up to two Milestones that you would like to link to Start-up Valuation increase (optional).

The following pages contain three types of Milestones checklists:

- Biomarkers Diagnostics
- Medtech
- Digital

Biomarkers Diagnostics Milestones

Innovation Maturity Level	Name	Overall Description	Innovation Maturity Level Milestones			
			Clinical	Market/Business	Regulatory	Technology
1	Need	Insights into unmet clinical needs and available solutions	❑ Unmet need statement ❑ Disease state characterization	❑ Needs screening & selection ❑ Existing solutions characterization	❑ Regulatory familiarization	❑ State-of-the-Art summary
2	Idea	Potential solution to unmet need described, evaluated and selected	❑ Clinical Workflow scenario ❑ Updated need statement ❑ Envisioned benefit statement ❑ Feedback from 5+ clinical stakeholders	❑ Competitive landscape ❑ Envisioned Value Proposition ❑ Key stakeholders identified ❑ Reimbursement familiarization	❑ Medical device determination (MDR in EU) ❑ Comparable identified	❑ Idea screening and selection ❑ Preliminary Target Product Profile ❑ Biological mechanism of action identified ❑ Institutional IP disclosure
3	Proof of Concept (PoC)	Key component concepts validated in models and value proposition tested	❑ Feedback from clinical stakeholders in 5+ settings ❑ Updated need statement and workflow scenario ❑ Target outcomes	❑ Competing solutions characterization ❑ Preliminary value proposition ❑ Path-to-Payment plan ❑ Stakeholder map ❑ Business protection model	❑ Preliminary regulatory classification ❑ Preliminary regulatory pathway ❑ Preliminary intended /indications for use	❑ **Key mechanism of action validated** ❑ Updated Target Product Profile (TPP) ❑ Preliminary Freedom to Operate (FTO) Assessment ❑ Updated institutional IP disclosure ❑ Key in-sourcing requirements
4	Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	❑ Feedback on users in 20+ settings ❑ Updated need statement and Use Case scenario/workflow ❑ Updated target outcomes	❑ Feedback from 5+ economic buyers ❑ Preliminary business model ❑ Development plan ❑ Key relationships identified ❑ Business advisory board	❑ Draft essential requirements checklist ❑ Draft product claims ❑ Draft instructions for use ❑ Institutional approval request(s) ❑ Submission pathway defined	❑ Updated Target Product Profile (TPP) ❑ "Works Like" and "Looks Like" packaging prototypes ❑ Essential experiment results ❑ Provisional IP filing & initial FTO review ❑ Key in-sourcing plans ❑ Manufacturing/QMS plan

5	**Proof of Value (PoV)**	**The potential of the solution to work and create value for all stakeholders is demonstrated**	❑ Feedback from 100+ users ❑ Feedback from 5+ KOLs ❑ Animal/first in/with man experiments ❑ Medical advisory board ❑ Clinical trial endpoints	❑ Key management team committed ❑ Investor ready business plan ❑ Feedback from 20+ economic buyers ❑ Initial Seed Investment ❑ Key relationships formalized ❑ Incorporation & Founders agreement	❑ Essential requirements checklist ❑ Application form to competent authority submitted ❑ Clinical Investigation approval(s)	❑ "Works Like, Looks Like, Made Like", "Made Like" prototypes ❑ Updated TPP & Essential technical experiments results ❑ IP search report ❑ cGMP compliant pilot manufacturing process ❑ Key in-sourcing requirements committed ❑ Conference/poster session/paper submitted
6	**Initial Clinical Trials (ICT)**	**Regulated production of prototypes and collection of clinical and economic data**	❑ **Endpoints achieved in Feasibility clinical trials** ❑ Peer reviewed publication(s) submitted	❑ Value quantification ❑ Feedback from 25+ economic buyers ❑ **1st institutional investment**	❑ Data requirements confirmation ❑ Pre-submission filed	❑ cGMPs compliant manufacturing process ❑ Updated TPP & experimental validation ❑ All in-sourcing licensing requirements achieved ❑ **Full IP application**
7	**Validation of Solution (VoS)**	**The solution is shown to be effective and its value to all stakeholders is validated**	❑ **Endpoints achieved in pivotal clinical trials** ❑ Peer reviewed publication(s) accepted	❑ Purchasing intent from 10+ buyers ❑ **2nd round of institutional investment**	❑ Submission of Technical file to regulatory body	❑ Quality assured process validation (cGMP) ❑ Updated TPP & experimental validation
8	**Approval & Launch (A&L)**	**Institutional and regulatory approval received and sales launch**	❑ Training materials & support established ❑ Specialty medical groups review in place	❑ **Initial sales** ❑ Regionalization plans	❑ **Registration and listing** ❑ **CMS/Public Coverage and CPT/DRG code determination**	❑ Finalized cGMP production environment ❑ IP for improvements filed
9	**Clinical Use (Use)**	**The solution is used successfully in day-to-day clinical practice**	❑ Included in local practice guidelines ❑ Peer reviewed publications	❑ **Profitable sales** ❑ New markets launched	❑ Monitoring/ inspections	❑ Improvement plan ❑ Key patents issued
10	**Standard of Care (SoC)**	**The solution is recognised as the standard of care**	❑ Recommended practice by medical specialty	❑ Dominant market share ❑ Health economics study	❑ Product Obsolescence plan	❑ Component Obsolescence plan

For more information on the specific meaning of each of the biomarkers diagnostics milestones, you can access: https://www.gaits.org/web/biomarker-diagnostic

Medtech Milestones

Innovation Maturity Level	Name	Overall Description	Innovation Maturity Level Milestones			
			Clinical	Market/Business	Regulatory	Technology
1	Need	Insights into unmet clinical needs and available solutions	❑ Unmet need statement ❑ Disease state characterization	❑ Needs screening & selection ❑ Existing solutions characterization	❑ Regulatory familiarization	❑ State-of-the-Art summary
2	Idea	Potential solution to unmet need described, evaluated and selected	❑ Workflow scenario ❑ Updated need statement ❑ Envisioned benefit statement ❑ Feedback from 5+ clinical stakeholders	❑ Competitive landscape ❑ Envisioned Value Proposition ❑ Key stakeholders identified ❑ Reimbursement familiarization	❑ Medical device determination (MDR in EU) ❑ Comparable identified	❑ Idea screening and selection ❑ Paper Prototype ❑ Institutional IP disclosure
3	Proof of Concept (PoC)	Key component concepts validated in models and value proposition tested	❑ Feedback from clinical stakeholders in 5+ settings ❑ Updated need statement and workflow scenario ❑ Target outcomes	❑ Competing solutions characterization ❑ Preliminary value proposition ❑ Path-to-Payment plan ❑ Stakeholder map ❑ Business protection model	❑ Preliminary regulatory classification ❑ Preliminary regulatory pathway ❑ Preliminary intended /indications for use ❑ Preliminary risk and hazard analysis	❑ Key component PoC prototypes ❑ Demonstration results ❑ Preliminary Freedom to Operate (FTO) Assessment ❑ Updated institutional IP disclosure ❑ Key in-sourcing requirements
4	Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	❑ Feedback on users in 20+ settings ❑ Updated need statement and Use Case scenario/workflow ❑ Updated target outcomes	❑ Feedback from 5+ economic buyers ❑ Preliminary business model ❑ Development plan ❑ Key relationships identified ❑ Business advisory board	❑ Draft essential requirements checklist ❑ Draft product claims ❑ Draft instructions for use ❑ Institutional approval request(s) ❑ Submission pathway defined	❑ Product Requirement Document (PRD) ❑ "Works Like" and "Looks Like" prototypes ❑ Essential experiment results ❑ Provisional IP filing & initial FTO review ❑ Key in-sourcing plans ❑ Manufacturing/QMS plan

5	**Proof of Value (PoV)**	**The potential of the solution to work and create value for all stakeholders is demonstrated**	❑ Feedback from 100+ users ❑ Feedback from 5+ KOLs ❑ Use Case/ scenarios testing with 10+ users ❑ **Animal/first in/with man experiments** ❑ Medical advisory board ❑ Clinical trial endpoints	❑ Key management team committed ❑ Investor ready business plan ❑ Feedback from 20+ economic buyers ❑ **Initial Seed Investment** ❑ Key relationships formalized ❑ Incorporation & Founders agreement	❑ Essential requirements checklist ❑ Application form to competent authority submitted ❑ Clinical Investigation approval(s)	❑ "Works Like, Looks Like, Made Like" prototypes ❑ Essential technical experiments results ❑ IP search report ❑ GMP compliant pilot manufacturing process ❑ Key in-sourcing requirements committed
6	**Initial Clinical Trials (ICT)**	**Regulated production of prototypes and collection of clinical and economic data**	❑ **Endpoints achieved in Feasibility clinical trials** ❑ Demo feedback from 25+ users ❑ Peer reviewed publication(s) submitted	❑ Value quantification ❑ Feedback from 25+ economic buyers ❑ **1st institutional investment**	❑ GDPR/HIPAA compliance ❑ Security and vulnerability certifications ❑ Data requirements confirmation ❑ Pre-submission filed	❑ cGMPs compliant manufacturing process ❑ Updated specification & experimental validation ❑ All in-sourcing licensing requirements achieved ❑ **Full IP application**
7	**Validation of Solution (VoS)**	**The solution is shown to be effective and its value to all stakeholders is validated**	❑ **Endpoints achieved in pivotal clinical trials** ❑ Peer reviewed publication(s) accepted	❑ Purchasing intent from 10+ buyers ❑ **2nd round of institutional investment**	❑ Submission of Technical file to regulatory body	❑ Quality assured process validation (cGMP) ❑ Updated specification & experimental validation
8	**Approval & Launch (A&L)**	**Institutional and regulatory approval received and sales launch**	❑ Training materials & support established ❑ Specialty medical groups review in place	❑ **Initial sales** ❑ Regionalization plans	❑ **Registration and listing** ❑ **CMS/Public Coverage and CPT/DRG code determination**	❑ Finalized cGMP production environment ❑ IP for improvements filed
9	**Clinical Use (Use)**	**The solution is used successfully in day-to-day clinical practice**	❑ Included in local practice guidelines ❑ Peer reviewed publications	❑ **Profitable sales** ❑ New markets launched	❑ Monitoring/ inspections	❑ Improvement plan ❑ **Key patents issued**
10	**Standard of Care (SoC)**	**The solution is recognised as the standard of care**	❑ Recommended practice by medical specialty	❑ Dominant market share ❑ Health economics study	❑ Product Obsolescence plan	❑ Component Obsolescence plan

For more information on the specific meaning of each of the milestones you can access: https://www.gaits.org/web/medtech

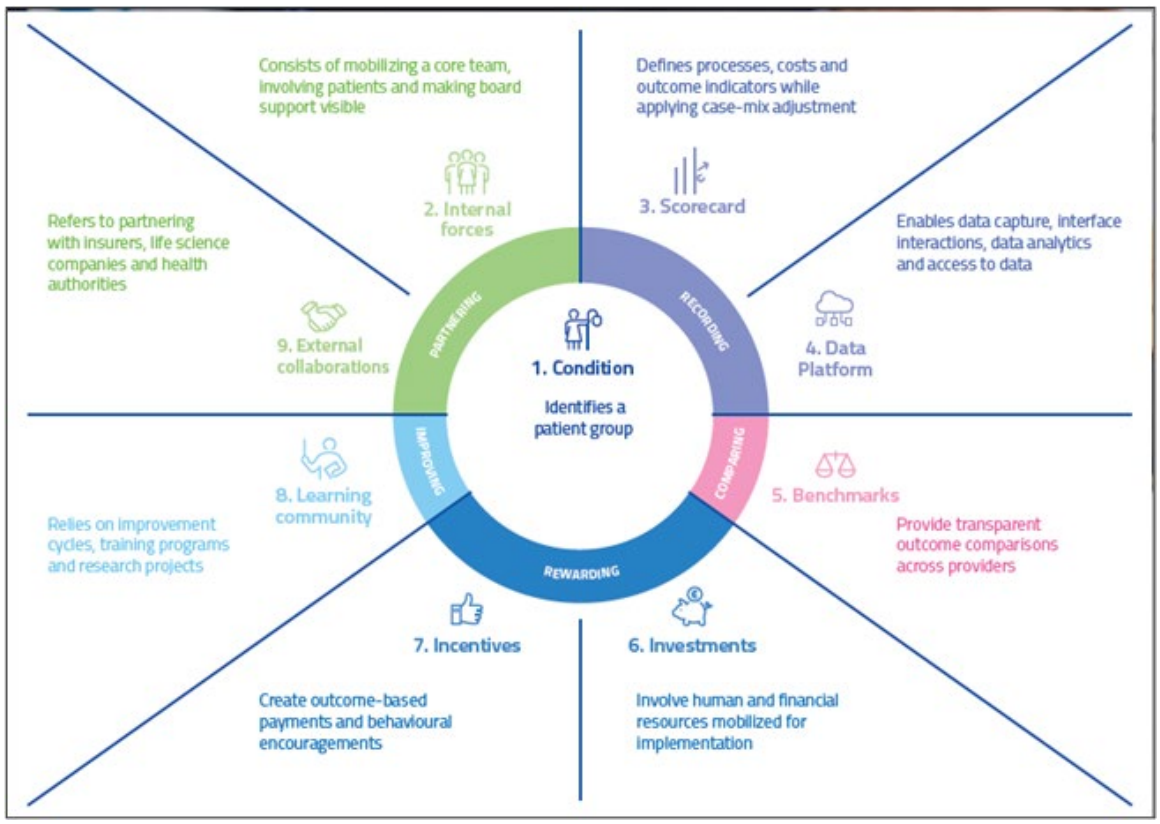
Digital Health Milestones

Innovation Maturity Level	Name	Overall Description	Innovation Maturity Level Milestones			
			Clinical	Market/Business	Regulatory	Technology
1	Need	Insights into unmet clinical needs and available solutions	❑ Unmet need statement ❑ Disease state characterization	❑ Needs screening & selection ❑ Existing solutions characterization	❑ Regulatory familiarization	❑ State-of-the-Art summary
2	Idea	Potential solution to unmet need described, evaluated and selected	❑ Workflow scenario ❑ Updated need statement ❑ Envisioned benefit statement ❑ Feedback from 5+ clinical stakeholders	❑ Competitive landscape ❑ Envisioned Value Proposition ❑ Key stakeholders identified ❑ Reimbursement familiarization	❑ Medical device determination (MDR in EU) ❑ Comparable identified	❑ Idea screening and selection ❑ System and module requirement specification ❑ Interface mock-ups ❑ Institutional IP disclosure
3	Proof of Concept (PoC)	Key component concepts validated in models and value proposition tested	❑ Feedback from clinical stakeholders in 5+ settings ❑ Updated need statement and workflow scenario ❑ Target outcomes	❑ Competing solutions characterization ❑ Preliminary value proposition ❑ Path-to-Payment plan ❑ Stakeholder map ❑ Business protection model	❑ Preliminary regulatory classification ❑ Preliminary regulatory pathway ❑ Preliminary intended /indications for use ❑ Preliminary risk and hazard analysis	❑ Preliminary system and software architecture ❑ Key module PoC prototypes ❑ Demonstration results ❑ Updated institutional IP disclosure ❑ Key in-sourcing requirements
4	Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	❑ Feedback on users in 20+ settings ❑ Updated need statement and Use Case scenario/workflow ❑ Updated target outcomes	❑ Feedback from 5+ economic buyers ❑ Preliminary business model ❑ Development plan ❑ Key relationships identified ❑ Business advisory board	❑ Draft essential requirements checklist ❑ Draft product claims ❑ Draft instructions for use ❑ Institutional approval request(s) ❑ Cyber security plan	❑ Product Requirement Document (PRD) ❑ Software and hardware architecture ❑ "Works Like" prototype ❑ Essential experiment results ❑ Provisional IP filing & initial FTO review ❑ Key in-sourcing plans

					❑ Submission pathway defined	❑ Risk mitigation and interoperability plan
5	**Proof of Value (PoV)**	**The potential of the solution to work and create value for all stakeholders is demonstrated**	❑ Feedback from 100+ users ❑ Feedback from 5+ KOLs ❑ Medical advisory board ❑ Clinical pilot ❑ Clinical trial endpoints	❑ Key management team committed ❑ **Investor ready business plan** ❑ Feedback from 20+ economic buyers ❑ Initial Seed Investment ❑ Key relationships formalized ❑ Incorporation & Founders agreement	❑ Essential requirements checklist ❑ Application form to competent authority submitted ❑ Clinical Investigation approval(s) ❑ Protected Health Information (ePHI) plans	❑ "Works Like, Looks Like, prototypes ❑ Essential technical experiments results ❑ Interoperability validation ❑ cGMP medical software and production environments (s) ❑ Key in-sourcing requirements committed
6	**Initial Clinical Trials (ICT)**	**Regulated production of prototypes and collection of clinical and economic data**	❑ **Endpoints achieved in Feasibility clinical trials** ❑ Demo feedback from 25+ users ❑ Peer reviewed publication(s) submitted	❑ Value quantification ❑ Feedback from 25+ economic buyers ❑ **1st institutional investment**	❑ GDPR/HIPAA compliance ❑ Security and vulnerability certifications ❑ Data requirements confirmation ❑ Pre-submission filed	❑ Updated specification & experimental validation ❑ All in-sourcing licensing requirements achieved ❑ Full IP application
7	**Validation of Solution (VoS)**	**The solution is shown to be effective and its value to all stakeholders is validated**	❑ **Endpoints achieved in pivotal clinical trials** ❑ Peer reviewed publication(s) accepted	❑ Purchasing intent from 10+ buyers ❑ **2nd round of institutional investment**	❑ Submission of Technical file to regulatory body	❑ Quality assured process validation (cGMP) ❑ Updated specification & experimental validation
8	**Approval & Launch (A&L)**	**Institutional and regulatory approval received and sales launch**	❑ Training materials & support established ❑ Specialty medical groups review in place	❑ Initial sales/deployment ❑ Regionalization plans	❑ **Registration and listing** ❑ **CMS/Public Coverage and CPT/DRG code determination**	❑ Finalized cGMP production environment ❑ Regionalization requirements
9	**Clinical Use (Use)**	**The solution is used successfully in day-to-day clinical practice**	❑ Included in local practice guidelines ❑ Peer reviewed publications	❑ **Profitable sales** ❑ New markets launched	❑ Monitoring/ inspections	❑ Improvement plan ❑ Regionalization implemented
10	**Standard of Care (SoC)**	**The solution is recognised as the standard of care**	❑ Recommended practice by medical specialty	❑ Dominant market share ❑ Health economics study	❑ Product Obsolescence plan	❑ Component Obsolescence plan

For more information on the specific meaning of each of the milestones you can access: https://www.gaits.org/web/-digital-medicine

5. High Value Care Implementation Framework



The new framework will be used as a guiding template for new HVC projects. For those new to the field the framework will serve as the basis on how to start and for those ready to scale will ensure the successful deployment in different settings or countries. A brief description of the 9 building blocks can be found below:

1. **People with a health condition:** Identifies a patient group
2. **Internal forces:** Consists of mobilizing a core team, involving patients and making board support visible.
3. **Scorecard:** Defines processes, costs and outcome indicators while applying case-mix adjustment.
4. **Data platform:** Enables data capture, interface interactions, data analytics and access to data.
5. **Benchmarks:** Provides transparent outcome comparisons across providers.
6. **Investment:** Involve human and financial resources mobilised for implementation.
7. **Incentives:** Creates outcome-based payments and behavioural encouragements.
8. **Learning community:** Relies on improvement cycles, training programs and research projects.
9. **External alliances:** Refers to partnering with insurers, life science companies and health authorities.

For further detail please visit: *Implementing Value-Based Health Care in Europe: Handbook for Pioneers*

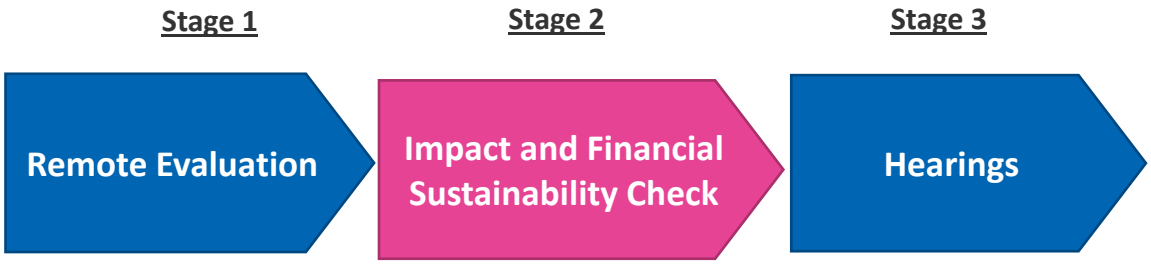
6. Impact and Financial Sustainability Check

The Impact and Financial Sustainability Check is a new secondary stage in the Innovation projects evaluation process.

To allow for a fair and equal comparison of the impact expected from three different types of Innovation projects during the evaluation of proposals, EIT Health will implement the Impact and Financial Sustainability Check. This will become the new Stage 2 of the Innovation projects evaluation process.

6.1 Main Principles of the impact and Financial Sustainability Check

- **Timing**: Impact and Financial Sustainability Check will take place after Remote Evaluation (Stage 1) and before Hearings (now Stage 3). The Impact and Financial Sustainability Check is a process led by EIT Health HQ.



- **Content**: The Impact and Financial Sustainability Check was developed to evaluate three dimensions of impact that are important to EIT Health:

1. Health impact,
2. Financial contribution to EIT Health, and
3. Co-funding.

These three dimensions of impact can be created by any type of Innovation project.

- **Effect**: The result of Impact and Financial Sustainability Check will condition the invitation to Hearings. However, the final funding decision will be made based on scores from Remote Evaluation (25%) and Hearings (75%).
- **Data:** Data regarding the three dimensions of impact will be collected on Plaza in each activity proposal, and then translated into comparable numbers to be evaluated.

6.2 Why the Impact and Financial Sustainability Check was created

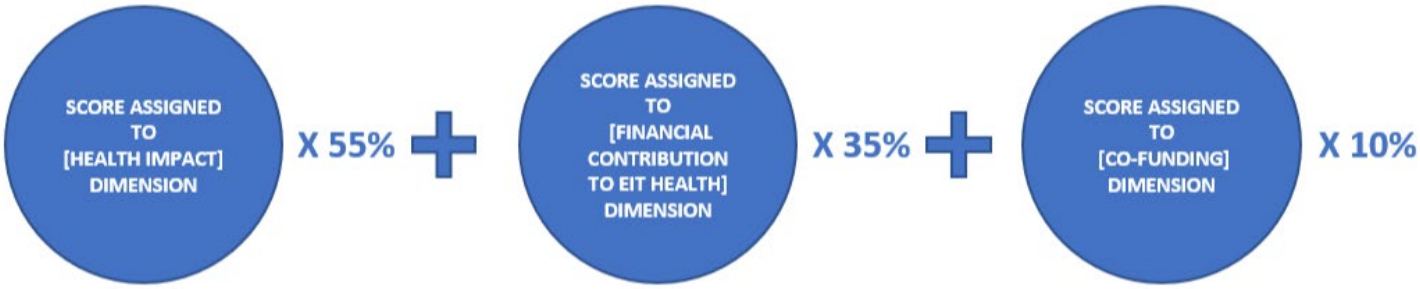
Three different types of Innovation Projects can be included in the Business Plan. Each has different characteristics, project structure and requirements proposed by EIT that must be satisfied. The Impact and Financial Sustainability Check was created to account for all three types of Innovation projects on a fair and comparable basis. The Impact and Financial Sustainability Check is a way to measure impact from numbers and metrics provided by consortia in the proposals.

6.3 How the Impact and Financial Sustainability Check is implemented

This new process will be composed of two steps, combining the three dimensions of impact that are important to EIT Health strategic growth in one calculation, and then taking scores from Remote Evaluation into account, to result in a comparable and unbiased ranking for all projects, which will finally be the basis of invitation to Hearings.

Step 1. Each project will get one new score (which is different from the score obtained from Remote Evaluation) according to its performance in all three dimensions of impact. This step will provide an overall understanding for all projects in terms of degree of impact, without considering project excellence or implementation quality. This new score will serve to sort the projects. Only the ones getting the highest scores in step 1 will be considered as eligible to be invited to hearings.

The new score for each project will be obtained by calculating:



Step 2. A new ranking will be created for all projects according to the sequence of scores from Remote Evaluation and the best scored projects based on their impact score (from Step 1). Invitations to Hearings will be based on this new ranking. Top projects (number to be decided according to EIT Grant funding available for BP2022) on this new ranking will be invited to Hearings.

6.4 KPIs and metrics of Impact and Financial Sustainability Check

Units and timeframes of different dimensions included in the Impact and Financial Sustainability Check are described in detail:

1. **Health impact**: there are two metrics included in this dimension. The tiime frame for this dimension is the same for both Metrics: **The third year after project completion (i.e., third year after the EIT Health funding period ends).**

   Metric 1 (weighs 30% of the Health impact dimension): number of patients, citizens, users or beneficiaries touched within Europe and positively impacted by the launched innovation resulting from project implementation, in the third year after funding period ends. This dimension should be expressed as KPI13 (Number of citizens/patients that benefitted from solutions developed or implemented in EIT Health activity). KPI13 can include global citizens but Metric 1 only considers European impact. The consortium will provide self-assessment and citations to support the self-

assessment in the Proposal Deck uploaded to Plaza upon submission. Please refer to the Complementary Proposal Deck provided on Connections. Paediatric and rare/ultra-rare diseases will be assessed in a fair way. Note: "Europe" here includes the EU27, UK, Switzerland, Iceland, Norway, the Western Balkans, Turkey and Ukraine.

Metric 2 (weighs 70% of the Health impact dimension): self-assessment on health gains, including quality of life, life expectancy and patient experience improvement, brought forth by the proposed solution – the consortium will provide self-assessment and important citations to support the self-assessment in the Proposal Deck uploaded to Plaza upon submission. Please refer to the Complementary Proposal Deck provided on Connections.

From this dimension, EIT Health will understand direct impact created by the project after the solution is launched – at the third year after funding period ends – on patients, citizens, users or beneficiaries.

2. **Financial contribution to EIT Health:** Monetary contributions (cash, option ownership…etc.) to EIT Health from project consortia, from first year after EIT Health funding period up until fifth year after funding period. The source of financial contributions could be revenue sharing, option agreement, or one-off contributions within designated years, or any other format agreed between consortia and EIT Health. To be noted that the financial contribution should NOT be confused with revenue projection generated from solution. Financial contributions to EIT Health should be discussed and agreed upon within consortia members, then be presented and expressed as a form of commitment, i.e. a contract signed by all consortia members as soon as consortia will be invited to hearings. This applies for all projects except Start-up-driven projects for which Term Sheet and Option Agreement are due at a later stage as planned in the implementation of the Start-up Amplifier instrument. In addition, an Excel template to reflect projects' financial contributions must be submitted to EIT Health before the Call closes.

   From this dimension, EIT Health will understand the impact consortia members are willing to commit to EIT Health's long-term financial sustainability, in terms of financial contributions, within the 5 years after funding period.

3. **Co-funding**: Percentage of co-funding from all consortia members out of total requested funding, annual average from start to end of EIT Health funding period. The minimum average co-funding for the EIT Health 2022 Innovation portfolio is 30%.

   From this dimension, EIT Health will understand how much consortia members are willing to commit to the project, in terms of co-funding throughout funding period, to create continuous impact during project implementation.

Quality check

The collection of required KPIs and metrics for Impact and Financial Sustainability Check will be done once proposals are submitted. To assess the data quality of the inputs for these three dimensions, external reviewers will review the three dimensions during Remote Evaluation and score the feasibility. This score of feasibility will affect the data used for Impact and Financial Sustainability Check. Feasibility will be evaluated again in the Hearings, and the result will feed into Portfolio Development.

This table presents the dimensions of Impact and Financial Sustainability Check in summary:

DIMENSIONS	KPI/METRIC	UNIT	TIME REFERENCE	WEIGHTS
1. Health impact	Metric 1: Number of citizens/patients in Europe that benefitted from solutions developed or implemented in EIT Health activity	KPI13 or a part of KPI13 if the solution targets other non-European markets	3rd year after funding period (single-year)	55% of the Impact and Financial Sustainability Check
	Metric 2: Self-assessed health gains from proposed solution	n.a.		
2. Financial contributions to EIT Health	Financial contributions to EIT Health, expressed in a commitment before Hearings	EURO (€)	Up until 5th year after funding period (multiple-year)	35% of the Impact and Financial Sustainability Check
3. Co-funding	Average co-funding from all participants of the project	%	From start to end of funding period (multiple-year)	10% of the Impact and Financial Sustainability Check

6.5 An Illustrative Example of Impact and Financial Sustainability Check implementation

The following is an example of how the framework could be implemented. All numbers, figures and names mentioned in this section are for illustrative purposes.

Suppose EIT Health received 160 eligible activity proposals. Among these eligible proposals, we now follow the journey for this specific proposal called "Project A", which is a Start-up-driven project, with "Startup A" at the center and plans to launch an innovative product to market by year 2027. Project A passed Eligibility Check, and in Stage 1 (Remote Evaluation) scored 85.5, which positioned Project A as the 25th ranked project according to Stage 1 scores.

Project A and all other projects then proceed to Stage 2, Impact and Financial Sustainability Check.

Step 1.

Project A and all other projects will get one new score according to their performance in all three dimensions of impact, which are Health impact, Financial contributions to EIT Health, and Co-funding.

- **Health impact:** Project A foresees its product to bring benefits to more than 60,000 patients for Metric 1 and provided self-assessment for Metric 2 at year three after project completion.
- **Financial contributions to EIT Health:** Since it is a Start-up-driven Project, Project A will arrange Term Sheet and Option Agreement (of Startup A) with EIT Health, without proposing other additional forms of contribution.
- **Co-funding:** According to Project A proposal, the project will have 35% average co-funding throughout project lifetime.

Taking all above dimensions into consideration, all projects obtained a new score, and suppose Project A obtains a new score of 90, which represents strong and balanced performance in all dimensions, and positioned Project A as the 10th ranked project according to Stage 2 scores. However, this does not change the fact that in terms of Remote Evaluation scores, 24 other projects are "better" than Project A.

Step 2

A new ranking will be created for all projects based on the sequence of scores from Remote Evaluation. Suppose that one top project called "Project X" scored 86 during Remote Evaluation, and was ranked 24th, which was one position above Project A. However, in Step 1, Project X obtained low score from Impact and Financial Sustainability Check due to low co-funding, low financial contributions to EIT Health and low Health impact. In the new ranking, Project A will replace Project X to assume the 24th position.

Suppose this year, according to EIT Grant funding available, 24 projects could be invited to Hearing. Project A, being the 24th project on the new ranking after Impact and Financial Sustainability Check, will then be invited to Hearings.

Note that even though Project Z obtained higher scores than Project A during Stage 2, the new ranking still follows the order of score from Remote Evaluation.

Please refer to the following table for a summary of this example.

Stage 1			Stage 2		
Remote Evaluation scores by external reviewers			Step 1: obtain new score		Step 2: create new ranking based on Remote Evaluation
Ranking based on Remote Evaluation	Project name	Score from Remote Evaluation	Score from Impact and Financial Sustainability Check	Ranking based on Impact and Financial Sustainability Check	New Ranking
23rd	Project Y	87 points	92 points	8th	23rd
24th	Project X	86 points	50 points	69th	Not ranked
25th	Project A	85.5 points	90 points	10th	24th
26th	Project Z	85 points	91 points	9th	25th

6.6 Frequently Asked Questions

General Questions

What has changed regarding Innovation evaluation process?

"Impact and Financial Sustainability Check" will be introduced as Stage 2 to give priority to projects that create most impact in terms of health impact, financial contributions, and co-funding. Invitation to Hearings will be based on both scores of Remote Evaluation and Impact and Financial Sustainability Check.

What has NOT changed regarding Innovation evaluation process?

Scores from Remote Evaluation and Hearings will still be the main determinants during the selection process, i.e. the calculation of the final score remains the sum of 25% Remote Evaluation scores plus 75% Hearing scores. Remote Evaluation scores of each project will NOT be altered by the Impact and Financial Sustainability Check. Evaluation of overall project excellence will be indicated by external evaluators.

When will Impact and Financial Sustainability Check take place?

This stage will take place between the Remote Evaluation and the Hearings as Stage 2

Is there a feedback report to be provided after Impact and Financial Sustainability Check?

No feedback report will be provided after Impact and Financial Sustainability Check. All expert opinions are captured and collected at Remote Evaluation and Hearings.

Criteria and dimensions

What are the evaluation criteria for Impact and Financial Sustainability Check?

There are three dimensions for Impact and Financial Sustainability Check: Health impact (55%); financial contributions (35%); and co-funding (10%).

What are the metrics/KPIs for each dimension in Impact and Financial Sustainability Check?

- **Health impact:**
    - Metric 1: KPI 13 - Number of citizens/patients in Europe that benefitted from solutions developed or implemented in EIT Health activity, in the third year after funding period ends. This dimension should be expressed as part of KPI13 (Number of citizens/patients that benefitted from solutions developed or implemented in EIT Health activity) found in Plaza. Please refer to the Complementary Proposal Deck provided on Connections.
    - Metric 2: self-assessment on heath gains, including quality of life, life expectancy and patient experience improvement, brought forth by the proposed solution – the consortium will provide self-assessment and citations to support the self-assessment in the Proposal Deck uploaded to Plaza upon submission. Please refer to the Complementary Proposal Deck provided on Connections.
- **Financial contributions:** monetary contribution to EIT Health committed by consortia and expressed in written agreement or contract, for all projects except Start-up-driven projects. This dimension should be indicated in Euros (€) annually in the Excel template.
- **Co-funding:** average percentage of co-funding throughout project funding period will be calculated automatically on Plaza. Please indicate co-funding figures for each consortia member in Plaza, as done in previous years.

How do I calculate Health impact?

Metric 1: A bottom-up approach is recommended: estimate the number of markets or settings within Europe that you are confident to reach in the third year after project completion and estimate direct users / patients / citizens / beneficiaries of each market benefitting from the innovation launched as a result of the project. Multiply the two numbers, and this will be a close estimation of Health impact about which you are confident.

Here are some important references to investigate when estimating your Health impact:

- Users/patients/citizens/beneficiaries positively impacted by a comparable product or service that is already in the market or setting.
- Estimated market share or percentage use in different settings, and integration in clinical workflow.
- Regulatory timeline and overall trends of the innovation to be launched.

Metric 2: determine the baseline for your estimations for the three assessment items (quality of life, life expectancy, and patient experience), and self-assess the level of improvement brought forth by your proposed solution. For further information, please refer to the Complementary Proposal Deck provided on Connections.

How do I calculate Financial contributions?

- Financial contributions to EIT Health can be a certain percentage of revenue sharing, option agreements, one-off returns within designated years, or any other format that is agreed between consortia and EIT Health.
- Financial contributions to EIT Health should NOT be confused with revenue projection generated from solution.
- Inflation can be ignored when estimating financial contributions to EIT Health.

Amendments

The Annex was updated on 14 December 2020 with the following changes:

Page	Changes made
3-8, 12	A specific case was included for start-up driven projects with non-incorporated start-up: • Start-up should be incorporated by October 1, 2021 the latest. • Start-up should meet all Start-up Amplifier criteria outlined in 1.1 by October 1, 2021. • Right after the incorporation, a start-up will go through due diligence and valuation analysis. • Should the start-up not accept the valuation and/or not pass due diligence, its innovation project will not be funded in BP 2022.
3-16, 33	The participation of EIT Health via "options" is optimised from the legal perspective. Instead of "options", EIT Health has an option to buy shares in the case of a "financial event", a contractual claim to assume shares when there is an occurrence of the defined financial events (asset deal exit, share deal exit, IPO, liquidation). This change in wording has no effect on the economic terms of the Start-up Amplifier and Option Agreement.
5, 6, 9, 12, 15, 16	Term Sheet is updated to accommodate the change in wording (from "options" to option to buy shares in the case of a "financial event").
5, 9	Term "CLC/InnoStars" was substituted by "regional Innovation Hubs"
16-17	It was made more explicit that start-ups receiving sub-grants in other EIT Health programmes in 2021, in case they will be selected to be funded through Start-up Amplifier, should receive, and spend all their sub-grant by the end of 2021. Their sub-granting agreements should also have an end date no later than 31 December 2021.

The Annex was updated on 11 January 2021 with the following change:

21-23	Section 2.6 is added to explain the process for selection of an HVC pilot project.

The Annex was updated on 11 March 2021 with the following changes:

19-23	• Updated HVC Pilot Selection Process information to reflect the decision taken by the EIT Health Management on not making mutually exclusive the participation in the HVC Pilot Selection Process and BP 2022 Call Process. • Included and clarified definitions on "payors".
35-40	Section 6 is updated with the new Health Impact metric (Metric 1 and Metric 2).