# **IMPLEMENTATION HANDBOOK**

Business Plan 2023-2025 | November 2024





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# **Version Updates**

Updates to the Implementation Handbook may be made to reflect updated processes and will be indicated in the below table. This version replaces all other versions of the Implementation Handbook.

Version	Major Changes	
22 November 2024	Updated timelines, processes, pre-financing requirements &	
	contacts updated	
19 July 2024	Payment schedule updated	
24 January 2024	Payment schedule updated	
10 January 2024	Payment schedule updated	
	Contact details updated	
1 July 2023	Contact details updated	
20 January 2023	First version published	





# About the Implementation Handbook

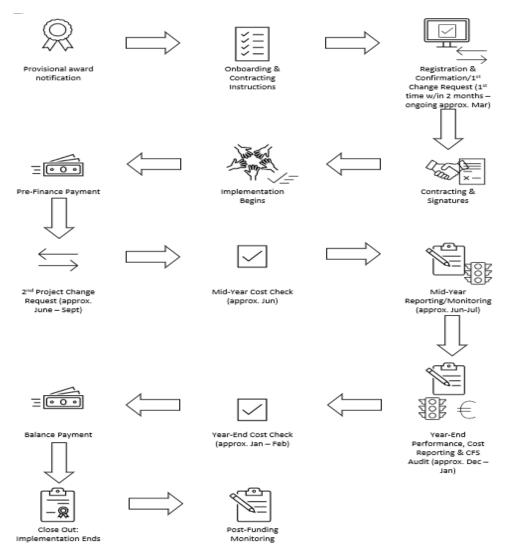
The purpose of this Handbook is to provide recipients of third-party funding, referred to as subgrantees, that receive European Institute of Innovation and Technology (EIT) Horizon Europe (HE) funding<sup>1</sup> through EIT Health with clear instructions and timelines for projects in the Business Plan (BP) 2023-2025 cycle.

# Relationship Between EIT, EIT Health, & Subgrantees

EIT Health is a Knowledge and Innovation Community (KIC) that was created by EIT. EIT Health receives public funding under HE through EIT. To receive funds from EIT, EIT Health has a Grant Agreement (GA) and BP<sup>19</sup> for 2023-2025. To meet our goals, EIT Health runs open calls and awards funding to subgrantees to deliver activities in support of EIT Health's mission.

# Project Lifecycle

This Handbook covers the life of a subgranted activity, also referred to as a project. Projects may begin throughout the calendar year and each project will follow similar steps.



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<sup>&</sup>lt;sup>1</sup> Projects that receive non-EIT funding may also follow the processes outlined in this Handbook, unless otherwise notified by EIT Health.





# 1 Onboarding & Contracting

Once provisionally selected and awarded through a call process to implement project(s), organisations are contacted by the Project Management Office (PMO) <u>Partnership Manager</u> and provided with instructions and deadlines related to onboarding and contracting.

## 1.1 Onboarding

Subgrantee registration in EIT Health's web-based grant management system (GMS), subsequent input of organisational information, and confirmation of project details are required. Information in the GMS provide the data needed for the lifecycle of the project, including contacts to sign legal documents in the contracting phase.

The requirements and steps in this stage must be successfully completed within the timelines provided by the PMO before moving to the next stage.

## 1.1.1 Grant Management System (GMS)

EIT Health uses a web-based GMS as its system of record to manage subgrantee projects. It includes:

- Organisational level details, including required contacts and banking information; and
- Project level details, including a project description, subgrantee consortium member information, and budget for each subgrantee consortium member.

#### 1.1.2 Connections

<u>Connections</u><sup>2</sup> is where subgrantees find EIT Health resources and guidance. The site is accessed with the same credentials as the GMS. Once an individual user is successfully registered in the GMS, they use the same credentials to access Connections.

Notably, Connections contains training materials and recordings related to Cost Reporting, Performance Reporting, templates, and Key Performance Indicator (KPI) guidelines.



Materials on Connections are updated regularly. Please be sure to always check Connections before proceeding with a process.



For questions regarding the onboarding process, contact the EIT Health <u>Partnership</u> <u>Manager</u>.

<sup>&</sup>lt;sup>2</sup> https://connections.eithealth.eu/





# 1.2 Contracting

Projects selected during EIT Health's open calls that are funded with EIT funds become part of the BP. As a result, any organisation that is implementing projects must comply with the EIT and EIT Health legal requirements.

Contracts serve as the legal basis for the relationship between EIT Health and subgrantees. Contracts must be signed to receive funding, including any prefinance payments. The contracts contain the rights and obligations of the subgrantee (referred to as the Recipient throughout the agreements). Throughout this document, we have highlighted areas where a process is based on a specific section in the contract documents and cited them accordingly.

### 1.2.1 Relationship between EIT, EIT Health, & Subgrantees

The rights and obligations between EIT and EIT Health are outlined in the Model Grant Agreement (MGA), which governs all Horizon Europe funded activities, including EIT Health and its portfolio. EIT Health and EIT sign a new GA every few years. The current GA expires 31 December 2025, and a new one is expected to be signed for the period of 2026-2028.

The signed GA between EIT and EIT Health contains requirements that must be passed on to subgrantees. Those requirements are reflected in the Financial Support to Third Parties (FSA) agreement, which is signed by EIT Health and subgrantee organisations. The Project Agreement (PA) contains project-specific activities, which is signed by each member of a subgrantee consortium, per project.





#### 1.2.2 Contract Documents

The following table contains a description of each required subgrantee contract, signing requirements, and whether the agreement template is negotiable. The following is applicable as of 1 January 2025.

Document Name	Description	Signature/Requirements	Negotiable?
Financial Support Agreement (FSA) Annex 5 of the FSA: Declaration of Honour in Annex 5	Contains conditions for receiving financial support from EIT Health and imposes the provisions of the GA to subgrantees and includes the Declaration of Honour. The FSA is the umbrella agreement which PAs fall.  Annex 5 Declaration of Honour is part of the FSA. By signing the declaration, the Affiliated Entity accepts joint and several liability with the EIT Health subgrantee that it is linked to (e.g. main entity). By signing the declaration both parties (main and Affiliated Entity) acknowledge that there is a legal link established between the entities <sup>3</sup> .	One FSA signed by each individual subgrantee organisation receiving financial support and signed once per BP period with the effective date being the first project during that BP.  Signed by any Affiliated Entities <sup>4</sup> of the subgrantee.	No.
Project Agreement (PA)	The PA governs the relationship between EIT Health and the subgrantee consortium members, per project. An organisation may have one or more PA at any time, depending on how many projects in which it is participating.	Signed by the subgrantee consortium member organisations that are part of the project. One PA is signed per project with the earliest effective date being the date of call award.	
Financial Sustainability agreement (FS)	Per Article 8: Financial sustainability of the FSA, financial sustainability is a requirement.	Signed by a subgrantee consortium member organisation.	Yes.
Ethical Approval	<ul> <li>Innovation projects with clinical studies must include:</li> <li>A study initiation package before enrolment of the first study participant, midterm recruitment report, and report on the status of posting results; and</li> </ul>	Both the study initiation package and ethical certificate be submitted by the subgrantee Activity Lead to the Innovation Single Point of Contact (SPOC), per their instruction by the deadlines provided.	No.

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<sup>&</sup>lt;sup>3</sup> In cases where a subgrantee main and Affiliated Entities are switching roles, the former Affiliated Entity will need to register in the GMS, sign the FSA, and then update the project record in the GMS before signing the PG. The former main would sign the Annex 5: Declaration of Honour.

<sup>&</sup>lt;sup>4</sup> As it relates to subgranting, Affiliated Entities (formerly known as Linked and Affiliate Third Parties) are defined in Articles 2 and 8 of the HE MGA and Article 187 of the EU Financial Regulation.





Document Name	Description	Signature/Requirements	Negotiable?
_	An ethical certificate.		





#### 1.2.3 Notable Compliance Requirements

The contracts contain rights and obligations, therefore it is vital for subgrantees to be familiar with the contents of the contract documents that will be signed. Highlighted below are some pertinent sections. Note this is not a comprehensive list of requirements.

#### 1.2.3.1 Branding Compliance Requirements

Per Article 11: Communication, dissemination and visibility rules of the FSA and section 2.3 in Annex 3 of the FSA, all activities funded by EIT Health must comply with the communication, dissemination and visibility requirements. Additionally, subgrantees must follow EIT Health's <u>Brand Book</u>, which serves as the guidance for all communication, dissemination and marketing related topics. This document, templates, and logos must be used during the activity implementation and are available on EIT Health Connections under <u>Communication guidance</u>.



For questions about branding requirements, contact Corporate Affairs at <a href="mailto:internal.communications@eithealth.eu">internal.communications@eithealth.eu</a>.

# 1.2.3.2 Cost Eligibility Requirements

Per Article 5: Project Contribution in the FSA, the eligibility of costs reported to the EIT are evaluated according to Horizon Europe's general and specific cost eligibility criteria. For guidance on cost eligibility, refer to Horizon Europe's Annotated Model Grant Agreement (MGA).

#### 1.2.3.3 Subcontracting Requirements

Use of third-party subcontractors in an EIT Health subgrant agreement is allowed if the subcontractor is **not** already a member of the subgrant consortium and provided that the subcontract selection followed the subgrantee's usual purchasing practices in accordance with Articles 6 and 12 of the MGA.

A subcontractor participating in one project does not prevent them from participating as a subcontractor or consortium member in another, unrelated project.

To avoid cost eligibility challenges, EIT Health discourages the use of subcontractors in providing work toward implementation, and strongly recommends, that if a subgrantee wishes to undertake project tasks in a consortium/activity, it does so as a subgrantee consortium member with duly allocated EIT financial support as a subgrantee.

Please see section 4.4 Involvement of third parties, including affiliated entities, subcontractor, of the FSA for additional details.

#### 1.2.3.4 Certificate on Financial Statement (CFS) Audit Requirements

Per section 6.1.4 of the FSA, CFS audits are required per subgrantee, per grant period for any EIT funded amount that is equal or greater than 430,000 € cumulatively. See more information in the Certificate on the Financial Statements (CFS) Audit section of this Handbook.



For questions on cost eligibility, cost reporting, or audits, contact the <u>Grant Assurance</u> <u>team</u>.

#### 1.2.3.5 Post-Funding Monitoring Requirements

Post-funding monitoring is an obligation of the MGA on all funded activities in the EIT Health portfolio, especially KPIs. As such, the obligation has been transposed into Article 6.8 of the PA. Please see the Post-Funding Monitoring section in this Handbook for further information.





# 1.2.4 Onboarding & Contracting Checklist & Timelines<sup>5</sup>

This table contains the overall steps in the Onboarding and Contracting processes and target deadlines.

Goal	Process Du	ration/Deadline	Example
Onboarding information	subgrantee Activity Lead with the	nt within 5 business days of e provisional call award tification.	<ul> <li>Award notification sent 1         January 2025.     </li> <li>Onboarding sent by 8         January 2025.     </li> </ul>
Ethics approval & certificate information	-	nt shortly after the aboarding information.	Ethics sent by 8 January 2025.
Financial sustainability agreement (fs) information	_	nt shortly after the nboarding information.	FS sent by 8 January 2025.
GMS registration at organisational & user levels	and consortium organizations register in with	MS registration completed, thin 7 business days of boarding information.	Registration completed by 17 January 2025.
Accurate information on the consortium, budget for contracting & pre- financing	subgrantee consortium member and adjust the budget accordingly per the Consortium Change Requests section.  Any approved consortium member on	bgrantee consortium ember requests must be ade and registered in the MS within the window of the boarding and ideally prior to e PA being sent for signature.	Requested, approved, registered in GMS before 7 February 2025.
Prepare & send organisational level contracting	6. PMO Partnership Manager prepares Ser	nt within 5 business days om registration deadline.	Sent by 24 January 2025.

<sup>&</sup>lt;sup>5</sup> All timelines are goals and may be adjusted based on the season and other factors and actual deadlines will be set by the PMO.





Goal	Process	<b>Duration/Deadline</b>	Example
	each consortium organisation their respective FSA for electronic signature.		
Signature of FSA to legally bind the parties at an organisational level	7. Subgrantee Activity Lead organisation and each consortium organisation sign their respective FSA.	Each Activity Lead and consortium organisation signs their own FSA within 10 business days after organisational contract send date.	Signed by 7 February 2025.
Confirm project details in the GMS to prepare PA	8. Subgrantee Activity Lead checks project information in the GMS to confirm accuracy.	Confirmed 10 business days after registration deadline.	Confirmed 31 January 2025.
Signature of PA at project level	9. PMO Partnership Manager sends PA electronically to the subgrantee Activity Lead and consortium members to sign jointly.	Sent within 5 business days of project confirmation deadline.	Sent 7 February 2025.
	10. Subgrantee Activity Leader and consortium members sign the PA.	Signed within one month of confirmation of project details.	Signed by subgrantee Activity Lead and any subgrantee consortium members by 7 March 2025.
Signature of the FS at project level	11. After successful negotiation, FS is sent for signatures and signed.	Negotiated and signed within three months of FS information.	Signed by a member of the subgrantee consortium by 7 April 2025.
Ethics approval & certificate per site level	12. After issuance and approval of study protocol, subgrantee Activity Lead submits certificate per SPOC instructions.	Within three months of Ethics information.	Finalised and sent by subgrantee Activity Lead by 7 April 2025.





# 2 Implementation

Once the contracts are signed and counter-signed by EIT Health, a project may begin. During implementation, it is vital that subgrantees communicate with their assigned contacts within EIT Health. There are two main contacts within EIT Health: Single Point of Contact (SPOC) and Project Managers (PM).

# 2.1 Single Point of Contact (SPOC)

Each project has a designated programmatic SPOC who is specialised in the programmatic areas of Education, Innovation, or Business Creation, with whom subgrantees should be in regular contact throughout the project.

During implementation, subgrantees must work with their SPOC to discuss progress, identify potential risks and improvements. During the interactions, SPOCs also ensure that subgrantees are aware of the expected outcomes of the project.

# 2.2 Project Manager

Additionally, each project has an assigned PM, who provides necessary information related to processes such as project change requests, reporting, and monitoring of the project.

Assigned SPOCs and PMs will be communicated to the subgrantee Activity Leader and be reflected in the GMS<sup>6</sup>.



Both SPOCs and PMs should be contacted concurrently. This allows for clearer communication and allows each team member to consider any implications on their remit. For programmatic and content-related questions, the assigned SPOC is responsible. For

subgrant operational topics, such as project change requests, reporting, and monitoring questions, the assigned PM is responsible.

# 2.3 Subgrantee Consortiums

All subgrantee Activity Leads must arrange an implementation kick-off meeting with their consortium members. The kick-off meeting should take place no later than one month after the start date of the project. The lead subgrantee should invite their SPOC to their kick-off meeting.

#### 2.3.1 Subgrantee Consortium Agreements

Note that EIT Health is not involved in the drafting of the consortium agreements between consortium members. With that said, subgrantee consortiums may wish to use the Development of a Simplified Consortium Agreement (DESCA) model: <a href="https://www.desca-agreement.eu/desca-model-consortium-agreement/">https://www.desca-agreement.eu/desca-model-consortium-agreement/</a>.

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<sup>&</sup>lt;sup>6</sup> EIT Health is currently building an improved GMS and information and training will be provided in advance of any new GMS system use requirements.





# 3 Project Change<sup>7</sup> Requests

Subgrantees may need to make changes to their project during their project life cycle. Some changes require approval, while others do not.

# 3.1 Changes that do not Require Approval

Some project changes do not require approval. These include:

- Adding individual project members from organisations who are already part of the consortium;
- Updating the Activity Leader<sup>8</sup> to an individual from the same subgrantee lead organisation.

Please note that to be assigned as the new subgrantee Activity Leader or to be added as an individual user, the user must already be registered and associated with the subgrantee lead organisation in the GMS.

These types of changes may be made at any time in the project period and are managed directly by the Activity Leader in the GMS.

# 3.1.1 Updating a Primary Contact<sup>9</sup>

While updating the Primary Contact does not technically require approval, only EIT Health PMs can update the Primary Contact in the GMS. Requests to update the Primary Contact must be documented, in writing, and must be sent to the assigned PM or submitted through the GMS. Please note that to be assigned a Primary Contact, the user must already be registered and associated with the organisation in the GMS.

# 3.2 Requests that Require Approval

All requests that require approval will be evaluated by the PM and SPOC.

#### 3.2.1 Consortium Change Requests During Contracting

The first opportunity to request a change occurs during the <u>Contracting</u> phase and before the contracts are sent. This means that the Activity Leader typically has one month from the onboarding email to make such requests. During this phase, subgrantees may request to update their project to add subgrantee consortium members and allocate the budget to consortium members accordingly.

It is important for subgrantees to adhere to the deadlines set by the PMO during this phase. This allows EIT Health to issue the appropriate pre-financing payment and balance payment to the subgrantee consortium members 10.



Requests that materially change the project implementation from the call award and requests for increase in total budget will not be accepted.

<sup>&</sup>lt;sup>7</sup> Previously, these were referred to as project amendments and may sometimes be referred to as such. However, the distinction is that an amendment occurs when there is a change to the legal document after signature. Only some project changes require a contract amendment.

<sup>&</sup>lt;sup>8</sup> In this context, the Activity Leader is an individual who is part of the Lead Organisation or Consortium Leader.

<sup>&</sup>lt;sup>9</sup> May also be referred to as a Master Contact.

<sup>&</sup>lt;sup>10</sup> Consortium changes beyond this period may not be accepted and must be requested during the next project change request period. In some cases, consortium changes may impact pre-finance amounts and reclaiming funded amounts may be required.





### 3.2.2 Project Change Requests

After the contracting period, and during a full year of implementation, subgrantees have two opportunities to request changes. The first is typically during March/April and the second typically takes place in July/September.

Subgrantees may request to adjust their project, including to add a new consortium member and make budget changes during those periods.



Requests must be submitted in writing and as instructed by the PMO, within the deadlines provided by the PMO. Requests received outside of the process provided by the PMO may not be accepted. Again, it is vital to adhere to the deadlines set by the PMO to ensure that the requests can be considered and implemented if approved.



Any changes that require approval will not be considered approved until they appear in the GMS as approved or final. In the case of adding a new organisation to the subgrantee consortium, the changes will not be considered official until the required contracts have been dually signed.

The request type and follow up steps, if approved, are as follows:

Request type	If approved, implementation of change
<ul> <li>Budget changes within a year's budget, including changing budget descriptions, subcontracting costs, or reducing EIT funding amounts (see also <u>Co-Funding &amp; Budget Changes</u> in this Handbook)</li> </ul>	Adding and balancing budget reflected as approved in the GMS
Extension of project with no additional funding	Updating the GMS and showing as approved in the GMS
<ul><li>Adjusting KPI targets</li><li>Adjusting deliverables, outputs, milestones</li></ul>	<ul> <li>Updating the GMS and showing as approved in the GMS</li> </ul>
<ul> <li>Adding a new subgrantee consortium member who is not already part of the consortium</li> <li>Adding budget for a new consortium member<sup>11</sup></li> </ul>	<ul> <li>After approval, Partnership Manager contacts new subgrantee consortium member and follows the Onboarding and</li> <li>Contracting processes in this Handbook</li> <li>Additional signature to the contract documents (PA effective to the 1 January of that year)</li> <li>Adding and balancing budget showing as approved in the GMS</li> </ul>
Removing a subgrantee consortium member (see also the <u>Pre-Close Out Termination</u> in this Handbook)	<ul> <li>Updating the budget in the GMS and showing as approved in the GMS</li> <li>Ensuring that the departing organisation understands the remaining obligations of the project per the FSA and PA</li> </ul>

#### 3.2.3 Budget Carry Forwards

Note that pre-approval to carry forward funding from one year to the next is required from EIT Health. Actuals are typically known by mid-February to early March in the year following the cost reporting period.

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 $<sup>^{11}</sup>$  Note that the addition of a new consortium member must be approved and reflected in the contract documents.





Carry forwards are not allowable across BP periods. For example, funding from a 2023-2025 project cannot be carried forward to 2026. Approval for carry forwards of unspent funds are conditional, including consideration of whether performance is satisfactory. Carry forwards from a closed-out year is also not allowable. For example, a project may not, in 2025, carry forward previously unused funding from 2023.

### Co-Funding & Budget Changes



The co-funding share at project level may only be reduced upon an exceptional reduction of EIT financial support. Any budget changes must be accompanied with appropriate and adequate descriptions.

Please note that budgets of existing subgrantees in the project consortium may only be reallocated between cost categories and an increase of EIT financial support is not possible. Any substantial change in the consortium construction must be evaluated and approved by EIT Health.

### Changes In the Last Year of Implementation



In the last year of the project, project changes must be requested during the closest and most appropriate change request period. If the project ends before another change request period, changes should no longer be made.

#### 3.2.6 Project Extensions (with no additional funding)



Subgrantees may request "no-cost" project extensions, which will be evaluated for approval as outlined above. This is when a project may require additional time to complete its work with no increase to the total budget. Note that projects cannot be extended beyond a BP period.





# 4 Payments

For most projects, payments are made in two tranches based on a yearly planning and reporting cycle.

# 4.1 Pre-Financing Payment

The pre-financing payment is typically sent within three months following the successful signature of all required organisational and project level contract documents. The pre-financing payments are made at the *subgrantee-project level*. This means that a subgrantee will receive as many pre-financing payments as the number of projects in which it participates. The payment is based on a percentage of the EIT funded amount a subgrantee has been allocated in the GMS for the year N (e.g. 2023, 2024, or 2025, respectively) by the time of the execution of the payment, provided it does not have outstanding balance payments due to EIT Health. The exact amount paid is communicated to subgrantees by the time of the execution of the payment.



Per Article 7: Financial provisions of the FSA, only once contracting is complete and no balance is due from subgrantees, EIT Health releases the agreed upon pre-financing amount via electronic transfer. These payments are released on business days between the 15<sup>th</sup> and

20<sup>th</sup> of each month for subgrantees who successfully completed<sup>12</sup> the contracting by the 5<sup>th</sup> of that month. As of 1 January 2025, the pre-financing payment is no longer contingent on payment of membership fees. However, any open balance must be cleared before EIT Health can execute pre-financing payment.

# 4.2 Balance Payment

The balance payment occurs after the yearly cost reporting and/or cost check, and/or CFS audit. The balance payment is released after satisfactory monitoring, no outstanding previous year balance payment to EIT Health, satisfactory cost reporting, cost check, and CFS audit requirements have been met, and sent latest by September of the year N+1. Balance payments are usually made between the business days on the 15<sup>th</sup> and 20<sup>th</sup> of the month following successful completion of all requirements.

This payment is made at the *subgrantee level*. This means that a subgrantee receives one single balance payment calculated using the total **accepted** EIT Health financial support amount across all activities and the sum of all pre-financing payments received for each project in which it has participated.



The balance payment is contingent upon satisfactory monitoring and no outstanding balance payment due to EIT Health. In cases of severe underperformance and negatively assessed final report according to article 4.3 in the FSA, the final balance payment of financial support may be reduced.

Both pre-financing and balance payments are communicated to the Primary, Legal and Finance<sup>13</sup> contacts in the GMS.

# 4.3 Payment to Micro and Small Sized Enterprises<sup>14</sup>

The exception to the payment rules above applies to micro and small sized enterprises, which drive Innovation projects. These entities are entitled to a pre-financing based on the yearly planned financial support. This will be released in two tranches. A first tranche after successful contracting (as outlined above) and a second one after an interim cost check covering costs claimed within up to six project months.

<sup>&</sup>lt;sup>12</sup> Successful completion is defined as the required contracts being signed and counter signed. Organisational details, including bank details must also have been correctly entered in the GMS.

<sup>&</sup>lt;sup>13</sup> Primary contact is used interchangeably with Master Contact.

<sup>&</sup>lt;sup>14</sup> See the definition: https://single-market-economy.ec.europa.eu/smes/sme-fundamentals/sme-definition en





Micro-small companies in Innovation projects, which will fall under this payment scheme will be go through the cost check unless going through the CFS audit, e.g. year N+1 with requested cumulated EIT financial support equal or greater than 430,000 €. See the

<u>Cost</u> Check and <u>Certificate on the Financial Statements (CFS) Audit</u> sections of this Handbook for more detail.

See the

<u>Cost</u> Check section of this Handbook for more detail. Balance payment will be released as outlined above. No additional exceptions, i.e. different rates, outside of this scheme will be considered.





# 5 Performance Reporting & Monitoring

All projects are required to report on their activities, per Article 6: Monitoring and reporting of the FSA. Projects that are in their first and last years of implementation may only have one reporting and monitoring cycle if the start and end dates are not full years.

# 5.1 Performance Reporting

Performance reporting is required for all projects and must be submitted in the GMS by the subgrantee Activity Lead. Subgrantees report against their project and provide explanations for each achievement, any deviations, and corresponding justification in the project. The typical areas of reporting are:

Area	Description	Required
		Documentation
		& Templates
Progress & outputs	Description of achievements against the BP	N/A
Work implemented	Description of the work implemented to date	
Key Performance Indicator	Although may be achieved throughout the	
(KPI) achievement	year, reported at year end	Yes. See
Outputs	Reported throughout the year, in accordance	Connections
	to workplan	N/A
Consortium	Roles & descriptions of consortium members	
KPI deviations	Description of over or under achievement of	
	the KPIs	
Lessons learned	Optional section to highlight insights on	
	project implementation	
Horizon Europe	Demonstrate results and impacts through	
Questionnaire <sup>15</sup>	Horizon Europe indicators	
Follow Up Report on Use of	Description of actual spending deviations	
Resources (see Follow Up	compared to the budget	
Report on Use of Resources for		
more information)		

During reporting, subgrantee Activity Leaders must ensure that reporting is submitted:

- By the PMO provided deadline;
- Of sufficient quality (i.e. branding, appropriate language);
- With all required content according to the description (i.e. including graphs, tables, images); and
- Using the required templates available on <u>Connections</u>, when required.

Projects have the following performance reporting frequency:

- A mid-year report is an annual mid-point report that contains the progress thus far.
- A **year-end report**<sup>16</sup> is the final report that includes annual achievements.

# 5.1.1 Mid-Year Performance Reporting

Projects are required to submit mid-year performance reporting, with some exceptions based on the project's first year start month. Mid-year reporting typically begins in June and subsequent monitoring occurs in July. Actual deadlines will be determined by the PMO and communicated to the subgrantees accordingly.

Since projects may begin throughout the calendar year, the following is an estimate of when mid-year reporting will occur for projects with the following start months in the first year:

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<sup>&</sup>lt;sup>15</sup> This is usually sent as a separate questionnaire collected outside of Plaza. PMO is working to incorporate it in the GMS reporting process for future years.

<sup>&</sup>lt;sup>16</sup> Referred to as an Activity Performance Report in Plaza.





First Year Project Start Month	Reporting Period
January	
February	June of the same year
March	
October	
November	June of the following year
December	

#### 5.1.2 Year-End Reporting

All projects, regardless of when they begin must submit year-end performance reporting. Year-end reporting typically begins in December and is typically due on the last business day of January. Actual reporting components and deadlines will be determined by the PMO and communicated to subgrantees accordingly.

If a project begins in one of the below months, the year-end reporting is used as the basis for subsequent monitoring, occurring in February.

First Year Project Start Month	Reporting Period
April	January of the
May	following year
June	
July	
August	
September	

#### 5.2 Monitoring

Performance reporting serves as the basis for monitoring, which takes place after a performance report has been submitted. Each report is read by the assigned PM. The goal of monitoring is to assess project performance, spending deviations, and impact related to the EIT Heath Strategic Objectives. Monitoring also allows EIT Health to evaluate risk, underperformance, underspending, and to provide mitigation through a stage-gate (e.g. go/no go) framework.

### 5.2.1 Monitoring Meeting & Go/No Go Categories

Monitoring meetings are scheduled between the PM and subgrantee Activity Lead at least one month in advance. A monitoring meeting may take place either after the mid-year report or year-end report. Monitoring meetings occurs at least once every 12 months, unless a previous monitoring or other risk factors indicate the need for additional monitoring meetings.

The monitoring meeting results in one of four go/no go categories:

Category	Assessment Criteria	Resulting Action
Green (No risk/o Overperformance)	To receive a <i>Green</i> status, the project must meet <u>all</u> of the following:  • Deliverables, outcomes, KPIs have been achieved or are on track for overachievement and are of high quality and/or the project has an outstanding achievement contributing significantly to the EIT Health objectives; and  • No over/under spending and no significant budget deviations; and	<ul> <li>Continue implementation.</li> <li>Process payments on established schedule.</li> <li>May be proposed to Management Board (MB) for further funding, depending on available funding.</li> </ul>





Category	Assessment Criteria	Resulting Action
	Subgrantee demonstrates compliance with all obligations in the legal documents and Handbook.	
White (Low risk, meeting expectations)	To receive a White status, the project must meet the following:  Deliverables, outcomes, KPIs have been achieved or are on track for achievement and are of good quality; and Any deviations are accepted by EIT Health, and the overall scope remains; and No over/under spending with no significant budget deviations; and Subgrantee demonstrates compliance with all obligations in the legal documents and Handbook.	<ul> <li>Continue implementation.</li> <li>Process payments on established schedule.</li> </ul>
Orange (Some risk/underperformance)	To receive an <i>Orange</i> status, the project must meet the following:  Deliverables, outcomes, KPIs are between 50% and 80% achieved or are of poor quality or missing; or  Spending is moderately under/over given the remaining time in the project and/or the project has moderate budget deviations; and/or  Subgrantee demonstrates incompliance with one or more obligation in the legal documents and Handbook.	<ul> <li>The consortium is given between 14 days<sup>17</sup> and up to 8 weeks to implement the required remedial actions.</li> <li>PMO schedules a follow up meeting to review completed remedial actions.</li> <li>Projects that fail to implement remedial actions are appraised in a meeting with EIT Health.</li> <li>Based on the appraisal, the project may continue, be proposed to the MB for potential continuation with grant reduction or be terminated<sup>17</sup>.</li> </ul>
Red (High risk/severe underperformance)	To receive a <i>Red</i> status, the project must meet one or more of following:  • Achievement of deliverables, outcomes, KPIs are below 50% achievement or are of poor quality or missing; or  • The main goals of the original plan will not be reached within project lifetime and cannot be remedied; and/or  • Spending is significantly under/over given the remaining time in the project and/or the project has significant budget deviations; and/or	The project is proposed to the MB for termination, as outlined in Article 6 of the FSA and Article 6.2 of the PA <sup>17</sup> .

 $<sup>^{17}</sup>$  See section 3 Effects of Termination of the FSA for information on surviving obligations after termination.





Category	Assessment Criteria	Resulting Action
	Subgrantee demonstrates incompliance with the legal documents and Handbook.	

# 5.2.2 Examples of Green, Orange and Red Statuses per Pillar

5.2.2 Examp	les of Green, Orange and F <b>Green</b>	·	Red
Pillar Education	<ul> <li>KPI achievements are exceeded compared to the plan (e.g. higher number of leaners)</li> <li>Additional impact can be achieved (e.g. citizens trained, investment attracted)</li> <li>Good practices or success stories can be identified</li> <li>Additional funding was attracted</li> <li>Additional members joined the consortium to add value to the project or speed up development</li> <li>KPIs, Deliverables, work plans, outcomes and milestones are overachieved within the timeframe</li> </ul>	Delays in the first 6 months of the project     Delays due to the ethics approval process     Potential underachievement of KPIs     Critical consortium member leaving the consortium without a replacement     Marketing and recruitment strategy not aligned with the learner targets     Evaluation plan not in place     No clear commercialisation plan is in place or commercialisation plan is not aligned with the project timeline	<ul> <li>Majority of KPIs cannot be achieved, especially EIT KPIs</li> <li>No mitigation plan is put in place to address shortcomings</li> <li>There is limited timeframe left to implement significant changes</li> <li>Shortcomings can no longer be solved (e.g. recruitment of students not possible, creating a start-up with sales is not possible)</li> <li>Majority of KPIs cannot be achieved, especially EIT KPIs</li> <li>No mitigation plan is put in place to address shortcomings</li> <li>There is limited timeframe left to implement significant changes</li> <li>The planned targets and overall project progression strategy change significantly throughout the project and are not aligned with the original targets any longer</li> </ul>
Business Creation	<ul> <li>KPIs, Deliverables and Outputs overachieved with regards to the workplan (e.g., investment attracted was higher than planned)</li> <li>Additional funding was granted to extend the scope of the programme beyond the activities funded by EIT</li> </ul>	<ul> <li>Delays from the original timelines (e.g., recruitment)</li> <li>Critical consortium member leaving the consortium without a replacement</li> <li>Sustainability model not realistic and not aligned with project timeline</li> </ul>	<ul> <li>Serious         underperformance of         the original workplan         (e.g., less start-ups         supported than what         was originally planned)</li> <li>KPIs were incorrectly         chosen and traded for         others without support         from EIT Health staff</li> <li>No ambitions towards         sustainability</li> </ul>





Pillar	Green	Orange	Red
	Broad communication and dissemination to start-up community was achieved (e.g. high number of quality applicants, start-up features for achieving key financial/outcome milestone impacted by programme)		





### 6 Cost Related Processes

### 6.1 Cost Reporting

Cost Reporting is the process by which subgrantees report their actual costs against their budget. Each subgrantee reports their costs incurred in the **reporting period across all projects**, in which they participated. Cost reporting is required by all subgrantees. Cost reporting is completed in the GMS and usually begins in December of the year and is usually open for six weeks following the end of the calendar year. Exact deadlines will be communicated to subgrantees by the PMO and/or Finance teams.

Despite subgrantees reporting their yearly costs for all their projects in one single cost statement, projects are considered independently, i.e. there is no compensation between a project under claiming EIT financial support and a project over claiming EIT financial support.

The reporting period is the period for which costs are to be reported by the subgrantee. The reporting period is annually. This means that all subgrantees must report their costs incurred from January 1 (or from their eligibility date if after January 1) until December 31 each year.

Costs incurred in the activity implementation can only be reported through the GMS during the period specified. Failure to correctly complete the cost reporting by the given deadline would imply no EIT financial support is being requested by the subgrantee for the year N and, if applicable, lead to the recovery of the full pre-financed amount.



During cost reporting and generally during the last quarter of the year, subgrantees may not adjust the allocation of the budget/EIT financial support amounts consortium members anymore, as this may only be requested during the <a href="Project Change Requests">Project Change Requests</a>. The same applies for the allocation of co-funding amongst consortium members.

#### 6.1.1 Cost Reporting in the GMS

Only the Primary Contact and the Legal and Finance Contact(s) registered in the GMS have access to the cost reporting section of the GMS. The Primary Contact is the only role able to add or remove other contacts, such as the Legal and Finance contacts. An organisation may have multiple Legal and Finance contacts assigned in the GMS. To assign or change a Primary Contact, please contact the <a href="Partnership">Partnership</a> Manager.

The GMS contains the co-funding and EIT grant budgeted values and deducts the budgeted co-funding and EIT grant amounts automatically as **costs** are entered. The table below depicts examples of EIT grant and subgrantee own-funding allocation in three different cost reporting scenarios.

	Examples	<b>Budgeted Costs</b>		Reported Costs		Notes
1.	Overspending	Budgeted KAVA	600,000.	Reported KAVA	610,000.	Overspending is
		costs		costs		covered by
		Budgeted EIT grant	500,000.	Accepted EIT	500,000.	subgrantee own
				grant		funding.
		Budgeted	100,000.	Realised	110,000.	
		subgrantee own		Subgrantee own		
		funding		funding		
2.	Underspending	Budgeted KAVA	600,000.	Reported KAVA	560,000.	First the full
		costs		costs		subgrantee own
		Budgeted EIT grant	500,000.	Accepted EIT	460,000.	funding budget is
				grant		allocated to cover





	Examples Budgeted Costs		Reported Costs		Notes	
		Budgeted subgrantee own funding	100,000.	Realised Subgrantee own funding	100,000.	reported KAVA costs & remainder is covered by EIT grant.
3.	Severe underspending	Budgeted KAVA costs	600,000.	Reported KAVA costs	95,000.	First the full subgrantee own funding budget is allocated to cover
		Budgeted EIT grant	500,000.	Accepted EIT grant	0.00.	reported KAVA costs & the remainder is covered by EIT
		Budgeted subgrantee own funding	100,000.	Realised Subgrantee own funding	95,000.	grant. In this case, the underspending is so severe that the reported KAVA costs are lower that the subgrantee own funding, which means there is no EIT grant allocated.

The table above highlights the importance of correct budgeting as overestimation of budgeted costs might lead to underspending when actual costs are reported which in turn affects the co-funding share.



Subgrantees are not required to submit documentation justifying costs, such as timesheets, invoices, contracts in the GMS, but the documentation must be readily available and kept, as it may be requested in case of an audit per Annex 3 of the FSA<sup>18</sup>.

# 6.1.2 Follow Up Report on Use of Resources

After reporting costs, subgrantees are required to submit a Follow Up Report on Use of Resources, which requires subgrantees to report on the deviations and justifications for over/underspending in budget categories. This will be used during monitoring. The actual deadline for this report will be communicated to subgrantees by the PMO.

### 6.2 Certificate on the Financial Statements (CFS) Audit

In cases of subgrantees with a cumulatively requested EIT financial support equal or greater than 430,000 €, subgrantees must undergo a CFS audit carried out by an external auditing company. Note, the cost reporting and the CFS audit are two independent processes. The cumulative nature mentioned above is explained in the following examples:

2023 EIT financial support requested (€)	2024 EIT financial support requested (€)	2023 cost CFS audit?	2024 cost CFS audit?	Notes
200,000.	200,000.	No	No	

<sup>-</sup>

<sup>&</sup>lt;sup>18</sup> In general, for at least five years after the balance is paid at project close (three years for low-value subgrants up to 60,000 €) or longer if there are ongoing procedures (audits, investigations, litigation, etc). In this case, the evidence must be kept until ongoing procedures end.





2023 EIT financial support requested (€)	2024 EIT financial support requested (€)	2023 cost CFS audit?	2024 cost CFS audit?	Notes
600,000.	100,000.	Yes	No	No CFS audit in 2024 because the 2023 costs were already subjected to a CFS audit & no longer count towards the threshold.
400,000.	100,000.	No	Yes	The scope of the CFS would include both 2023 & 2024 costs (because the 2023 costs were not subjected to a CFS audit).
600,000.	500,000.	Yes	Yes	Two separate CFS audits; one covering each year.

#### 6.3 Cost Check

EIT Health conducts cost checks at least twice per year to ensure compliance with <u>Cost Eligibility Requirements</u>. Cost checks usually occur mid-year and after the year-end cost report process. Subgrantees may be selected for the cost check and those selected are required to report their costs for the specified period within the designated timeframe in the GMS. Those costs are sampled for eligibility.

#### 6.3.1 Mid-Year Cost Check

The mid-year cost check provides an "earlier look" at costs incurred in the first half of the year, covering expenses from the project start date to June 30. This early assessment uses the same verification standards as the comprehensive annual cost check.

#### 6.3.2 Year-End Cost Check

For annual cost reporting, the timeframe is generally January to February of the following year (N+1). Cost data submitted will then undergo a random sampling process, in which selected cost items are reviewed for eligibility for a period covering up to 12 months from the project start date to December 31.

# 6.3.3 Overview of Cost Check Process

EIT Health will communicate deadlines and specific requirements in advance and provide training to support selected subgrantees in meeting the cost check requirements. For sampled cost items, subgrantees must provide supporting documents through a dedicated secure, web-based environment.

The assessment of supporting documents may require clarification from and collaboration with subgrantees to resolve any discrepancies. Following the review, EIT Health will provide subgrantees with an outcome report that may include observations, recommendations, and/or cost rejections. If costs are deemed ineligible, the rejected amounts will impact the balance payment, adjusting the total eligible EIT Health financial support accordingly.





### ' Close Out

Project close out occurs at the end of the subgrant project period. Prior to close out, subgrantees Activity Leaders must ensure all required reporting has been satisfactorily completed, including any subgrantee consortium member cost reporting.

# 7.1 Projects that Span the BP

Sometimes EIT Health runs calls that seek projects that span beyond the BP. In this case, projects that will continue beyond the BP must still comply with all close out requirements. If the project has had satisfactory monitoring results, has complied with all reporting requirements (performance and cost) and has no outstanding balance or issues, a new set of contract documents will be drafted and sent for signature for the new BP cycle following the <a href="Contracting">Contracting</a> process, after EIT and EIT Health have signed a new GA.

#### 7.1.1 Budget for Projects that Span the Business Plan

Due to the funding relationship between EIT and EIT Health, EIT Health is not able to confirm budgets beyond the current BP until a new GA has been signed between EIT and EIT Health. In this case, EIT Health will notify subgrantee Activity Leaders of continuing projects as soon as possible.

### 7.2 Pre-Close Out Termination

During a project's lifecycle it may be necessary for a consortium member to terminate their participation before the end of the project. In this case, all subgrantees are required to follow Article 3. Entry into force, duration and termination of the FSA. The same must be followed by EIT Health in case of EIT Health termination.

#### 7.2.1 Termination Process Overview



Any termination must occur, in writing, and be submitted to the <u>Partnership Manager</u>, and include the subgantee Activity Leader, Primary Contact of the subgrantee consortium lead, PM, the SPOC, and any other relevant contacts in EIT Health.

At minimum, the letter must include:

- Project code
- Project name;
- Name of the consortium member organisation;
- Reason for leaving
- Planned date of leaving (the date must comply with the terms in Article 3 of the FSA and should also be no later than the last date of incurred costs); and
- Signature of the legal representative with date.

Once received by EIT Health, the Partnership Manager will send a receipt confirmation. Once reviewed by EIT Health for compliance with Article 3 of the FSA, EIT Health will provide a written response with next steps. Generally, the next steps are for the Activity Leader to redistribute the budget and work packages, activities (e.g. deliverables, outputs) of the leaving consortium member in the next <a href="Project Change Requests">Project Change Requests</a> period in the GMS. The overall co-funding must be maintained. Decisions on distribution of financial support and co-funding must be decided by the consortium, per any established consortium agreement.



Please note that leaving the consortium does not relieve the consortium member from the section 3.3.1 Survival of rights and obligations of the FSA. For example, year-end performance and cost reporting will still be required in the next appropriate reporting period(s).





# 8 Post-Funding Monitoring

The goal of post-funding monitoring is to collect information on the project's KPIs and financial sustainability goals during the three years following the project close (e.g. end of project's financial support). Post-funding monitoring requires all previously funded activities to report on the impact of their work and the terms of financial sustainability after the EIT Health funding period is over.

Subgrantees may expect post-funding monitoring approximately 10 to 12 months after the project has ended.





# 9 Resources

# 9.1 Abbreviations & Definitions

Abbreviation/Term	Longform & Definition				
Activity	Used synonymously with Project for the purpose of the subgrantee perspective				
ВР	Business Plan <sup>19</sup> refers to EIT Health's Business Plan and is an annex to the Grant Agreement (GA) and outlines the activities that will contribute to accelerate positive change in the healthcare sector				
Call	A process to outline projects, evaluation criteria, and to collect and evaluate proposals/applications to implement such projects				
CFS	Certificate on Financial Statements				
Cost Report	Also referred to as a Cost Statement				
EC	European Commission				
EIT	European Institute of Innovation and Technology <sup>20</sup> , a body of the EU				
EU	European Union				
Financial Signatory	Authorised financial representative who can sign the cost statements and used interchangeably with Financial Representative.				
FSA	Financial Support Agreement signed at the organisational level by subgrantees for each BP cycle in which the subgrantee participates				
GMS	Refers to EIT Health's Grant Management System (Plaza and/or NetSuite)				
HE	Horizon Europe <sup>21</sup> , which is the programme through which EIT funds EIT Health, and EIT Health funds many subgrantees.				
KAVA	KAVA is a KIC Added Value Activity. Regarding subgrants, used synonymously with project.				
KPI	Key Performance Indicator.				
LEAR	Legal Entity Appointed Representative.				
Legal Signatory	Used synonymously with Legal Representative.				
Master Contact	Used interchangeably with Primary Contact.				
MB	EIT Health Management Board.				
MGA/GA	Horizon Europe Model Grant Agreement <sup>22</sup> which is the model agreement used for the Grant Agreement between EIT and EIT Health. The current Grant Agreement (GA) signed between EIT and EIT Health is for a three-year period 2023-2025 with EIT.				
PA	Project Agreement signed by subgrantee consortium members at a project level for each project.				
PM	EIT Health Project Manager.				
PMO	EIT Health Project Management Office.				
Primary Contact	Used interchangeably with Master Contact. The contact on an organisational level that will be the main point of contact.				
Project	Used synonymously with Activity. For this Handbook, refers to EIT Health funded subgrantee projects.				
Recipient	For this Handbook, used synonymously with subgrantee or financially supported third party.				

<sup>&</sup>lt;sup>19</sup> EIT-Health Business-Plan 2023-2025.pdf

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 <sup>&</sup>lt;sup>20</sup> European Institute of Innovation & Technology (EIT) | EIT
 <sup>21</sup>Read about Horizon Europe here: Horizon Europe - European Commission

<sup>&</sup>lt;sup>22</sup> Read the AGA here: <u>aga\_en.pdf</u>





Abbreviation/Term	Longform & Definition
SME	Small, Medium and Micro-sized Enterprise, as defined by the European Union.
SPOC	EIT Health Pillar Single Point of Contact EIT Health.
Subgrantee	Used synonymously with recipient or financially supported third party. The term <i>partner</i> is often used to refer to both paid members and subgrantees, however, the distinction is that subgrantees receive funding from EIT Health. Prior to this version of the Handbook, referred to as External Project Partners. This term may still be used occasionally.

# 9.2 Support

In case of questions, which have not been addressed in the Handbook or other materials available on Connections<sup>2</sup>, contact the appropriate member of the EIT Health team<sup>23</sup>.

Support	Name	Email
Onboarding, GMS registration,	Patricia Chacon,	partnershipmanager@eithealth.eu
contracting, termination	PMO Partnership	
processes, & paid membership	Manager	
processes		
Innovation projects as they relate	Guillermo	guillermo.montero@eithealth.eu
to project change processes,	Montero, PMO	
reporting/monitoring & the GMS	Project Manager	
Business creation, Cross-KIC, non-	Justin Horvath,	<u>iustin.horvath@eithealth.eu</u>
EIT funded projects as they relate	PMO Project	
to project change processes,	Manager	
reporting/monitoring, & the GMS		
Education projects as they related	Tania Lessenka-	tania.lessenska@eithealth.eu
to project change processes,	Teodosiev, PMO	
reporting/monitoring & the GMS	Project Manager	
KPIs tracking, analysis, post-	Oana Neagu,	oana.neagu@eithealth.eu
funding reporting & impact	Senior Impact	
	Manager	
BP, PMO processes, & legal	Gilda Kemper,	Gilda.kemper@eithealth.eu
documents	Head of PMO	
Communication & dissemination	Corporate Affairs	internal.communications@eithealth.eu
	Team	
Ethical Approval	Assigned SPOC	
Financial Sustainability		
Cost reporting, cost eligibility, cost	Grant Assurance	grantassurance@eithealth.eu
check, CFS audit, & payments	Team	
Implementation	Assigned SPOC	Will be provided during onboarding

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 $<sup>^{23}</sup>$  This list is subject to change. Please communicate with EIT Health as requested and when available to do so, directly in the GMS.