IMI2 Project ID 101034366
FACILITATE

FrAmework for ClInicaL trIal participants daTA reutilization for a fully Transparent and Ethical ecosystem

WP1 – Project Management and Administration

D1.1 Consortium handbook

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Reviewers	all
Due date	31/03/2022
Delivery date	30/03/2022
Submitted version	V1.5
Deliverable type	Report
Dissemination level	PU (public)

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Document History

Version	Date	Description
V1.0	19.10.2021	Start of drafting by UNIMORE & Sanofi
V1.1	24.01.2022	First draft by UNIMORE & Sanofi
V1.2	11.03.2022	Feedback from the Steering Committee
V1.3	21.03.2022	First draft ready for review
V1.4	29.03.2022	Approval by the ExCom
V1.5	30.03.2022	Final version

Definitions

- **Participants** of the FACILITATE Consortium are referred to herein according to the following codes:
  1. **UNIMORE.** Università degli Studi di Modena e Reggio Emilia
  2. **VUB.** Vrije Universiteit Brussel
  3. **TUNI.** Tampereen Korkeakoulousaatio SR
  4. **EUPATI.** Stichting EUPATI Foundation
  5. **ACN**. Associazione Cittadinanzattiva Onlus
  6. **PN.** PRIVANOVA SAS
  7. **ODY**. Odysseus Data services SRO
  8. **ZEN.** Privredno drustvo Zentrix Lab Drustvo sa ogranicenom odgovornoscu Pancevo
  9. **INPECO.** Inpeco SA
  10. **BPE.** ADERA
  11. **AOU.** Azienda Ospedaliero Universitaria di Modena Policlinico
  12. **MUG.** Medizinische Universitat Graz
  13. **UJ.** Universytet Jagiellonski
  14. **IMR.** Institute for Medical Research, University of Belgrade
  15. **SCC.** Spitalul Clinic Colentina Bucuresti

16. **PNZW.** St Antonius Hospital Gronau Gmbh
17. **EURAC.** Accademia Europea di Bolzano
18. **EURORDIS.** EURORDIS – European Organization for rare Diseases Association
19. **SARD.** SANOFI Aventis Recherche et Développment
20. **MED.** Mdsol Europe LTD
21. **ABV.** Abbvie Inc
22. **AZ.** AstraZeneca AB
23. **BAY.** Bayer Aktiengesellschaft
24. **PFZ.** Pfizer limited
25. **TAK.** Takeda Pharmaceuticals International AG
26. **ALM**. Almirall SA
27. **SERV**. Institut de Recherches Servier

Linked third parties.

4.1 EUPATI IT. Accademia del Paziente Esperto EUPATI

9.1 INPECO TPM. Inpeco TPM SRL

- **Grant Agreement**. (Including its annexes and any amendments) The agreement was signed between the beneficiaries of the action and the IMI2 JU for the undertaking of the FACILITATE project (Grant Agreement No. Project n° 101034366).
- **Project**. The sum of all activities carried out in the framework of the Grant Agreement.
- **Consortium**. The FACILITATE Consortium, comprising the above-mentioned participants.
- **Consortium Agreement**. The agreement was concluded amongst FACILITATE participants for the implementation of the Grant Agreement. The agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.
- **Work plan**. Schedule of tasks, deliverables, efforts, dates, and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.
- **Deliverable review**: An evaluation procedure by one or more reviewers, which precedes the distribution of a deliverable (as defined in the Work plan) to the IMI2 JU.tium
- **Quality assurance**: All the planned and systematic activities implemented to provide adequate confidence that an entity will fulfill requirements for quality.
- **Quality policy**: A set of principles on which quality assurance procedures are based.
- **Risk**: Uncertainty that may significantly impact the execution or outcome of the project, and which effect may be negative – a threat risk, or positive – an opportunity risk.

Abbreviations

- **CA.** Consortium Agreement
- **CFS.** Certificate on the Financial Statements
- **DoA.** Description of Action
- **EEA.** European Economic Area
- **EFPIA.** European Federation of Pharmaceutical Industries and Associations
- **EDC.** Expert Decision Committee
- **EU.** European Union
- **ExCom.** Executive Committee
- **FS.** Financial Statement
- **GA.** General Assembly
- **IMI.** Innovative Medicines Initiative

- **IMI2 JU.** Innovative Medicines Initiative Programme 2.
- **IP.** Intellectual Property
- **NDA.** Non-Disclosure Agreement
- **pm.** person-months
- **PP.** Project Partner
- **PL.** Project Leader
- **PMO.** Project Management Office
- **RTD.** Research, technology, and development
- **SAB.** Scientific Advisory Board
- **SC.** Steering Committee
- **SME.** Small and Medium Enterprise
- **WP.** Work Package
- **WPL.** Work Package Leader

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Executive Summary

The purpose of deliverable D1.1 The Consortium Handbook is to define the management and administrative procedures and principles that will ensure efficient execution of the FACILITATE project and thus contribute to the production of high-quality project results. The handbook is intended to support partners in the effective and efficient administration of the project and guide the project participants through all aspects of the project's management and coordination providing a clear set of rules and expectations. As the project evolves over the next 48 months, the handbook will be updated after its initial submission whenever needed to ensure that the information remains coherent with the development of the project.

The main objective of the Handbook is to provide an understandable and short reference 'manual' that describes the management structure, tasks, decision-making processes, responsibilities, and procedures on all levels of the project execution. All the information and general principles in the Handbook are taken from the Grant Agreement, the Description of Action, and the Consortium Agreement provisions, but it also draws from best practice, IMI2 rules, and accepted project management standards.

This document specifically covers the following areas:

- Administrative project management processes that ensure accurate financial reporting and justification of the work being carried out and secure intellectual property.
- General project management processes that guarantee tight coordination of research, technology, and development (RTD) activities resulting in high-quality Deliverables.
- An internal communication strategy that ensures clear and effective communication between the Participants and allows for early mitigation reducing the escalation of problems and the timely resolution of management and technical issues.
- An overview of the methods and procedures adopted by the Consortium to identify, analyse, assess and monitor risks affecting the project or its results, and the development and monitoring of associated mitigation and contingency plans that aim at reducing the potential negative effects and maximizing the potential benefits.

Please note that this Handbook is circulated as a guidance document only. It should not be relied upon for making any legal assessments and decisions, for which Participants should always refer to the FACILITATE Grant Agreement and the Consortium Agreement (including their annexes). In case of any discrepancies or doubts, the latter shall prevail.

1. Introduction

1.1 Purpose, scope and structure

The purpose of the present document is to provide an overview of the management and administrative procedures and principles that will guarantee efficient execution of the FACILITATE project and thus contribute to the production of high-quality project results. Special attention will be paid to ensure that the project results are delivered in due time, within budget, and incorporate the formal quality standards developed for the project.
The handbook will be updated every quarter to ensure that the content is in line with the development of the FACILITATE project.

The established procedures are based mainly on the general principles and policies set out in the grant regulations and official guidelines under the IMI2 Programme (Grant Agreement and its annexes, Consortium Agreement). The procedures established in this document should be understood as a starting point and will be adjusted according to need as the project evolves.

The document reports the procedures and principles which refer to generic coordination and management tasks and follow best practices and principles for project management (established by the internationally recognized Project Management Institute -PMI-). Consequently, they can be supplemented at the level of technical Work Packages (WPs) or activities as needed. The activities described in this document will be mainly undertaken within the framework of Work Package 1 *Project Management and Administration,* but they may also refer to or involve other WPs.

The main areas described are:

- Project coordination and management structure
- Quality assurance and project assessment
- Deliverables and quality procedures
- Progress reporting
- Financial management
- Risk management
- Internal communication
- Legal management

1.2 Caveats

The general principles guiding the project execution are defined in the Grant Agreement, the Description of Action, and the Consortium Agreement. This project handbook shall not replace any of the established agreements within the consortium or with the IMI2 JU, or any of the IMI2 JU guidelines for project implementation. In the case of any apparent or real inconsistencies between these documents the following order of precedence shall be applied (see Section 3 “Key legal documents” of this document for further details on these documents):

1. Grant Agreement (including Annexes)
2. Consortium Agreement (CA)
3. Project handbook

1.3 Basic project information

Project acronym: FACILITATE
Project title: FrAmework for ClInicaL trIal participants daTA reutilization for a fully Transparent and Ethical ecosystem
Grant Agreement number: Project n° 101034366
IMI call topic: IMI2 Call 23 (H2020-JTI-IMI2-2020-23-01), topic 1: entitled '*Returning Clinical Trial Data to study participants within a GDPR compliant and approved ethical framework'.*
Project start date: 1st January 2022
Project end date: 31st December 2025
Number of participants: 27
IMI project officer: Oussama Karroum
Financial Project Officer: Marisol Molinuevo
Legal Officer: Barry Desmond
Total project costs (included non-EU funded): € 6.886.711,00
Requested EU Contribution (IMI2 JU funding): € 3.260.000,00
EFPIA and in-kind participants total contribution: € 3.626.711,00

2. Project coordination and Management Structure

The project coordination and management activities of FACILITATE are mainly covered in work package (WP) 1 but they have also been described in other parts of the Grant Agreement, including the Description of Action (DoA) and the Consortium Agreement (CA). FACILITATE is a rather complex project therefore it has been structured to have both executives as well as distributed management systems.

2.1 Objectives

Within FACILITATE, WP1 – *Project management and Administration* is responsible for the operational project management activities by providing professional management to ensure satisfactory progress and successful completion. This will entail work plan development and partnership management, financial and administrative tasks (including reporting), contractual arrangements and support on legal issues, including independent project reviews, handling in accordance with provisions of the Grant Agreement / Consortium Agreement, risk management (identification, assessment, follow-up, mitigation/contingency plans), quality control procedures on deliverables, and support for internal communication. It will coordinate dissemination activities and outreach to key stakeholders and provide oversight and guidance of ethical aspects relevant to the project. WP1 will also provide strategic direction for the scientific and technical activities. To ensure that scientific activities are managed effectively this WP will also pay special attention to the project work plan, interdependencies and will direct special attention to cross-WP activities.

The main objective of this WP is the overall project management and administration of the project and the consortium. Detailed work-package objectives are:

1. Project coordination and KPI follow-up
2. Preparation and evaluation of reports, technical and overall project management
3. Consortium communication and resource mobilization.

The following sections include an operational summary of these activities in relation to project coordination and management.

2.2 Coordination and management structure: roles and composition

The governance structure of FACILITATE has been devised to respond to the needs of the project, its size, and complexity.

FACILITATE will adopt a governance model that promotes the active participation of all involved beneficiaries, including all public and EFPIA partners, as well as other interested third parties such as pharmaceutical companies, patient groups, regulators, HCPs, etc. to achieve the maximum level of collaboration. The management structure of FACILITATE has been developed to respond to the needs of an international large-scale multi-stakeholder project and is based on a traditional management structure adapted to the attributes of FACILITATE.

The following section will give a brief overview of the governance structure (Fig 1). For a detailed description, voting rights (Table 1), and tasks of the committees, please refer to the DoA and the Consortium Agreement.

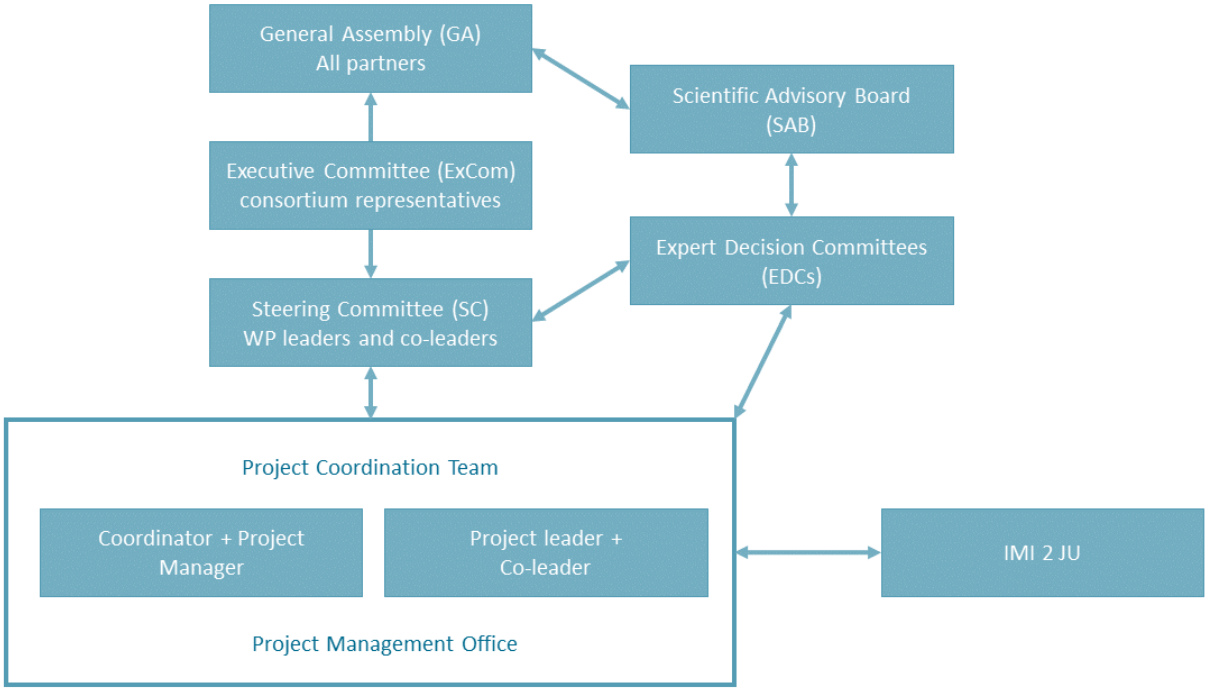

Figure 1. FACILITATE Governance Structure

- **General Assembly (GA):** Ultimate decision-making body in the project when dealing with critical issues, such as major changes in the overall project strategy, the composition of the consortium, and other matters that the Steering Committee (SC) and Executive Committee (ExCom) bring to attention. The GA will host scientific discussions and supervise the implementation of the governance structure. The GA is composed of one representative nominated by each beneficiary (partner) and will meet at least every twelve (12) months.

  ➔*Detailed responsibilities can be retrieved from the Consortium Agreement, Clause 11.3.*

- **Executive Committee (ExCom):** Consists of the leaders of the public and the private industry partners, keeping a public-private balanced composition: UNIMORE, Sanofi, Medidata, EURAC, TAU, EURORDIS, Takeda, and Pfizer. The Project Management Office will attend ExCom meetings without voting rights. The ExCom will be responsible for:

    - the overall scientific leadership of the project
    - the strategic oversight, of determining project policies,
    - approving minor changes to the project work plan and deliverables before submission to IMI,
    - minor budget allocations,
    - solving emerging issues or escalated issues to the SC and GA.

    ➔ *Detailed responsibilities can be retrieved from the Consortium Agreement Clause 11.4*

    Steering Committee (SC): The SC is composed of WP Leaders (WPL). The SC will be an escalation body for issues that cannot be solved at the ExCom level. The SC will meet typically every one to two months and is responsible for:

    - the overall execution of the action,
    - alignment across all WPs,
    - decision making and
    - the initial realization of amicable solutions for any disputes between beneficiaries related to the execution of the action.

    ➔*Detailed responsibilities can be retrieved from the Consortium Agreement, Clause 11.6*

- **Project Coordination Team (PCT):** The coordination team has overall responsibility for ensuring the success of FACILITATE, from inception to completion. The responsibilities of the PCT include:

    - the overall management of the Consortium and administration of the project,
    - developing the data management plan,
    - setting-up the Project's organizational and internal communication,
    - the overall quality control of all deliverables including their timely delivery to the EU project officer
    - Collaboration with the IMI2 JU project officer and negotiating any changes to the project structure, where necessary
    - supporting the management of timely compilation of reports to be submitted to IMI2 JU, and supervising a sustainability plan.
    - encouraging the timely Dissemination of Results,
    - ensuring full ethical compliance

    ➔*Detailed responsibilities can be retrieved from the Consortium Agreement, Clause 11.7*

- **Project Management Office (PMO):** Responsible for the day-to-day operational aspects of the project and the support of the project governance and advisory committees at the management and operational levels. The PMO will prepare meetings for the GA, SC, and

ExCom, including but not limited to the distribution of the agenda, preparation, and distribution of the meeting minutes.

➔*Detailed responsibilities can be retrieved from the Grant Agreement, chapter 3.2*

- **Scientific Advisory Board (SAB):** The SAB will advise the SC and GA upon request of the Project Coordination Team. It is composed of 3-5 experts on scientific/technical matters related to the project.

  ➔*Detailed responsibilities can be retrieved from the Consortium Agreement, Clause 11.8*
  ➔*Definition of rules and its composition in Deliverable D1.8*

- **Expert Decision Committees (EDCs):** The EDCs will advise the GA and SC upon request of the Project Coordination Team. It is composed of several experts organized in 3 fundamental areas:

  - Technical and Medical Expert Decision Committee, EDC-A
  - Ethical and Legal Expert Decision Committee, EDC-B
  - Patients and Regulators Expert Decision Committee, EDC-C

  ➔*Detailed responsibilities can be retrieved from the Consortium Agreement, Clause 11.9*
  ➔*Definition of rules and its composition in Deliverable D1.2*

2.2.1 FACILITATE decision-making bodies

The FACILITATE decision-making process is made up of different quorum and majorities:

	COMPOSITION	QUORUM	DECISIONS
GA	1 representative per partner	75%	Double majority: 51% - beneficiaries receiving funding 51% - beneficiaries not receiving funding The chairperson shall have a casting vote.
ExCom	UNIMORE, Sanofi, Medidata, EURAC, TAU, EURORDIS, Takeda, and Pfizer – 1 representative for each	75%	Double majority: 51% - beneficiaries receiving funding 51% - beneficiaries not receiving funding The Project Leader shall have a casting vote.
SC	Coordinator Project Leader WP Leads – 1 public and 1 private	75%	Simple majority The Project Leader shall have a casting vote.
PCT	UNIMORE, Sanofi	75%	Simple majority The Project Leader shall have a casting vote.

Table 1. FACILITATE decision-making system

2.2.2 General Assembly (GA)

The FACILITATE GA is the ultimate decision-making body in the project dealing with matters requiring decisions and solving critical issues, such as major changes in the overall strategy. Full description of functions, meeting frequency, and voting rights of the GA are described in the FACILITATE Consortium Agreement, in section 11.3. Several members of each organization can participate in the GA, but only one vote per partner is allowed. Each representative has 1 voting right, which will serve for scientific discussion and follow-up on the general progress of the project. See more details regarding the decision-making bodies and a list of representatives (Table 2).

PARTICIPANT	GA MEMBERS	
UNIMORE	Luca Pani	Johanna Maria Catharina Blom
VUB	Paul Quinn	
TUNI	Antonios Michalas	Bin Liu
EUPATI	Maria Dutarte	Silvia Scalabrini
ACN	Daniela Quaggia	
PN	Dordje Djokic	Farhan Sahito
ODY	Gregory Klebanov	Sebastiaan van Sandjik
ZEN	Nenad Gligoric	
INPECO	Andrea Costaglioli	
BPE	Nicolas Thurin	Angela Grelaud
AOU	Simona Guerzoni	
MUG	Kurt Zatloukal	
UJ	Agnieszka Słowik	
IMR	Oligica Djurkovic Djakovic	
SCC	Andrei Dan	
PNZW	Sami-Ramzi Leyh-Bannurah	Jens Breer
EURAC	Deborah Mascalzoni	
EURORDIS	Sandra Courbier	Veronica Popa
SARD	Véronique Poinsot	Nadir Ammour
MED	Andrew Kopelman	Anthony Ford
ABV	Alexandra Perreau	Sean Turner
AZ	Lisa Winstanley	Jorgen Jensen
BAY	Cornelia Peters-Wulf	Axel Diefenbach
PFZ	David Leventhal	Debbie Mitchell
TAK	Giuseppe Cognetti	Nuala Ryan
ALM	Diego Herrera Egea	Jesus Miguel Cativiela Rodriguez
SERV	Marta Garcia	Maxence Vincart

Table 2. FACILITATE GA Representatives

2.2.3 Executive Committee (ExCom)

The Executive Committee is made up of leaders of the public and industry consortium with a balanced composition from UNIMORE, SANOFI, Medidata, EURAC, TAU, EURORDIS, TAK, Pfizer, as well as a non-voting representative from the PMO.

The ExCom will meet frequently (ad hoc meetings may be scheduled as agreed by members of the ExCom) to monitor the project progress and to address any issues that may arise.

The ExCom will determine project policies, approve minor changes to the project work plan, minor budget allocations. The ExCom will also solve emerging issues or escalate issues to the SC and the GA.

Specific responsibilities of the Executive Committee are defined in the Consortium Agreement in section 11.4.2. The ExCom members are:

Public representatives		EFPIA representatives	
UNIMORE	Johanna Maria Catharina Blom	SANOFI	Véronique Poinsot
TAU	Antonios Michalas	MEDIDATA	Andrew Kopelman
EURAC	Deborah Mascalzoni	TAKEDA	Giuseppe Cognetti
EURORDIS	Veronica Popa	PFIZER	David Leventhal

Table 3. FACILITATE Executive Committee Members

2.2.4 Steering Committee (SC)

The Steering Committee shall be made up of the Project Leader, the Coordinator, the Work Package Leaders, and Work Package Co-leaders and a representative of the Coordination and Management Office (the latter shall have no voting rights).
The SC will deal with amendments to the work plan and changes in budget allocation between WPs. It will approve project deliverables, ensure that objectives and milestones are fulfilled with appropriate quality, and decide on technical roadmaps with regard to the project. The SC will meet every one to two months. Full description of functions and voting rights are described in the FACILITATE Consortium Agreement, section 11.6.

WP	8 seats	EFPIA (7 seats) + EURAC
WP1	Johanna Maria Catharina Blom (UNIMORE)	Véronique Poinsot (SANOFI)
WP2	Paul Quinn (VUB)	Anne Bahr (SANOFI)
WP3	Gianluigi Fioriglio (UNIMORE)	Andrew Kopelman (MEDIDATA)
WP4	Stevan Jokic (ZENTRIX)	Nadir Ammour (SANOFI)
WP5	Sebastiaan van Sandjik (ODYSSEUS)	Lionel Winglet (SERVIER)

WP6	Daniela Quaggia (ACN)	Nuala Ryan (TAKEDA)
WP7	Farhan Sahito (PRIVANOVA)	Davide P. Leventhal (PFIZER)
WP8	Johanna Maria Catharina Blom (UNIMORE)	Deborah Mascalzoni (EURAC)

Table 4. FACILITATE SC composition and seats

2.2.5 FACILITATE Project Coordination Team (PCT)

FACILITATE is co-led by a Coordinator and a Project Leader which are jointly responsible for the overall scientific progress of the project. Luca Pani represents UNIMORE, the Coordinator of the Project and Veronique Poinsot represents SANOFI, the Project Leader. The representatives will be supported in their tasks by the Project Management Office (PMO).

The Coordinator shall act in close collaboration with the Project Leader because they represent a central point of contact between the Partners and IMI2 JU. The Coordinator (UNIMORE) will receive and distribute the IMI2 funding. The Project Leader will liaise with the EFPIA partners' matters.

The Coordinator and the Project Leader will jointly chair the meetings of the General Assembly, the Steering Committee, and the Executive Committee. Functions and responsibilities of the Coordinator and the Project Leader are described in the FACILITATE Consortium Agreement Art. 11.1 and 11.2.

Project Coordinator	UNIMORE, represented by Luca Pani Deputy-Coordinator Johanna Maria Catharina Blom
Project Leader	SANOFI, represented by Veronique Poinsot Deputy-Leader Nadir Ammour

Table 5. FACILITATE Coordinator and Project Leader

2.2.6 FACILITATE Project Management Office (PMO)

The PMO is a support office and will be operationalized by UNIMORE with the support of SANOFI. The PMO supports the ExCom and the SC at the management and operational level, dealing with:

- The day-to-day management of the project, including work plan follow up:
- Reporting, administration, legal management;
- Risk management;
- Quality control procedures on project deliverables, dealing with the day-to-day management of the project. Regular meetings, mostly by teleconference, will be established to appropriately follow up on management matters.

UNIMORE	Nadja Sändig, Laura Chiaranda, Project Manager
SANOFI	Philippe Bordes

Table 6. FACILITATE PMO composition

2.3 FACILITATE meetings

The Coordinator and the Project Leader, supported by the PMO, are responsible for convening meetings of the management and scientific bodies at the FACILITATE overall level (i.e., GA, SC, ExCom, and other committees), complying with the frequency of ordinary meetings as defined in the FACILITATE Consortium Agreement. WPLs hold the responsibility of calling meetings within their respective WPs as needed.

2.3.1 FACILITATE Face-to-face and virtual meeting organizations

All FACILITATE partners may volunteer to host FACILITATE General Assembly Meetings (GAMs) and other meetings related to the project. The hosting organization and SANOFI will share the responsibility of the meeting organization.

The list below is indicative and intended to help identify the commitments at both sides for any type of meeting organized during the project (it may vary slightly for each specific meeting):

Host responsibilities

Before the meeting:

- Identification, initial visits, and initial negotiation with meeting venues (ideally 2-3 options). Venue requirements:
  - Reasonable cost (range to be confirmed) via a daily delegate rate.
  - Flexibility to implement a delegate rate.
  - Availability of plenary room (for 30 - 50 people approximately, > 100 for Annual Meetings), plus smaller break-out rooms (3-4 breakout rooms in accordance to needs, but at least for up to 30 people).
  - Catering service.
  - Audio-visual equipment / Teleconference (TC) equipment
  - Audio-visual technician(s).
- Identification, initial visits, and negotiation with the hotel (ideally the same as the meeting venue). Negotiation of special rate if possible. Pre-blocking of rooms if possible.
- Identification, initial visits, and negotiation with the restaurant for one project dinner (for practical reasons, it is recommended to have it in the same place as the venue if possible).
- Join the organization team during one on-site visit (timing to be confirmed, preferably before closing the contracts with the venue/hotel/restaurant).
- Support the organization team in dealing with issues with the accommodation or catering if any.
- Participate in meeting organization teleconferences (TCs) as needed.
- Facilitate contact with the provider to print the meeting material.
- Participation in the press release.

During the meeting:

- Provide support personnel during the meeting (for the registration desk, audio-visual equipment, TC facilities tests, etc.) - desirable.
- Support with the accommodation of catering if any.

Responsibilities of the organizing team

Before the meeting:

- Creation and follow up of a GAM plan (i.e., an overview of all preparatory actions, associated timelines)
- Participate in the venue/hotel/restaurant selection or the selection of a technical support company in case of a virtual meeting, close negotiations with the venue/hotel/restaurant and/or the technical support company in case of a virtual meeting
- Drive the agenda configuration and produce the meeting logistics document (input for on-site transportation will be requested from the host)
- Prepare and send meeting save-the-dates, invitations, and reminders to partners and invitees
- Set up an electronic form for attendants' registration and follow up of registrations
- Arrange and pay the hotel booking and travel of Associated Collaborators and advisors or reimburse those costs after the meeting
- Keep track of the financial aspects of the meeting (in collaboration with the host)
- Prepare badges (support may be agreed upon with the host organization if practical and available)
- Prepare any communication materials needed for the meeting
- Organize and chair meeting preparation TCs as needed

During the meeting:

- Representatives of the PMO for meeting organization support: gathering and uploading the presentations, dealing with logistic aspects of the meeting (catering, technician, etc.), registration desk.
- Arrange minutes.

After the meeting:

- Reimbursement of expenses to the Invited speakers and/or advisors by UNIMORE
- Financial follow-up
- Coordinate minutes' production together with PMO representatives
- Upload meeting materials in Teams (such as final presentations, minutes, etc.) and circulation of any additional documents relevant for the Consortium

Any other meetings not foreseen but arranged by the Work Packages themselves will be held remotely. If hosted by an EFPIA Partner, the host will cover organizational costs on their own funds.

Travel and accommodation to these meetings need to be covered by the participating organization themselves using their allocated travel budget. Refreshments/lunch and snacks may be covered as eligible costs. A fixed agenda and minutes need to be presented.

2.3.2 FACILITATE meeting participation

Each FACILITATE partner should book their travel, accommodation and pay her/his dinner costs and delegate rate (if applicable), which should be covered by themselves from their own project travel

budget and then claimed directly to IMI at the time of their organization's periodic financial reporting (if eligible to receive IMI funding/ public partner). The process of how to claim the travel costs can be found in section 6.2 of this handbook.

For the FACILITATE invited speakers, expert decision committees' members, and advisors, the travel and accommodation costs are covered by UNIMORE, after invitation and formal approval before the meeting. UNIMORE reimburses travel (economy class flight/train/bus tickets) and accommodation (best value for money and according to other reimbursement rules of the IMI rules/EU commission) of invited speakers and advisors based on a written request including the original receipts after the meeting from the contingency fund. The travel and accommodation expenses and their documentation need to be in line with the travel policies of the H2020, IMI2, and UNIMORE rules, e.g., original receipts are required for all expenses that are being claimed (see annex VI for details).

The expenses will be covered if:

- There is a signed agreement.
- There is a written invitation to participate in a specific Project activity for which it is explicitly stated that travel will be reimbursed.
- A written reply has been provided accepting the invitation within the given deadlines if any.

2.3.3 How can Participants change their representative in the GA?

The representatives of each of the Participants are by default maintained throughout the project. Any representative in the GA may nominate a substitute to attend and vote at any meeting. Given this, any change in representative in the GA must be communicated by the original representative, in writing (by email), directly to the Chairs (Coordinator and/or Project Leader) and the PMO at least one week before an ordinary GA meeting takes place (supposedly every 12 months), indicating the reason for substitution and identifying the new representative.
GA Representatives can be accompanied by other participants of their respective institutions at meetings, but only one vote per institution is allowed in the GA.

2.4 What are the main partners' responsibilities?

Partners must strive to perform and fulfil all their obligations, promptly, and on time, under the Grant Agreement and the Consortium Agreement, to accomplish the purpose and objectives of the FACILITATE project and act in cooperation and mutual trust. Partners shall also provide their respective contributions to deliverables, information, and reports as required by the GA, SC, ExCom, and PMO, to help these bodies to fulfil their obligations.

Partners shall promptly notify the Coordinator, the Project Leader, and the PMO through the appropriate WPL of any significant problem or delay likely to affect the success of the project.

In summary, each Participant must:

a) Do the work they have been assigned to do in the DoA, and any other detailed work plan derived from it, on time and with an appropriate level of quality.
b) Finalize the deliverables with the ultimate goal of future exploitation of the project results in mind.
c) Collaborate with all other partners as required by the tasks, including contributing to relevant deliverables.
d) Not hinder the work of others or delay it unnecessarily.
e) Attend meetings and teleconferences as required.

f) Promptly notify the relevant governance body of any potential issues affecting performance. The normal chain of reporting would be, in this order: WPL -> PMO + SC -> GA.
g) Notify the PMO and SC about any risk that may be detected in the course of the work, and that may affect future performance.
h) Fulfil the administrative, technical, and financial reporting obligations according to IMI2 rules – spend the costs foreseen only for the work expected in FACILITATE and report it faithfully.

2.5 How are internal conflicts resolved?

Any complaint arising between FACILITATE Consortium partners should be solved amicably. If a partner wishes to complain about other partners in the Consortium, such complaint should be detailed and in writing. Such complaints should be addressed to the respective Work Package Leads (WPLs).

If unresolved, the Coordinator, Project Leader with support of the PMO will use mediation, expert, and referred powers to objectively assist in resolving the issue.

If still unresolved, the conflict is escalated to the ExCom, who may also choose to escalate the matter to the SC. The ExCom can finally forward the conflict to the General Assembly (GA) for further discussion, if necessary.

Should no resolution be validated throughout this process, the disputes would be escalated for arbitration in Brussels as described in the CA.

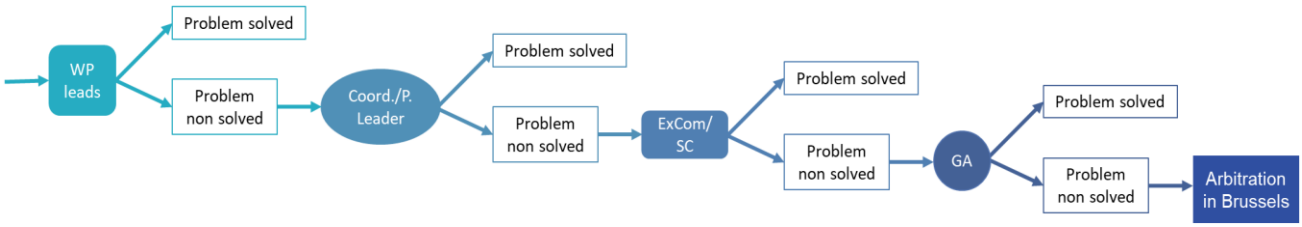

Figure 2. FACILITATE dispute resolution process

3. Key legal documents

3.1 The Grant Agreement (GA)

The Grant Agreement is the main legal document underpinning the project's execution effectively, and is a contract between the participants and the IMI2 JU. It is first signed by the IMI2 JU and the Coordinator. Each FACILITATE beneficiary then accedes to the Grant Agreement by signing an accession form. The Grant Agreement mainly provides information on the grant (parties, duration, start date, budget, maximum funding, etc.), obligations of the beneficiaries towards the IMI2 JU (such as reporting requirements), as well as the intellectual property framework and other legal conditions. The Grant Agreement is dated 11/10/2021 and has the number Project n° 101034366.

Beyond its core terms and conditions, mostly standard text, the Grant Agreement also includes the following annexes, which form an integral part of the contract:

- Annex I. Description of the action (DoA)
- Annex II. Estimated budget for the action

- Annex III. Accession forms
- Annex IV. Model for the financial statement
- Annex V. Model for the certificate on financial statements
- Annex VI. Model for the certificate on the methodology

The GA core document includes a standard text (i.e., it is essentially the same for any IMI2 project) describing the general rules and regulations governing IMI2 projects, including financial rules (e.g. which costs are acceptable, how payments are handled, etc.), Intellectual Property Rights (who owns the results, how access to such results is enabled, etc.) and other general conditions applicable to IMI2 projects. These generic provisions can be supplemented (but not contravened) with project-specific provisions via a CA (see section 3.2 below), which enables projects to set out their specific IPR detailed rules, governance mechanisms, etc.

The most extensive and important Annex to the Grant Agreement is the Description of Action (DoA), which comprises the technical description of the work to be undertaken in the project (work packages, tasks, deliverables, milestones), the description and roles of the different partners, allocated efforts in person-months, and budget details. The DoA is derived from the original proposal submitted to the IMI2 JU for evaluation and approval, and it is the benchmark against which project progress will be judged. Compared to the rest of the Grant Agreement and annexes, which are mostly model texts, the DoA is specific to each project. It is important to remember that the DoA is an integral part of the Grant Agreement, and therefore represents a commitment from all participants.

The Grant Agreement and all its Annexes are available on the FACILITATE Teams platform.

3.1.1 Changes to the Grant Agreement

The Grant Agreement can and must be changed when any important project parameter changes: Consortium composition, project duration, project budget, allocation, etc. The PMO will collect all issues to be amended and will prepare an amendment once a year. Implementation of such changes must follow a specific procedure called '**Grant Agreement Amendment'**. Most changes that trigger Grant Agreement Amendments relate to updates in the DoA (e.g., changes in tasks and deliverables, changes in efforts allocated, additional partners, budget transfers across participants, etc.). These can be relatively minor, in which case they tend to be grouped and implemented together in one go, or major, which might trigger an amendment on its own, especially if the change must be officially integrated into the contract rapidly.

Grant Agreement amendments are submitted to the IMI2 JU by the Coordinator on behalf of the Consortium. This implies that the Consortium must be aware of and approve any proposed changes before the amendment is requested.

The PMO will be responsible for following up on amendments to the Grant Agreement during the project. The PMO will also communicate the contents of these changes to the SC and ExCom.

The overall procedure for amending the Grant Agreement is described in Article 55.2 of the Grant Agreement. In addition, the internal procedure required before the submission of the Amendment request is as follows (see figure below):

1. The PMO will keep track of all amendments requested by the beneficiaries/partners. Meetings and communications with the participants affected will enable to compile all the necessary information in support of the changes. The PMO will also liaise with the SC on this tracking.
2. The PMO will circulate a list of requested changes to the SC for information, validation, and approval.
3. The PMO will prepare the following documentation:

a) A new version of the DoA with the modifications in track changes.
b) A first version of a "Request Letter" to be sent to IMI2 including the changes and their rationale.
c) Other documents needed to request the modifications

4. The SC will receive a copy of the prepared documentation and proceed with a final review.
5. The approval by the GA will be required for any Amendment to the Grant Agreement, as defined in the Grant Agreement article 55.2 (Amendments to the Grant Agreement – Procedure) & in the CA Article 11.3 (General Assembly).
6. As a final step, the Coordinator supported by the PMO will submit, on behalf of the Consortium, the Request Letter, the new version of the DoA, and all the additional documentation required by IMI2 JU for the changes submitted. The new version of the DoA will also be accessible in Teams.

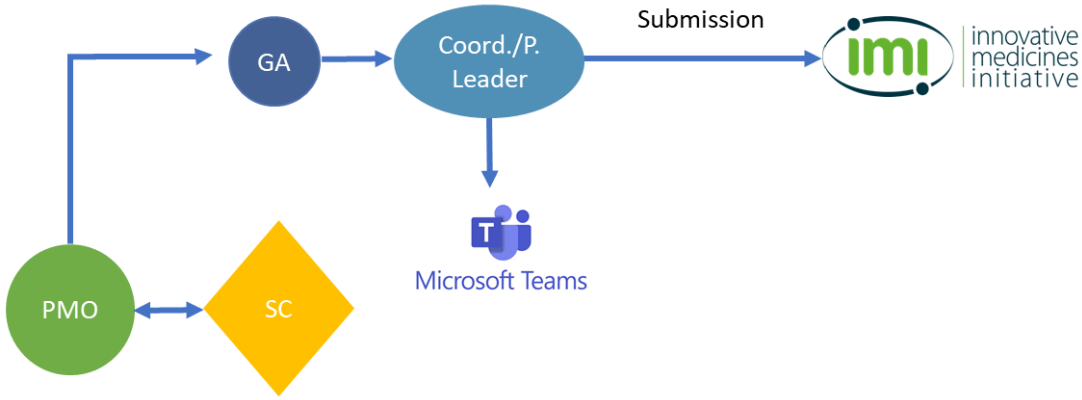

Figure 3. Grant Agreement Amendment Process

The Grant Agreement may be affected by other types of minor changes which do not constitute an amendment, but which must be communicated to the Consortium and the IMI2 JU through an informative procedure.

In any case, participants should contact the PMO to confirm the procedure to follow for any modification needed.

3.2 The Consortium Agreement (CA)

The CA is concluded between the Participants aiming to provide a legal framework for their collaboration within the boundaries of the Grant Agreement. The CA includes provisions on governance, intellectual property, dissemination, and liability among others. The IMI2 JU is not a party to the CA. The signed version of the CA is accessible in Teams.

Amendments to the CA may also be necessary during the project, sometimes purely because of Grant Agreement amendments. These CA amendments will be handled separately by agreement of all participants, under the coordination of the Coordinator and the Project Leader, with the support of the PMO.

4. Deliverables and quality

4.1 Quality policy

High-quality standards are to be applied to all work undertaken throughout the project. Quality and its pursuit are regarded as important for every individual activity within the project. Criteria and standards by which the quality of both the results of the project and the processes involved in their production are detailed below.

4.2 Project quality control

The overall quality control of the project results includes the coordination of quality review for deliverables, before their submission to the IMI2 JU. The project must ensure that deliverables, as official results of the project, are reviewed and checked for quality. This may also apply to other outcomes of the project that are addressed by parties external to the project.

A document produced in a project generally aims to provide information concerning the work, its progress, or the derived results. Each document should be carefully drafted with rich content, a clear structure, and a professional presentation.

In FACILITATE, the three basic aspects for building quality into project documents are **content, appearance, and timing**. It is generally accepted that the relative importance of each document varies, and it is important that over-zealous quality criteria do not compromise timing for a marginal benefit to the project.

4.3 Who generates project deliverables?

As official results of the project, deliverables deserve special attention and are generated and reviewed according to specific procedures (see section 4.4.2). As a general rule, the generation of deliverables is the responsibility of the corresponding WPLs, who need to gather contributions from WP participants as appropriate. Before submission to the IMI2 JU, deliverables will undergo an internal review process that is detailed hereunder.

To ensure homogeneity in the presentation and facilitate consolidation of contributions from different partners, a template for deliverables has been generated by UNIMORE based on the official IMI2 JU template and is available in the Teams repository.

With regards to the **naming convention** for electronic files, it is strongly recommended to use a reference that allows an easy and rapid understanding.

Example: ACRONYM_Del#_Title_Version#.
(e.g., FACILITATE_D1.1_Project Handbook_v1.0.pdf)

4.4 How are the project deliverables reviewed?

4.4.1 Quality criteria

The review process uses the following quality criteria as reference.

Regarding content:

- **Completeness and correspondence to what is described in the DoA:** Information must address all aspects related to the purpose of the deliverable. The deliverable should be complete and in line with the original specifications of the project and thus should fulfil the required criteria outlined in the DoA. On the other hand, redundancy of information must be avoided, as it obscures the clarity of documents.
  Related indicators: Missing content, Redundancy.

- **Methodological accuracy and data integrity:** Information contained in the document must be reliable and verifiable. This means that all background information used in the reports should be appropriately supported by references. Information on results should be sufficiently supported so that misinterpretation is avoided. The use of statistically validated objective data is to be prioritised. Adherence to methodological accuracy is required.
  Related indicators: Error, Insufficient references/objective supporting data, Ambiguity.

- **Accuracy on logic/writing/depth**: All information used, should be provided to the depth needed for the purpose of the document.
  Related indicators: Lacking detail, Excessive detail.

- **Relevance:** Information used in the document should be focused on the key issues and be written in a manner that considers the target audience.
  Related indicators: Irrelevant information.

Regarding appearance and structure:

- **Adherence to standards:** documents must be prepared with uniform appearance and structure so that, even if they are produced by different authors, they appear as originating from a single initiative.
  Related indicators: Lack of uniformity in presentation.

- **WP Leads:** Before submitting the first draft to the 3 peer reviewers it is recommended to align content and completeness on WP-level with the WP Leads, to make sure that there are no constraints regarding confidentiality, incompleteness, or unsuitable content.
  Related indicators: Alignment on content and suitability on WP level

4.4.2 Deliverable review process

Within the FACILITATE Project, the deliverable review process is coordinated by the PMO. The review process is initiated by the PMO sending a request, 60 calendar days before the submission date (whenever possible), to the WPLs of the corresponding work package to which the deliverable or project document is ascribed in the DoA and to the deliverable lead participant organization representative.

A first draft (version 1.x) of the document is generated by the author(s) and submitted to the PMO in due time i.e., within **a minimum of 40 calendar days before the due date**. The authors/WPLs should also provide a suggestion for one reviewer within the project and one reviewer within the Scientific Advisory Board that have adequate expertise to assess the document content from a scientific/technical perspective. Ideally, the two reviewers should not have been involved in the production of the deliverable.

The entire process is built on the following steps:

I. The authors/WPLs submit the draft deliverable to the PMO for the first review;

II. After the PMO's review, the deliverable will go to
   A. One internal reviewer;
   B. One reviewer within the Scientific Advisory Board for the deliverables closely connected to the milestones;

   Reviewers will be asked to check the deliverable against the quality criteria described above and submit their comments to the PMO by using the "track changes" tool of the document editor. Additionally, reviewers shall fill in the reviewer's document (Annex I);

III. The PMO will receive the comments from the reviewers and forward them to the principal author(s), who must proceed with the amendments and provide the PMO and reviewers with either a completed summary form, specifying the corrective actions undertaken (in track changes) or with comments on the reviewed document justifying how each major feedback point has been addressed.

IV. The new version (final version) of the deliverable is then produced and submitted to the PMO, who distributes it to the ExCom and the other EFPIA partners for review and approval.

V. Once approved, PMO submits the final document to the IMI2 JU via the Participant Portal online tool. The final document will be published in Teams.

The entire process is depicted in the figure below.

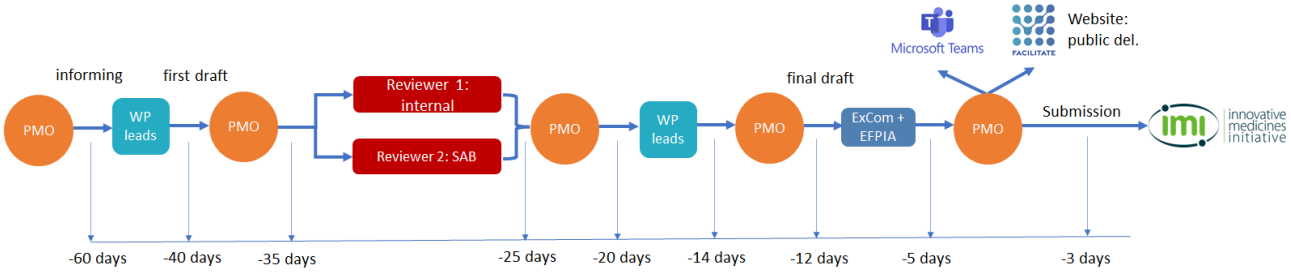

Figure 4. FACILITATE review process for deliverables

During the entire process, it is recommended that there is one responsible author who acts on behalf of all authors and coordinates the development of the document.

4.4.3 FACILITATE deliverable dates

The deliverable due dates of the FACILITATE project are expressed in the DoA as project months, meaning that project month 1 is the first month of the Project, January 1st, 2022.
Figure 5below shows the overview of the number of deliverables due per project month. The deliverables have to be submitted to IMI no later than the last day of the indicated month. They are listed in ANNEX IV.

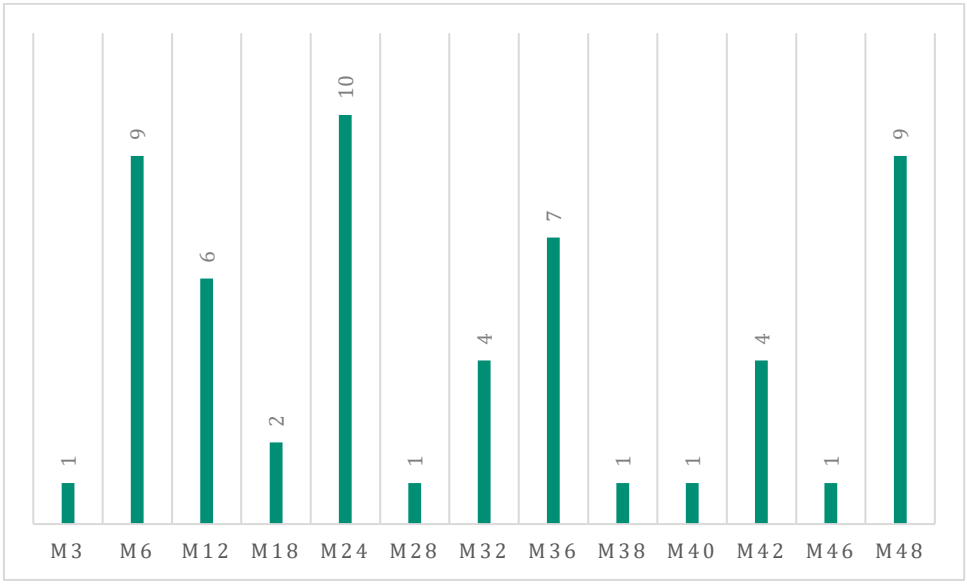

Figure 5. Number of Deliverables due per month

5. Progress reporting

5.1 Periodic reports

Throughout the entire project execution period (January 1st, 2022 until December 31st, 2025), the Consortium will have to submit **4 periodic reports** and a series of deliverables to the IMI2 JU, according to the following planning:

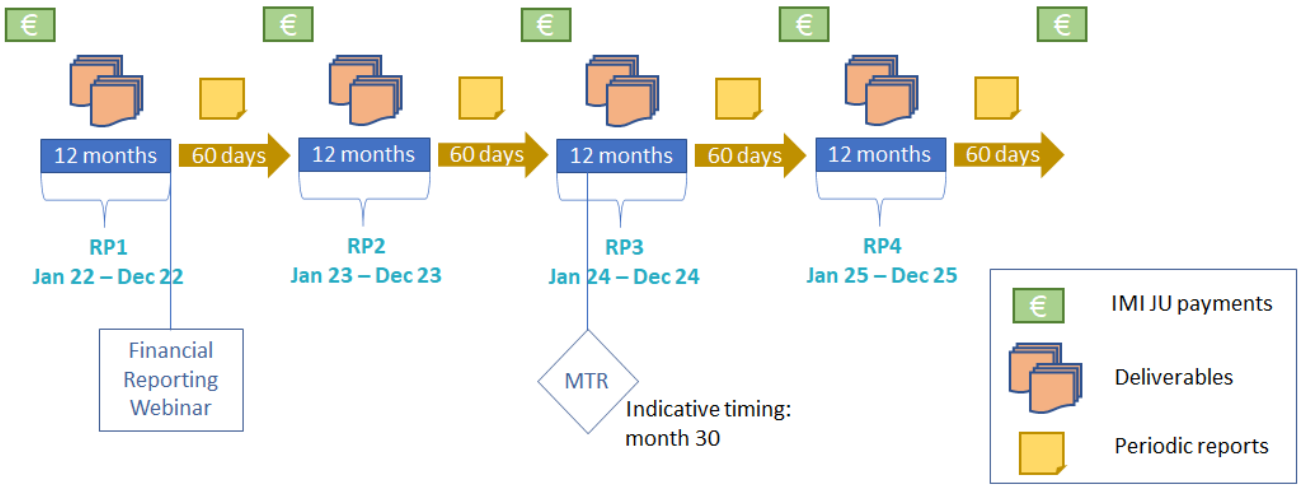

Figure 6. Reporting periods progress

As depicted in

Figure 6, the project execution period is officially divided into 4 reporting periods (RP) for technical and financial reporting to the IMI2 JU. The mid-term review (MTR), a key point in the lifetime of the

project, will take place in month 30 (M30).

The main reporting periods are:

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36 (Mid-term report in M30)
- RP4: from month 37 to month 48

Project deliverables are to be submitted at specific times, stated in the work plan tables of the DoA. Deliverables reflect the results achieved during the lifetime of the project, and they are important documents to assess the progress achieved.

In compliance with the rules specified in Article 20 of the FACILITATE Grant Agreement (Reporting – Payment request), periodic reports must be submitted to the IMI2 JU within 60 days after the end of each reporting period.

Periodic reports include detailed information on both scientific/technical and financial aspects of the project for the covered reporting period and must follow the template provided by the IMI2 JU, which will be available in Teams before the first reporting deadline (12 months).

The scientific/technical section of the report will contain:

1. An explanation of the work carried out by the partners;
2. An overview of the progress towards the objectives of the action, including milestones and
   2.1. An explanation justifying the differences between work expected to be carried out in accordance with the DoA and work actually carried out;
   2.2. The report must detail the dissemination, communication and exploitation of the results and include an updated “Dissemination, Communication and Exploitation Plan”.
3. An executive summary for publication by IMI;
4. The answers to the ‘questionnaire’, covering issues related to the action implementation and the economic and societal impact, notably in the context of the key performance indicators and monitoring requirements of Horizon 2020 and the JU.

Each partner shall send to the PMO, by e-mail, information about work performed and efforts devoted in the corresponding period, within 30 calendar days after the end of the reporting period. Effort figures can, however, be requested by the PMO at any point in time during the project and for now, is envisioned to be programmed at a bi-annual interval. For the purpose of accountability, participants are requested to keep track of their efforts at the task level. This facilitates the linkage between effort and progress when reporting to IMI2 JU.

5.2 Final report

Within 60 days after the end of the project, and in addition to the periodic report for the last reporting period, the Consortium must also submit a final report to the IMI2 JU. This final report must include the **‘final technical report’** with a summary for publication containing:

a) An overview of the results and their exploitation and dissemination,
b) The conclusions of the action, and
c) The socio-economic impact of the action.

This final report will be prepared by the PMO, with input from the WPs. The PMO will also coordinate

the elaboration of the final financial report that accompanies the technical report and in which reported figures from all participants throughout the project are consolidated.

6. Financial reporting

6.1 Basic documents and principles

As in any other IMI2 project, FACILITATE's budgeting and financial flows are based on a few key concepts.

Each participant has a budget, which includes the estimated costs that will be incurred in the project. These costs can be covered with IMI2 funding, direct cash contributions from EFPIA partners, or both. Total funding received by a participant cannot exceed its costs (i.e., it cannot generate a profit derived from participation in the project). EFPIA participants have planned costs, but they receive no funding; all costs are understood as an in-kind contribution to the project.

IMI2 funding follows IMI2 reimbursement rules, which imply a maximum, of 100% of the costs being reimbursed for research and development activities. IMI2 funding is paid in several instalments: an advance payment (pre-financing) at the beginning of the project, two interim payments reimbursing the costs reported and accepted in each Periodic Report, and a final payment of around 10% of the total funding.

If included in the estimated budget of the project activities, any direct EFPIA cash payment is regulated by specific contracts between the paying EFPIA participant and the participant receiving the cash.

Budgets can be adjusted by transfers of amounts between beneficiaries or between budget categories (or both)[1]. This does not require an amendment, provided that the action is implemented as described in the DoA. In the case of subcontracting, these costs should be included in the DoA (via Amendment if needed) to make sure they are accepted by IMI as eligible costs.

For further information on claiming costs under the umbrella H2020, beneficiaries can also consult the following document published on the H2020 website: Avoiding errors claiming costs under H2020 grants

6.2 Costs that can be claimed for reimbursement/accounted for as an in-kind contribution

To consider project costs as eligible and therefore to get them approved by the IMI2 JU, they must fulfil the following general conditions as detailed in Article 6 of the Grant Agreement:

1. Actual, economic, and necessary for carrying out the project;
2. Determined in accordance with the usual accounting principles of the participant;
3. Incurred during the duration of the project, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report;
4. Recorded in the participants' accounts;
5. Comply with the applicable national law on taxes, and social security;

[1] The GA allows transfers of budget but NOT of tasks. In addition, a beneficiary CANNOT transfer budget to a form of expense that they have not specified in their estimated budget — except within the personnel costs category and to costs of internally invoiced goods and services.

6. Reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;
7. Indicated in the estimated overall budget in the DoA

In the day-to-day administration of the project, Beneficiaries should consider some practical advice that may facilitate their financial management:

- Need to be aware of their own budget distribution;
- Need to coordinate their financial flows: budget, funding, expenditure, justification, payments;
- Need to avoid inconsistencies between efforts spent in the project (recorded in timesheets) and personnel cost justification.

Beneficiaries should note that 'budget' means the costs that each partner is expected to incur, as declared in the DoA and in Annex 2 of the Grant Agreement. The amount contributed by the IMI2 JU is called 'funding' or 'IMI2 JU contribution'. A participant must justify its costs according to its total budget to get the expected funding in full. The actual costs incurred during the project (the 'practical' implementation of the planned budget) are what we call 'expenditure'. The justified costs represent what we call 'justification', which is the core objective of financial reporting. Lastly, 'payments' refer to the actual amounts transferred to the partners' accounts during the project. These depend on the funding of each partner and the justification accepted by the IMI2 JU and cannot exceed the total funding of each partner.

6.2.1 Direct personnel costs

The IMI2 JU follows a policy of full cost justification for all partners. This means that the hours devoted by all the personnel involved in a project should be justified, irrespective of them being newly hired for the project or permanent staff.

For the justification of personnel costs in the periodic financial statement, beneficiaries must consider the efforts reported for the same period so that these are consistent with the amounts justified. Personnel costs are understood to include salaries, social charges, etc. – all the actual costs that the person represents for the institution.

The personnel costs are normally calculated by the hourly rate multiplied by the number of actual hours worked for the project.

The hourly rate (based on actual costs) can be calculated as actual annual personnel costs, divided by the number of annual productive hours. The number of annual productive hours that make a person-month can vary between partners. All partners must calculate their specific productive hours according to the general practice in their organization. In case different categories of personnel have different working conditions, individual productive hours may be calculated. The productive hours per year should exclude annual leave, public holidays, training (if not project-related), and sick leave.

In addition, for personnel costs, the beneficiaries must keep time records for the number of hours declared for all actual work performed for the project. Time records must be in writing and approved by the persons working for the action and their supervisors, at least monthly (Time records in Annex II of this Handbook). The time record template is uploaded in Teams.

Time records should include (see template provided in Annex II):

1. the title and number of the project, as specified in the GA;
2. the participant's full name, as specified in the GA;
3. the full name, date, and signature of the person working for the action;

4. the number of hours worked for the action in the period covered by the time record; it is highly recommended that the number of hours is detailed per day (hours worked for the action in each day);
5. a short description of the work carried out during the month;
6. the supervisor's full name and signature.

Provided that partners cover all the information needed as indicated here and in the template in Annex II, partners can also use their own template.

In accordance with the Grant Agreement, Article 18.1.2 as an exception, for personnel working exclusively on the action, time records do not need to be kept, if the participant signs a declaration confirming that the people concerned worked exclusively on the action.

6.2.2 Subcontracting costs

Regarding subcontracting costs, the DoA must include a specification that enables approval by IMI. The current FACILITATE budget does not include any tasks that will be carried out by external parties.

The ground rule is that all partners must have the technical and financial resources needed to carry out the project themselves, but if it is necessary to implement the project, a participant may call upon subcontractors to implement "action tasks" described in the Grant Agreement.

The costs for subcontracting (to develop project tasks) are eligible if the following criteria are met:

1. Subcontracting may cover only a limited part of the action;
2. Need for a subcontract must be substantiated, taking into account the specific characteristics of the action;
3. Principles of "best price-quality ratio" or "lowest price";
4. Beneficiaries that are public bodies: compliance with national procurement rules;
5. Avoid any conflict of interests;
6. Tasks to be implemented and costs must be mentioned in DoA; otherwise, an amendment is required;
7. Total estimated costs of subcontracting per participant must be set out in Annex 2 Estimated budget;
8. Exceptionally: approval without formal amendment at IMI's discretion.

Otherwise, to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment, use of in-kind contributions provided by third parties free of charge, or linked third parties (subcontracting, third parties).

Third-party with a legal link to a partner is any legal entity that has a legal link to the partner implying that collaboration is not limited to the action.

The main differences between third parties linked to partners and subcontractors are shown here:

LINKED THIRD PARTY

- Relationship not limited to the IMI grant agreement.
- The duration of the collaboration goes beyond the duration of the project and usually pre-dates and outlasts the IMI grant agreement.
- The relationship sometimes has formal external recognition (association, affiliate, holding companies) or both institutions might share common infrastructure and resources (joint laboratory).
- The name of the third party, tasks and resources have to be described in DoA at the same level of detail as partner.
- This type of third party fills in its costs in an individual Financial Statement. The partner will submit both forms.
- The threshold of EUR 325.000 applies to the cumulative funding of the partner and its third parties.

SUBCONTRACTOR

- Agreement based on "business conditions".
- Best value for money, transparency and equal treatment conditions. Internal rules of the institution for the selection of subcontractors apply.
- The responsibility vis-à-vis the IMI JU for the work subcontracted lies fully with the partner.
- Costs of the subcontractor declared by the participant (no overhead can be charged).
- IPR: subcontractors do in general not have any IP rights on the foreground of the project.
- The subcontracting tasks need to be indicated in the DoA.

Figure 7 below shows a guidance overview on how to determine a subcontractor, third party, or in-house consultant:

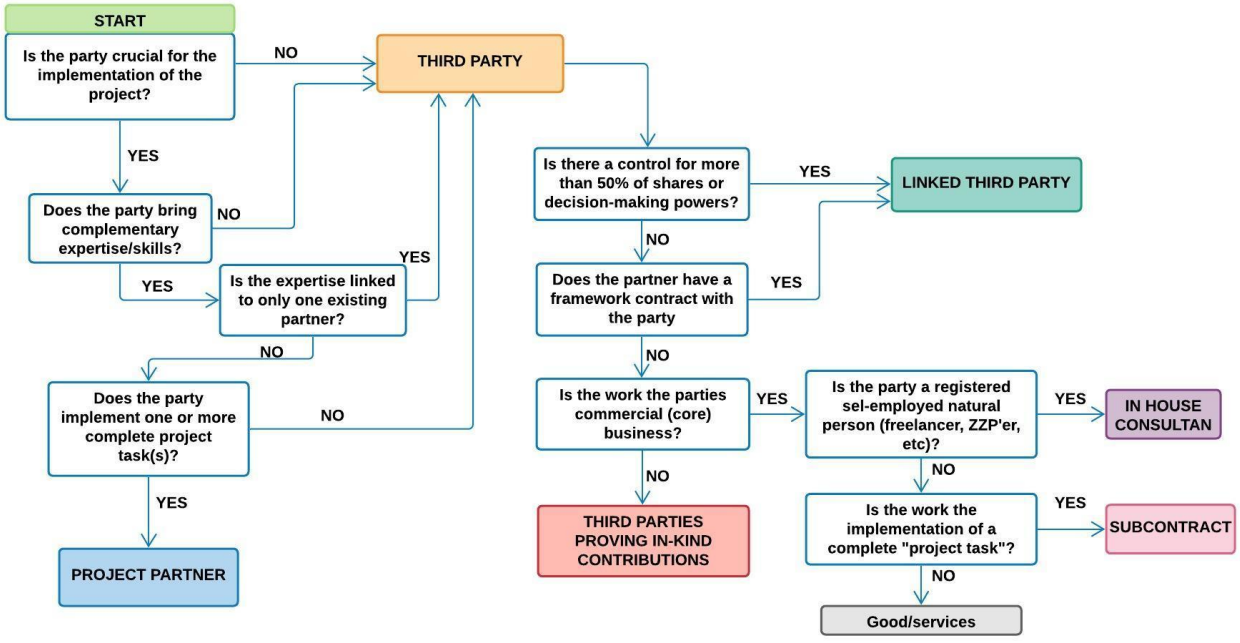

Figure 7. Third parties' options

If you have planned to involve a non-FACILITATE organization in the project activities, please contact the FACILITATE PMO to find the optimal solution, taking into account the current IMI2 rules.

6.2.3 Other direct costs

Travel and subsistence costs have been identified in the FACILITATE Project.

1. The project meetings will be held at Chilly-Mazarin Research & Development site of Sanofi. The related organisation costs will be part of the in-kind contribution of Sanofi.
2. Travel costs to the project meetings are covered by the "other costs" budget of the academic consortium and in-kind contributions of the EFPIA partners.
3. Travel costs related to conferences, workshops or other events which are related to the project are eligible. Travel costs should be limited to the necessity for the project; any extension of the travel for other professional or private reasons is not an eligible cost.

1. Each partner must apply the travel rules of their own organisation (i.e., some organisations reimburse a flat rate allowance for meal expenses, others reimburse the actual costs).
2. Travel costs and related subsistence allowances should be in line with the partner's usual practices (keep boarding passes and other proofs).
3. Travel costs of the Expert Decision Committees or the Scientific Advisory Board have to be in line with UNIMORE's internal rules (Reimbursement rules in Annex VI of this Handbook)

The **depreciation costs** of (new or second-hand) equipment as recorded in the participant's accounts are eligible if they are purchased and written off in accordance with the participant's usual accounting principles. The only portion of the costs that will be considered is that which corresponds to the duration of the action and the rate of actual use for the purpose of the action.

Costs of **other goods and services equipment, infrastructure, or other assets** (consumables, supplies, dissemination, protection of results, certificates on the financial statements, certificates on the methodology, translations, publications, etc.) are reported as "other direct cost" category.

Please note IMI2 rules allow partners to report as eligible costs the **non-deductible VAT** according to specific methods of calculations. In case of doubts, please contact the PMO for further information.

6.2.4 Indirect costs

Indirect costs or overheads (e.g., heating, lighting, security, office supplies, etc.), which represent a fair apportionment of the overall overheads of the institution, are to be added to the above-mentioned categories. As they are indirect, these costs are not justified using invoices, etc., but simply stated in the Financial Statement, generally, as a percentage of the direct costs explained above. They are eligible if they are declared based on the flat rate of **25% of the eligible direct costs**, excluding their direct eligible costs for subcontracting and the costs of resources made available by third parties which are not used on the premises of the participant. EFPIA companies might include their indirect costs in the fully loaded FTE rate.

If any doubt arises concerning project expenses or cost justification during the project life, participants are strongly encouraged to raise the issue to the PMO for guidance.

6.2.5 Costs that cannot be claimed for reimbursement

Some costs cannot be considered as eligible (detailed in Article 6.5 of the Grant Agreement) and therefore their justification in the financial cost statement is not allowed, in particular:

1. Costs related to return on capital.
2. Debt and service debt charges.
3. Provisions for possible future losses or charges.
4. Interest owed.
5. Doubtful debts.
6. Currency exchange losses.
7. Bank costs charged by the partner's bank for transfers from the JU.
8. Excessive or reckless expenditure.
9. Deductible VAT.
10. Costs incurred during a suspension of the implementation of the action.
11. Costs declared, incurred, or reimbursed in respect of another EU or IMI project.
12. Any cost which does not meet the conditions established in the previous section.

6.3 How must financial statements be submitted?

Financial statements are specific documents in which each participant declares all the costs incurred during each reporting period and the funding requested to the IMI2 JU when applicable.

6.3.1 Public Reporting

The justification of costs is done by means of an online application tool of the IMI2, called Participant Portal. The costs must be filled in by non-EFPIA Consortium participants through the system.

In addition to the Financial Statement, IMI-funded participants will be also asked to provide an explanation of the use of resources and the information on subcontracting (see Article 13 of the Grant Agreement) and in-kind contributions provided by third parties (see Articles 11 and 12 of the Grant Agreement) from each participant and each linked third party, for the reporting period concerned. (Use of resources in Annex III of this Handbook)

Specific guidelines for accessing the IMI Reporting tool will also be provided by the PMO. These guidelines will include instructions and recommendations for adequate reporting. In addition, a webinar will be organised in December 2022 for supporting staff members.

Costs must be filed in the Funding & Tenders Portal within 45 calendar days after the end of the reporting period together with the use of the resources' explanation in the cost table. It is wise for participants to prepare in advance for reporting and liaise with any relevant financial or administrative department in their respective institutions at least one month in advance of the end of the reporting period.

6.3.2 EFPIA Reporting

Under the IMI2 framework, EFPIA in-kind contribution to IMI2 projects and SGG (Strategic Governance Groups) is to be reported by each company **on an annual basis** and on a portfolio level, independently of the project deadlines set in the Grant Agreement.

When reporting actual in-kind contribution, costs shall be

1. determined in accordance with the usual accounting practices, to the applicable International Accounting Standards (IAS) and International Financial Reporting Standards (IFRS);
2. connected to the Action (project) as described in Annex I of the Grant Agreement (DoA);
3. reasonable, necessary, justified, identifiable, and verifiable;

The reporting period concerns the previous calendar year (n-1), i.e., from January 1st to December 31st.

The value of the contribution should be detailed at the level of each action (project), including both in-kind (in-kind EU/non-EU) and direct financial contributions.

In addition, total contributions to SGGs (Strategic Governance Group) involving a company should be reported. For Strategic Governance Group in-kind contribution, costs shall normally be made for personnel costs and meetings travel costs, where representatives from EFPIA company have participated/contributed.

The contributions reported should be actuals or estimates (if actuals are not available).

The information on the contributions to be submitted may be indicative (e.g., can be reported under personnel (regardless of the category), if the breakdown per category is not yet known. The actual costs including an explanation of the use of resources as outlined above should be submitted and certified annually (please check the terms of reference for this certification in SharePoint). Costs certified at a later date will be considered as such in the following year's exercise.

Further information can be obtained from the guidelines:

IMI2 JU guidelines for reporting in-kind and financial contributions

Avoiding errors claiming costs under H2020 grants

6.3.3 Who needs to submit an audit certificate

A **certificate on the financial statement (CFS)**, also called an audit certificate, is a statement from a competent auditor in which the correctness and compliance with IMI2 JU rules of a cost justification are certified.

A CFS should be provided by participants once the threshold in the IMI Grant Agreement of € 325,000 of funding/in-kind has been claimed at the end of the project. This certificate will cover all reporting periods.

Auditors eligible to deliver audit certificates must be “external auditors” or “public competent officers” who are “independent” and “qualified to carry out statutory audits of accounting documents”. It is highly recommended to determine an adequate auditor well before the end of the reporting period to ensure his/her availability for a timely generation of the audit certificate.

One original and one copy of the audit certificate, signed by an authorised person of the auditing entity, will be sent to the CMO within 45 calendar days after the end of the reporting period, preferably by courier, and together with the corresponding original financial statement.

Partners required to submit an audit certificate:

- UNIMORE
- Odysseus
- SANOFI
- Medidata
- Abbvie
- Astra Zeneca
- Bayer
- Pfizer
- Takeda
- Almirall
- Servier

6.4 IMI2 JU Funding

The IMI2 JU funding (€ 3.260.000,00) is paid from the IMI2 JU funding account to the Project Coordinator, who distributes it to the partners without unjustified delay.

Some general rules apply concerning the payments:

1. The IMI2 JU paid a **pre-financing** at the start of the project of 32,5% of the total funding (less 5% retained by the JU and transferred into the Guarantee Fund);
2. **Interim payments** will be depending on costs justified and accepted after each reporting period, and distributed after receipt by the IMI2 JU;
3. A **final payment** will be released by the IMI2 JU corresponding to the costs accepted for the last reporting period plus any adjustment needed.

Total payments during the project cannot exceed 90% of the total funding. The remaining 10% of the funding will only be paid after final reports are approved, provided that the total amount of costs budgeted are claimed and accepted.

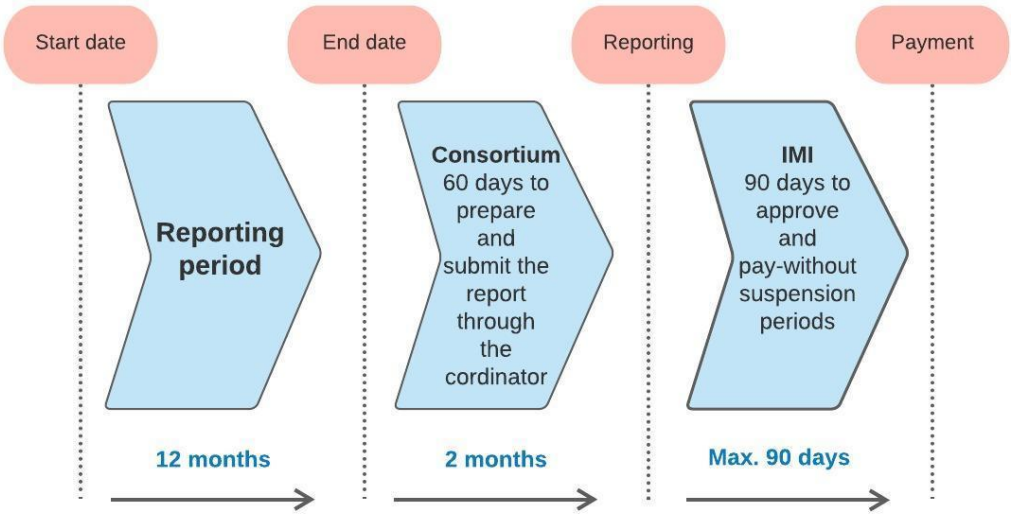

Figure 8. Timelines for reporting and IMI2 JU payments

The most important notion for participants to bear in mind is that payments follow costs reported – and costs reported follow work done for the project. The Coordinator has the right to reject costs reported by any participant if they are not in line with the work performed.

6.5 Receipts of the project

The receipts (in lay terms, 'income received due to the project') of the project are:

1. Financial contributions to the beneficiaries made by EFPIA companies and/or their affiliated entities or made by participants that are neither a participant nor an EFPIA company. The financial contribution received by the participant from EFPIA companies must be declared by the participant as a 'financial contribution', in the Financial Statement. The EFPIA company must declare those costs in its Financial Statement when reporting yearly to IMI.

2. Resources made available by third parties to the partner by means of financial transfers or contributions in kind which are free of charge:
    i. Shall be considered a receipt of the project if they have been contributed by the third party specifically to be used on the project.
    ii. Shall not be considered a receipt of the project if their use is at the discretion of the participant's management.
3. Income generated by the project:

i. Shall be considered a receipt for the participant when generated by actions undertaken in carrying out the project and from the sale of assets purchased under the grant agreement up to the value of the cost initially charged to the project by the participant;
ii. Shall not be considered a receipt for the participant when generated from the research use or direct exploitation of foreground resulting from the project

In the FACILITATE Project, from the total EFPIA in-kind contribution of € 3.626.711,000, an amount of € 1.162.807,000 is planned as a non-EU in-kind contribution (costs which part will be made outside Europe).

6.6 Adjustments to financial reporting

Any adjustment (retroactive modification of costs submitted in previous periods) requires the submission of a supplementary Financial Statement for the period, where the details of that adjustment will appear. Together with the new Financial Statement, the details and justification for the adjustment must be provided by the participant in the periodic report.

Therefore, for correction of financial statements submitted in previous reporting periods, the following needs to be submitted:

- One Financial Statement for the current period;
- One separate Financial Statement for every previous period where adjustments are needed, which will include those adjusted (negative/positive) costs of that specific previous period.

If these costs need to be covered by a Certificate on Financial Statements (CFS), they could be supported within the CFS for the current period but with a specific indication by the auditor certifying both the supplementary costs incurred in previous periods and those claimed in the current one.

7. Risk Management

7.1 Why is risk management necessary?

Risks are inherent in any activity, especially when it is unique, as is the case of a project. The presence of risk increases dramatically when projects include a significant research component, due to its inherently exploratory nature and uncertain outcome. The inevitability of risks does not imply however the inability to recognize and manage risks to minimize the potential negative consequences while taking advantage of the opportunities for improving performance and results that may arise. Risk management in the FACILITATE project is the process that commences with the identification of risks and links this through to the resolution of individual risks. It encompasses the methods and procedures undertaken by the Consortium to **identify, analyze, assess and monitor risks affecting the project or its results**, and the development and monitoring of associated mitigation and contingency plans that aim at minimizing the potential negative effects (for *threat* risks) and maximizing the potential benefits (for *opportunity* risks).

Figure 9. FACILITATE risk analysis process

A broader list of potential risks is listed in the GA, Annex I, part A, 1.3.5 *WT5 Critical implementation risk and mitigation actions.*

7.1.1 Main objectives

The main objectives of Task 1.3 – *Project planning, Risk Management, Ethics requirements, and KPI tracking* in FACILITATE are the following:

- To provide visibility and raise awareness of uncertainties that may affect the project development and/or results through a structured mechanism that ensures that both completeness and accuracy will be achieved in the process;
- To allow the project to focus on major risks by appropriate assessment and prioritization according to risk exposure, a value that results of combining the estimated probability and impact values for any given risk;
- To proactively manage uncertainties that can affect the project performance, schedule, and/or budget, with proper feedback channels to project management, allowing for the development of contingency plans, mitigation, and/or risk avoidance strategies.
- To continuously monitor the evolution of risks throughout the project, providing a framework to incorporate them in the work plan (as risks become issues) or disregard them (risks becoming pure concerns);
- To document risks, activities, and decisions made to allow for capitalization of the knowledge acquired with a view on facilitating planning and development of the post-project phase and future projects.

7.1.2 Risk Management procedures

The risk management procedures in FACILITATE have been developed to take into account the specific characteristics of the project, and are partly adapted based on lessons learnt from past projects by the Consortium beneficiaries, from guidelines produced by international standards bodies, and by recognised institutions such as the Project Management Institute (PMI).

The PMO is responsible for the procedures of the Risk Management, including identification, assessment, and follow-up of threats and opportunities likely to affect the project performance as a whole. This base operational structure facilitates straightforward and timely communication with the ExCom. However, risk management activities certainly benefit from the active participation of all involved actors, therefore an open structure that allows for contributions from all project partners is promoted. Taking the characteristics of the FACILITATE project into account, only the most appropriate procedures have been selected, giving priority to a pragmatic approach that focuses on the project success and the fulfilment of the Grant Agreement. As a consequence, the accent is put on risk identification processes that raise awareness on uncertainties and also on risk avoidance strategies. Qualitative analysis of risks is prioritized.

Four main steps compose the risk management process:

- Risk Identification
- Risk Assessment
- Risk Action Plan
- Risk Monitoring

After the end of the project, the project management will make documentation available to all partners to implement a fifth step related to the capitalisation of lessons learnt according to their own strategies. The project management will make documentation available for this purpose upon request. Importantly, in a project like FACILITATE where sustainability in the long term is a core objective, and

where the project activities serve to 'pilot' future ongoing activity, lessons learnt from managing risks during the project are of special importance.

7.2 Risk identification

Before risks can be managed, they must be identified. Identification raises awareness of risks before they become problems and adversely affect the project. The first phase of the risk management process deals with systematic research for threats to the successful achievement of the project objectives, or for opportunities that may be hidden therein, and their appropriate classification. This process relies heavily on the encouragement of project personnel to raise concerns and issues for subsequent analysis, as past experience has demonstrated that most risks are usually known by the personnel, who usually experience them as uneasy feelings, concerns, or doubts about aspects of the project that would not be defined as risks per se and thus remain hidden. The Risk Identification process must create and sustain a non-judgmental and non-attributive risk elicitation environment so that tentative or controversial views are not discouraged.

7.2.1 Activities for risk identification

- In the FACILITATE project, the following variety of activities will be considered for risk identification, including the following: Structured and facilitated brainstorming sessions. These can be normally organized taking advantage of ExCom meetings to ensure availability of participants, management involvement, and face-to-face interaction[2]. However, these sessions are susceptible to being dominated by stronger personalities, therefore complementary procedures such as online risk identification forms that can be freely submitted to the PMO are recommended. Brainstorming sessions internal to the PMO with WP leads will be carried out regularly; WP Leads will look at the risks for their WPs and discuss them during WP meetings.
- Structured interviewing. This method will normally be used to clarify details of risks, investigate new risks, or for checking areas of the project that have been re-planned. One-on-one interviews or group meetings will be used depending on the issues to be discussed.
- Unstructured interview and informal reporting (at meetings, etc).
- Analysis of formal reporting by participants in the Interim and Periodic Progress reports.
- Analysis of critical path and WP interdependencies by the PMO and WP participants.

The outcome of the risk identification process will be the creation of a Risk Documentation Form (see template provided in Annex IV of this Handbook) for each identified risk. A Risk Registry composed of the regularly updated Risk Documentation Forms will be maintained by the PMO. Furthermore, a Risk Owner will be assigned to each risk who will lead the process through the following steps.

Both opportunity and threat risks will be identified in the same way.

7.3 Risk assessment

An initial risk assessment is normally carried out as a natural consequence of the identification process. Assessment turns risk data into risk decision-making information and provides the basis for the PMO to work on the "right" risks. It aims at estimating the likelihood (probability) of a risk becoming a problem, the estimated impact ("damage" or "severity" in relation to the project objectives fulfilment), and associated risk exposure, which is a consequence of the two former variables. In FACILITATE,

[2] Note that some risks, such as those related to the Consortium (e.g., underperformance of one partner) may need to be managed privately by the CMO and ExCom.

a qualitative method will be initially used for estimation, ranking both probability and impact on a three-point scale (high, medium, or low). In this simple scheme, risks having at least one dimension graded as "high" are always to be closely examined. However, quantification of the risk exposure is done by multiplying the numerical values ascribed to each grade in the scale as follows:

	Impact	Low	Medium	High
Probability	Values	1	2	3
Low	1	**1**	**2**	**3**
Medium	2	**2**	**4**	**6**
High	3	**3**	**6**	**9**

Table 7. Risk assessment and exposure

Opportunity and threat risks are assessed in the same way, but threat risks have always priority over opportunity risks. Additionally, proximity in time is used to prioritize among risks with equal exposure.

If needed, the method will be refined according to the following alternative method to allow for more precise prioritization of the top-ranked risks.

In the alternative method, the probability could be estimated on a scale ranging from 0.1 (highly improbable) to 1.0 (certain to happen) while impact could be estimated on a scale from 1 (extremely reduced impact) to 10 (huge impact), in which case prioritization will be derived from the risk exposure factor (the result of multiplying the probability and impact factors). However, estimating in these longer scales is known to have caused difficulties in past projects and resulted in arbitrary prioritization due to bias of the risk owners, therefore the simpler three-level scale will be initially used in the project.

It is important to take into account that interaction and inter-dependence between risks can occur and that in some cases these complex situations should be treated as independent risks in themselves.

Risk assessment encompasses therefore a prioritization of the risks that can be made according to exposure but that can also be filtered according to risk category or imminence in time. This phase also comprises a specification of the Risk Owner, understood as the partner in the best position to recommend mitigation strategies for the risk, develop and document a contingency plan and monitor the status of the risk. This normally corresponds to the partner responsible for the activity/WP to which the risk is ascribed. The partner being the Risk Owner is responsible for closely following up the risk and reporting to the PMO.

7.4 Risk registry and action plan

Based on the previous assessment, the planning phase turns risk information into decisions and actions (both present and future) to address individual risks. This phase comprises the definition of mitigation approaches (strategies to control, avoid, minimize or otherwise mitigate the risk, addressed to reduce risk probability and/or impact for threat risks, and the opposite for opportunity risks), identification of trigger events (conditions that indicate that the risk is turning into an issue) and configuration of contingency plans (actions to be taken to deal with the situation if the risk becomes a problem). All threat risks with "high" or "medium" probability or impact should have a mitigation strategy that must be immediately tackled and all risks having an exposure equal to or greater than 4 must have a contingency plan prepared within FACILITATE. Additionally, a mitigation plan is required to be produced for all risks that can be easily mitigated, or that the PMO wishes to mitigate for strategic

reasons. A mitigation strategy contains a plan for controlling either or both of the following:

- The risk cause/cause-impact relationship with the aim to reduce the impact probability of occurrence.
- The impact itself and/or its effect on the project.

Implementation of a mitigation approach is the responsibility of the Risk Owner, who will be supported by the Risk Management team in the PMO when other partners are involved.

Contingency plans should identify the proposed management activity or alternative path to be taken should the risk give clear indications (understood as the occurrence of trigger events) that it cannot be avoided. Contingency plan implementation is a Project Management issue and often has to be agreed by FACILITATE with the IMI2 JU services to be entered into the work plan. Contingency plans and responsibilities for their implementation are agreed upon at ExCom level.

In summary, mitigation actions are what one does before the risk happens; once trigger events are detected, the risk becomes an issue and contingency plans are activated. If mitigation is successful, trigger events are de-activated and the risk is managed out or becomes irrelevant.

In all cases, risk avoidance strategies (which normally imply taking a lower risk path) have to be carefully considered provided that they do not endanger the Grant Agreement fulfilment.

7.5 Risk monitoring and updating

Risks and related actions undertaken have to be monitored and re-assessed continuously throughout the project until they are managed out. Previously identified risks with mitigation strategies and contingency plans need to be closely tracked to ensure that any consequential or residual risks are identified as early as possible and that actions decided are duly carried out.

The PMO is responsible for maintaining the Risk Documentation Forms and following up risks and related actions with the respective owners, coordinating the re-assessment of risks if necessary, and promoting the early identification and documentation of new risks. The PMO will support Risk Owners in the carrying out of mitigation actions that involve other partners as well.

The PMO is also responsible for organizing risk review meetings internal to the PMO to track top risks, and for documenting the whole risk management process, including mitigation ad implemented contingency plans and their results. Communication will be maintained with all partners and proactive participation and visibility of current risks will be promoted, possibly using Teams. Risk reviews will be held during ExCom meetings to have a basis to decide on contingency plans to be executed (see below workflow in Figure 9). The PMO is responsible for checking with the IMI2 JU services about the appropriateness of any contingency plans that have the potential to endanger the work plan fulfilment and the successful completion of the project.

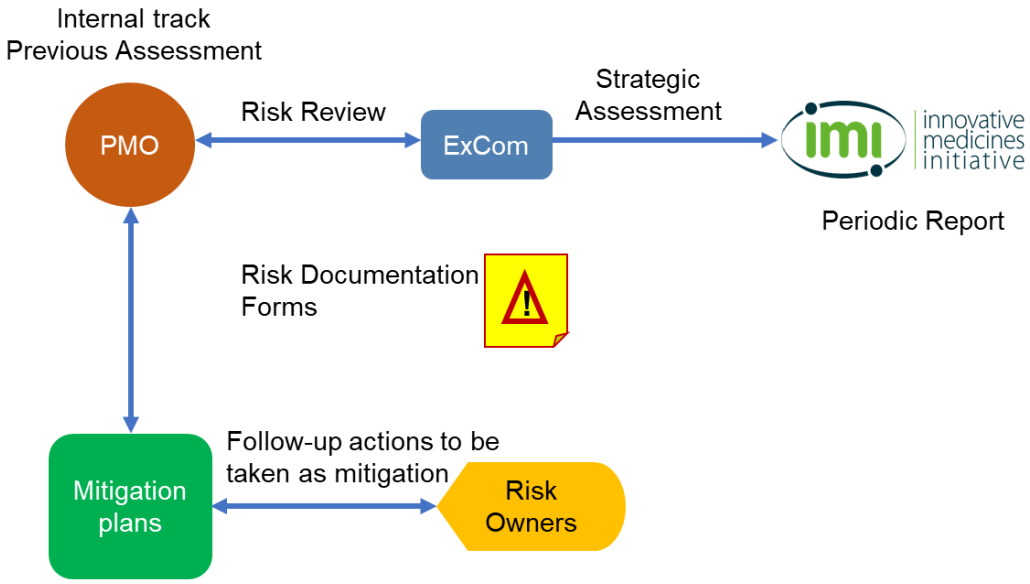

Figure 10. Risk monitoring workflow

8. Internal communication

The activities related to external communication are included in Task 6.1 – *Communication, Dissemination, and Exploitation*, while activities related to internal communication are covered by Task 1.1 – *Consortium and Administrative Management*. This section will briefly cover internal communication.

8.1 Teamwork platform

A Microsoft **Teams folder** has been created for FACILITATE to be used as a repository of relevant information and files, which enables the exchange of documents within the Consortium (i.e., meeting minutes, documents in progress, deliverables, final versions, and other relevant reports or announcements). The Teams platform also provides the possibility to publish meetings and events, work simultaneously in documents and upload files at Project and WP-level.
All partners, Third Linked Parties, Affiliated Partners, and members of the FACILITATE are granted access to Teams from UNIMORE (by using their own Microsoft account). To add any additional responsible person, UNIMORE should be contacted.

The Teams folder includes different channels: general space, administration, General Assembly, Steering Committee, Executive Committee, WPs spaces.
The three Expert Decision Committees, as well as the Scientific Advisory Board, have a separate space in Teams, with access limited to the members.

8.2 Contact lists & Emails

To ensure that communication within the project complies with the principles listed above, the Consortium will adopt the following approach in that respect:

1. Use of **electronic mail** as the main tool for communication within the Consortium.
2. Minor doubts can be solved quickly by using Microsoft Teams as a chat tool, in the respective channel.
3. Documentation of discussions, agreements, and decisions made by TC meetings is encouraged. Specifically, TCs should always have an **agenda and minutes**, for which a template is available in Teams. Responsible persons for each WP have been identified and will take charge of ensuring documentation of activities such as meetings to streamline the process.

8.2.1 Email addresses

The following Email addresses have been activated as main contacts for internal/external communication. The table below shows the Email addresses created at the time of publishing this Handbook.

The list will be amended and extended throughout this project:

Email address	Responsible	Scope
coordinator@facilitate-project.eu	UNIMORE	Sending/receiving requests to/from the Project Coordinator
pmo@facilitate-project.eu	UNIMORE	Sending/receiving requests to/from the Project Management Office (i.e., Administrative or financial issues, meetings)
stakeholder@facilitate-project.eu	ACN	Sending/receiving requests to/from stakeholders involved in the project

Table 8. FACILITATE email addresses

8.2.2 Distribution lists

Several **distribution lists** have been initially created which can be used by any participant depending on the subject of the message. Additional lists may be created as the project evolves, if necessary. UNIMORE, together with ZENTRIX, will be responsible for updating the above-mentioned lists with the information received from Participants. When a list is used, care should be taken by Participants to use the “reply to all” feature only when relevant. The table below shows the distribution lists created at the time of publishing this Handbook. WP Leads will notify PMO to update the lists if they change anything in the excel list.

The list will be amended and extended throughout the course of this project:

Distribution List	Description
consortium@facilitate-project.eu	All Consortium
ga@facilitate-project.eu	General Assembly
excom@facilitate-project.eu	Executive Committee
sc@facilitate-project.eu	Steering Committee
wp1@facilitate-project.eu	Work Package 1
wp2@facilitate-project.eu	Work Package 2
wp3@facilitate-project.eu	Work Package 3

wp4@facilitate-project.eu	Work Package 4
wp5@facilitate-project.eu	Work Package 5
wp6@facilitate-project.eu	Work Package 6
wp7@facilitate-project.eu	Work Package 7
admin@facilitate-project.eu	Project partners administrative contacts
edca@facilitate-project.eu	Technical and Medical Expert Decision Committee
edcb@facilitate-project.eu	Ethical and Legal Expert Decision Committee
edcc@facilitate-project.eu	Patients and Regulators Expert Decision Committee
sab@facilitate-project.eu	Scientific Advisory Board
commWG@@facilitate-project.eu	Working Group for communication and dissemination

Table 9. FACILITATE mailing lists

8.2.3 Contact list

To enable communication a **contact list** has been created in Excel and is uploaded to Teams >> General channel where it will be constantly updated. The participants' contact information with clear information of who is included in every mailing list, will be based on the periodic updates by each of the WP Leaders.

A good practice when using email is essential. We strongly recommend you adhere to the 'FACILITATE E-Mail Principles' guidelines as described in Annex V. Participants must respond promptly to any email received. When that is not possible, at least acknowledgment of receipt of all messages is strongly recommended, especially when answering an explicit request. Carefully consider whether "reply to all" is required.

All emails sent to any of the mailing lists created so far should be labelled by default with "FACILITATE" in the subject section and senders should add the subject of the message. When individual messages between participants are exchanged, the use of the same tag is strongly encouraged (e.g., FACILITATE SC meeting agenda).

Messages need to be clear, especially when requests are made. Deadlines must be made explicit, if these are missing, please ask the sender to clarify. No relevant issues for the work to be performed should remain unclear.

Security of intra-Consortium emails and Teams may be reinforced by appropriate means as the project unfolds to ensure confidentiality and integrity of information exchanged, especially if specific, potentially sensitive data is to be exchanged.

The use of *de facto* standards based on MS Office-compatible files for electronic document exchange among participants is required when possible. PDF format can alternatively be used to avoid the excessive size of files when no editing is required. For technical documents (including programming codes or methodical papers on statistics) plain text files or PDFs can be used, where necessary.

8.3 IMI2 JU online tools

In addition to the conventional communication channels already in place, IMI2 JU uses a Participant Portal/Funding Portal of the EC. This is an online tool functioning as the main channel of interaction between IMI projects' Participants and the IMI2 JU, covering the stages of the project life cycle from proposal submission to project completion.

9. Intellectual Property Rights

According to the Consortium Agreement, participants agree to respect their **Individual Intellectual Property Rights** and intend to cooperate with respect to the management of all matters relating to the protection and exploitation of all knowledge arising from the project and of the Intellectual Property Rights pertaining to such knowledge, embracing the view to promote innovation.

9.1 Who owns the Project Results?

A project result (referred to as "Result" in the Grant Agreement and the Consortium Agreement) is the property of the Participant that carries out the work that generates that Result. Participants remain free to transfer their ownership rights in Results.

9.2 What happens in the case of joint ownership?

When several Participants have generated a **Result** and where it is not possible to distinguish their respective shares therein, the Participants (Co-Owners) will jointly own this **Result**.

In the case of joint ownership of Results, each Co-Owner will conclude in writing a joint ownership agreement defining their respective rights and obligations with respect to the Results. Unless otherwise agreed in the joint ownership agreement, each Co-Owner is granted a non-exclusive, worldwide, fully paid up, royalty-free, perpetual, irrevocable license to use the jointly owned Results for Research Use, including the right to grant non-exclusive sub-licenses to its Affiliated Entities and Third Parties without the need to inform the other Co-Owners. Each Co-Owner and its Affiliated Entities will have a license to use for Direct Exploitation of the jointly owned Results, including the right to grant non-exclusive licenses subject to the following conditions:

(a) prior notice of at least forty-five (45) Days must be given to any other Co-Owner(s); and,

(b) fair and reasonable compensation must be provided to the other Co-Owners, to be decided on a case-by-case basis

9.3 How should Project Results be protected?

Each Participant will examine the possibility of protecting its Results, and, where appropriate, adequately protect them by any means for an appropriate period and within appropriate territorial coverage if:

a) the **results** can reasonably be expected to be commercially or industrially exploited, and,
b) protecting the r**esults** is possible, reasonable, and justified (given the circumstances).

When deciding on the protection of such Results, the Participant must consider its own legitimate interests, in particular the commercial interests, and the legitimate interests, in particular the commercial interests, of the other Beneficiaries. Means of protection may therefore include but are not limited to, patenting or maintaining the Results as confidential know-how.

In connection with the statements above, if the Results - which can be industrially or commercially applied- have not been protected, no dissemination activities may be carried out either by the owner or by other participants (otherwise access to IP rights protection may be seriously jeopardised).

9.4 What are the access rights?

Access rights are the licenses or authorisation rights that allow using the information owned by a participant of a project.

Participants in a project generally arrive at the project with their own knowledge, data, know-how, etc. (the so-called “Background” in the Grant Agreement and the Consortium Agreement). Some elements of this Background may have to be shared with other participants to carry out the project. Reciprocally, participants are in contact with information held by other participants. In addition, the project itself will generate new results which, in some cases, might be exploitable only with the Background of certain participants or with the foreground that will be the property of certain participants.

For detailed information on Access Rights, please refer to section 8 of the Consortium Agreement.

Annexes

ANNEX I. WP# Management template

WP# [To complete for each task in the work package]

Task #.# – [TITLE]

WP schedule	Start month		End month	
Milestone				
Deliverable				
Lead and associated partners	Task leader			
	Partners			
Requires inputs from: *(List WP no. and task no.)*				
Provides inputs to: *(List WP no. and task no.)*				
Task objectives (what we need to do)				
Workplan: Tasks, Timeline & Deadlines				
Partner Tasks Partner Specific Tasks				

ANNEX II. How to review a deliverable

Dear reviewer,

First of all, we would like to thank you for accepting to review the deliverable. It is a key milestone in the creation of great quality output for our project. We have created the following template to support your review, to keep track of them, and to get them structured across the project and reviewers. Overall, this is to make your life, the life of the authors, the life of the project coordinator, and managers easier.

According to the project handbook, your review should be based on the following criteria:

- Completeness (missing content or redundancy, …)
- Accuracy (error in content, Insufficient references/objective supporting data or ambiguity, …)
- Relevance
- Depth (lacking details, too many details, …)

The authors of the deliverable need you to be as precise as possible, indicating the page number and paragraph for instance relevant to your comment.

In short, the process is as follow:

- The authors produce the first draft. This is the document you agreed to review. The project coordinator also reviews it
- The reviewers and the project coordinator review the draft and store on SharePoint the draft with track changes and the template to review on p2
- The project manager creates a single document combining all the comments
- The authors produce a 2nd draft with the comments received. It is up to the authors to decide to take, or not, the comments from the reviewers but needs to document the rationale.
- The project coordinator checks that no major comments were not taken on board or at least justified
- The project manager checks for administrative details and consistency
- The project coordinator submits the final version for approval to the Steering Committee
- The Steering Committee approves the deliverable (if not, then the authors have to modify the draft)
- The project manager submits the final version to the IMI Participant Portal.

There is also an opportunity for you to (not only) use the track change mode in word as you may spot minor mistakes (grammar, spelling, etc…) or you would suggest new content. This would be appreciated.

Voilà, this is it. Now, it is up to you to review the draft of the deliverable.

With our best regards

YOUR COMMENTS

Review report of Deliverable

1. COMPLETENESS (MISSING CONTENT OR REDUNDANCY, …)

Authors' rationale for not taking certain comments onboard

2. ACCURACY (ERROR IN CONTENT, INSUFFICIENT REFERENCES/OBJECTIVE SUPPORTING DATA OR AMBIGUITY, …)

Authors' rationale for not taking certain comments onboard

3. RELEVANCE

Authors' rationale for not taking certain comments onboard

4. DEPTH (LACKING DETAILS, TOO MANY DETAILS, …)

Authors' rationale for not taking certain comments onboard

ANNEX III. Time sheet templates

FACILITATE

IMPORTANT NOTE : This timesheet shall not only record the time spent on a specific project, but shall reconcile the total working time of one person

Name of staff member	
Name of Beneficiary/ Partner 1	
Name of Beneficiary/ Partner 2	
Total of working hours *	36/week
Calendar Year	2022
Calendar Month	January

* indicate number of working hours per day, week or month

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	TOTAL
Calendar Day	Sa	So	Mo	Tu	We	Th	Fr	Sa	So	Mo	Tu	We	Th	Fr	Sa	So	Mo	Tu	We	Th	Fr	Sa	So	Mo	Tu	We	Th	Fr	Sa	So	Mo	
FACILITATE WP1	WE	WE						WE	WE						WE	WE						WE	WE						WE	WE		0,0
FACILITATE WP2	WE	WE						WE	WE						WE	WE						WE	WE						WE	WE		0,0
FACILITATE WP3	WE	WE						WE	WE						WE	WE						WE	WE						WE	WE		0,0
FACILITATE WP4	WE	WE						WE	WE						WE	WE						WE	WE						WE	WE		0,0
FACILITATE WP5	WE	WE						WE	WE						WE	WE						WE	WE						WE	WE		0,0
FACILITATE WP6	WE	WE						WE	WE						WE	WE						WE	WE						WE	WE		0,0
FACILITATE WP7	WE	WE						WE	WE						WE	WE						WE	WE						WE	WE		0,0
...																																0,0
Total worked hours	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

Absences	
Weekend	WE
Sick leave	SL
National holidays	NH
Personal holidays	PH
Other absence	OA

Date and signature of staff member **Date and signature of person in charge of the work**

The time sheet templates are available on TEAMS Documents >> General >> Tools >> Time sheets.

ANNEX IV. List of deliverables, WPs, and tasks

Deliverables

Del No	Deliverable name	Short name	Diss level	Delivery date (in months)
D1.1	Consortium handbook	UNIMORE	PU	3
D1.2	Expert Decision Committees establishment and management rules	UNIMORE	PU	6
D1.7	Data management plan	UNIMORE	CO	6
D2.1	Initial Report on Legal Requirements	UNIMORE	CO	6
D6.1	Communication, dissemination, and exploitation plan	UNIMORE	PU	6
D6.2	FACILITATE Website	ZEN	PU	6
D6.3	Stakeholder involvement plan	ACN	CO	6
D8.1	H-Requirement No. 1	UNIMORE	CO	6
D8.2	POPD - Requirement No. 2	UNIMORE	CO	6
D8.3	NEC - Requirement No. 3	UNIMORE	CO	6
D1.3	ExCom meeting minutes, risk management, ethical requirements, and KPI follow up No.1	UNIMORE	CO	12
D1.8	Scientific Advisory Board establishment and management rules	UNIMORE	PU	12
D2.2	EDC(B) meeting to discuss and align with DP authorities	UNIMORE	CO	12
D3.1	Ethical framework	EURAC	PU	12
D3.5	Report on case studies for the technical development of FACILITATE	UNIMORE	CO	12
D6.4	Report of the stakeholders' involvement plan results No. 1	ACN	PU	12
D3.3	Ethical standards and guidelines No. 1	EURAC	PU	18
D4.1	Platform specification and requirements	ZEN	CO	18
D1.4	ExCom meeting minutes, risk management, ethical requirements, and KPI follow up No. 2	UNIMORE	CO	24
D1.9	Data management plan update	UNIMORE	CO	24
D2.5	Initial report on necessary IMI DO-IT ICF template language updates	VUB	CO	24
D3.2	Final set of guidelines	EURAC	PU	24
D4.3	FACILITATE API Specification No. 1	ZEN	CO	24
D5.1	Assessment and specification of interoperability solutions	BPE	CO	24
D5.3	FACILITATE platform components, interoperability tools, and data-sharing mechanisms No. 1	ODY	CO	24
D6.5	Report of the stakeholders' involvement plan results No. 2	ACN	PU	24

D2.4	Report on language to be inserted in privacy notices and informed consent form	UNIMORE	CO	24
D4.2	FACILITATE Architecture design No. 1	ODY	CO	24
D7.1	Report on stakeholders' needs and potential barriers	PFZ	PU	28
D2.3	Outcome of consultations with patients and local DP authorities	UNIMORE	CO	32
D2.6	Legal clauses	UNIMORE	PU	32
D3.4	Ethical standards and guidelines No. 2	EURAC	PU	32
D7.2	FACILITATE business use case analysis report	PFZ	CO	32
D1.5	ExCom meeting minutes, risk management, ethical requirements, and KPI follow up No. 3	UNIMORE	CO	36
D2.7	EDC(B) workshop to discuss and align with DP authorities	EURAC	PU	36
D4.4	FACILITATE API Specification No. 2	ZEN	CO	36
D5.2	Federated privacy and security components and mechanisms	TUNI	CO	36
D5.4	FACILITATE platform components, interoperability tools, and data-sharing mechanisms No. 2	ODY	CO	36
D5.5	FACILITATE End-user tools	ZEN	CO	36
D6.6	Report of the stakeholders' involvement plan results No. 3	ACN	PU	36
D2.8	Outcome of consultations with local DP authorities	UNIMORE	PU	38
D2.9	Final legal report	UNIMORE	PU	40
D3.6	Workable prototype process	UNIMORE	CO	42
D4.3	FACILITATE Architecture design No. 2	ODY	CO	42
D4.5	FACILITATE API Specification No. 3	ZEN	CO	42
D5.6	PoC Evaluation report	ODY	CO	42
D6.8	Manifesto and project results presentation workshop	ACN	PU	46
D1.6	ExCom meeting minutes, risk management, ethical requirements, and KPI follow up No. 4	UNIMORE	CO	48
D1.10	Final Data Management Plan	UNIMORE	CO	48
D2.10	Guidance document for clinical studies	VUB	PU	48
D3.7	Reutilization of data for returning and secondary use strategy	UNIMORE	PU	48
D6.7	Lay person summary/guideline	ACN	CO	48
D6.9	Training guidelines	EUPATI	PU	48
D6.10	Participation in the Open Research Data Pilot	UNIMORE	PU	48
D7.3	Final business sustainability and implementation strategy report	PFZ	CO	48
D7.4	Translation strategy in the healthcare system	PFZ	CO	48

Workpackages and Tasks

WP no	WP title	Short name	Start	End
1	Project Management and Administration	UNIMORE	1	48
2	Legal and Data Privacy framework	VUB	1	48
3	Ethics, standardization and regulatory framework	UNIMORE	1	48
4	Platform architecture design and requirements	ZEN	12	42
5	Technology framework and interoperability solutions	ODY	12	42
6	Communication and dissemination	CAN	1	48
7	Business exploitation and sustainability	PN	18	48
8	Ethics requirements	UNIMORE	1	48

Task no	Task title	Short name	Start	End
1.1	Consortium and Administrative Management	UNIMORE	1	48
1.2	Establishment and Management of Expert Decision Committees	UNIMORE	1	48
1.3	Project planning, Risk Management, Ethics requirements monitoring, and KPI tracking	UNIMORE	1	48
1.4	Data Management Plan	UNIMORE	1	48
1.5	Scientific Advisory Board	UNIMORE	1	48
1.6	Periodic technical and financial reporting	UNIMORE	1	48
2.1	Legal compliance	UNIMORE	1	48
2.2	Develop legal texts (for privacy notices, informed consent forms, contracts)	UNIMORE	1	48
2.3	Develop standards for the development of a study participants portal for managing Future Research with their data and exercising their rights	EURAC	1	48
2.4	Development of guidance documents for clinical studies	VUB	24	42
3.1	Developing the ethical framework	EURAC	1	48
3.2	Co-creation process and stakeholders' interests	EURAC	1	42
3.3	Clinical trials data use case specification and stakeholders' requirements	UNIMORE	1	12
3.4	FACILITATE Process Validation	UNIMORE	36	42
3.5	Seek approval of standards by regulators both in Europe and beyond	UNIMORE	36	48
4.1	FACILITATE PoC requirements	ZEN	12	18
4.2	Platform architecture design	ODY	12	36
4.3	API specification	ZEN	12	42
5.1	Assessment and alignment of interoperability solutions	ODY	12	24
5.2	Federated Access, Authorization, and Privacy-preserving Data Sharing Mechanisms	TUNI	12	36
5.3	Deployment and extension of the network collaboration platform	ODY	12	36
5.4	User UI and End-user Tools development	ZEN	18	36
5.5	Deployment of the PoC solutions and validation of the prototype process	ODY	24	42
6.1	Communication, Dissemination, and Exploitation	UNIMORE	1	48
6.2	Stakeholder involvement	ACN	1	48
6.3	Developing training documentation and recommendations	ACN	42	48
7.1	FACILITATE business plan/use case strategy options	PN	18	48
7.2	FACILITATE business sustainability and implementation strategy	PN	18	48
7.3	Translation strategy of FACILITATE into the healthcare ecosystem	UNIMORE	42	48

ANNEX V. Financial Statement template

This form is included in the Grant Agreement, annex. 4

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/ LINKED THIRD PARTY [name]]* FOR REPORTING PERIOD [reporting period]

	Eligible[1] costs (per budget category)													Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	[C. Direct costs of fin. support]	D. Other direct costs			E. Indirect costs[2]	[F. Costs of ...]		Total costs	Receipts	Reimbursement rate %	Maximum EU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary			*[C.1 Financial support]* *[C.2 Prizes]*	D.1 Travel D.2 Equipment D.3 Other goods and services	*[D.4 Costs of large research infrastructure]*	D.5 Costs of internally invoiced goods and services		*[F.1 Costs of ...]*	*[F.2 Costs of ...]*		Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit		Actual	Actual	Actual	Actual	Unit	Flat-rate[5] 25%	Unit		[Unit][Lump sum]					
	a	Total b	No hours	Total c	d	*[e]*	f	*[g]*	Total h	i=0,25 x (a+b+c+f+*[g]* + h+ *[i.1]*[6]+*[i2]*[6]-*p*)	No units	Total *[i1]*	Total *[i2]*	k = a+b+c+d+*[e]*+f+ *[g]*+h+i+ *[i1]*+*[i2]*	l	m	n	o	p
[short name beneficiary/linked third party]																		

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim indirect costs unless you can demonstrate that the operating grant does not cover any costs of the action.

[3] This is the *theoretical* amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may be less.

[4] See Article 5 for the forms of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E)

[6] Only specific unit costs that do not include indirect costs

ANNEX VI. Risk identification form

Risk ID ([3]) **Resolved** ☐ **Active** *(4 and above)* ☐ **Inactive** *(below 4)* ☐

RISK TITLE			
TYPE OF RISK	Threat ☒	Opportunity ☐	
CLASSIFICATION: Select an option.			
WORK PACKAGE/ACTIVITY:			
DETECTION DATE		RISK REPORTER	
RISK OWNER[4]			
LAST UPDATE		VERSION	

Description
(Summarize the risk, indicating causes and consequences. Where possible identify the stakeholders that may be impacted). Indicate whether other Work Packages may be affected.)

Proximity in time: Select an option.
Impact on the project: Select an option. (a)
Probability of happening: Select an option. (b)
Exposure[5]: Select an option. (a)*(b)

Mitigation & Avoidance Approaches[5]
(Actions to be carried out before the risk happens to affect impact, probability or proximity) (Actions to be carried out after a risk has happened)

Triggering Events
(Conditions that indicate that the risk is becoming an issue and trigger onset of a contingency plan)

Contingency Plans[6]
(Actions to carry out if the risk actually happens)

Notes

[3] Risk ID codes are completed by the PMO.
[4] The Risk Owner is the partner in the best position to recommend mitigation strategies, develop contingency plans and monitor the status of the risk.
[5] All threat risks with medium or high probability or impact should have a mitigation strategy.
[6] All risks having an exposure equal or greater than 4 should have a contingency plan in advance.

ANNEX VII. Email principles

Short and Simple

- Keep emails as concise as possible. Details are better saved for a conversation. And don't be offended by a short response as it's a sign of efficiency.
- Help colleagues prioritize and add the following at the beginning of the subject line:
- Avoid sending attachments. Whenever possible, use links to documents on FACILITATE Teams.

INFORM: Provides information and no action is necessary

ACTION: Requires action by the "To" recipient(s) by a deadline provided.

APPROVAL: Requests approval by the "To" recipient(s) by a deadline provided.

REQUEST: Requests something from the recipient(s) by a deadline provided.

URGENT: Requires immediate attention. Should be used very sparingly.

- If you have a brief question, type it in the subject line, end it with "EOM" (End of Message), and hit send. This saves the recipient from having to open the email. You can also use Microsoft Teams to solve minor doubts.
- To get information quickly and avoid needless emails, consider alternatives. Pick up the phone / walk down the hall or use an alternative tool (e.g., Office Communicator if available) rather than email.

Save Time, Yours and Mine

- State the specific reason for the email in the first sentence.
- Avoid asking open-ended questions requiring a lengthy response. Make it simple for the recipient to respond. E.g., "Would you like me to a) call you, b) set up a one-on-one, or c) stay out of it?"
- Remove unnecessary threads. Rarely should an email include more than three threads of content for context.
- Share documents by using a link to the Teams.
- Think twice before attaching a file the recipient must open. If you're sharing a slide or two as an FYI, think about simply copying and embedding them in the email.

Reduce Your Readership

- Reconsider your use of the “CC” function. Only include colleagues who absolutely need to know about the topic. Every recipient included dramatically multiplies email traffic and total response time.
- Only use “Reply All” when absolutely necessary. “Reply All” should be like Latin – rarely used.
- Consider your audience. In some cases, there’s no need to reply to every email. Every one or two-word response, like “Great,” “You too” or “OK” can cost the recipient up to 30 seconds of time.
- “Thank You” emails should be reserved for acknowledging a job well done. Please keep in mind the above “CC” and “Reply All” guidance.

Disconnect From the Distraction

- Make a commitment to spend less time on email. If we all reduce the churn, we’ll all benefit.
- Consider blocking “offline” time at work to get things done.
- It’s OK to disconnect. Unless it’s critical, leave emails for when you’re at work. Enjoy your weekends and if you’re on vacation, be on vacation.

ANNEX VIII. Reimbursement of travel costs policy

Members of the Expert Decision-Making Committees (EDCs) and the Scientific Advisory Board (SAB), and invited speakers may be reimbursed by the project coordinator for the following expenses: travel, subsistence, and accommodation expenses. The Italian law and the internal UNIMORE rules must be taken into account.

Travel and accommodation expenses may be reimbursed by UNIMORE upon invitation and formal approval before the meeting. The approval must contain the following data:

- First and last name of the invited person
- qualification
- Workplace
- Place of assembly
- Date of the meeting
- Purpose of the mission
- Mode of transport

UNIMORE reimburses travel expenses:
Economy class air/train/bus/coach/boat/taxi tickets - use of car must be authorized –

and accommodation (best value for money and as per other IMI Rules/EU Commission remuneration rules). Travel and accommodation expenses and their documentation must comply with the travel guidelines of the H2020, IMI2, and UNIMORE rules:

- Original receipts are required for all expenses claimed
- Boarding passes in case of using flights
- Car rental expenses are eligible upon presentation of the original rental agreement and payment documentation
- Travel duration between 8-12 hours: reimbursement of 1 meal (max. 60 Euro); longer than 12 hours 2 meals (max. 60 Euro each)
- Travel longer than 12 hours: reimbursement of accommodation in a hotel with a maximum of 3 stars.

Complete original travel and accommodation documents must be mailed to the PMO, who will prepare the claim for reimbursement, which must then be signed by the invitee. The PMO will take care of the further reimbursement process and will inform the invited person as soon as this is complete.

ANNEX IX. FACILITATE Glossary

This glossary is aimed to align the knowledge of the whole team.

TERM		DEFINITION
Adverse event	EMA	Any unexpected medical occurrence in a subject to whom a medicinal product is administered and that does not necessarily have a causal relationship with this treatment.
Assent	FDA	A child's affirmative agreement to participate in a clinical investigation. Assent must be sought in addition to the consent of a legally authorized representative or surrogate when the individual is sufficiently cognitively capable of understanding the nature of his/her participation in a research study.
Attrition	FDA	A reduction in the number of participants in a clinical trial over the course of the trial.
Biomarker	EMA	A biological molecule found in blood, other body fluids, or tissues that can be used to follow body processes and diseases in humans and animals.
Blinding/ Masking	FDA	One or more parties of the clinical trial are kept unaware of the treatment assignment. Patients, investigators, and health care providers may all be blinded to the treatment a patient is receiving.
Care Partner	FDA	A person helping to care for a loved one who is unable to manage day-to-day life alone due to an illness. This role includes helping with daily needs, managing the household, and supervising health care.
Centralized procedure	EMA	The European Union-wide procedure for the authorization of medicines, where there is a single application, a single evaluation and a single authorization throughout the European Union. Only certain medicines are eligible for the centralized procedure.
Clinical Benefit	FDA	A therapeutic intervention may be said to confer clinical benefit if it prolongs life, improves function, and/or improves the way a patient feels.
Clinical Significance	FDA	Change in a subject's clinical condition regarded as important whether or not due to the test intervention.
Clinical study	EMA	Under the EU Clinical Trials Regulation, any investigation in relation to humans intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of medicinal products; to identify any adverse reactions to medicinal products; or to study their absorption, distribution, metabolism and excretion, with the objective of ascertaining the safety and/or efficacy of those medicinal products.
Clinical study report	EMA	Report on the clinical trial presented in an easily searchable format, prepared in accordance with Directive 2001/83/EC (Annex I, Part I, Module 5). The report shall accompany an application for marketing authorisation.
Clinical trial	EMA	Under the EU Clinical Trials Regulation, a clinical study which fulfils any of the following conditions: (a) the assignment of the subject to a particular therapeutic strategy is

		decided in advance and does not fall within normal clinical practice of the Member State concerned; (b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or (c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.
Clinical Trial Clinical Investigation Clinical Study	FDA	An investigation or research that involves one or more human subjects, undertaken to assess/evaluate the safety or effectiveness of a medical device.
Compliance in relation to clinical trials	FDA	Adherence to all the trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements.
Confidentiality	FDA	Prevention of disclosure to others than authorized individuals of a sponsor's proprietary information or of a subject's identity.
Informed Consent Form	FDA	Informed consent is a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.
	EMA	A subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate. In case of minors and of incapacitated subjects, the authorisation or agreement to include them in the clinical trial is given by their legally designated representative. Informed consent in the fields of medicine and biology is a fundamental right under the Charter of Fundamental Rights of The European Union (art. 3).
Data exclusivity	EMA	The period of eight years from the initial authorisation of a medicine during which the marketing-authorisation holder benefits from the exclusive rights to the results of preclinical tests and clinical trials on the medicine. After this period, the marketing authorisation holder is obliged to release this information to companies wishing to develop generic versions of the medicine.
End of a clinical trial	EMA	Last visit of the last subject. It might be defined at a later point in time by the protocol.
Endpoint	FDA	Principal indicator(s) used for assessing the primary question (i.e., hypothesis) of a clinical trial. A variable that pertains to the efficacy or safety evaluations of a trial. An endpoint is more specific as compared to an outcome since it relates to the planned objective of the study.
Enrolment	FDA	The process of registering or entering a patient into a clinical trial. Once a patient has been enrolled, the participant would then follow the clinical trial protocol. Clinical investigations are designed to enrol a set number of participants to increase the likelihood of answering the trial questions.

Ethics Committee	EMA	An independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations
EudraCT	EMA	A database that includes information on clinical trials taking place in the European Union and clinical studies conducted worldwide in accordance with a paediatric investigation plan. A subset of the data is publicly accessible via the European Clinical Trials Register. Each study related to the development of new drugs has a EudraCT code.
Good clinical practice	EMA	A code of international standards concerning the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials. Good clinical practice provides assurance that a study's results are credible and accurate and that the rights and confidentiality of the study subjects are protected.
Good laboratory practice	EMA	A code of standards concerning the testing of medicines in laboratories during their development.
Health Care Provider (HCP)	FDA	One who directly or indirectly administers interventions that are designed to improve the physical or emotional status of patients. A person otherwise authorized or permitted by law to administer healthcare in the ordinary course of business or practice of a profession, including a healthcare facility.
Hypothesis	FDA	A testable statement regarding the investigational medical device safety or performance (effectiveness) that is used to design the clinical trial and that can be accepted or rejected based on the results of the clinical trial and statistical calculations.
Inclusion/Exclusion Criteria	FDA	The medical or other guidelines that determines whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. The criteria are not used to reject people personally, but to identify appropriate participants for the trial and keep them safe. Also known as Eligibility or Enrolment Criteria
Institutional Review Board (IRB)	FDA	Any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. Also known as Ethics Committee (EC).
Indication for Use (IFU)	FDA	A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.
Intervention	FDA	The diagnostic or therapeutic device, biologic, and/or drug under investigation in a clinical trial that is believed to have an effect on outcomes of interest in a study.
Investigator	FDA EMA	A person responsible for the conduct of the clinical trial at the trial site. An investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site is the principal investigator (PI).

Labelling	FDA	All text, tables, and figures in labelling as described in regulations for a specific product.
Lost to Follow Up	FDA	The act of concluding participation, prior to completion of all protocol-required elements, in a trial by an enrolled subject.
Low-intervention clinical trial	EMA	Under the EU Clinical Trials Regulation, a clinical trial in which the investigational medicinal products, excluding placebos, are authorised; either the investigational medicinal products are used in accordance with the terms of the marketing authorisation or the use of the investigational medicinal products is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products. Furthermore the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects. Those clinical trials are subject to less stringent rules as regards monitoring, requirements for the contents of the master file and traceability of investigational medicinal products
Medical Device Report (MDR)	FDA /EMA	A report submitted to the FDA / competent authority by a manufacturer, a physician, or a patient about a marketed device that may have caused or contributed to a death or serious injury. In the USA, the report can be submitted at the following link: https://www.fda.gov/medicaldevices/safety/reportaproblem/default.htm In the EU, every Member State has its own authority competent (https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_contact_points_of_national_authorities.pdf).
Medical Device	FDA	An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory, which is – (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term ‘device’ does not include software functions excluded pursuant to section 520(o).

	EMA	Under Regulation 2017/745, any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: (1) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease; (2)diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability; (3) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; (4) providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations; (5) and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Devices for the control or support of conception, and products specifically intended for the cleaning, disinfection or sterilisation of devices are also deemed to be medical devices.
Multicentre Trial	FDA	A clinical trial conducted according to a single protocol but at more than one site, and, therefore, carried out by more than one investigator.
Non-interventional study	EMA	A clinical study that is not considered a clinical trial as per the EU Clinical Trials Regulation. These include observational studies.
Outcome	FDA	Events or experiences that clinicians or investigators examining the impact of an intervention or exposure measure because they believe such events or experiences may be influenced by the research intervention or exposure. Outcome is more general than endpoint in that it does not necessarily relate to a planned objective of the study.
Patient	FDA	Person under a physician's care for a particular disease or condition. When talking about engagement, patient refers inclusively to people who receive health care services; family members, friends, and other care partners; and any consumers of health care.
Patient Engagement	FDA	Involves meaningful involvement of patients throughout the clinical trial cycle from the initial design to the implementation of the trial and the dissemination of the study results. The goal is to have clinical trials more patient-centric and relevant to patient values leading to improved clinical trials and a greater intake by patients and providers when making treatment decisions.
Patient Preference	FDA	Patient perspectives include information relating to patients' experiences with a disease or condition and its management. This may be useful for better understanding the disease or condition and its impact on patients, identifying outcomes most important to patients, and understanding benefit-risk tradeoffs for treatment. Patient preference information is a specific type of patient perspective. It is the assessment of the desirability or acceptability to patients of specified choices among clinical outcomes or some other attribute that differs between potential medical interventions. https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM4466 80.pdf
Patient-Reported Outcome	FDA	An outcome based on a report that comes directly from the patient about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. Symptoms or other

		unobservable concepts known only to the patient can only be measured by PRO measures. PROs can also assess the patient perspective on functioning or activities that may also be observable by others. https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM446 680.pdf
	EMA	Any outcome directly evaluated by the patient and based on the patient's perception of a disease and its treatment(s).
Paediatric	FDA	CDRH defines paediatric patients as individuals who are younger than 18 years.
	EEA	Paediatric population means that part of the population aged between birth and 18 years.
Phase-I study	EMA	A type of clinical study where a new medicine is given to humans for the first time, usually in healthy volunteers. It looks at the way the medicine is dealt with by the body, its main effects and main side effects.
Phase-II study	EMA	A type of clinical study conducted after phase I studies to evaluate a medicine's effects in a particular condition and to determine its common short-term side effects.
Phase-III study	EMA	A type of clinical study usually conducted in a large group of patients to gather information about a medicine's efficacy and safety, to allow its benefits and risks to be evaluated.
Phase-IV study	EMA	A type of clinical study that takes place after the authorisation of a medicine.
Protocol	FDA	A document that describes the objectives(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. A protocol amendment is a written description of a change(s) to or a formal change of a protocol.
	EMA	A document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial
Randomization	FDA	The process of assigning trial subjects to investigational treatment or control groups (may use a comparator) using an element of chance to determine the assignments in order to reduce bias.
Randomized Controlled Trial	FDA	A study in which randomization is used to assign patients to treatments. The purpose of the randomized controlled trial is to: (1) to guard against any use of judgment or systematic arrangements leading to one treatment getting preferential assignment; i.e., to avoid bias; (2) to provide a basis for the standard methods of statistical analysis such as significance tests.
Recruitment	FDA	Active efforts by investigators to identify subjects who may be suitable for enrolment into a clinical trial. Subjects are selected on the basis of the protocol's inclusion and exclusion criteria during the clinical trial recruitment period. The number of subjects that must be recruited for enrolment into a study and meet the requirements of the protocol. In multicentre studies, each

		investigator has a recruitment target or defined number of subjects to be enrolled.
Retention	FDA	Activities by the clinical trial team to encourage and support a subject to remain enrolled and participate in the clinical trial.
Safety	FDA	Safety is relative freedom from harm. In clinical trials, this refers to an absence of harmful side effects resulting from use of the product and may be assessed by laboratory testing of biological samples, special tests and procedures, psychiatric evaluation, and/or physical examination of subjects.
Screening (of subjects)	FDA	A process of active evaluation of potential participants for enrolment in a trial. After a patient is recruited, screening occurs during the enrolment period to see if they meet the inclusion and exclusion criteria. If they meet the criteria, the subject is eligible to enrol in the trial.
Sponsor	FDA	An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.
	EMA	An individual, company, institution or organization which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial
Start of clinical trial	EMA	The first act of recruitment of a potential subject for a specific clinical trial, unless defined differently in the protocol.
Statistical Analysis Plan	FDA	A document detailing the methods of all planned analyses of the clinical study data.
Subgroup analysis	EMA	The separate analysis of clinical trial results in subsets of the trial's participants.
Subject/Participant	FDA	An individual who participates in a clinical trial either as a recipient of the investigational product(s) or as a control. The term "subject" is part of the federal regulation and may be used interchangeably with participant.
	EMA	An individual who participates in a clinical trial, either as recipient of an investigational medicinal product or as a control.
Suspension of a clinical trial	EMA	Interruption of the conduct of a clinical trial by a Member State
Temporary halt of a clinical trial	EMA	An interruption not provided in the protocol of the conduct of a clinical trial by the sponsor with the intention of the sponsor to resume it.
Termination	FDA	Discontinuance, by sponsor or by withdrawal of IRB or FDA approval, of a clinical trial before completion. This termination can be at a site or the entire study.
	EMA	Early termination of a clinical trial' means the premature end of a clinical trial due to any reason before the conditions specified in the protocol are complied with

ETHICS DEFINITIONS		
Blanket consent		Consent whereby potential research participants are asked to consent to all possible future research uses of their data or samples.
Broad consent		Consent for an unspecified range of future research subject to a few contents and/or process restrictions.
Dynamic consent		A personalized, digital platform that facilitates two-way communication between researchers and participants. This approach is 'dynamic' because it allows interactions over time; it enables participants to consent to new projects or to alter their consent choices in real time as their circumstances change and to have confidence that these changed choices will take effect. Dynamic Consent is not the same as specific consent. Rather, it can be setup to accommodate different types of consent depending on the research objectives and context.
Tiered consent		Tiered consent allows research participants to choose from a number of options, but does not oblige research participants to consent to any, some, or all categories of research.
Transparency		Under the Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks, any relevant information on Health Databases must be made available to the public. According to the EU Clinical Trials Regulation to increase transparency in the area of clinical trials, data from a clinical trial should only be submitted in support of a clinical trial application if that clinical trial has been recorded in a publicly accessible and free of charge database
Participation and inclusion		According to the Declaration of Taipei, custodians of Health Databases must consult and engage with individuals and their communities.
LEGAL DEFINITIONS		
GDPR (Regulation)	EEA	Regulation (Eu) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC. The GDPR applies to the processing of personal data: In the context of the activities of an establishment of a controller or a processor in the Union, regardless of whether the processing takes place in the Union or not. Of data subjects who are in the Union by a controller or processor not established in the Union, where the processing activities are related to: the offering of goods or services, irrespective of whether a payment of the data subject is required, to such data subjects in the Union; or (b) the monitoring of their behaviour as far as their behaviour takes place within the Union. By a controller not established in the Union, but in a place where Member State law applies by virtue of public international law.
Accountability		As a general principle, custodians of Health Databases must be accessible and responsive to all stakeholders (Declaration of Taipei). Under the GDPR the controller shall be responsible for, and be able to demonstrate compliance

		with the principles relating to processing of personal data (lawfulness, fairness, transparency, purpose limitation, data minimization, accuracy, storage limitation, integrity and confidentiality)
Accuracy		Collected/generate personal data must be accurate and, where necessary, kept up to date.
Data minimization		Personal data shall be adequate, relevant and limited to what is necessary to the purposes for which they are processed.
Integrity and confidentiality		Personal data shall be processed in a manner that ensures appropriate security, including protection against unauthorized or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organizational measures.
Purpose limitation		Data are collected only for specified, explicit and legitimate purposes. Data shall not be further processed in a manner that is incompatible with those purposes.
Secondary use		Secondary use (or re-use) of data concerns the use of personal data for a different purpose than the one for which it was originally collected.
Storage limitation		Personal data shall be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which they have been processed
CTR (Regulation)	EEA	Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC The CTR applies to all clinical trials conducted in the EEA. It does not apply to non-interventional studies.
EEhrxF (Recommendation)	EEA	Commission Recommendation on a European Electronic Health Record exchange format (C(2019)800) of 6 February 2019. This Recommendation sets out a framework for the development of a European electronic health record exchange format in order to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data in the EEA.
Legal requirements		A requirement is a condition that must be fulfilled in order to be allowed to do something or to be suitable for something. Legal requirements are outlined in legally-binding instruments, such as statutes, regulations, and judgments.
Legal clauses		A specific provision in a legal agreement that can be enforced before a court.
Privacy notices	EEA	A public document from the controller that provides the data subject with information on the data processing (e.g., identity of the controller, contact details of the DPO, the purpose of and the legal basis for the processing, the data subject's rights under the GDPR) in a concise, transparent, intelligible and easily accessible form, using clear and plain language, in particular for any information addressed specifically to a child.
Soft law		Provisions that are not legally binding and therefore cannot be enforced before a court. UN General Assembly resolutions, European Commission recommendations are examples of soft law. The European Data Protection

		Board (EDPB) guidelines, recommendations and best practice are further examples: they are aimed at clarifying the law and promoting common understanding of EU data protection regulations.
Hard law	N/A	Legal provisions that are binding on the parties concerned and that can be legally enforced before a court.
Data subject	EEA	An identified or identifiable natural person whose data is being processed
Personal data	EEA	Any information relating to an identified or identifiable natural person ('data subject'). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.
Special categories of data ('sensitive' data)	EEA	Data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation. Processing of this kind of data is prohibited unless one of the following conditions apply: (a) Explicit consent; (b) Employment, social security and social protection law; (c) Vital interests; (d) Not-for-profit bodies; (e) Made public by the data subject; (f) Legal claims and judicial acts; (g) Substantial public interest conditions; (h) Health or social care; (i) Public health; (j) Archiving, research and statistics
Data processing	EEA	Any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means.
Data controller	EEA	The natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data.
Data processor	EEA	A natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller.
Recipient	EEA	A natural or legal person, public authority, agency or another body, to which the personal data are disclosed, whether a third party or not
Third party	EEA	A natural or legal person, public authority, or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorized to process personal data
Consent to personal data processing	EEA	Under the GDPR, any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her. Consent is a legitimate basis for processing personal data under the GDPR and art. 8 of the Charter of Fundamental Rights of The European Union (Protection of personal data).
Personal data breach	EEA	A breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, personal data transmitted, stored or otherwise processed

Cross-border processing	EEA	Either (a) processing of personal data which takes place in the context of the activities of establishments in more than one Member State of a controller or processor in the Union where the controller or processor is established in more than one Member State; or (b) processing of personal data which takes place in the context of the activities of a single establishment of a controller or processor in the Union but which substantially affects or is likely to substantially affect data subjects in more than one Member State.
Pseudonymization	EEA	The processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure that the personal data are not attributed to an identified or identifiable natural person
Profiling		Any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements.
TECHNICAL DEFINITIONS		
Access Control List	NIST	A list of permissions associated with an object. The list specifies who or what is allowed to access the object and what operations are allowed to be performed on the object.
Accession number	IHE	The unique identifier assigned by the LIS of an Anatomic Pathology laboratory to an imaging Study.
Accountability	NIST	A property that ensures that the actions of an entity may be traced uniquely to that entity.
Advanced Patient Privacy Consents	IHE	Advanced Patient Privacy Consents is a content profile that describes the semantics necessary to enable patient consent(s) to be captured, managed, and communicated between systems and organizations. This profile enables the capturing of consent(s) that cannot be adequately expressed using the Basic Patient Privacy Consents Profile.
Application Programming Interface	NIST	A system access point or library function that has a well-defined syntax and is accessible from application programs or user code to provide well-defined functionality.
Audit log	NIST	A chronological record of system activities. Includes records of system accesses and operations performed in a given period.
Attribute-Based Access Control	NIST	An access control approach in which access is mediated based on attributes associated with subjects (requesters) and the objects to be accessed. Each object and subject have a set of associated attributes, such as location, time of creation, access rights, etc. Access to an object is authorized or denied depending upon whether the required (e.g., policy-defined) correlation can be made between the attributes of that object and of the requesting subject.
Authentication/ Identification	NIST	The process of verifying the identity of a user, process, or device, usually as a prerequisite for granting access to resources in an IT system

Authentication Factor	NIST	The three types of authentication factors are something you know, something you have, and something you are. Every authenticator has one or more authentication factors.
Authentication period	NIST	The period between any initial authentication process and subsequent re-authentication processes during a single terminal session or during the period data is being accessed.
Authorization	NIST	The right or a permission that is granted to a system entity to access a system resource.
Authorization Decision	IHE	A security token that describes which documents can be accessed by a specific entity.
Automatic Identification and Data Capture	IHE	A technological solution like barcodes and RFIDs that allow information to be captured and entered into IT systems.
Baseline	NIST	Hardware, software, databases, and relevant documentation for an information system at a given point in time.
Baseline configuration	NIST	A documented set of specifications for an information system, or a configuration item within a system, that has been formally reviewed and agreed on at a given point in time, and which can be changed only through change control procedures.
Basic Patient Policy Profile	IHE	Provides a mechanism to record the patient privacy consent(s) and a method for Content Consumers to use to enforce the privacy consent appropriate to the use. This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g., EHR systems).
Clinical and Laboratory Standards Institute	IHE	CLSI and their volunteer members actively identify and develop new guidance on standards that raise laboratory testing quality, safety, and efficiency.
Clinical Data Acquisition Standards Harmonization	IHE	CDASH establishes a standard way to collect data, in a similar way, across studies and sponsors so that data collection formats and structures provide clear traceability of submission data into the Study Data Tabulation Model (SDTM), delivering more transparency to regulators and others who conduct data review.
Clinical Data Repository	IHE	A real time database that consolidates data from a variety of clinical sources to present a unified view of a single patient that is optimized to allow clinicians to retrieve data for a single patient rather than to identify a population of patients with common characteristics or to facilitate the management of a specific clinical department.
Clinical Decision Support	IHE	A system designed to assist physicians and other health care professionals with clinical decision-making tasks.

Clinical Document Architecture	IHE	An HL7 standard for the exchange for clinical documents that specifies the structure and semantics of clinical documents.
Cloud Service Provider	IHE	A trusted entity that issues or registers subscriber authenticators and issues electronic credentials to subscribers. A CSP may be an independent third party or issue credentials for its own use.
Cryptographic algorithm	NIST	A well-defined computational procedure that takes variable inputs, including a cryptographic key, and produces an output.
Cryptographic key	NIST	A parameter used in conjunction with a cryptographic algorithm that determines its operation in such a way that an entity with knowledge of the key can reproduce or reverse the operation while an entity without knowledge of the key cannot.
Digital signature	IHE	A useful legal equivalent to facsimile signature that may be generated for a variety of entities, including human and machine sources. Based on digital certificates attributable to well-known healthcare-oriented certificate authorities; incorporating cryptographically secure techniques for signature generation and validation.
Digital signature	NIST	The result of a cryptographic transformation of data that, when properly implemented, provides origin authentication, assurance of data integrity, and signatory non-repudiation
Electronic Data Capture	NIST	The process of collecting clinical trial data into a permanent electronic form
Electronic Health Record Exchange Format		European standard format for eHealth data exchange
Electronic Health Record	IHE	An electronic record derived from a computerized system used primarily for delivering patient care in a clinical setting.
Encryption	NIST	Cryptographic transformation of data (called “plaintext”) into a form (called “ciphertext”) that conceals the data’s original meaning to prevent it from being known or used. If the transformation is reversible, the corresponding reversal process is called “decryption,” which is a transformation that restores encrypted data to its original state
Entity	NIST	An individual (person), organization, device, or process
Healthcare domain/ secondary use domain	IHE	The healthcare domain and its central system, the EHR, exist to provide medical care to patients. Data are created by the healthcare domain which are of value to the secondary use domains such as research, public health, and quality reporting. In general, only tightly specified data are permitted to be exported by the healthcare domain to a secondary use domain.
Fast Healthcare Interoperability Resources	IHE	The interoperability standard from HL7 which builds on HL7 version 2, version 3, the RIM and CDA. It can be used in conjunction with existing data exchange standards as well as a standalone standard

Federated Identity Management	NIST	A process that allows for the conveyance of identity and authentication information across a set of networked systems
Federation	NIST	A collection of realms (domains) that have established trust among themselves. The level of trust may vary, but typically includes authentication and may include authorization.
Health Level 7	IHE	Health Level Seven International is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical.
Identity, Credential, and Access Management	NIST	Programs, processes, technologies, and personnel used to create trusted digital identity representations of individuals and non-person entities (NPEs), bind those identities to credentials that may serve as a proxy for the individual or NPE in access transactions, and leverage the credentials to provide authorized access to an agency‘s resources. See also attribute-based access control (ABAC).
Identity Proofing	NIST	The process by which a CSP or Registration Authority (RA) collect, validate and verify information about a person for the purpose of issuing credentials to that person.
Identity Provider	NIST	A trusted entity that issues or registers subscriber authenticators and issues electronic credentials to subscribers. A CSP may be an independent third party or issue credentials for its own use.
Identity Management System	NIST	One or more systems or applications that manage the identity verification, validation, and issuance process.
Integrating the Healthcare Enterprise Profile	IHE	Organize and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards, such as DICOM, HL7 W3C and security standards. They provide precise definitions of how standards can be implemented to meet specific clinical needs.
Interoperability	NIST	The ability of one entity to communicate with another entity
Interoperable	IHE	The ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities.
Multi-Factor Authentication	NIST	An authentication system that requires more than one distinct authentication factor for successful authentication. Multi-factor authentication can be performed using a multi-factor authenticator or by a combination of authenticators that provide different factors. The three authentication factors are something you know, something you have, and something you are.
Observation	IHE	A measurement of a single variable or a single value derived logically and/or algebraically from other measured or derived values. A test result is an observation.
Order	IHE	A battery or test ordered by a ward and/or a physician to a laboratory, to be performed on one or more specimens collected from a patient.

Patient Identifier Domain	IHE	A single system or a set of interconnected systems that all share a common identification scheme for patients. Such a scheme includes: (1) a single identifier-issuing authority, (2) an assignment process of an identifier to a patient, (3) a permanent record of issued patient identifiers with associated traits, and (4) a maintenance process over time. The goal of Patient Identification is to reduce errors.
Patient identity	IHE	All information used for identifying the patient, such name, phone, gender, birth date, address, marital status, photo, others to contact, preference for language, general practitioner, and links to other patient identities.
Patient Privacy Policy	IHE	A Patient Privacy Policy will identify who has access to information, and what information is governed by the policy (e.g., under what conditions will a document be marked as containing that type of information). The policy may also describe the patient's rights to specify their consent preferences, notifications, complaints, or requests as well as the mechanism that allows them to do so.
Patient Privacy Policy Domain	IHE	The domain for which a Patient Privacy Policy applies. When using XDS this would likely be equivalent to the XDS Affinity Domain.
Platform as a Service	NIST	The capability provided to the consumer is to deploy onto the cloud infrastructure consumer-created or acquired applications created using programming languages, libraries, services, and tools supported by the provider. The consumer does not manage or control the underlying cloud infrastructure including network, servers, operating systems, or storage, but has control over the deployed applications and possibly configuration settings for the application-hosting environment.
Pseudonymization	NIST	A particular type of de-identification that both removes the association with a data subject and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms. Typically, pseudonymization is implemented by replacing direct identifiers with a pseudonym, such as a randomly generated value.
Public Key Infrastructure	NIST	A set of policies, processes, server platforms, software and workstations used for the purpose of administering certificates and public-private key pairs, including the ability to issue, maintain, and revoke public key certificates.
Reference architecture	CMU	A reference architecture is the generalized architecture of several end systems that share one or more common domains. The reference architecture defines the infrastructure common to the end systems and the interfaces of components that will be included in the end systems. The reference architecture is then instantiated to create a software architecture of a specific system. The definition of the reference architecture facilitates deriving and extending new software architectures for classes of systems. A reference architecture, therefore, plays a dual role with regard to specific target software architectures. First, it generalizes and extracts common functions and configurations. Second, it provides a base for instantiating target systems that use that common base more reliably and cost effectively.
Scalability	NIST	The ability to support more users, concurrent sessions, and throughput than a single SSL VPN device can typically handle

Unified Code for Units of Measure	IHE	A code system intended to include all units of measures being contemporarily used in international science.
Weak Identity Assertion	IHE	A presumption of patient or device unique recognition using factors that provides a low degree of accuracy and certainty (e.g., name, location).
Weak Identity Factors	IHE	Factors which can contribute to identification, but typically are not unique to patient; for example, name, sex, date of birth.
Cross-Enterprise Document Sharing	IHE	XDS is an interoperability profile that facilitates the registration, distribution and access across health enterprises of patient electronic health records
XDS Affinity Domain	IHE	A group of healthcare enterprises that have agreed to work together using a common set of policies and which share a common infrastructure of repositories and a registry.
XDS Document	IHE	An XDS Document is the smallest unit of information that may be provided to a Document Repository and registered in a Document Registry. An XDS Document may contain simple text, formatted text (e.g., HL7 CDA Release 1), images (e.g., DICOM) or structured and vocabulary coded clinical information (e.g., CDA Release 2, CCR), or may be made up of a mixture of the above types of content.