Gravitate-Health

WP8 – Project management, collaboration agreements, communication & Dissemination

D8.1 Quality Management Plan

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Document History

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V0.2	09/12/2020	Edited
V0.3	15/12/2020	Edited
V0.4	18/12/2020	Edited
V0.5	31/12/2020	Review and feedback
V1.0	15/02/2021	Final approved version

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EXECUTIVE SUMMARY

Gravitate-Health is a digital health information project with a mission to equip and empower citizens as users with digital tools that make them confident, active, and responsive in their patient journey, enhancing access, understanding and adherence and driving improved health outcomes.

This **Quality Management Plan (QMP)** describes the project's organizational structures, governance model, management procedures, internal quality processes and collaboration platforms/tools that have been defined in order to enable the consortium to work effectively, deliver on its objectives. The QMP will ensure that the work conducted and the project's Deliverables are of the highest standard and in compliance with all relevant best practices, standards and ethical/legal requirements.

It is an expectation that all members of the consortium will be aware of and implement the procedures and practices set out within this plan.

1 INTRODUCTION

The **Gravitate-Health mission** is to equip and empower citizens as users with digital tools that make them confident, active, and responsive in their patient journey, specifically encouraging safe use of medicines for improved adherence, better health outcomes and higher quality of life. It is our vision that these future benefits for personal health can only be achieved when actionable, understandable, relevant, reliable and evidence-based information meets the user's needs, health context, and literacy level. **Our ambition** is to provide a key piece to advancing this vision, the Gravitate-Health Lens or G-lens, offering personalized, focused (not concealed or filtered) content from trusted health information sources to the user, and to demonstrate its benefits for access to and understanding of information, and adherence through the patient journey.

2 ORGANIZATIONAL STRUCTURE, ROLES & FUNCTIONS

Within the Gravitate-Health consortium, the implementation plan for the Action is organized in interdependent workstreams, with a set of ***Operative*** *WPs, Transversal,* ***Supportive*** *WPs* and high-level project milestones.

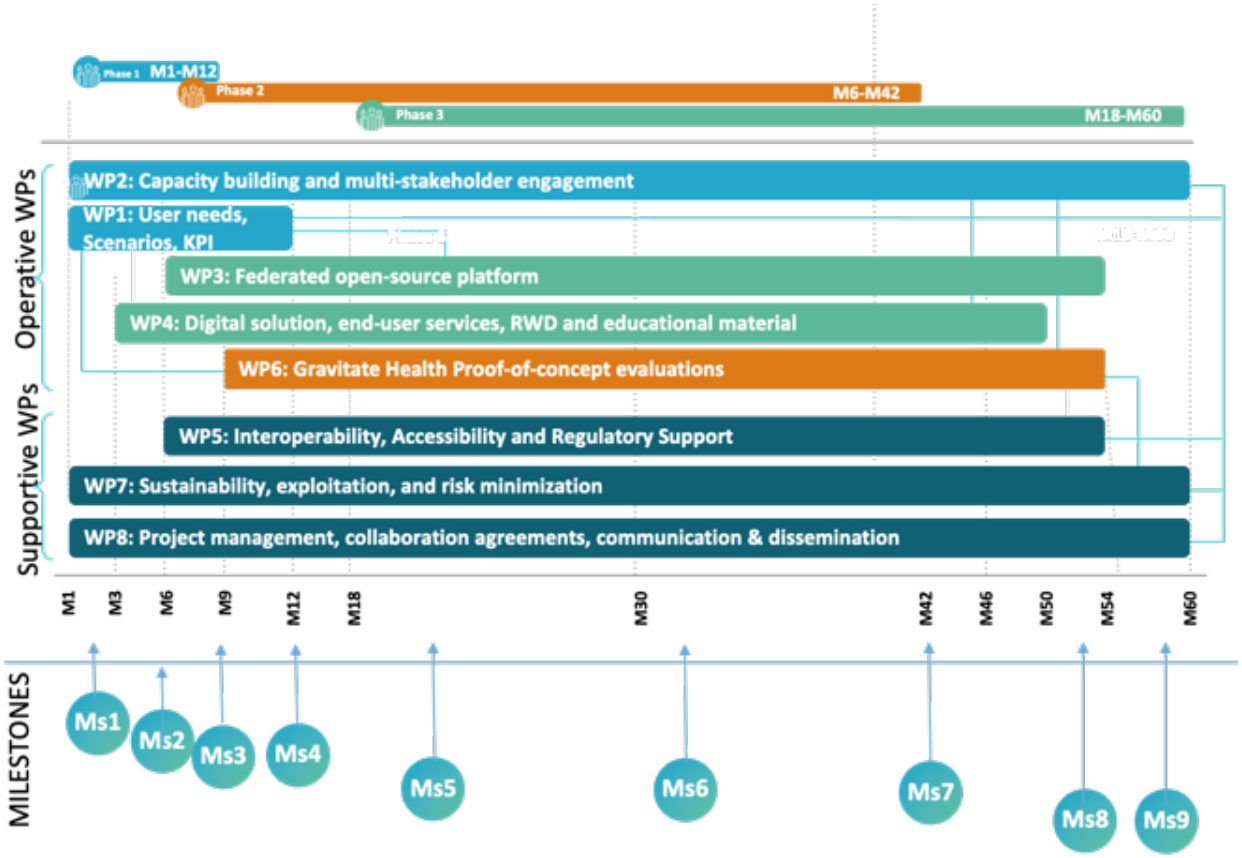


Figure 1. Gravitate-Health implementation plan

Therefore, implementation of the project work is distributed across a set of tasks organized in 8 work packages (WPs) with specific objectives:

1. Generate G-lens requirements, information flows and models for user scenarios and refine Key Performance Indicators (KPIs) of the Gravitate-Health solution, taking into

account ePI, healthcare standards, regulatory frameworks and processes, and insights from stakeholders.

2. Advance stakeholder engagement and capacity-building: ensure co-creation of evidence-based, value-creating services that benefit individuals throughout the patient journey, including disease prevention and health promotion for all users. Specific engagement with individuals such as health care professionals (medical doctors, nurses / nurse practitioners, pharmacist), patient advisory groups, health ecosystems in the EU and beyond, incubators, government agencies and regulators will ensure wide-ranging identification of user needs and offer new insights into focusing of ePI and development/usability of the open-source platform.
3. Design, implement and validate a comprehensive, scalable and sustainable Federated Open Source Platform and Services (FOSPS): demonstrate a federated approach to interoperability and sharing from heterogeneous data sources for risk minimization, connecting to ePIs, IPS and EHR portals, ePrescription, and eDispensing modules and facilitating agile evaluation of user scenarios.
4. Design, implement and validate a set of digital tools focusing on user experience (UX) with G-lens functionality to evaluate understanding, access and adherence with focused ePI, health educational material (HEM) and Real World Data (RWD): assess, integrate, and validate ePI content transformation in G-lens mock-ups and associated minimum viable products (MVP) in agile 2-week sprints to meet diverse health information / literacy needs across the patient journey, including health prevention and promotion, of different personas for various product types in proof-of-concept pilots.
5. Identify, conform, and contribute to development of relevant interoperability, accessibility standards as well as technical, semantic, operational and legal standards, highlighting gaps and barriers to ideal data flow. Provide support to other WPs in relation to the legal and regulatory framework; contribute to EU ePI common standard; provide (synthetic) ePI data to support testing and validation of G-lens and supporting tools; build on the HL7 FHIR® related ePI initiative of EMA, HL7/CEN IPS, ISO IDMP, and GDPR and MDR on FHIR® standards and implementation guides; connect to patient portals and CEF eHDSI services. Support applications to Research Ethics Committee for the proof-of-concept pilots, including materials for GDPR and MDR compliance.
6. Prioritize, develop and deploy reference implementations and interventions, validating G-lens scenarios of use through proof-of-concept pilots with multifaceted evaluation: demonstrate and validate that G-lens can advance access, understanding and adherence for different patient journeys while at the same time gather, use, analyze RWD, measure access, understandability, treatment adherence, and safe medication use, assessing risk minimization with KPIs. Applying the “evaluation by design” approach, G-lens will be evaluated in more than 8 countries reaching more than 5000 individuals, and we seek to point out cross-regional relevance, “transferability – generalization” as part of the effort.
7. Develop and maintain the Gravitate-Health exploitation and long-term sustainability plan to drive short to-medium term adoption of G-lens, and evolution and extensions of G-lens as part of the “digital first” strategy for the ePIs, using the federated Gravitate-Health FOSPS as a risk minimization measure: generate visibility and broad stakeholder engagement with partnerships, and targeted efforts to drive exploitation of the project's results; maintain an up-to-date sustainability plan linked to KPIs to

engage small and medium scale businesses and the large pharmaceutical value chain partners with health and care stakeholders across Europe.

8. Ensure effective governance and project management across all project activities including collaboration agreements, dissemination, communication and stakeholder activities, and development and maintenance of the data management and quality plans.

The milestones and their contributing WPs and deliverables for verification are as follows:

Table 1. Gravitate-Health milestones

MS	Milestone name	Lead Beneficiary	Related WP(s)	Due	Means of verification
Ms1	Project Kick off meeting Establish project's main bodies (GA, SC, PCT), set up PMO, Web landing page, social media profiles	1 - UiO	WP8, WP2	M2	D8.1, D8.2
Ms2	Use cases, personas designed, and stakeholders involved – prioritization in testing scenarios	20 - The Synergist	WP1, WP2, WP4,	M9	D1.1, D1.2
Ms3	G-lens mock-ups and KPI definition complete	16 - KI	WP1, WP5, WP8	M12	D1.3, D1.4, D1.5, D5.1, D5.5, D8.3
Ms4	Requirement gatherings and prepare FOSPS architecture, α-development version, first round UX, testing FOSPS platform and G-lens	5 - UPM	WP3, WP4, WP5, WP6, WP7	M20	D3.1, D3.5, D3.6, D3.9, D3.11, D4.1, D4.2, D6.1, D7.1
Ms5	Concept validation and technical integration, β-development version, second round of UX, testing FOSPS platform and G-lens	3 - HL7 Europe	WP1, WP2, WP3, WP5, WP6	M32	D1.4, D2.4, D3.2, D3.13, D4.2, D4.3, D4.4, D5.2, D5.4, D5.6, D6.2, D6.3
Ms6	Use case prioritizing for real-world validation, γ-development version, third round of UX and testing gamma version of FOSPS platform and G-lens	1 - UiO	WP2, WP3, WP4, WP5, WP6	M42	D2.1, D2.2, D2.5, D2.8, D3.3, D3.8, D3.10, D3.12, D3.14, D4.5, D5.7, D6.4
Ms7	Use care evaluation, final version of FOSPS with Gravitate-Health solution	21 - Open Evidence	WP2, WP3, WP4, WP5,	M56	D2.4, D2.6, D3.4, D4.6, D5.3, D5.7,

	and G-lenses completed		WP6, WP7		D6.4, D6.5, D6.6, D7.3
Ms8	White paper on recommendations released for consultation	6 - Empirica	WP7	M59	D7.5
Ms9	Agreement with H2O IMI project 945345	8 - I~HD	WP1, WP6, WP7	M6	Signed collaboration agreement with H2O, IMI Action on Health Observatories (topic#2)

2.1 Project management structure

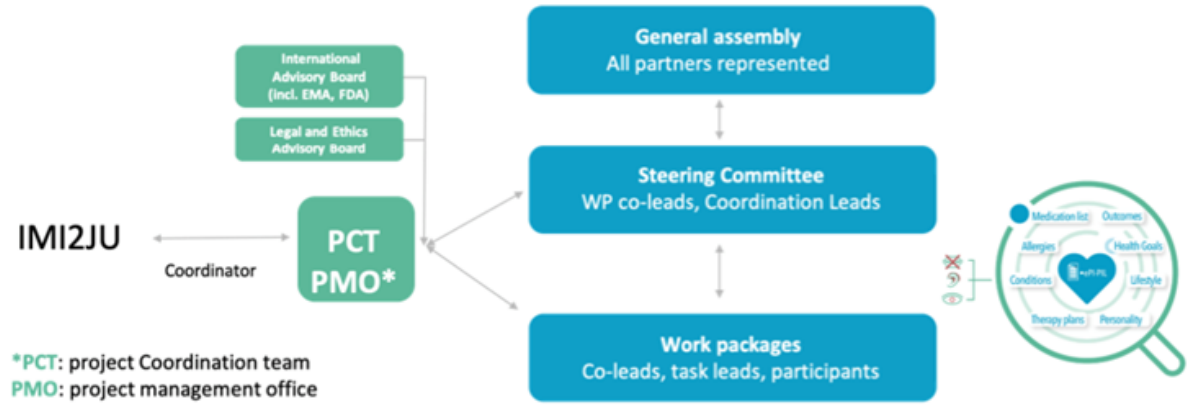


Figure 2. Project management structure

The **Gravitate-Health management structure consists of the following bodies and** operates as follows:

- The **General Assembly** (GA) is the body that implements the top-level decision-making within the project, and is composed of one nominated representative from each partner. The General Assembly is chaired by the Coordinator and co-chaired by the Project Lead. The General Assembly will act as the ultimate democratic decision-making body in the project. Modus operandi is described in 2.6 *Meetings, their management and documentation,* of this document.
- The **Steering Committee (SC)** is chaired by the Coordinator and co-chaired by the Project Lead. In addition to these, the SC also consists of the Project Manager, the WP co-leads, and the Coordination Leads. The Steering Committee is responsible for the overall operation and execution of the project, ensuring the establishment of appropriate communication and quality frameworks for the project, alignment across work packages and making decisions on key issues. Modus operandi is described in 2.6 *Meetings, their management and documentation,* of this document.

- **The Project Coordination Team (PCT)** consists of the Coordinator, Project Lead and Project Manager, with assistance from the Project Management offices, where relevant. It will meet regularly, mainly via teleconference, to discuss and resolve day-to-day issues, where necessary referring to the SC.
- **International Advisory Board (IAB):** This board includes independent members and will undertake regular review of the strategic approach and work performed. It will receive regular updates on the work progress and will take part in a project meeting once per year. It will provide feedback to the SC to challenge and improve the project, maximize its impact and enable it to meet its objectives. Modus operandi is described in 2.6 *Meetings, their management and documentation* of this document.
- The **Ethics and Legal Advisory Board** (ELAB) oversees work involving human subjects. This board will ensure the project abides by all ethical rules, applicable laws and agreements. In case any issues arise, it will guide on the best corrective procedures to follow. Modus operandi is described in 2.6 *Meetings, their management and documentation,* of this document.

A detailed description of management bodies and their operation can be found in section 2.6 below, the Description of Action (Grant Agreement Annex 1, section 3.2) and Consortium Agreement. These documents are available within the project Teams site for reference in channel **General**, folder **Description of Action.** The Folder can be accessed here.

Additionally, an operational meeting, the **Gravitate-Health Forum**, may meet virtually monthly, in line with project needs in order to facilitate progress and interactions across the Consortium. This is not a decision-making body, however, may refer topics to the PCT for consideration as needed.

2.2 Work team: roles and functions

2.2.1 Project Coordination Team (PCT)

The following **roles** have been defined as part of the project management structure:

- **Coordinator** – Prof Anne Moen, University of Oslo. As Coordinator, University of Oslo is responsible for all project management activities, and will work closely with the Public, EFPIA and IMI2 associated partners for overall coordination and execution of the Gravitate-Health project. The Coordinator is the main contact to IMI for project reporting and coordination matters.
- **Project Lead** – Dr Giovanna Maria Ferrari, Pfizer. As the EFPIA Project Lead, Pfizer oversees overall scientific and action-related governance and will act in close collaboration with the Coordinator during execution of the Gravitate-Health project in line with agreed responsibilities.
- **Project Manager** – Line Løw, University of Oslo. University of Oslo will host the PMO and support the execution of the action, project reporting and coordination matters.

2.2.2 Work Package Co-Leads

The Gravitate - Health Action has eight WPs, which are Co-Led by a public and a private partner. The co-Leads are as follows (Table 2).

Table 2. WP Co-Leads

Industry lead	Partner	WP	Public consortium lead	Partner
Koen Nauwelaerts	Bayer	1	Martin Ingvar	KI
Ronnie Mundair	Pfizer	2	Valentina Strammiello	EPF
Ray Grant	Medidata	3	Alejandro Medrano	UPM
Charles Flint	Pfizer	4	Lucia Comnes	DW
Amy Cramer	Pfizer	5	Catherine Chronaki	HL7 Europe
Juergen Bentz	UCB	6	Dipak Kalra	I~HD
Alan Mark Hochberg	Roche	7	Veli Stroetmann	Empirica

Within the WPs, specific task leads are identified with responsibility for delivery of specific task objectives, see Grant Agreement, Annex1, part A for details of each task.

2.2.3 Coordination Leads

To facilitate cross-WP alignment and synergies in specific areas of importance for completion of the action, we have identified six coordination leads, with their specific area of focus:

Table 3. Coordination Leads

Juergen Hauck, Pfizer	Technology		Catherine Chronaki, HL7 Europe	Interoperability
Janos Karovits, Roche	Sustainability & Innovation		Valentina Tageo, ECHA	Dissemination & Communication
Deborah Bebbington, Bayer	Regulatory & ePI		Petra Wilson, HIMSS Europe	Ethical – legal

These **Coordination Leads** are appointed among the public and industry partners (equal numbers) to ensure synergies in managing inter-dependencies and facilitate cross-WP alignment. The Coordination Leads serves specifically to strengthen governance of the project as well as support overall coordination between and within the main workstreams.

2.3 General operating principles for the Consortium

The overall ambition for the operating principles is to ensure integrity, respect and trust in all collaborative activities and create conditions for excellence in the performance within the Action. Partners and their participants are expected to contribute necessary expertise and experience to complete all the foreseen activities as outlined in the implementation plan (Annex 1, section A, Grant Agreement). The goal is to build professionalism into all aspects of the work and secure joint commitment from public

and private partners to solve the challenges set forth in the DoA. Furthermore, transparency in the governance delivered through the project management structure will help balance predictability and steadiness with change and uncertainty in a way that will drive innovation within the framework of the PPP.

Beneficiaries will take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest (ref. GA for details). Several measures will be implemented to ensure protection of consortium assets, collected personal information and empirical material from participants in R&D activities. The communication principles set out within this plan will also ensure the compliance with best practices and align with the clauses set out in the Grant Agreement.

2.3.1 Consortium protection

To protect the interests of the consortium as a whole you may use the information generated through the work in Gravitate-Health only for the benefit of the project and the consortium. Any extracts, including from recordings, screen captures, presentations etc. may only be used with the consent of the parties referenced or whose material is captured in the recording. Any such agreement between two or more consortium members to use a material like a capture from a recording should be reported in writing to the Coordinator to be included in the data management materials.

2.3.2 Privacy notice

The Gravitate-Health activities may involve collection of personal data from consortium members, e.g., recordings, pictures or field notes. This means the following data can be recorded about you: a) your name and the registration details you provide, b) your image if you choose to turn on your camera at any time, and c) your voice if you choose to ask a question or make a comment orally, as well as any text you may choose to write in the zoom tool.

The data controller for information kept in Teams is the University of Oslo (UiO), and UiO undertakes to keep your data safe. We will make recorded presentations available through the Gravitate-Health Teams platform where you find the URL to the recorded meeting. The recording is available to all project partners who have a right to access the Teams platform where they will find the URL to the Gravitate-Health YouTube channel.

The recorded data will be used only for project purposes and will not be used beyond the project without your specific consent. The recorded data may be important information about the project work and results that shall not be shared outside the consortium, without specific notice. The data will be kept for the duration of the project.

Personal information is available for internal project use on the following “Best Practice” terms:

1) As per the privacy note and etiquette, recordings, pictures or field notes from meetings are made available in the project Teams channel “Recordings” where you will find the URL to the Gravitate-Health YouTube channel.
2) Material is made available for internal project use only. No project partner or employee of a project partner may further share the recordings on any public platform.

3) Insofar as any personal data of individuals are included, these are included on the basis of consent as set out in privacy information notice provided for each recorded meeting
4) UiO is the data controller for the personal data in the material kept in Teams.

Management of Research data, including consent forms as well as storing and analysis of personal data and personal sensitive data collected in the empirical work, e.g., testing scenarios, will be outlined in detail in the Data Management Plan.

2.3.3 Communication principles

The following general communication principles are applicable across all members of the consortium in relation to materials generated by Gravitate-Health for external communication:

- Maintaining a commitment to Open Access publications, following FAIR principles and the Grant Agreement clauses pertaining to dissemination and confidentiality
- Maintaining a commitment to publication of product results and insights in Journals, Web, SoMe (Twitter, LinkedIN), Flyers with the following cautions:
  - *References to specific medicinal products/product names should be avoided*
  - *Any form of promotional materials for products is not in scope for this project*

In the case of major communications releases, it is important to allow adequate time for internal review by Coordinator and Project Lead prior to external communication. In such cases, timelines should be consulted on and agreed in advance to avoid delays.

Additionally, the elements in 1) and 2) below should be included within all external communications prepared for Gravitate-Health

1. Statement of acknowledgement of funding (plus associated logos)

   "This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 945334. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and Datapharm Limited"

   Display EU emblem and the logos of IMIJU, EFPIA and Datapharm Limited

2. Disclaimer excluding JU responsibility

   This communication reflects the views of the authors and neither the IMI nor the European Union, EFPIA, or Datapharm Limited are liable for any use that may be made of the information contained herein.

If a partner presents further developed material, derived from Gravitate-Health activities, we ask that the following statement, is included to acknowledge the relationship:

3. Acknowledge contributions from Gravitate-Health

   Part of the work presented in this paper draws on knowledge, insights, experiences in Gravitate-Health, funded under IMI2 JU grant agreement No 945334. The material reflects only the authors' view, and IMI JU nor other Gravitate-Health consortium members are not to be held responsible for any further use.

Please consult Appendix 12, Consortium Agreement for details of "Permitted Communications", and Activities that may be permissible according to provisions like consent or privacy notice, and to terms in the Consortium Agreement, including those on Dissemination and Confidential Information.

3 MANAGEMENT PROCEDURES

3.1 Information, collaboration and document sharing

The University of Oslo through the PMO will offer Zoom videoconferencing and Microsoft Teams as collaboration platforms. Please see here the information on how to use Teams. The University of Oslo assumes the role as Data Controller for material kept in Teams, and for use of Zoom hosted through the Gravitate-Health PMO.

3.1.1 Virtual collaboration - Zoom or Teams meetings

The virtual meeting platforms preferred for Gravitate-Health project meetings at any level are either Zoom (uio.zoom.us) or Teams. Consortium members can book Zoom meetings through PMO (UiO) for their activities through the PM. The PM will book generic meetings where the first person to enter becomes the host of the meeting. Partners can book single meetings or series according to need. For Teams use either Calls (found in the menu at the left) or Meet function in the Channel you are in (found at the right upper level of the window as a camera icon).

Partners can also use their own virtual collaboration tools as permitted, including Zoom account, Teams, WebEx, Google meet etc.

3.1.2 Microsoft Teams Document Management Structure

Teams is our main collaboration space that brings together chat, content, and everyday tools in one place, including file storage and note taking, and is integrated with Office 365. In Teams, a ***team*** is a collection of people, content and tools; the ***channels*** under each team organize the team by project or topic. Chats are threaded and persistent - the chat history is always available.

The whole consortia have access to the channels. The structure of General Channel is shown below.

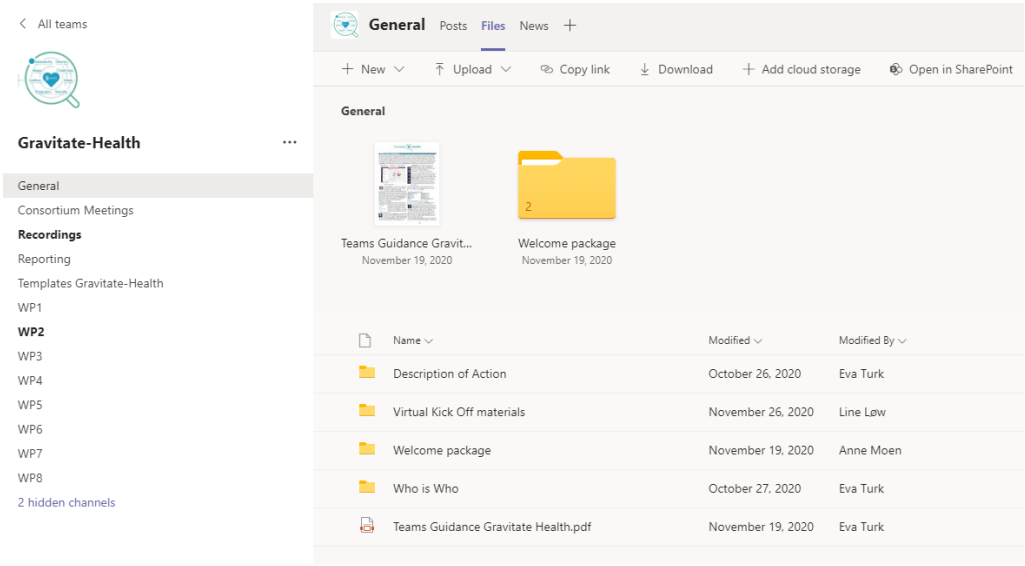


Figure 3. Gravitate-Health Teams space General channel structure

There is the same basic structure within each of the WP channels (see Figure 4), comprised of WPx Archive, WPx Charter and Contact details, WPx Deliverables, WPx Meetings, WPx Presentations, WPx Project Management and WPx Tasks. In addition, each WP has their Work area available, set up as Microsoft OneNote. The WP Co-Leads, Task Leads and members can use and manage their WP channel as they like to conduct the work. However, we strongly recommend to review/maintain the channel periodically, remove un-used folders, and archive documents in appropriate folders for further reference. Should there be any need for additional channels, general assistance or re-structuring, please contact the PMO.

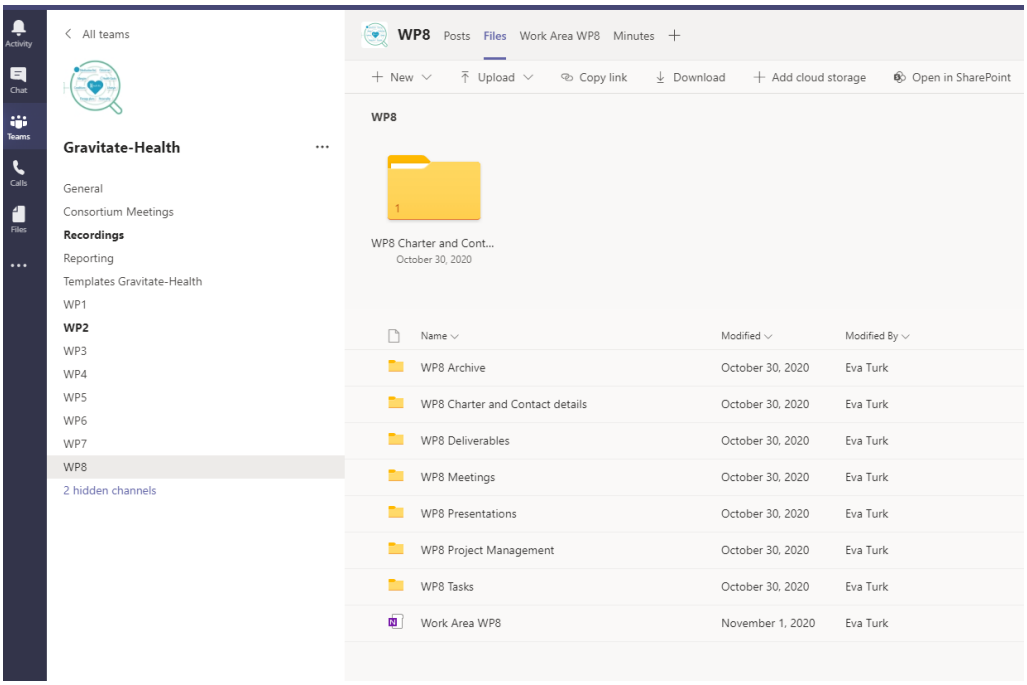


Figure 4. Gravitate-Health Teams space WP channel (example)

3.1.3 Internal Communication using Teams

Gravitate - Health internal communication will be carried out primarily through Teams.

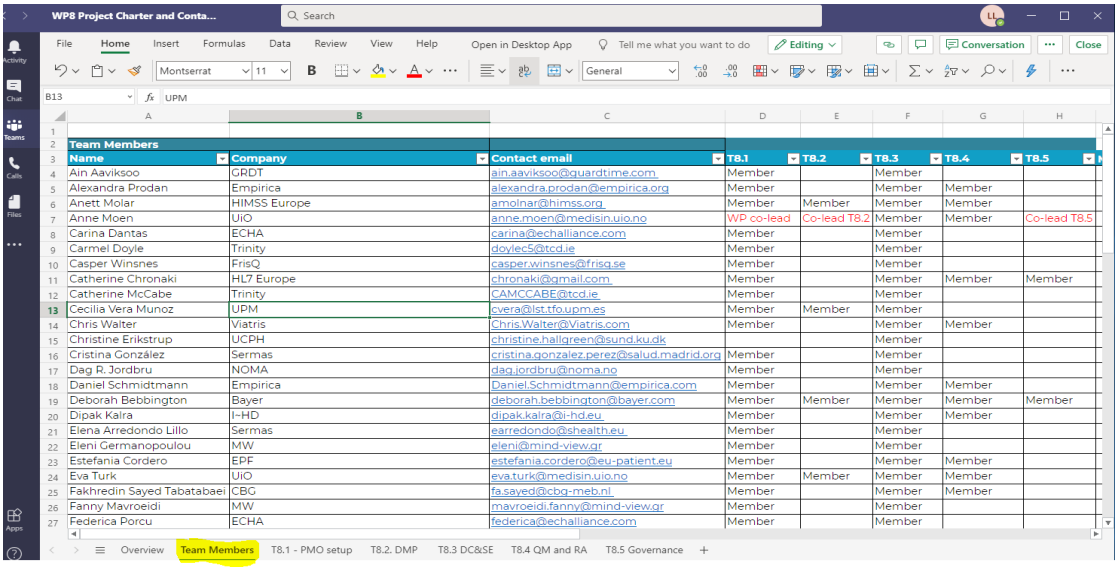
When using the chat function, it is recommended to include the @ symbol followed by a teammate's full name (no space between @ and the name) to notify the recipient that you are requesting input or action or enter the channel name after @ to notify the entire team (for example, **@AmySmith** or **@General**). You can choose to add a subject to keep your conversations organized. Just place your cursor to the left of **Add a subject** and start typing; larger, bold font is pre- selected for the subject. **TIP**: If you attach a file to your chat, it is stored under the **Files** tab at the top of the channel page for others to easily find later.

You can access Teams on-the-go, to chat, manage your files, and more, using the Teams mobile app. The Teams mobile app looks similar to the PC version. Tap the icons at the bottom of the screen to view your **Activity**, **Chat** or **Teams**.

3.1.4 Resources: WP Charter, Contact lists in Teams and Direct Mailing lists

3.1.4.1 Team Members in each WP Channels – WP - Charter and Contact details

In each WPX Channel, you will find the folder WPX Charter and Contact details and Excel file WPX Project Charter and Contacts. To access the Contact list please look into the sheet/tab **Team Members**. The Contact list will be the last updated contact list for your WP. Here you will find the name, company, contact email, task involvement and member from date of your Team members. It is very important that WP Co-Leads and Task Leads check the contact details from time to time, since this will be a dynamic and living list of members. To use this list for emailing all participants within the WP please just copy the contact email column and add to the address field in your email. Please see excerpt - example from WP8 below.



Team Members

Name	Company	Contact email	T8.1	T8.2	T8.3	T8.4	T8.5
Ain Aaviksoo	GRDT	ain.aaviksoo@guardtime.com	Member		Member		
Alexandra Prodan	Empirica	alexandra.prodan@empirica.org	Member		Member	Member	
Anett Molar	HIMSS Europe	amolnar@himss.org	Member	Member	Member	Member	
Anne Moen	UiO	anne.moen@medisin.uio.no	WP co-lead	Co-lead T8.2	Member	Member	Co-lead T8.5
Carina Dantas	ECHA	carina@echalliance.com	Member		Member		
Carmel Doyle	Trinity	doylec5@tcd.ie	Member		Member		
Casper Winsnes	FrisQ	casper.winsnes@frisq.se	Member		Member		
Catherine Chronaki	HL7 Europe	chronaki@gmail.com	Member		Member	Member	Member
Catherine McCabe	Trinity	CAMCCABE@tcd.ie	Member		Member		
Cecilia Vera Munoz	UPM	cvera@lst.tfo.upm.es	Member	Member	Member		
Chris Walter	Viatris	Chris.Walter@Viatris.com	Member		Member	Member	
Christine Erikstrup	UCPH	christine.hallgreen@sund.ku.dk			Member		
Cristina González	Sermas	cristina.gonzalez.perez@salud.madrid.org	Member		Member		
Dag R. Jordbru	NOMA	dag.jordbru@noma.no	Member		Member		
Daniel Schmidtmann	Empirica	Daniel.Schmidtmann@empirica.com	Member		Member	Member	
Deborah Bebbington	Bayer	deborah.bebbington@bayer.com	Member	Member	Member	Member	Member
Dipak Kalra	I-HD	dipak.kalra@i-hd.eu	Member		Member	Member	
Elena Arredondo Lillo	Sermas	earredondo@shealth.eu	Member		Member		
Eleni Germanopoulou	MW	eleni@mind-view.gr	Member		Member		
Estefania Cordero	EPF	estefania.cordero@eu-patient.eu	Member		Member	Member	
Eva Turk	UiO	eva.turk@medisin.uio.no	Member	Member	Member	Member	
Fakhredin Sayed Tabatabaei	CBG	fa.sayed@cbg-meb.nl	Member		Member	Member	
Fanny Mavroeidi	MW	mavroeidi.fanny@mind-view.gr	Member		Member		
Federica Porcu	ECHA	federica@echalliance.com	Member		Member		

Figure 5. WP Contact list structure (example)

All WP Co-Leads and members of the consortium can add members to relevant WPX Charter and Contact list where the member will actively participate. However, for the PM to be able to update and maintain the Contact list master file and the direct mailing lists, it is very important that the column ***member from*** is updated with the date the new member joins the WP.

3.1.4.2 Direct Mailing lists

Formal announcements and communication to ***all consortium members*** can also be made using the direct mailing list gravitate-health-partners@medisin.uio.no. The full consortium direct mailing list is maintained by the PMO. Please be aware of that emails

to the industry partners may 'bounce' when using this mailing this. It is important to notify both PMO and the partners if you experience this by using the "all consortium direct mailing list".

The Coordination group in Gravitate-Health consists of the Coordinator, the Project lead, the WP co-Leads, the Coordination Leads and the PMO. The direct mailing list for the Coordination group is found here: gravitate-health-coordination@medisin.uio.no

The mailing lists for the different WPs are found here:

- WP1 members: gravitate-health-WP1@medisin.uio.no
- WP2 members: gravitate-health-WP2@medisin.uio.no
- WP3 members: gravitate-health-WP3@medisin.uio.no
- WP4 members: gravitate-health-WP4@medisin.uio.no
- WP5 members: gravitate-health-WP5@medisin.uio.no
- WP6 members: gravitate-health-WP6@medisin.uio.no
- WP7 members: gravitate-health-WP7@medisin.uio.no
- WP8 members: gravitate-health-WP8@medisin.uio.no

Each WP Direct Mailing lists will be updated every 3rd week based on the information in the WP's Charter Contact list. To be sure you have the latest updated contact list please crosscheck with the WP Charter.

3.1.5 PMO Contact points

Contact points and responsibilities for maintenance of the project collaboration tools are as noted below. In case of questions, consortium members should approach the appropriate contact point.

Table 4. PMO contact list

Procedure	Tool	Responsible	Contact details
Adding new member	Teams	WP Co-Leads and Task Leads to update their WP Charter and Contact list, and notify PM	line.low@medisin.uio.no
Adding new member and/or technical support	Teams	Access to Teams and technical support	victor.bredholt@medisin.uio.n
Documents and Information Sharing, updated Partner Logos and description, Partner changes, DoA changes	Teams, email	PM for all content, PCT to be informed	line.low@medisin.uio.no
Internal communication	Teams Charter and Contact details or Direct Mailing lists	PM for updated lists	line.low@medisin.uio.no

Scheduling conference calls	Teams or Zoom	PM to book generic meetings	line.low@medisin.uio.no
Project economy, financial interim reports, periodic financial reporting	Teams or email	Kirsti Langvatn	kirsti.langvatn@medisin.uio.no

In the case that there are new colleagues joining the project, changes in established contact points and/or WP composition, or other important updates must be communicated to the PMO in order to ensure that the Contact list master file is maintained, and new members are given access permissions for the Teams site.

3.2 Project Management

The PMO has developed a series of processes to lead the work of the Gravitate-Health team, to achieve goals and meet success criteria within the specified time. The PMO has developed project documentation to capture, maintain, and report on the tasks, deliverables, milestones, activities and cross WP dependencies and a series of key procedures to describe how this documentation will be used to capture the scope, stakeholders, decisions, risks and changes across the lifetime of the project.

The following sections describe the procedures for developing and managing the project plan, WP charters, stakeholder identification, change management and risk management.

3.2.1 WP charters

The high-level project plan, tasks, deliverables and milestones are described in the DoA. The **detailed activity-level** project plan is maintained in Microsoft Project and kept in the Teams environment in WP8. The plan is co-developed and maintained between the PMO and WP co-Leads and Task Leads. Any changes to the scope or timing of tasks, deliverables or milestones are subject to approved change via the change management process, see section 2.4.

Every work Package has a pre-filled charter within their Teams WP channel. The charter has a sequence of tabs. WP charter (example from WP8) see below, with row of tabs and first tab marked with yellow (for awareness).

3.2.2 Task charter

Task charters are found on the tabs of the WP Charter and Contact details spreadsheet in WP Teams channels. There is one task charter for every task in the WP. The PMO have prepopulated the information, taking it from the Description of Action (Grant Agreement Annex 1) section A. The WP Co-Leads complete the actual dates as deliverables are realized. The WP Co-Leads can also document any activities considered out of scope of their tasks within the Task Charter. Any changes to timings of tasks or deliverables or scope of the tasks as defined in the DoA are subject to the change management procedure.

WP 8 Charter		
WP Name	WP Leads	
Project management, collaboration agreements, communication & dissemination	UiO & Pfizer	Anne Moen and Giovanna Ferrari
Involved Partners	Total Effort (PM)	219.9
All partners		
Timeline	Start Month	End Month
Description of the WP (problem statement, purpose)	1	60
Objective of WP8 is effective project management for the Gravitate Health project, and specifically to · Encourage and facilitate meaningful interaction between all partners and manage conflict resolution. · Coordinate at management level all scientific, technical, standardization, dissemination & exploitation activities for long-lasting effects of digital tool deployment to improve citizens' access, understanding of trusted information, and drive adherence, safer, efficient use of medication and well-being. · Provide project structure, coordination, quality standards and assist decision making, internal and external communications, innovation management and encourage greater accountability. · Facilitate document sharing, exchange of information, real-time on-line discussions and close monitoring of the progress and quality of the team's activities. · Prepare and manage the consortium agreements amongst the partners; including contractual, legal, financial, ethical aspects and administrative management. · Assure ethical behavior and data protection, meaningful interaction with regulators as well as identify/mitigate potential project's risks. · Meet obligations to IMI, including timely finalization of all deliverables with optimal quality, and implement quality control and assurance procedures		
Deliverables & Milestones (Activity / Month)	planned	realised
M1 Project Kick off meeting	M2	
D8.1 Project management and quality management plans, reporting templates	M2	
D8.2 Setup project visual identity, website, handles for external-facing media, LinkedIn, Twitter	M2	
D8.3 Data management plan	M5	
D8.11 Dissemination and communication plan	M6	
D8.4 Y1 - Periodic annual Reports on dissemination, scientific production, communication, stakeholder engagement, partnerships, liaison activities	M12	
D8.5 Y2 - Periodic annual Reports on dissemination, scientific production, communication, stakeholder engagement, partnerships, liaison activities	M24	
D8.6 Y3 - Periodic annual Reports on dissemination, scientific production, communication, stakeholder engagement, partnerships, liaison activities	M36	
D8.7 Y4 - Periodic annual Reports on dissemination, scientific production, communication, stakeholder engagement, partnerships, liaison activities	M48	
D8.8 Final report on dissemination, scientific production, communication, stakeholder engagement, partnerships, liaison activities	M60	
D8.9 Report on governance models, impact activities, harmonization, policy dissemination	M36	
D8.10 Report on governance models, impact activities, harmonization, policy dissemination	M60	
Tasks	Task Leads	Timeline
T 8.1. Project management and coordination, periodic reporting	UiO, Pfizer	[M1 – M60]
T 8.2. Data Management Plan, and management of ethical and regulatory issues	UiO, HIMSS Europe	[M1 – M60]
T 8.3 Dissemination, Communication and Stakeholder Engagement plans and overviews	ECHA, UiO, Pfizer	[M1 – M60]
T 8.4 Quality management and risk assessments in Gravitate Health	UiO	[M1 – M60]

Overview | Team Members | T8.1 - PMO setup | T8.2. DMP | T8.3 DC&SE | T8.4 QM and RA | T8.5 Governance

Figure 6. WP charter (example)

3.2.3 Stakeholder Analysis

Every WP should identify audiences and complete a stakeholder analysis to guide their contribution to the Action's communication plan and sustainability efforts. WP Co-Leads consult with the Dissemination and Communication Lead and share at the Steering Committee for overarching stakeholder management and communication plan development. The stakeholder analysis template can be found in the Project Management folder in each WP channel in Teams. Any update to the initial stakeholder analysis should be communicated at the Steering Committee.

Stakeholder Name	**Contact Person** *Name, address, contact details*	**Power** *Their ability to stop or change the project*	**Interest** *The size and location of the overlap between their interests and the project goals*	**Engagement Strategy** *The type and frequency of communication*
Stakeholder				
Stakeholder				
Stakeholder				
Stakeholder				

Figure 7. Stakeholder analysis charter example

3.3 Risk Management Process (RMP)

The Risk Management Process (RMP) is intended to surface, document, manage and mitigate risk across the project during its lifetime. An initial overview of Critical Implementation risks and mitigation were identified in the DoA (part A, table 1.3.5), and are captured on the central risk register, see Appendix III, and on the WP-specific risk register log, see Appendix IV. These documents are maintained in WP8 and in specific WP project management files in the WP Teams channels. Throughout the life span of the project WP will continue to capture additional risks identified using the process described below. As a general principle, potential risks should be communicated at the earliest opportunity to the PCT and SC, to maximize the opportunity for mitigation.

3.3.1 Risk assessment and evaluation Principles

The methodology for and process for Risk Management in Gravitate – Health comprises four sequential and iterative steps, as follows:

Risk identification determines which risks might affect the project and documents their characteristics. Risks will be identified by: a) Identifying conditions or situations that may lead to risks and b) Determining the specific risks associated with these conditions or situations. This can be identified and surfaced by any team contributor.

Risk analysis: Establishment of the impact for the project if the risk does occur. Risks Matrixes will serve to prioritize and manage the identified risks (low, moderate, high). This will take place in consultation with WP co-leads and task leads.

Risk response and mitigation actions: The objective of this step is to mitigate the potential occurrence of the identified risks and to reduce threats to the project objectives by taking appropriate, realistic and effective actions within the project context. This will be developed by WP co-Leads and task leads.

Risk monitoring and control covers on-going follow-up of residual risks, identifying new risks, executing risk-reduction actions and evaluating their effectiveness throughout the project life cycle. This constant application of the risk management process maximizes the usefulness of the RMP. The WP risk management plans will be a routine mechanism for monitoring and control at the Steering Committee meetings.

3.3.2 Risk analysis: Self-assessment process

As the project progresses, each WP is expected to identify additional risks that emerge on an ongoing basis using the WP risk register log and using the guidance set out below. See Appendix IV for the template. In addition, each WP has this register log within their folder project management in their Teams WP channel. This will help consider any impact on dependent work streams and communicate this to the WP co-leads and task leads. The impacted work stream(s) will capture the risk in their own risk spreadsheet and communicate to the project coordination team. The Project Coordination Team (PCT) will capture each new risk on the central risk register for the project, see Appendix III, which will be stored in the WP8 Teams folder. Risk review is carried out at by Steering Committee and reported to the GA and added to the Gravitate-Health annual technical report.

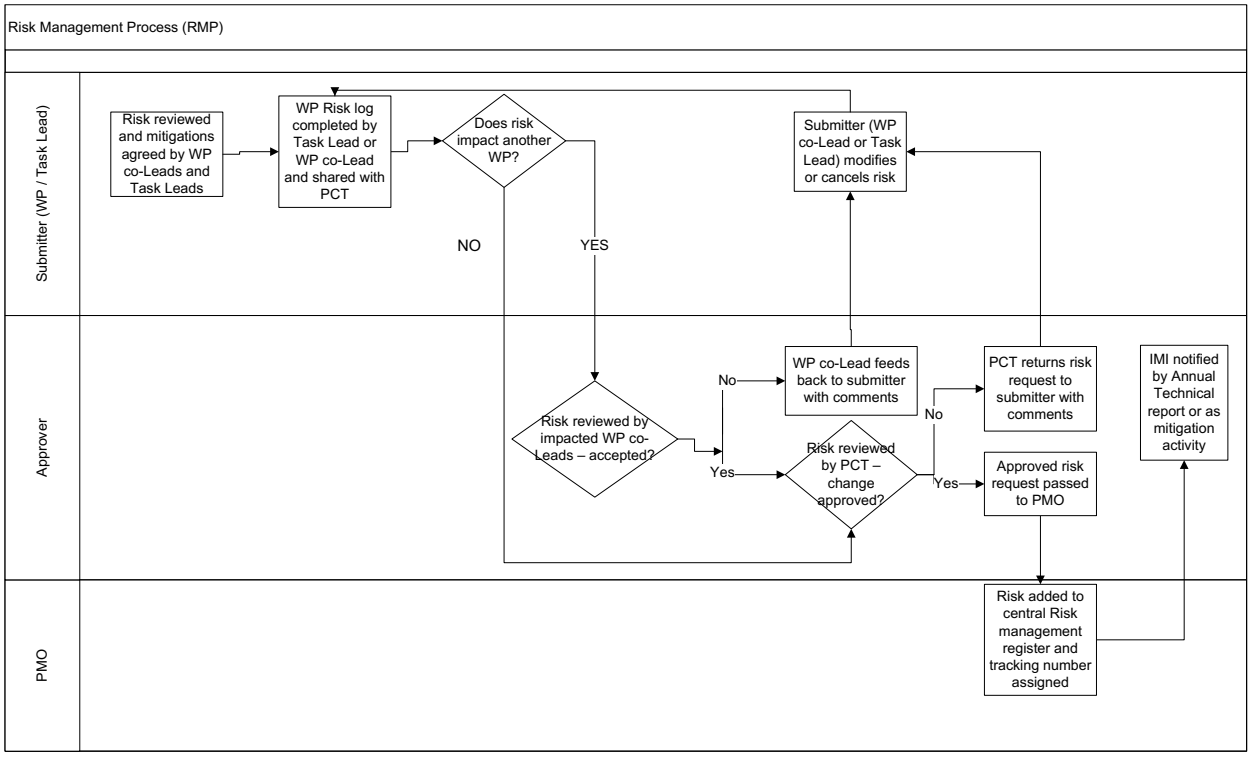


Figure 8. WP risk register guidance

3.3.3 Roles and Responsibilities

Table 5. Risk management roles and responsibilities

Role	Responsibility
Task Lead	Approve proposed risk and add to WP risk log. Document decision in WP decision log.
WP co-Leads	Approve risks within WP and ensure added to the WP risk log. Document decision in WP decision log. Ensure dependent WP leads are notified. File final approved changes in Teams. If impacted by a change request from another WP assess impact on WP activities, tasks and deliverables and approve or reject change, document in decision log and notify WP team.
PCT	Assess impact of risk on project tasks, deliverables and milestones. Ensure correct dependent WP are informed of the risk and have already accepted and added the risk to their own WP risk log. Accept or reject risk. Notify IMI of risk, either as part of the annual technical report or as a special change mitigation action, if critical and urgent.
PMO	Add the risk to the central risk register and assign the next tracking number from the spreadsheet to the risk.

3.3.4 Conflict Resolution related to Risk Management

Final responsibility for decision-making and conflict resolution in the project rests with the General Assembly. The voting rules for the General Assembly are described in the

Consortium Agreement. In each WP, the WP co-Leads assume responsibility for progress and delivery within that WP. Any conflict arising that cannot be resolved at this level, will in the first instance be resolved by the Project Coordination Team (PCT) with input from the Steering Committee members as required. Failing such a resolution, the General Assembly will discuss the issues and vote on a resolution to achieve a binding solution.

3.4 Change Management Process

3.4.1 Procedure

A change may be suggested by any team member, for example they may identify the need for additional time to complete a task or suggest additional activities within a task which were not originally in scope. The initial review of the change occurs at the WP level, including input from the WP leads and other members of the WP as applicable, including a determination of whether the change is in scope for the formal CMP and a decision made if the change is approved by the team, alongside rationale and potential impact to dependent workstreams. Changes to the following areas are in scope of the Change Management Plan:

- Project plan
- Project charter
- Project deliverables
- Project milestones
- Project resource or budget

The decision to make a change is initially documented in the WP decision log, see Appendix VII, which is kept in the WP Teams file. For changes not in scope of the formal Change Management Plan, the process ends here. For changes in scope of the Change Management Plan, the WP co-Leads or task lead will complete a Change Request Form, see Appendix VI, which is submitted to the PCT and impacted WP leads for approval. The Coordinator logs the change request in the central project change management register, see Appendix V, where it is assigned a reference number which is added to the change request form. The completed approved form is copied to the central change management file in WP8 Teams file and a copy is sent to the submitting WP and task leads. Changes in scope of this process will be notified to IMI by the Coordinator.

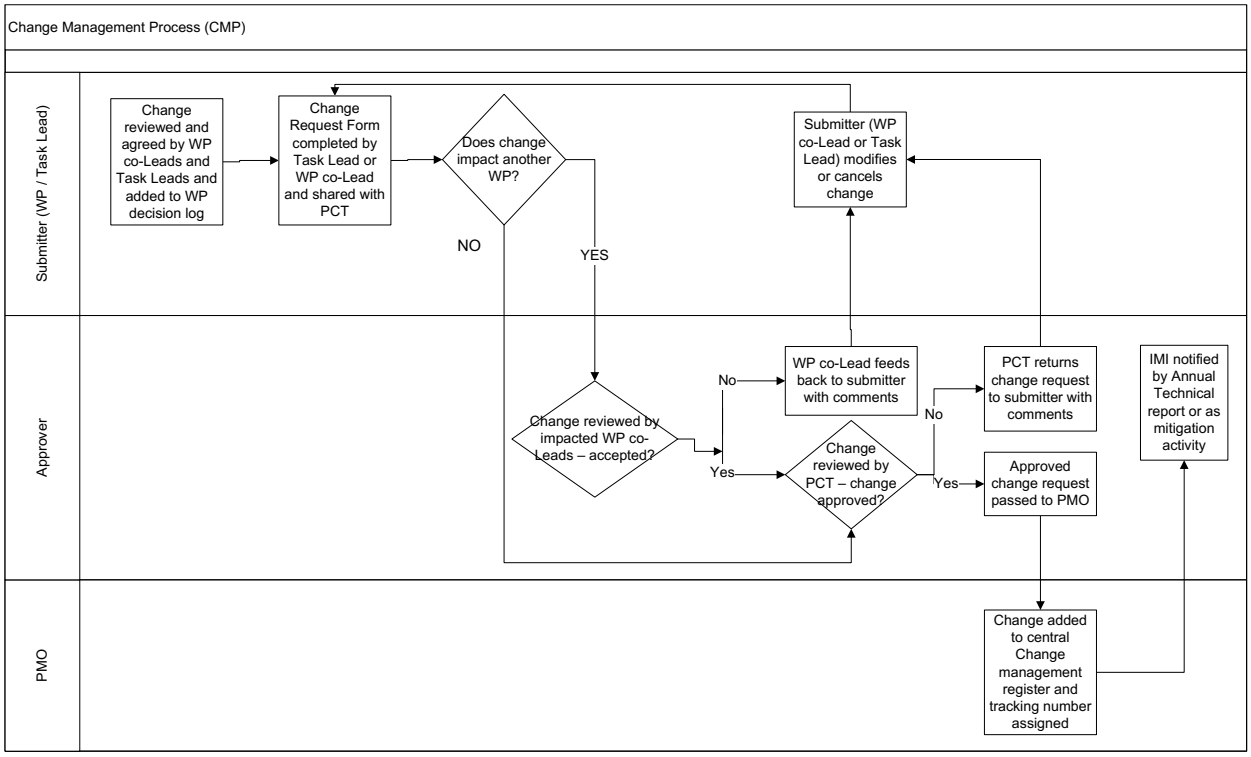


Figure 9. Change management process

3.4.2 Roles & Responsibilities within the Change Management Plan

Table 6. Change management roles and responsiblities

Role	Responsibility
Task Lead	Approve proposed change and submit change request. Document decision in WP decision log. File final approved changes in Teams.
WP co-Leads	Approve changes within WP and submit change request. Document decision in WP decision log. Ensure dependent WP leads are included in the approval of the change request. File final approved changes in Teams. If impacted by a change request from another WP assess impact on WP activities, tasks and deliverables and approve or reject change, document in decision log and notify WP team.
PCT	Assess impact of change on project tasks, deliverables and milestones. Ensure correct dependent WP are informed of the change and have already approved the change request. Approve or reject change request. Notify IMI of the change, either as part of the annual technical report or as a special mitigation action, depending on the importance and urgency.
PMO	Add the change to the central change management register and assign the next CI tracking number from the spreadsheet to the change request. Return the final approved change request to the requestor.

3.5 Quality of Technical Work

All tasks shall be carried out in accordance with the project work plan described in the Description of Action, the quality system of the relevant partner, and this Quality Management Plan (QMP). This means that:

- Necessary input is obtained from the appropriate consortium members and duly considered
- Relevant methods, techniques and tools are employed, and applicable internal procedures of the relevant partner are complied with
- Measurements, tests and analyses are performed in accordance with standards, rules, specifications and/or good practices.
- Interpretations and conclusions are technically sound and logically correct.
- Checking of the work performed and its results is carried out, including self-checking and internal verification.
- Non-conformities and errors are reported to the appropriate personnel unless satisfactory corrections can be made on the spot.

3.6 Meetings, their management and documentation

The project has planned a set of reporting tasks allowing the regular tracking of the progress of the project`s outcomes and ensuring the early identification of possible problems that may require mitigation.

3.6.1 Project meetings - levels, members and frequency

A detailed description of management bodies and their operation is found in the Description of Action (Grant Agreement Annex 1) and in the Consortium agreement. Minor adjustments in operational aspects, e.g. minor adjustments to scheduling, may be agreed upon by the Steering Committee on occasions and will be appropriately documented. The schedule of project meetings will be announced in an annual cycle and/or in the calendar function in Microsoft Teams.

3.6.2 GA Meeting management and Documentation

The GA is held once a year, typically as an in-person meeting. However, any Representative of the General Assembly may participate in meetings of the General Assembly by tele-conference, videoconference or any other technology that enables interactive and simultaneous communication (as per 11.3.3.5 in CA).

The meeting date will be notified to the consortium 3 months prior the meeting is convened. The Agenda and supporting documents will be uploaded in Teams – channel **Consortium Meetings** - folder **General Assembly** 21 days prior the meeting. Meeting minutes will be taken by PM and uploaded to the same folder 14 days after each meeting. Request for amendments to the meeting minutes or objections to the meeting minutes must be notified to the GA Chairperson within 2 weeks from the date that the representatives of the General Assembly receive written notice that the Meeting minutes have been uploaded in Teams. Attendance will be noted in Meeting minutes

3.6.3 SC Meeting Management and Documentation

The SC will meet at least quarterly. The SC will typically meet face 2 face twice a year; one of those meetings will be scheduled in connection with GA. The dates will be announced

in an annual cycle and/or the calendar function in Teams. The Agenda and supporting documents will be uploaded in Teams – channel **Consortium Meetings** - folder **Steering Committee** 14 days prior the meeting. Preparatory materials for the meeting (e.g. pre-reads) and traffic light reports from WP co-Leads shall be uploaded to the channel **Steering Committee** no later than 21 days prior the meeting. Meeting minutes will be taken by PM and uploaded to the same folder within 14 days after each meeting. Members of the SC will find the Meeting minutes in the tab Steering Committee Meeting minutes next to files.

Request for amendments to the meeting minutes or objections to the meeting minutes must be notified to the SC Chairperson within 2 weeks from the SC members receives a written notice that the Meeting minutes has been uploaded in Teams. Within three weeks after the first draft has been circulated among the SC members the Meeting minutes shall be uploaded in the channel **Consortium Meetings** – folder **Steering Committee** so that the meeting minutes are available for all Beneficiaries. Attendance will be noted in Meeting minutes.

If, in order to better meet the needs of the project, the Steering Committee is operating at an increased frequency, e.g. monthly, there may be adjustments/ reductions to these timelines however the same general practices will be applied.

3.6.4 Ethical & Legal Advisory Board (ELAB) Meeting Management and Documentation

The ELAB is composed of experts with detailed knowledge of ethical policies. ELAB is chaired by Petra Wilson, Coordination Lead for Ethical and Legal issues. ELAB consists of the Coordinator, Project Lead and three independent members accepted by the SC. The ELAB will meet upon request of the GA or the SC, but at least once every 12 months during the Action. Meetings will be organized and managed according to best practices such as those outlined for the conduct of the SC (e.g., timely notification of meeting scheduling, availability of relevant meeting materials in advance and further to the meeting following finalization). The annual technical report will include a synopsis of the issues, questions and concerns dealt with by the ELAB.

3.6.5 International Advisory Board (IAB) Meeting Management and Documentation

The IAB shall consist of at least 5 and not more than 15 members. Any Beneficiary may submit nomination for the membership of IAB to the SC. The IAB will meet upon request from the Coordinator and Project Lead, at least every 12 months during the Action, preferably in connection to the GA. Meetings will be organized and managed according to best practices such as those outlined for the conduct of the SC (e.g., timely notification of meeting scheduling, availability of relevant meeting materials in advance and further to the meeting following finalization).

3.6.6 Gravitate-Health Forum, Meeting Management and Documentation

The **Gravitate-Health Monthly Forum (GH Forum)** will act as the operational body and a driving force to keep the project running. It will discuss relevant issues and look ahead for upcoming activities. The GH Forum is open for all members of the consortium and enables communication across the consortium as a whole to share progress and discuss key topics. The GH Forum will meet regularly in line with project needs, initially at a monthly basis. Meeting dates will be announced in an annual cycle and/or in the calendar function in Teams. The Agenda and supporting documents will be uploaded in Teams – channel **Consortium Meetings**, folder **Gravitate-Health Forum** 2-3 days prior the meeting. Meeting Minutes will be taken by PM and uploaded in the same folder within 7 days after each meeting. Attendance will be noted in the Meeting minutes.

3.7 Reporting

3.7.1 WP progress reports – the "traffic light" overview

- The WP progress report, represented as a "traffic light" overview, shall be delivered bi-monthly, to give the Steering Committee a snapshot of the current situation. The traffic light report shall be uploaded in the **Channel Steering Committee**, folder Traffic light reports in due time before the SC meeting when the report is due, named **Gravitate-Health_WPX_RX_report_2021** (see Appendix VIII for example). When reporting please take a 6-9 months perspective on your reporting to ensure timely awareness of updates/changes. You may hide the columns not relevant for the report for ease of viewing.
- The WP bimonthly traffic light report shall be prepared according to the template that is uploaded in each **WPX** channel
- The WP traffic light reports will be set-up by PM, including WP-specific details, and uploaded in Teams - channel **Reporting** – folder **WP traffic light reports** for each corresponding year, named **Gravitate-Health_WP_congregated_RX_report_2021** in folder **2021 WP reports**

3.7.2 Deliverables

Deliverables are identified in Grant Agreement, Annex 1, section A, with details of the timetable and specified WP responsible. The deliverables should be produced considering the following points:

- Use the official template for preparing the deliverable, see Appendix I and the channel **Templates Gravitate-Health** in Teams
- Keep working versions of the Deliverable report in the concerned WP set up in Teams
- Upload the final version of the produced Deliverable – report to channel **Reporting** - folder **Deliverables and Technical report** - **Deliverables**
- Name of the deliverable according to the following structure:

  Gravitate-Health_DXX.YY _title_VX.X_final

Deliverables are reviewed and submitted by Coordinator at due date in Grant management portal.

3.7.3 Financial Interim reports – Horizon 2020 Beneficiaries

- The Financial Interim report shall be delivered per reporting period after month 6 in the reporting period. The Financial Interim report shall be submitted to **PMO@UiO** by **May 31st** each year
- The Financial Interim report shall be prepared according to the Gravitate-Health Financial Guideline that is uploaded in Teams – channel **Reporting,** folder **Reporting templates and resources**
- The report template to be used for the financial interim reports are uploaded in Teams - channel **Reporting,** folder **Reporting templates and resources.**
- The financial interim report from each public partner shall be submitted in Teams – channel **Reporting** – folder **Interim Financial reports 20XX** for each corresponding year, e.g. ***Gravitate-Health_Financial Interim report_PartnerName_2021*** in folder **Interim Financial reports 2021**

3.7.4 Annual technical and financial Reports to IMI

The Coordinator must submit to JU the periodic technical and financial reports set out on the following documents. The Project deliverables and reports comprise the outputs of the activity tasks of each WP; provided by WP co-Leads and Tasks Leads, as follows:

Periodic Project Reports - the periodic report and request for interim payments will be submitted by the Coordinator within 60 days of the end of each reporting period. The project is divided into five reporting periods, with the following duration:

- RP1: From M1 (01/11/2020) to M12 (31/10/2021)
- RP2: From M13 (01/11/2021) to M24 (31/10/2022)
- RP3: From M25 (01/11/2022) to M36 (31/10/2023)
- RP4: From M37 (01/11/2023) to M48 (31/10/2024)
- RP5: From M49 (01/11/2024) to M60 (31/10/2025)

For H2020 beneficiaries the deadline will be November 30th each year.

The PMO needs this time to go through the collected reports from all partners to collate the information from activities and write the technical report.

The periodic report to IMI from the Coordinator shall comprise:

> A) The *periodic technical report* contains **a narrative explanation of the work carried out** by the beneficiaries, **an overview of the progress** towards the objectives of the action, including milestones and deliverables (as described in Annex 1 in the Grant Agreement). It shall also **contain a summary for publications** by the JU, and answers to the **"questionnaire"**, notable in the context of the JU and the Horizon 2020 monitoring requirements. The Coordinator consolidates the contributions, to the WP8 deliverables D8.4, D8.5, D8.6 and D8.7.
>
> B) The *periodic financial report* contains **an individual financial statement** from each beneficiary and from each linked third party for the reporting period concerned, **an explanation of the use of resources** and **a periodic summary financial statement** created automatically by the electronic exchange system.

The Project Financial report will be prepared following the IMI templates for reporting in the Participant Portal. The templates are divided into categories according to budget.

The public partner reporting should also reflect private partner in-kind contribution.

The Beneficiaries shall provide the Coordinator their financial reports by Oct 31st, in each reporting period. They have 30 days from the Period end to submit their reports in the Grant Management portal so that project controller can go through the report and approve the report according to budget. Every partner is responsible for their own reporting, but since the Coordinator is responsible for the reporting to the JU, we will review the reports.

Final Reports: within 60 days after the end of the project the Final Reports will be submitted by the Coordinator. This final report shall comprise:

- The **final technical report**: this comprises a final **publishable summary** report covering results, conclusions and socio-economic impact of the project; an **overview of the results, the exploitation foreground** and plans for exploitation, as well as **all dissemination activities** of the project (publications, conferences, workshops, web sites/applications, press releases, flyers, articles published in the

popular press, videos, media briefings, presentations, exhibitions, thesis, interviews, films, TV clips, posters).

- The **final financial report**: this comprises the '**final summary financial statement**' (created automatically by the electronic exchange system), consolidating the individual financial statements for all reporting periods, and the **request for payment of the balance;** the '**certificate on the financial statements**' for each beneficiary.

Each (periodic or final) report shall be prepared by the Coordinator and the beneficiaries of the consortium together, by filling out the forms directly in the Electronic exchange system, i.e., "My Area" in the Participant portal.

3.8 Document preparation and quality review procedures

3.8.1 Deliverables and reports production and peer review process

The following **Deliverable preparation and Review Procedure** describe the actions and measures that will be taken by the Consortium, to ensure the high-quality level of the project outcomes and its full conformance with its contractual requirements. The **Deliverable Review Report** serves as internal quality control for deliverables to assure consistency and high standard for documented project results. The lead partner for the deliverable is responsible for assuring the initial quality control of the report, Review of the Deliverable. Review of each Deliverable is performed individually by two selected reviewers.

The scope of the Review procedure is to provide a guide for the actions required by each partner involved in the preparation of a Deliverable, and to establish a process for reviewing all Deliverables before submitting them to the IMI JU. This procedure should be used and followed by:

- All Consortium Beneficiaries responsible for preparing, contributing to or amending Deliverables.
- Any responsible person of a Consortium Beneficiary for approving work to be done by third parties, in order to complete Deliverables.
- Any external Expert responsible for reviewing or producing any project key Deliverable.

Review of each Deliverable is performed individually by two selected reviewers. The allocated time for the review is 5 working days. The author of the Deliverable has the final responsibility to reply on the comments and suggestions of the Peer Reviewers and decide what changes to the document and actions are to be undertaken.

The **Project** Consortium uses the **Deliverable Review Report** process for its internal review and quality control for deliverables to assure consistency and high standard for documented project results. The lead partner for the deliverable is responsible for assuring the initial quality control of the report and providing for the Quality Review of the Deliverable.

Unless otherwise specified or agreed, deliverables are prepared using the template provided in Appendix II. The lead partner for the deliverable is responsible for assuring the initial quality control of the report prior to hand-off for the formal Deliverable Review process, including content and presentation to the PCT. Additional support may be provided by the PMO in formatting/editorial review if needed. The Deliverable provided

for quality review should include the documents that have been used for produced for the achievement of the task provided as Appendices/Annexes

The Deliverable Review process is applied to the deliverables to assure consistency and the Deliverable Quality Review Report Template sets expected standard for documented project results. Each deliverable will be reviewed individually by two selected expert reviewers to be nominated by PCT and overseen also by a Coordination Lead (CL). The assigned reviewer will not be involved in the Deliverable preparation, in order to ensure neutral feedback (mandatory, best practice). It is not necessary that the Consortium reviewer is working directly in the project, i.e., it can be an employee/colleague of a Beneficiary who is working in the project.

The review is documented using the "Deliverable Quality Review Report" template (see Appendix II), which is divided into several sections to direct the reviewers' assessment of the deliverable content in general, including aspects such as thoroughness, correspondence to project and its objectives; relevance and the quality of achievements; quality of presentation (see Teams repository of template – Channel Templates Gravitate-Health), and format requirements, including the deliverable layout, format, spelling, etc.

The final rating of the Deliverable draft will be marked as:

- Fully accepted.
- Accepted with minor corrections, as suggested by the quality reviewers.
- Rejected unless major corrections are applied, as suggested by the quality reviewers.

Where the need for corrections is identified, the document is returned to the author who has the final responsibility to reply on the comments and suggestions of the Reviewers and decide what changes to the document and actions are to be undertaken in order to prepare the documents for the final review step by the Project Coordinator and Project Lead. Additional changes may be returned to the Author at this stage, prior to finalize the deliverable for submission to IMI. All reviewers (expert reviewers, Coordinator, Project Lead), document completion of their review by updating the Deliverable Quality Review Report with their name.

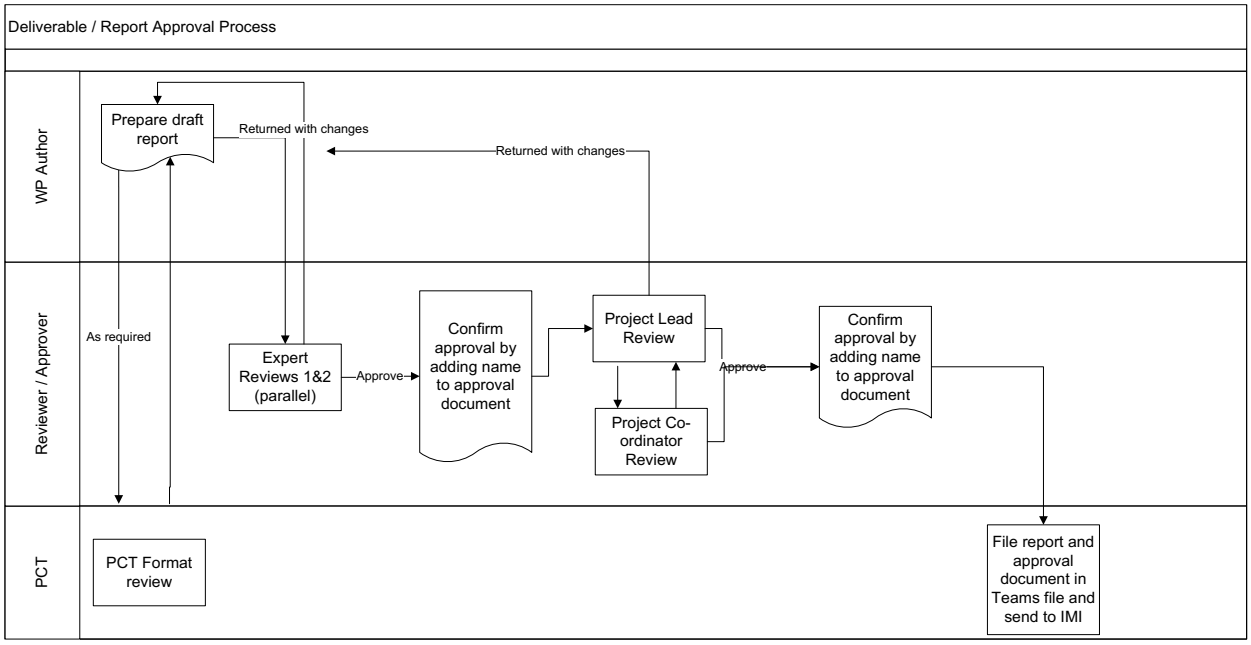


Figure 10. Deliverable/Report approval process flow

Note: Reviewers should in all cases express their opinion in a formal, objective and polite manner, as these reviews will be transmitted to the authors and could be also sent to the European Commission (by request).

Overall, we aim for an efficient review process and final preparation of each Deliverable, prior to Coordinator's submission to the IMI via the Participant Portal.

3.8.2 Document Format Style

The Gravitate-Health logo, the headings, fonts to be used and the Gravitate-Health color palette can be found in the channel **Templates Gravitate-Health**. The Deliverable Template (Appendix I) can be used as a guide. In order to ensure that all the project documents and presentations have a consistent quality and visual identity, the templates developed for Gravitate-Health shall be used for all internal and external communication. If there is a need for a Gravitate-Health template not found in the channel, please contact the PMO so that the missing template can be made.

3.8.3 Document Identifier

A unique document identifier to ensure effective version control must reference each document. The nomenclature is defined as: e.g.: "**D8.1_Gravitate-Health_Quality Management Plan_V1.0_Final**". This form of name is coupled to the file name: Deliverable number, project name, title and version number: e.g., final version should stand as Final.

3.8.4 Document History

The document history shows examples of different stages and reviews of the contractual document, either a report or deliverable. Sometimes the draft V0.2 would be approved already and be upgraded to V1.0. Sometimes one draft would go several rounds between different levels with comments, suggestions and amendments before the V1.0 (for instance within a Task group before reviewed by the whole WP). The document history comprises the following tables with respective information.

Table 7. Example of document history table

Version	Date	Description	Editor	Status
V0.1	DD/MM/YYYY	Document creation	Full name of author /editor	Draft
V0.2	DD/MM/YYYY	Edited or review by WP co-Leads	Full name of author /editor	Draft
V0.3 or higher depending on rounds of review before this stage	DD/MM/YYYY	For review by the Coordinator and Project Lead	Full name of author/editor	Draft
V1.0	DD/MM/YYYY	Final approved version	Full name of author /editor	Final
V2.0	DD/MM/YYYY	Approved updates to V1.0 version of Deliverable	Full name of author /editor	Final

Versioning of the document will start in 0.1 Creation of the document. The working versions among partners will add by 0.1 (e.g., draft version will be 0.2). The versioning will increase by 0.1 each time that the comments and suggestions from either Task Leads (the document might be reviewed within the Task group before the whole WP) or WP co-Leads (some WPs are large enough to be an Action in themselves). After being reviewed by the WP co-Leads, the document will be sent for review by the Coordinator and the Project Lead.

When comments and feedback are integrated from the Coordinator and Project Lead the versioning will increase with 0.X depending on the number of earlier rounds of review. It will first change to V1.0 when the document is considered final and ready for approval by the Coordinator and the Project Lead. The document reaching V1.0 should be a quick and final check from the Coordinator and Project Lead.

CONCLUSIONS

This **Quality Management Plan (QMP)** outlines the project's organizational structures, governance model, management procedures, internal quality processes and collaboration platforms/tools that have been defined in order to enable the consortium to work effectively, deliver on its objectives. The QMP will ensure that the work conducted and the project's Deliverables are of the highest standard and in compliance with all relevant best practices, standards and ethical/legal requirements.

It is an expectation that all members of the consortium will be aware of and implement the procedures and practices set out within this plan.

Appendix I: Deliverable Template

The official template to be used for preparing all the project deliverables is found in Teams – channel **Templates Gravitate-Health.** The structure of this template is the following:

Cover

It includes information about the deliverable such us title, due date, delivery date type of deliverable and dissemination level (see Figure 11).

Sections

The deliverables should have the following sections (some of them are optional):

- Document History
- Table of Contents
- Document Info
- *List of Figures (optional)*
- *List of References (optional)*
- *Acronyms (optional)*
- Executive Summary
- *References (optional)*
- *Annexes (optional)*

Gravitate-Health

WPX – WP Title

DX.Y Deliverable Title

Due date	dd/mm/yy
Delivery date	dd/mm/yy
Deliverable Type	e.g. R (see DoA)
Dissemination Level	e.g. PU (see DoA)

Lead contributor	Organisation Number & Short Name, Authors' name

Other contributors	[Please include all organisations involved in this deliverable] Organisation Number & Short Name, Contributors' name

The project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 945334. This joint undertaking receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Associations [EFPIA]. The total budget is 18.5M€ for a project duration of 60 months.

Figure 11. Deliverable cover

Appendix II: Deliverable Review Report Template

The official template to be used for preparing all the project deliverables quality reviews is found in Teams – channel **Templates Gravitate-Health.**

Deliverable Review Report

Deliverable No. and title	Dx.yy Title
Work package No.	WPx
Task No. and title	Tx.z Title
Review Organization and name	
Date of Review	
File Name	Gravitate-Health_Partner_ReviewerName_Dx.y_vx.x.doc

Overall Peer Review Result:

Deliverable is:

☐ Fully accepted	☐ Accepted with minor corrections, as suggested by the reviewers	☐ Rejected unless major corrections are applied, as suggested by the reviewers

Approver 1:	Approver 2:	Project Coordinator	Project Lead

COMMENTS OF DELIVERABLE REVIEWERS

(Please note that they will be transmitted to the author and the Coordinator).

The PCT will work with the Coordination – Leads to identify two reviewers pr. Deliverable, and will notify the Steering Committee member in advance of the planned review schedule.

The Deliverable Review expectation is to assess the deliverable from a content expert perspective, in order to convey key comments and perspectives on the subject matter to the consortium members and the IMI appointed reviewers. We expect maximum one page of text in total, using the scheme below:

General Comments on the Deliverable, e.g., clarity and comprehensiveness
Relevance and Quality of achievements, e.g., content clarity
Correspondence to project, work package and task objectives

The Lead partner for the deliverable is responsible for appropriately addressing all concerns coming from the Quality Review process, prior to hand off the Deliverable to the Coordinator for submission to IMI.

Figure 12. Template for deliverable review

Appendix III: Central Risk Registry Document template

Table 8. Risk registry sheet

Risk Identifier	Date	Description	Impact (H/M/L)	WP(s) Impacted	Mitigation	Responsible Person	Status (open / closed)	IMI Notified (Y/N)
RI-0001								
RI-0002								
RI-0003								

Appendix IV: Work Package Risk Log

Table 9. WP Risk Log

Risk / Constraint	Impact Description / (H/M/L)	Mitigation

Appendix V: Central Change Management Register

Table 10. Change management register sheet

Change Identifier	Date	Description and Justification	Deliverable / Task / Milestone impacted	WP(s) Impacted	Responsible Person	IMI Notified (Y/N)
CM-0001						
CM-0002						

Appendix VI: Change Request Form

CM Reference: CM-XXXX

CHANGE REQUEST FORM

Requestor	
Work Package	
Date	

Detail of Change:

What is being impacted? (WP or task scope, deliverables. Milestones, timings, budget, resource)	
Description of change	
Justification for Change	
Impact to project (including dependent WP activities)	
Does this change introduce a new risk? Define.	

Approvals:

Role	Name	Date
WP Lead Requesting Change		
WP Lead Impacted by Change		
Project Lead		

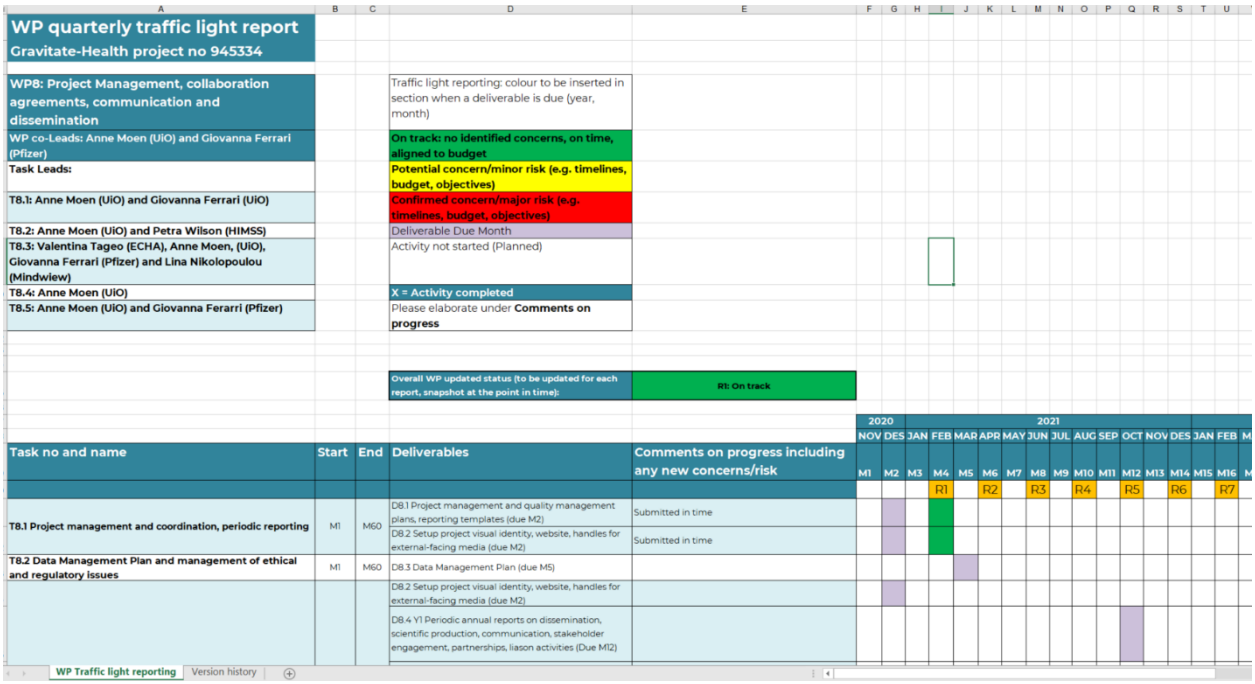
Figure 13. Change request form

Appendix VIII: Decision Log per WP

Table 11. WP decision log

Decision	Rationale	By Whom	When	Who should be informed?

Appendix VIII: Traffic light report



WP quarterly traffic light report
Gravitate-Health project no 945334

WP8: Project Management, collaboration agreements, communication and dissemination	Traffic light reporting: colour to be inserted in section when a deliverable is due (year, month)
WP co-Leads: Anne Moen (UiO) and Giovanna Ferrari (Pfizer)	On track: no identified concerns, on time, aligned to budget
Task Leads:	Potential concern/minor risk (e.g. timelines, budget, objectives)
T8.1: Anne Moen (UiO) and Giovanna Ferrari (UiO)	Confirmed concern/major risk (e.g. timelines, budget, objectives)
T8.2: Anne Moen (UiO) and Petra Wilson (HIMSS)	Deliverable Due Month
T8.3: Valentina Tageo (ECHA), Anne Moen, (UiO), Giovanna Ferrari (Pfizer) and Lina Nikolopoulou (Mindwiew)	Activity not started (Planned)
T8.4: Anne Moen (UiO)	X = Activity completed
T8.5: Anne Moen (UiO) and Giovanna Ferarri (Pfizer)	Please elaborate under **Comments on progress**

Overall WP updated status (to be updated for each report, snapshot at the point in time):	**R1: On track**

Task no and name	Start	End	Deliverables	Comments on progress including any new concerns/risk
T8.1 Project management and coordination, periodic reporting	M1	M60	D8.1 Project management and quality management plans, reporting templates (due M2)	Submitted in time
			D8.2 Setup project visual identity, website, handles for external-facing media (due M2)	Submitted in time
T8.2 Data Management Plan and management of ethical and regulatory issues	M1	M60	D8.3 Data Management Plan (due M5)	
			D8.2 Setup project visual identity, website, handles for external-facing media (due M2)	
			D8.4 Y1 Periodic annual reports on dissemination, scientific production, communication, stakeholder engagement, partnerships, liason activities (Due M12)	

2020: NOV DES | 2021: JAN FEB MAR APR MAY JUN JUL AUG SEP OCT NOV DES JAN FEB

M1 M2 M3 M4 M5 M6 M7 M8 M9 M10 M11 M12 M13 M14 M15 M16

R1 R2 R3 R4 R5 R6 R7

WP Traffic light reporting | Version history

Figure 14. WP quarterly traffic light progress report