101005177 – COVID-RED

COVID-19 infections - Remote Early Detection

WP7 – Project management, coordination, and sustainability

D7.1 Project management plans: Project handbook

Lead contributor	1 UMCU
Other contributors	N/A

Document History

Version	Date	Description
V1.1	30/07/2020	Draft 1st version
V1.2	27/11/2020	Final version
V1.3	26/02/2021	Final version with fast track for reviews

Abstract

COVID-RED is a public-private partnership, funded by the Innovative Medicines Initiative running from 1 July 2020 until 1 January 2022 under GRANT AGREEMENT NUMBER 101005177. This project is composed by a multi-stakeholder approach with 9 beneficiaries (Annex 1 of Consortium Agreement). The overall goal of COVID-RED is to change the current paradigms combining clinical epidemiologic strategies with digital health approaches in order to detect early symptomatic cases triaging for medical care, efficiently allocating testing capacity and ultimately reducing the time-to-detection of new COVID-19 cases and limiting the risk of disease spread and contamination and improving prognosis for patients. To achieve this, this project presents the first European clinical and digital epidemiology efforts including large cohort studies, digital devices (wearables and mobile app), and PCR and antibody testing to allow a fast and reliable detection for COVID-19 carriers and symptomatic individuals suspected of COVID-19 infection.

The present document aims at providing an overview of the management and administrative procedures and principles that will ensure an efficient execution of the COVID-RED project and thus contribute to the production of high-quality project results.

Contents

Introduction

The main objective of Work Package 7 (WP7) Project management, coordination, and sustainability is to house all project management and coordination activities, including facilitating project governance activities, internal communications and project meetings. The WP will help assure that the consortium's contractual duties are carried out. A special area of focus is assuring that collaboration between the WPs is optimized. In addition, the Work Package is responsible for activities around the sustainability of the results of the project.

In order to fulfil the project management objective, the PMO has developed a project handbook that, in combination with the Description of Action (DoA), forms the core of the project management plans for COVID-RED Initiative. The manual describes the structure, key processes, roles and responsibilities of the management bodies and decision-making supporting the COVID-RED consortium.
The established procedures are based on the general principles and policies set up in the grant regulations and official guidelines under the IMI2 Programme (Grant Agreement and its annexes, Consortium Agreement). The procedures set up in this document must be understood as a starting point although these procedures may be adjusted as the project evolves.

Effective project management implementation is key to the success of COVID-RED Initiative.
The project handbook will be made available to the main management bodies and relevant stakeholders of the consortium.
Special attention will be paid to ensure that project results are delivered in due time, within budget and considering the formal quality standards developed for the project.

1. Basic project information

Project acronym: COVID-RED
Full project title: COVID-19 infections - Remote Early Detection
Grant Agreement Nº: 101005177
Call: H2020-JTI-IMI2-2020-21-single-stage
Project start date: 1 July 2020
Project end date: 31 December 2021
Project duration: 18 Months
Project budget: € 10,329,253.75
EU Contribution: € 9,592,028.75
EFPIA in-kind contribution: € 637,225.00
Project officer: Magda Gunn

Project logo(s) *(all logos can be downloaded from the member area: General > Consortium information > Communication > Logos):*

1. Project coordination and management

WP7 (project management, coordination, and sustainability) aims at ensuring a proper execution of the project. As project leads, UMCU and Roche will be responsible for running an effective project management for the COVID-RED consortium, which includes:

- overall coordination and management of the project;
- keeping track of the project schedule and budget;
- report on project progress along milestones and deliverables deadlines;
- holding track of project-level risks and developing the necessary risk-mitigation measures;
- coordination of the periodic technical and financial reporting;
- dealing with legal issues and contract management to ensure EC requirements and IMI 2 JU regulations are met;
- support other WPs and cross WP activities where possible and facilitate collaboration between partners and external parties;
- establish Governance in different bodies;
- In this task overall project coordination and management as well as legal and financial matters are safeguarded.

Coordination and management structure

The coordination and management structure of COVID-RED consists of several components:

- General Assembly (GA)
- Managing Board (MB)
- Management Team (MT)
- Project Management Office (PMO)
- External Advisory Board (AB)
- External stakeholders
- IMI Office

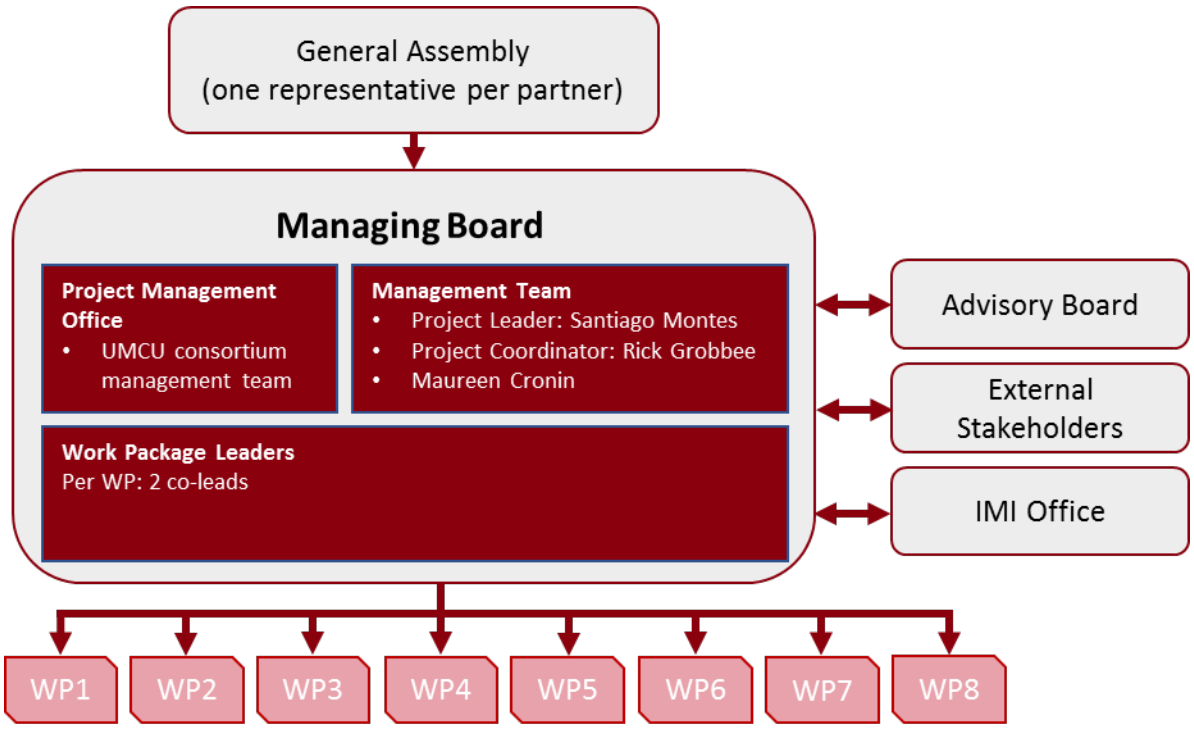


Figure 1 COVID-RED governance structure

General assembly (GA) is the highest managerial level and consists of representatives of all partners. The GA consists of representatives of all Beneficiaries, with each Beneficiary having one vote in the GA.The GA is responsible for decision making on issues on the strategic-project level. This includes decision making on issues such as (but not limited to) changes in the consortium partners (new partners or replacement of partners), changes in the overall objectives or approach of COVID-RED, conflicts between partners or changes in the composition of management bodies. The GA makes decisions preferably by consensus and if necessary by majority vote, as further explained below at 'Meetings and decision-making' and in the Consortium Agreement (section 11.3.4, page 36).

The **Managing Board (management team and WP leaders)** (MB) is responsible for making management decisions regarding the work within COVID-RED to ensure the effective running of the project. The Managing Board ensures overall project progress and integration of the recommendations into reports to the European Commission. The PMO will join all MB meetings for administrative issues but has no voting rights.

The **Management Team** (MT) is the day-to-day decision-making and management body. The MT's main responsibility is to oversee the project's progress and provide a forum for discussions on the strategic orientation and development of the project. The Management Team is made up of the project leader (Roche) and project coordinator (UMCU), the project management office, and representatives from Julius Clinical and Ava.

The **Project Management Office** (PMO) is based at the UMCU. The main tasks of the PMO include providing financial-administrative and managerial support to the overall project, as described in WP7. This includes (but is not limited to) internal technical and financial progress reporting, progress reporting as well as the preparation, implementation and follow-up of consortium meetings and maintenance of the Consortium Agreement. The PMO is responsible for the development and maintenance of project management plans and will maintain effective communication with all the COVID-RED participants and keep an overview of any potential conflicts of interest. Day-to day management of the work packages takes place at the work package level under the supervision of the Work Package Leaders.

The **WP Leaders** (WPLs), two participants per work package, are responsible for day-to-day management and coordination of the activities in their WP.

The WPLs inform the Managing Board about the scientific progress in their respective WP as well as possible barriers and potential improvements. This interaction will assure continuous synergy between the specific WP tasks and the project as a whole.

The main responsibilities of WPLs are:

- Coordinate and undertake all necessary day-to-day acts of management with respect to their WP in line with the Description of Action.
- Make decisions at a WP level on operational, scientific and functional aspects
- Instruct their WP Participants of due dates for deliverables and collect their supporting documents
- Organise technical meetings with the Participants in the WP
- Seek to ensure effective communication within the WP and with the MB
- Collaborate with the other WPLs to provide information regarding the progress of the WP

An **Advisory Board** (AB) will be installed. The AB is the independent consultant body for the management of the consortium. We aim to install a diverse AB specialised in relevant scientific and ethical fields. The AB does not have decision authority in the project but will provide advice and feedback on the activities and results of COVID-RED.

Meetings and decision-making

Meetings

The PMO is responsible for the planning, organising, executing and post-processing of major project meetings, such as the consortium/general assembly annual meetings, managing board meetings, management team meetings, as well as meetings with other IMI consortia and other adjacent projects. On request and in collaboration with WP6, the PMO will facilitate the organisation of external stakeholder meetings.

WP leads hold the responsibility of planning, organising and executing the meetings within their respective WPs.

Meeting frequency

- Management Team/PMO: every two weeks (TC)
- Managing board: Bi-monthly (TC/F2F)
- Consortium/General Assembly Meeting: Yearly F2F and/or TC (April/May)
- Stakeholder meeting: upon request
- Work Package: TBD by the WP leads

Due to the continuing COVID-19 crisis, we expect all consortium meetings to be virtual.

The PMO, supporting the project leader/coordinator, will aim at setting dates for the yearly GA meetings sufficiently in advance and notify the consortium members as soon as possible.
An agenda will be made available as soon as possible but at least 7 days before the meeting. Meeting minutes of both the annual meeting and all the managing board meetings (including TCs) will be made available within 14 days after the meeting on the member area in the designated folder.

Meeting minute template
The PMO drafted a template for meeting minutes (
Tendering procedure (incl. subcontracting)

When subcontracting or outsourcing to third parties or vendors, beneficiaries are urged to consult the latest version of the Annotated Model Grant Agreement provided by IMI (https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/Annotated_Model_Grant_Agreement–AGA.pdf).

Especially the section on third party resources on page 129 (Article 7), page 137 (Article 10 on the purchase of goods works or services) and page 147 (Article 13 on subcontracting).

As a general principle, the beneficiaries must base their purchases either on the best value for money (considering the quality of the service, good or work proposed, i.e. the best price-quality ratio) or on the lowest price.

The best value for money principle does NOT in all cases require competitive selection procedures. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is NOT automatically necessary to select the offer with the lowest price. Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Annex I - Meeting minutes template). For constancy purposes, it is encouraged to use this template for all COVID-RED meetings and post them on the COVID-RED space.

Decision-making

In principle, decisions should be made by consensus. In case consensus cannot be established a vote will be deciding.

General Assembly

Each partner in the Consortium Agreement has one vote in the GA meetings. For a valid and binding vote at least 75% of the beneficiaries should be present. Beneficiaries who cannot attend the meeting would have to arrange to be represented.

When a decision is circulated in writing, the beneficiaries will be given 14 days to reply, and will be considered approved after the deadline.

Each Beneficiary will, through its Representative, have one vote in the General Assembly. Decisions will be taken by a majority of sixty (60) percent of all Beneficiaries , except where a decision necessitates a major change to the Allocated Work or a change to the allocation of any funding. In either of those cases, any decision must be unanimous. The Coordinator will inform the IMI2 JU of any such decision. The Chairperson of the General Assembly will have a casting vote.

Managing Board

Each member of the managing board has one vote in the meetings.

By exception, where a decision necessitates a major change to the Allocated Work or a change to the allocation of any funding, such decision must also have the approval of the Beneficiaries whose Allocated Work or funding is changed.

as well as, the project leader and project coordinator. Decisions will be taken by a simple majority and the chairperson shall have the casting vote. The MB will chaired by the project lead or project coordinator in alternation.

Conflict resolution

If an internal conflict arises at any given time it is encouraged to handle the conflict in a bottom-up approach: task lead, work package lead and management structure.

- Conflicts between participants in any given task will be dealt with by the corresponding task leader, in the first instance.
- If task leaders are not able to reach an agreement or in case of conflict of interest, the issue will go up the hierarchy to the WP-Lead level.
- If needed, WPL will upgrade the conflict to the MB level, where a binding decision may be made.
- The MT may assist in conflict resolution, providing an analysis of the situation and using bilateral contact with participants involved, negotiation and mediation to solve the conflict, promoting consensus and proposing solutions at the relevant level.

2. Communication

A communication plan is being developed by WP6 and 7 which all have important communication tasks. This plan can be found in the deliverable reports for D7.10, D6.1 and D6.9. An overview of the different communication channels, both for internal and external communication, can be found in the tables below.
Pleases see table in next page for details.

Table 1. COVID-RED Target Audiences/Stakeholders

Audience/Stakeholder	Communication requirements
External	
Study participants	Specific requirements for participants in the study will be determined. General requirements include being informed of project progress, including study protocols, major findings, and any changes to the study.
Patients (including those with and those at risk for COVID-19)	Keep informed of project concept, progress, and outputs via relevant patient organizations (who may set up their own communication activities in which COVID-RED participates). Patients will also have direct access to publications, webinars, website updates and newsletters.
Patient & disease specific organizations	Establish frequent and efficient contact with overarching patient and disease specific organizations where appropriate to keep them informed of the progress of COVID-RED and any major project developments, e.g. via publications, webinars, website updates and newsletters.
Health-care providers and clinical researchers	Keep periodically up to date on project progress through publications, public webinars, website updates, and newsletters.
Healthcare provider organizations (including HCPs)	Keep periodically up to date on project progress through publications, public webinars, website updates, and newsletters.
Members of Ethics boards	Keep periodically up to date on project progress through publications, public webinars, website updates, and newsletters. Targeted communications re: specific outputs on ethical and related issues from WP8
Healthcare payers/insurers	Keep periodically up to date on project progress through publications, public webinars, website updates, and newsletters.
Industry R&D, Pharma, and related institutions	Keep periodically up to date on project progress through publications, public webinars, website updates, and newsletters.
Funding and "parent" organizations	Require submission of deliverables (reports etc.) and reports as scheduled in the project DoA, as well as 'success stories' and impact of project outputs COVID-RED to participate in communications and presentations organized by these organizations to showcase IMI projects
Media and (targeted) general public	Keep periodically up to date on project progress through publications, public webinars, website updates and newsletters.
Internal	
COVID-RED leadership and consortium management team	Need regular updates on WP activities and progress, including draft project outputs for review and approval WP leaders to drive topics and identify potential interviewees or speakers for webinars and podcasts
COVID-RED partners	Need to be updated on project activities and deliverables: Input sought from project partners on activities completed in the last

	quarter or where input from other WPs is needed. Project partners will update their own organizations on project activities and deliverables
Incoming communications from stakeholders	COVID-RED project partners will use various channels to seek input from stakeholders into the environment, planned activities such as the study, project outputs, and their communication to generate the most impact

Table 2. COVID-RED communication channels

Channel	Description
External	
COVID-RED website	The website is an important window into the project, housing original content generated by project partners
Journal publications	To be developed and submitted by internal project partners. Links to publications, summaries of content (abstracts), and full manuscripts (where permitted) will be made available on the COVID-RED website
Conference presentations	To be developed and submitted by internal project partners. COVID-RED will maintain a register of project presentations.
Press releases	Project members are encouraged to highlight major project events such as meetings, completion of key deliverables, presentations, and publications through a press release. All press releases need to be reviewed by COVID-RED project management to ensure that they are written in line with the key messages of the project. All press releases will be made available on the COVID-RED website.
Stakeholder engagement	Reaching out to scientific, clinical, and patient-focussed stakeholders to: participate in consortium quarterly meetings, engage in discussion with research partners, and develop specific activities such as specialized workshops for the discussion of specific issues.
Academic Collaborations	Collaborations with other relevant European projects to maximize the impact of EU funded research
Internal	
Monthly core meetings	A monthly opportunity for all core team members to meet in an online space and discuss overall progress and progress within each WP.
Quarterly project meetings	A regular opportunity for all project partners to meet in an online space and discuss overall project progress
Project reports	Internal dissemination of project results and protocols for review and revision among partners
“Kick-off” meetings	A series of online meetings at project initiation to allow all partners to present and discuss their role and progress within the project.

Table 3. Proposed communication activities

	Proposed channels	Target audience	Content	Frequency	Proposed metrics
Digital tools	External website, project-unique logo, and templates	Consortium partners and all relevant stakeholders	Regular updates; news and upcoming events	Major milestones	Number of new visitors, number of returning visitors, number of page views

Written formats	Scientific publications, white papers	Scientific community. Industrial partners and regulators	Relevant scientific outcomes	At least once during the project duration	Impact factor, number of citations,
	Content marketing/press releases/newsletters	All stakeholders	Updates; major milestones	Major milestones	Media coverage
Events and meetings	Internal and consortium meetings	Consortium partners and relevant stakeholders	Project progress	At least annually	Number of participants
	External conferences	Clinicians, SMEs, and other industrial partners, regulatory bodies	Project progress	At least 2 times during the project duration (depending on whether such conferences will take place)	Number of conferences
	Webinars	All relevant stakeholders	Updates; major milestones	Major milestones	Number of views/shares/likes
Social media	LinkedIn, Twitter, YouTube	All relevant stakeholders	Project progress	Major milestones	Number of posts/tweets; number of followers/ shares/likes/ retweets

Confidentiality

See Article 36 of the Grant Agreement and the Article 10 Consortium Agreement for information on confidentiality within the project.

Mandatory acknowledgement when communicating externally

All dissemination and communication activities should include a full project acknowledgement. In case of restricted space, partners are allowed to use an abbreviated version of the acknowledgement. The acknowledgement logos can be downloaded from the COVID-RED member area.

Full acknowledgement	The COVID-RED project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 101005177. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.
Abbreviated acknowledgement	This work has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking COVID-RED grant n° 101005177.

Templates for external communication

A COVID-RED PowerPoint template (empty and with general introduction to the project) and template for the deliverable reports can be found on the member area. When new templates are developed, these will be placed there as well.

Dissemination of project results

Definition of dissemination: The public disclosure (through journal articles, editorials and review articles, abstracts, posters and presentations at conferences, webinars and press releases, etc.) of project results.

The PMO has developed a Publication Policy, included in Annex 5. This policy is in line with the obligations set out in the Grant Agreement and Consortium Agreement. For more detailed information about the dissemination procedure please refer to the publication policy. In general, keep the following in mind:

1. Dissemination should always include a written acknowledgement and the acknowledgement logos
2. The COVID-RED logo should be depicted independent from the acknowledgement logos.
3. Where dissemination concerns a peer-reviewed scientific publication, every author must ensure open access (free of charge online access for any user) within six months of publication.
4. Authorship of peer-reviewed scientific papers should comply with ICMJE guidelines for authorship.
5. The dissemination activity needs to be reviewed by the General Assembly before submission (see 'Internal review procedure' below).
6. Authors must contact the GA themselves (email template available in the publication policy).
7. For reporting purpose, all dissemination is tracked by the PMO. Please, provide the PMO (covid-red@umcutrecht.nl) with the final version of your dissemination.

Internal review procedure

Before the public dissemination is allowed, the dissemination activity/document needs to be reviewed by the GA. A schematic overview of this procedure can be found on the next page (Figure 2). This overview is a summary of the procedure is based on the Grant Agreement and COVID-RED Consortium Agreement.

Schematic overview:
COVID-RED internal review procedure for dissemination of results

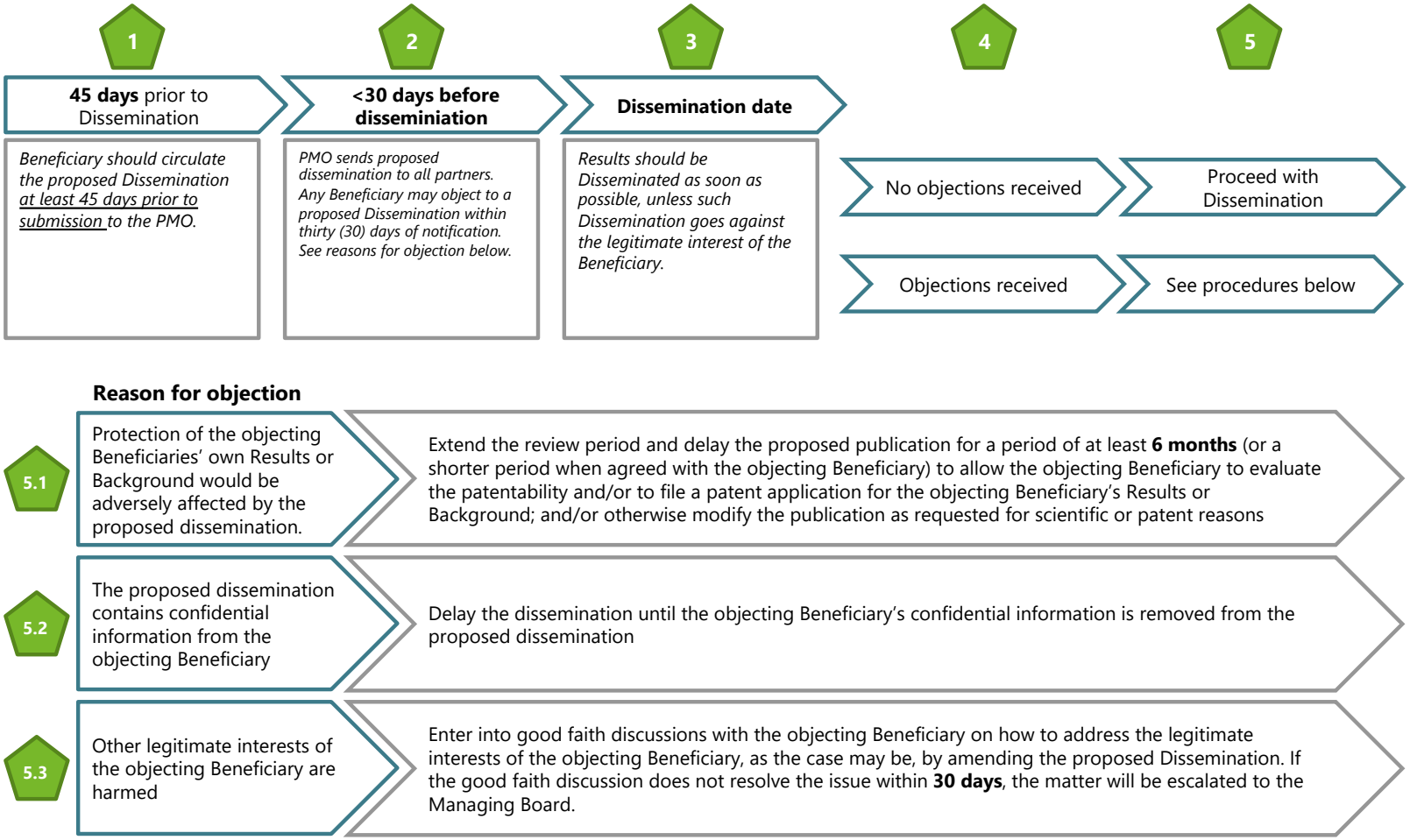


Figure 2 Schematic overview of the internal review procedure for all dissemination activities

External communication about project

Definition: All other external communication activities about the project or on behalf of the project other than dissemination (disclosure of results).

Most of the time the purpose the communication activity is to increase the visibility of the project. Examples of activities are presentations to external organizations (e.g. organisation or parties with no contractual relation to the project or a beneficiary), print of flyers or booklets, the launch of social media accounts and so on. Review for these activities is carried out by the Project Management Office (PMO) and the Management Team (MT) which will inform the IMI Communications team if needed. If possible, send your communications materials one week before exploitation to covid-red@umcutrecht.nl. When this is not feasible, please provide your materials as soon as possible after exploitation.

3. Reporting

Overall reporting process

Throughout the entire project (i.e. from 1 July 2020 until 31 December 2021) the consortium is supposed to submit, on time, multiple deliverable reports and one periodic report. The project is divided into 1 reporting periods of 18 months. Therefore, the first periodic report will also be the final report. After the period, the consortium has 60 days to complete the periodic report and needs to report on the progress. Additionally, the non-EFPIA partners need to complete a financial statement as part of the period report and provide this directly to EFPIA. More information on the period report can be found below.

Periodic reports/Final report

Periodic reports have to be submitted to IMI2 JU within 60 days after the end of each reporting period. The coordinator will, in close collaboration with the PMO, take the lead in completing and submitting the period report on time and will request input from the beneficiaries and work packages where necessary. The period report comprises of the following segments:

1. Summary for publication
    a. Summary of the context and overall objectives of the project
    b. Work performed during the reporting period and main results achieved so far
    c. Progress beyond the state of the art, expected results until the end of the project and potential impacts
    d. URL of project's public website
    e. Project logo
2. Deliverable reports due during or before the reporting period
3. Milestones due during or before the reporting period
4. Risk assessment
    a. Foreseen risks
    b. Unforeseen risks
5. Publications
6. Dissemination & Communication Activities
7. Patents
8. Innovation
9. SME impact
10. Open data
11. Gender
12. Technical Report (additional information below)
13. Financial Statement (additional information below)

Technical report

As mentioned above, the technical report is part of the periodic report and has to be completed

every reporting period. The technical report based on the IMI2 template and has 5 main sections:

1. Explanation of the work carried out by the beneficiaries and overview of the progress
   1.1. Objectives
   1.2. Explanation of work carried per WP
   1.3. Impact
   1.4. Consortium management
   1.5. Collaborations/synergies with other initiatives
2. Update of the plan for exploitation, dissemination and sustainability of results
3. Update of the data management plan
4. Follow-up of recommendations and comments from previous review(s) (if applicable)
5. Deviations from Annex 1 (=Description of Action) (if applicable)
   5.1. Tasks
   5.2. Use of resources

The PMO will reach out to every work package to provide input for the technical report. More detailed information on the requested input will follow in due time but in general, input is requested on '1.2 Explanation of the work carried per WP (approx. 1 page excluding figures/tables)', '1.5 Collaborations/synergies with other initiatives' and '5. Deviations from Annex 1')

Financial reporting

Please note the financial report is different for public partners and EPFIA partners.

Public partners

All the participant contacts of an organisation will receive an automatic notification from the Funding & Tenders Portal that reporting for the COVID-RED project has opened and that it is possible to enter your financial information in the system. Please keep the following in mind:

- All beneficiaries complete their own financial statement in the Funding & Tenders Portal, electronically sign it and submit it to the Coordinator. Users who can fill in the statement are Participant Contacts, Project Financial Signatories and Task Managers. Only the Project Financial Signatory (PFSIGN) can electronically sign and submit the statement in the system. Please make sure you have assigned a PFSIGN user role to your project in your organisation. The LEAR of your organisation can appoint PFSIGN user roles to the right people.
- The financial statement should cover the eligible cost from the previous reporting period.
- All costs must be declared **excluding VAT**, unless your institution is not able to recover VAT, in which case you will have to provide a relevant attestation issued by national VAT administration stating that you are not able to recover VAT.
- Conversion into euro costs incurred in other currencies shall be made at the monthly accounting rate established by the EC and published here.
- For a technical description of setting up your financial report in the Funding & Tenders Portal please to refer to this document (page 43-53). Also, the H2020 online manual provides additional information on the financial report.

EFPIA partners

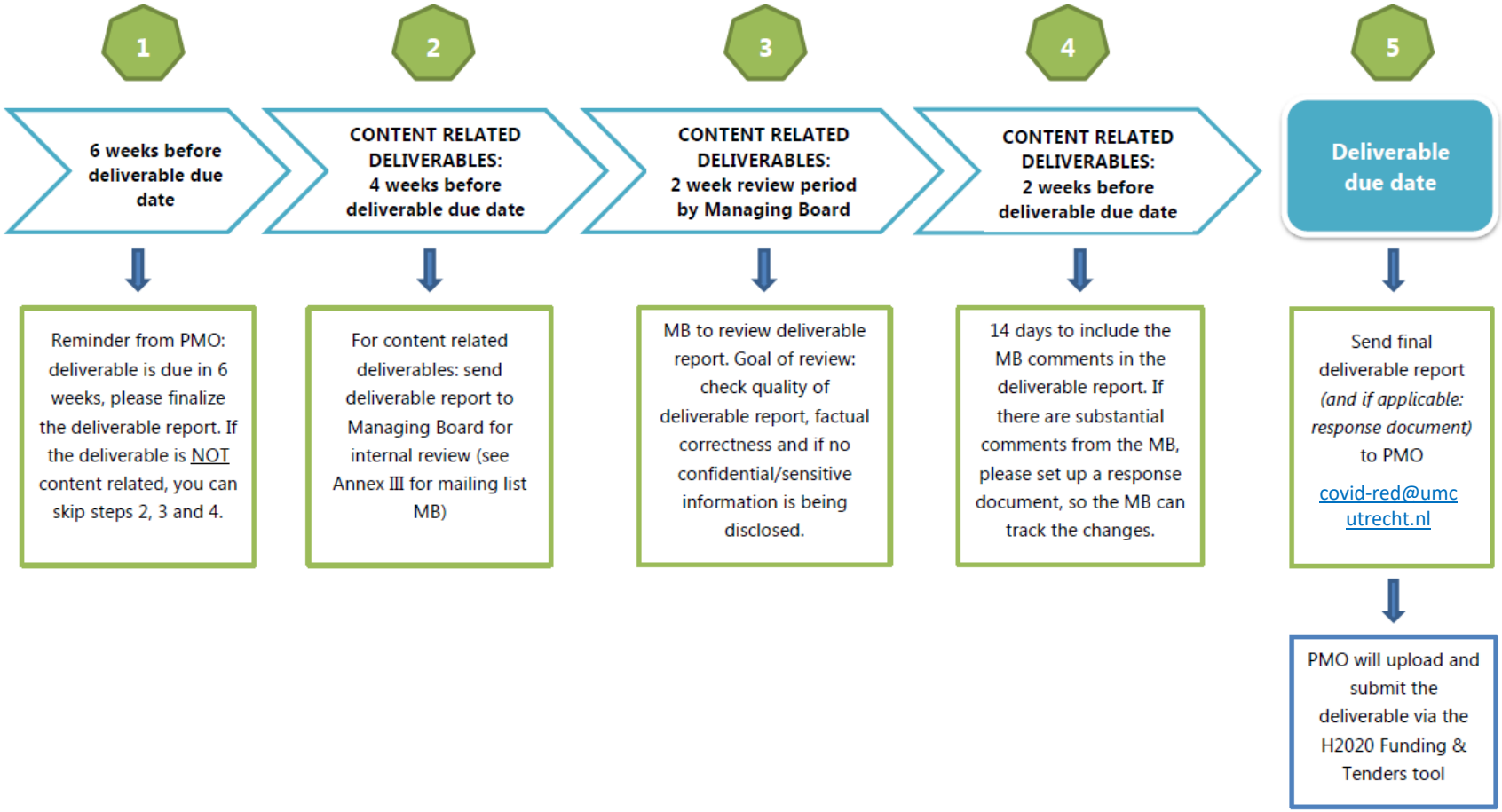
The financial statement for EFPIA partners happens independent from the period report and will be done by calendar, instead of project, year. Please contact your own IMI/Grant office for additional information.

Deliverables

Continuously over the course of the project, the consortium has to write and submit multiple deliverables. The due dates of the deliverables are stated in the DoA. In addition, for quality assurance, the so-called 'content-related' deliverables will be reviewed by the Managing Board. The PMO created a tracking document about the deliverables, their due dates and whenever the Managing Board will review the report (see D7.3). *Please note, for public deliverable reports, they should not contain any confidential information.*

A schematic overview of the review- and submission procedure for deliverable reports can be found on the next page (Figure 3).

Figure 3 Schematic overview of the submission and review procedure for deliverable reports



Delays

Whenever a deliverable report is delayed please inform the PMO (covid-red@umcutrecht.nl) as soon as possible with a brief justification and the new expected submission date. The PMO and MT will assess if the delay affects other tasks and, when necessary, inform IMI2 JU via the Funding & Tenders Portal.

4. Risk management

Main objectives

The main objectives of risk management are to:

- Provide visibility and raise awareness of uncertainties that may affect the project development and/or results
- Allow the project to focus on major risks by appropriate assessment and prioritisation according to risk severity, a value that results of combining the estimated likelihood and impact values for any given risk
- Proactively manage uncertainties that can affect the project performance, schedule and/or budget, with proper feedback channels to project management
- Continuously monitor the evolution of risks throughout the project
- Appropriately document risks, activities and decisions made

Risk management procedure

Risk management is performed by the PMO with a continuous contribution of the MT and MB. Nonetheless, risk management activities benefit from the participation of all involved parties. Therefore, open communication that allows contribution from all participants involved is encouraged. The risk management process can be summarised as follows:

1. A risk is detected by a consortium member, which can be WP leader (WPL) or not
2. The WP leaders of the associated WP will introduce the risk in the bi-monthly MB meeting and the MB will assess the risk *(when an acute risk arises the risk owner can contact the MT directly. The MT will assess the risk in their weekly meetings).*
3. During the assessment, the following topics will be addressed
    - Type of risk; Threat to successfully achieve project objects OR Risk of missing an opportunity
    - Assess the likelihood and severity of the risk (low-medium-high)
    - Propose initial actions
    - Identify Risk Owner; the consortium member in the best position to recommend mitigation strategies for the risk, develop and document a contingency plan and monitor the status of the risk.
4. Risk owner completes the risk documentation form, Annex IV *(when the risk owners is not a WPL, the associated WPL will support the risk owner in the completion of the risk documentation form)*
5. The Risk owner shares the risk documentation form with the MT and PMO
6. The PMO will include the risk in the risk registry
7. Risks are regularly monitored and updated by the MT assisted by the PMO. WP leaders/Risk owners are regularly consulted for monitoring purposes.

5. Legal issues

Project's key legal documents

The Grant Agreement
The Grant Agreement (GA) is the agreement signed by the Consortium and the IMI2 JU which defines the key aspects of the project and the rights and obligations of the participants and the IM2 JU. The COVID-RED Grant Agreement number is 101005177.

The GA includes the following annexes, which form an integral part of the contract

- Annex 1 Description of the action
- Annex 2 Estimated budget for the action
    - 2a Additional information on the estimated budget
- Annex 3 Accession Forms
    - 3a Declaration on joint and several liability of linked third parties
- Annex 4 Model for the financial statements
- Annex 5 Model for the certificate on the financial statements
- Annex 6 Model for the certificate on the methodology

The signed version GA with all the Annexes is available on the member area.

The Consortium Agreement
The Consortium Agreement (CA) is an internal, private agreement between the COVID-RED beneficiaries in order to legally state the project management, development and the future exploitation of results. The CA is developed to cover aspects that are particular to COVID-RED and that are not fully described in the GA.

The GA is to a large extent a standardized contract (only the Description of action (Annex I) is specific to the project). This means that it cannot provide for the particularities of every single project and consortium. In addition, the GA leaves room for internal negotiation and agreement upon many topics, such as the organisation of the project management and specification of several questions and procedures related to IP.

In case of conflict between the GA and the CA, the GA will prevail.

The signed version of the CA is available on the member area.

Amendments to the Grant Agreement

What is an amendment?

An amendment to a GA is a legal act modifying the original commitment between the parties. During the lifetime of the GA, amendments may create new rights, impose new obligations, or modify some of its parts. An amendment is necessary whenever the original GA has to be modified. This is typically the case for changes of the data included in the core part and/or

modification to the Annex I – Description of Action (DoA).

An amendment is generally requested by the consortium, however, the IMI2 JU is also allowed to propose an amendment.

Amendment procedure

The PMO will be responsible for the coordination and preparation of the amendments during the project. Overall one single amendment request will be submitted per project year (if necessary) after the completion of the periodic report. Special timeliness will apply in case of major or urgent changes. In general, the amendment procedure is as follows:

1. The PMO will keep track of all the needed amendments. To compile all necessary documentation the PMO will reach out to the affecting participants/beneficiaries. Please note, validation of a legal entity (e.g. when adding a new beneficiary or linked third party) needs to be done before the coordinator will 'submit an amendment request'.
2. A summary list with all the modifications will be circulated to the General Assembly (GA) for their information and approval.
3. Members of the GA have 2 weeks to raise objections.
4. Once the GA has accepted the modification, the PMO will prepare the official documentation for the amendment request and will include the changes in the Funding & Tenders Portal.
5. The Coordinator will submit, on behalf of the Consortium, the amendment request. Please note, a signed and submitted amendment request cannot be changed — only accepted, rejected or withdrawn.
6. The IMI2 JU will assess the request and must accept or reject the request within 45 days
7. The IMI2 JU may request additional information/documents, which will not change the amendment itself.
8. The coordinator must upload the requested information within 15 calendar days
9. Hereafter, the IMI2 JU has (a new) 45 days to assess the request
10. The amendment request gets accepted or rejected
11. The amendment enters into force on the day the IMI2 JU signs it
    - The amendment takes effect (i.e. the changes to the grant agreement start to apply) either:
        i. On a specific date agreed by the parties (clearly specified in the amendment)
            - This date should normally be after the entry into force. In justified cases it may – exceptionally - be before that date
        ii. On the date it enters into force (i.e. the date on which the amendment was signed by IMI2 JU).

For additional information about the amendment procedure, obligations and examples see to Article 55 of the Annotated Model Grant Agreement.

Third parties

What is a third party?
A legal entity which carries out work of the action (DoA), supplies goods or provide services for the action, but which did not sign the grant agreement.

Types of third parties
Linked third party: A legal entity with a legal link to one of the beneficiaries. A linked third party is allowed to carry out (part of) the tasks described in the DoA.

Third party: A legal entity providing resources, goods or services to the beneficiaries for them (the beneficiary) to carry out the work described in DoA. Note, a third party is not allowed to carry out (part of) the tasks themselves.

Subcontractor: A legal entity hired to perform one or more tasks for a beneficiary. Note, best value for money must be ensured and subcontracting between beneficiaries is not allowed.

Types of third parties	CHARACTERISTICS						
	Does work of the action	Provides resources or services	What is eligible?	Must be indicated in Annex 1	Indirect costs	Selecting the third party	Articles
Linked third party	YES	NO	Costs	YES	YES	Must be affiliated or have a legal link	Article 14
Subcontractors	YES	NO	Price	YES	NO	Best value for money, avoid conflict of interest	Article 13
Third party providing in-kind contributions	NO	YES	Costs	YES	YES	Not used to circumvent the rules	Articles 11 and 12
Contractors	NO	YES	Price	NO	YES	Best value for money, avoid conflict of interest	Article 10
Financial support to third parties	Only if allowed in the call The beneficiaries' activity consists in providing financial support to the target population			YES	NO	According to the conditions in Annex 1	Article 15

Figure 4 Characteristic of the different types of third parties
Costs: Actual costs
Price: Commercial price

Adding new third parties
The work conducted by a (linked) third party or subcontractor should be described in the DoA. If a new third party will contribute to the project, this party needs to be added to the DoA during the periodic report. The IMI2 JU can approve a new party to the project. Nonetheless, the beneficiary bears the risk of rejection.

Additional Third Party Procedure

1. A beneficiary has a request which cannot be for filled by another beneficiary or (linked) third parties already associated with the project.
2. The beneficiary informs the PMO with the request to add a new third party to the project. *Note, a linked third party can only be added through an official amendment (see Amendments to the Grant Agreement).*
3. The beneficiary may suggest a third party with specific expertise or access to certain recourses.
   Note, with all subcontracting, it is necessary to ensure the best value for money. This does not mean that you need to hire the cheapest provider, but it does mean that you should carefully consider the options based on quality and price. Usually, you may demonstrate best value for money by showing 3 quotations with a description on why the one supplier is the best fit for you. Keep this information on file so that in case of an audit, the accountant may ask for these quotations or your argumentation.
4. When no third party is suggested by the beneficiary, the MB is consulted for additional third parties who may be suited
5. The beneficiary contacts the third party
6. A Confidential Disclosure Agreement is signed according to the procedure below
7. The PMO will include the new third parties during the period report on a yearly basis

Intellectual property rights

All beneficiaries agreed on the intellectual property rights described in Article 6, 7 and 8 of the COVID-RED Consortium Agreement. Below gives a short description of some major agreements but is not legally binding. For your reference, the associated articles are mentioned.

Ownership of results *(Article 7.1 and 7.2)*

Results generated by the project are owned by the beneficiary who generates them. When two or more beneficiaries generate the result and it is not possible to: 1. Establish the respective contribution of each Beneficiary; or 2. Separate their contribution for the purpose of applying for, obtaining or maintaining their protection; beneficiaries shall have joint ownership over the results.

Protections of results *(Article 7.4.1)*

Each Beneficiary agrees to 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: 1. the results can reasonably be expected to be commercially or industrially exploited; and 2) protecting the results is possible, reasonable and justified (given the circumstances).
When deciding on the protection, the beneficiary must consider its own legitimate interests and the legitimate interests, in particular the commercial interests, of the other beneficiaries.

(Linked) third parties and result ownership *(Article 7.4.2.2)*

A beneficiary must, in advance, contractually agree on all necessary rights (transfer, licenses and other) from the (linked) third party in relation to the results, in order to be able to respect its obligations as if those results were generated by the beneficiary itself (e.g. the beneficiary will have ownership of the results). If obtaining these rights is impossible, the beneficiary must refrain from using the (linked) third party to generate results.

Confidential Disclosure Agreements (CDA)

Before sharing confidential information about the project with an external party, a CDA must be signed by the organisation and the consortium. Novartis and UMCU will jointly act as mandate holder on behalf of the consortium. CDA templates can be found as an Annex to the Consortium Agreement (Annex 8 and 9). In general, the one-sided CDA is used, unless a two-sided CDA is specifically requested by the third party.

Non-confidential information:

- Information disclosed on the public website
- Information disclosed in the press release(s)
- Aim and objective of the project
- Approved deliverables reports

Confidential information:

- Information disclosed in the consortium agreement
- The Description of Action
- (Ongoing) work, related to the tasks

CDA procedure

1. The beneficiary interacting with the external organization will compile a CDA
2. The CDA is sent to and (digitally) signed by the third party
    a. Note, generally the CDA is an agreement with an organization. In specific cases, a CDA can be arranged with an individual.
3. The interacting beneficiary sends the one-side signed CDA to the PMO (covid-red@umcutrecht.nl)
4. The PMO will have 14 days to get the CDA signed by the mandate holders
5. The PMO will return a fully (digitally) signed copy to the interacting beneficiary and the third party

CDA templates (one-sided and two-sided) are available in the Consortium Agreement, under:

- Appendix 8 Contracts under Mandate: One-sided CDA
- Appendix 9 Contracts under Mandate: Two-sided CDA

6. Tendering procedure (incl. subcontracting)

When subcontracting or outsourcing to third parties or vendors, beneficiaries are urged to consult the latest version of the Annotated Model Grant Agreement provided by IMI (https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/Annotated_Model_Grant_Agreement–AGA.pdf).

Especially the section on third party resources on page 129 (Article 7), page 137 (Article 10 on the purchase of goods works or services) and page 147 (Article 13 on subcontracting).

As a general principle, the beneficiaries must base their purchases either on the best value for money (considering the quality of the service, good or work proposed, i.e. the best price-quality ratio) or on the lowest price.

The best value for money principle does NOT in all cases require competitive selection procedures. However, if a beneficiary did not request several offers, it must demonstrate how best value for money was ensured.

For the best price-quality ratio, price is an essential aspect (together with quality criteria, such as technical quality, etc.), but it is NOT automatically necessary to select the offer with the lowest price. Selecting the lowest price may however be appropriate for automatic award procedures where the contract is awarded to the company that meets the conditions and quotes the lowest price.

Annex I - Meeting minutes template

Agenda / Meeting Minutes

Meeting: *WorkPackage X*	Meeting Date: *dd-mm-yy* Meeting Time: *London XX:00-XX:00* *Amsterdam XX:00-XX:00* *… (add other time zones if applicable)* Meeting Number: *add in details for type of meeting e.g. TC-Dial in details /meeting number*
Chairperson:	*Rotate within the team*
Attendees:	*Add in team members names*
Apologies:	

Agenda Topics for Discussion

1. Item 1	*Person introducing agenda item*
2. Item 2	
3. AOB	

Item 1	***Actions***
Item 2	***Actions***
AOB	***Actions***

Annex II - General assembly e-mail list

To (General Assembly):

First name	Surname	E-mail	Organization
Antonella	Chiucchiuini	antonella.chiucchiuini@takeda.com	Takeda
Billy	Franks	billy.franks@juliusclinical.com	Julius Clinical
Brianna	Goodale	brianna.goodale@avawomen.com	Ava AG
Jakob	Kjellberg	jakj@vive.dk	VIVE
Lorenz	Risch	lorenz.risch@risch.ch	Dr. Risch Anstalt
Richard	Dobson	r.dobson@ucl.ac.uk	University College London
Rick	Grobbee	d.e.grobbee@umcutrecht.nl	UMCU
Santiago	Montes	santiago.montes@roche.com	Roche NL
Theo	Rispens	T.Rispens@sanquin.nl	Sanquin

In cc (non-voting participants the GA requested to be kept informed):

First name	Surname	E-mail	Organization
Annemarijn	Douwes	a.r.degroot-11@umcutrecht.nl	UMCU
George	Downward	g.s.downward@umcutrecht.nl	UMCU
Nathalie	Vigot	n.c.s.vigot@umcutrecht.nl	UMCU
Pieter	Stolk	p.stolk@umcutrecht.nl	UMCU

Annex III - Managing board e-mail list

To (Management Team):

First name	Surname	E-mail	Organization
Maureen	Cronin	maureen.cronin@avawomen.com	Ava AG
Billy	Franks	billy.franks@juliusclinical.com	Julius Clinical
Annemarijn	Douwes	a.r.degroot-11@umcutrecht.nl	UMCU
George	Downward	g.s.downward@umcutrecht.nl	UMCU
Nathalie	Vigot	n.c.s.vigot@umcutrecht.nl	UMCU
Pieter	Stolk	p.stolk@umcutrecht.nl	UMCU
Rick	Grobbee	d.e.grobbee@umcutrecht.nl	UMCU

In cc (PMO):
Covid-red@umcutrecht.nl

Annex IV - Risk Documentation Form

Risk Title			
Type of Risk	Threat / Missing opportunity		
Associated Work Package			
Detection Date		Risk reporter	
Likelihood (high-medium-low)			
Impact (high-medium-low)			
Risk Owner			

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

Risk timing and monitoring
(Summarize in what timeframe will the risk evolve, how the Risk owner will activity monitor the risk and on what frequency is interaction between the Risk Owner and MT required)

Actions to prevent/conquer the Risk
(Summarise the initial actions (to be) taken to prevent the risk of happening or to conquer an ongoing risk)

Risk progress indicators
(List indicators that the risk is becoming an increasing problem or that the risk is eliminated)

Annex V – Publication policy

Routing guidelines for communication and dissemination activities

1. Introduction

The Publication Policy describes the approval routing within the COVID-RED management structure before publication of any communication/dissemination activity. It is based on the following articles of the Grant Agreement and Consortium Agreement:

Consortium Agreement
7.4.3. Mandatory Messaging in connection with Results
7.5 Disseminations of results
7.6 Communications
Appendix 12 Communication Guidelines

Grant Agreement
Article 27.3 – Information of JU funding and support from JU members
Article 28 – Exploitation of results
Article 29 – Dissemination of results

2. Dissemination principles

Dissemination is the public disclosure of project results. The review is carried out by the General Assembly (GA). For reporting purpose, all dissemination is tracked by the PMO. Please provide the PMO (covid-red@umcutrecht.nl) with the final version of your dissemination.

2.1. Review process for articles, white/discussion papers and press releases

Please circulate your publication at least forty-five (45) Days prior to planned submission to the other Beneficiaries through the Programme Management Office (PMO) by written notice: covid-red@umcutrecht.nl.
Each Beneficiary has thirty (30) Days after the initial circulation to object to the publication if its legitimate interest in relation to the publication would be significantly harmed (for details on grounds for objection, please refer to CA 7.5.5.2).
If no objection is received within 20 days following the first notification an e-mail reminder by the Beneficiary requesting the publication should be send to those who have not yet responded. If no objection is received within the 30 days the Beneficiary will be free to proceed with the publication, to the extent such Dissemination does not include or refer to Results or any Confidential Information of any other Beneficiary.

Fast track: for articles, white/discussion papers and press releases which require a shorter review period, the following shortened review process is possible.
Please circulate your publication at least twenty (20) days prior to planned submission to the other Beneficiaries through the Programme Management Office (PMO) by written notice: covid-red@umcutrecht.nl. Inform the other Beneficiaries that you would like to have a quick turnaround referring to this fast track.
Each Beneficiary has ten (10) Days after the initial circulation to object to the fast track. If no objection to the fast track is received within these 10 days, it may be assumed that the fast track is agreed.
Each Beneficiary has fifteen (15) Days after the initial circulation to object to the publication if its legitimate interest in relation to the publication would be significantly harmed (for details on grounds for objection, please refer to CA 7.5.5.2).

If no objection is received within the 15 days OR as soon as all Beneficiaries confirmed their endorsement of the material under review, the Beneficiary will be free to proceed with the publication, to the extent such Dissemination does not include or refer to Results or any Confidential Information of any other Beneficiary.

If an objection is received within the review period mentioned above, the Beneficiary disseminating the publication will:

a) where protection of another Beneficiaries' own Results or Background would be adversely affected by the proposed Dissemination ➔ Extend the review period and delay the proposed publication for a period of at least twelve (12) months to allow the objecting Beneficiary to evaluate the patentability and/or to file a patent application for the objecting Beneficiary's Results or Background; and/or otherwise modify the publication as requested for patent reasons;
b) where the proposed Dissemination contains Confidential Information from the objecting Beneficiary ➔ Delay the Dissemination until the objecting Beneficiary's Confidential Information is removed from the proposed Dissemination;
c) where other legitimate interests of the objecting Beneficiary are harmed ➔ Enter into good faith discussions with the objecting Beneficiary on how to address the legitimate interests of the objecting Beneficiary, as the case may be, by amending the proposed Dissemination.

By exception, when a student would like to submit a university thesis based on the Results of the Project, the Management Team will have to be informed, and the final draft shall be submitted to the Management Team for review prior to submission to the university.
Beneficiaries may comment on the contents of the thesis **within sixty (60) Days** of receipt of the thesis in accordance with Clause 7.5.2 of the Consortium Agreement.
All appropriate measures ensuring confidentiality must be taken by the Beneficiary with which the student is associated to ensure protection of Confidential Information and/or patent protection of the Beneficiaries (For example via an non-disclosure agreement prior to receipt of the thesis).

Details of any publication and an electronic copy of the published version must be provided to the IMI2 JU within two months following publication. A copy of each publication needs to be sent to PMO (covid-red@umcutrecht.nl) for recording purposes. In addition, please mention to PMO if a publication on the COVID-RED website is desired.

2.2 Dissemination review process for abstracts, posters, presentations

Please circulate this type of dissemination at least 14 days prior to planned submission and/or the event to the Management Team (MT) by written notice to PMO.
The MT has 7 days to object. If no objection is received within 7 days following the notification of the requesting partner, the Beneficiary is free to proceed. Note that also other types of presentations, for example webinars et cetera, need to comply to the same process.

A list of GA and MB/PMO contacts can be found in Annex II and Annex III of this Project's Handbook.

2.3 Open access

Where dissemination concerns a peer-reviewed scientific publication, every author must ensure open access (free of charge online access for any user) within six months of publication.

The open access mandate comprises 2 steps:
1. Depositing publications in data repositories and provide access to third parties
2. Providing information about tools and instruments for validating the results in case relevant

More information about open access publications can be found here beneath 'Open Access to Scientific Publications, article 29.2 of the Grant Agreement.

2.4 Mandatory acknowledgement when communicating externally

1) All dissemination and communication activities should include a full project acknowledgement. In case of restricted space, partners are allowed to use an abbreviated version of the acknowledgement. The acknowledgement logos can be downloaded from the COVID-RED member area.

Full acknowledgement	The COVID-RED project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 101005177. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.
Abbreviated acknowledgement	This work has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking COVID-RED grant n° 101005177.

2) In addition, it should be made clear in the text and layout that the communication reflects the author's view and that neither IMI nor the European Union or EFPIA are responsible for any use that may be made of the information contained therein. Therefore, please including the following statement in the acknowledgement section:

“The research leading to these results was conducted as part of the COVID-RED consortium. This paper only reflects the personal views of the stated authors.”

2.5 Logos

All dissemination and communication activities and products must include all the project’s logos:

Logos should be displayed in their entire and original forms, and, as stated in the Project’s handbook, the COVID-RED logo should be depicted independent from the acknowledgement logos.

2.6 Authorship

For defining who is an author on a publication, we follow the ICMJE recommendations on who qualifies as an author: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

It is strongly encouraged that the author team on each paper should reflect public and industry partners.

2.7 Procedure on theses or dissertations

The Managing Board (MB) will be informed on an on-going basis regarding the proposed contents of

the thesis or dissertation and the final draft shall be submitted to the Managing Board (MB) for review prior to submission to a university. The Managing Board (MB) may comment within 45 days of receipt of the thesis or dissertation. The Managing Board (MB)will also decide whether additional approval is required by the General Assembly (GA) based on the thesis at hand. External examiners to the university may be requested to sign an agreement of non-disclosure prior to receipt of the thesis.

2.8 Internal review procedure

For administrative reasons, we kindly ask you to contact the General Assembly's main contacts and MT/PMO for the internal review procedure regarding peer-reviewed articles and other dissemination activities yourself.
Two email templates can be found below. The most recent contact list can be found in Project's Handbook Annex II and Annex III.
If you receive an objection against publication, please forward it to PMO (covid-red@umcutrecht.nl).
The Managing Board (MB) will discuss together with the objecting Beneficiary and the Beneficiary requesting dissemination how to best proceed, depending on the reason for objection as stated in the consortium agreement article 7.5.2.

2.9 Email templates

For publications:

Subject: COVID-RED: Manuscript for internal review

Dear COVID-RED consortium partners,
I am pleased to share with you this manuscript for dissemination review, titled: "<enter draft title>", which was written under supervision of <enter lead author>. The targeted journal is <enter journal>.

For your reference, the goal of the dissemination review is:
• Factual correctness of the information;
• No authors have been omitted;
• No patent issues are adversely affected;
• No confidential information of another Participant is disclosed;
• No proprietary information of a Participant (e.g. background or foreground) is published without consent.

Please note that you do have 30 days from now on <(enter final date)> to raise objections. If no response is gathered by the deadline, then approval for submission is assumed to be granted.

Please find attached the manuscript.
Best regards,
<enter name>

For publications (fast track):

Subject: COVID-RED: Manuscript for internal review

Dear COVID-RED consortium partners,
I am pleased to share with you this manuscript for dissemination review, titled: "<enter draft title>", which was written under supervision of <enter lead author>. The targeted journal is <enter journal>.

For your reference, the goal of the dissemination review is:
• Factual correctness of the information;
• No authors have been omitted;
• No patent issues are adversely affected;
• No confidential information of another Participant is disclosed;

• No proprietary information of a Participant (e.g. background or foreground) is published without consent.

Please note that we would like to have a quick turnaround for the review of this manuscript. This means that you do have 15 days from now on <(enter final date)> to raise objections. If no response is gathered by the deadline, then approval for submission is assumed to be granted.
If you wish to object to this short deadline, please inform us within 10 days from now on <(enter final date)>. If no response is gathered by this deadline, then approval for the shorter timeline is assumed to be granted.

Please find attached the manuscript.
Best regards,
<enter name>

For posters, presentations, abstracts:

Subject: COVID-RED: <enter type of dissemination> for internal review

Dear COVID-RED Coordination Team,
I am pleased to share with you this poster/presentation/abstract for the conference <enter conference> for dissemination review.

For your reference, the goal of the dissemination review is:
• Factual correctness of the information;
• No authors have been omitted;
• No patent issues are adversely affected;
• No confidential information of another Participant is disclosed;
• No proprietary information of a Participant (e.g. background or foreground) is published without consent.

Please note that you do have 7 days from now on <(enter final date)> to raise objections. If no response is gathered by the deadline, then approval for submission is assumed to be granted.

Please find attached the <enter type of dissemination>.

Best regards,
<enter name>

3. Communication principles

COVID-RED has a dedicated work package, WP6, which is in charge of all external communication. WP7 has developed a communication guidance describing internal and external communication strategies that should be adhered to.