



WP1_D1.1

Project Management Guidelines

Università degli Studi di Verona (UNIVR)



Project Classification

Project Acronym:	ORCHESTRA
Project Title:	Connecting European Cohorts to Increase Common and Effective Response to SARS- CoV-2 Pandemic
Coordinator:	UNIVR
Grant Agreement Number:	101016167
Funding Scheme:	Horizon 2020
Start:	1st December 2020
Duration:	36 months
Website:	www.orchestra-cohort.eu
Email:	info@orchestra.eu

Document Classification

WP No:	WP1
Deliverable No:	D1.1
Title:	Project management Guidelines
Lead Beneficiary:	UNIVR
Nature:	Report
Dissemination Level:	Confidential
Delivery Date:	31/01/2021
Submission Date:	31/01/2021
Status:	Completed
Version:	0.3
Author(s):	Ruth Joanna Davis (UNIVR), Evelina Tacconelli (UNIVR), Stefania Vitali (UNIVR)

History of Changes

Version	Date	Created/Modified by
0.1	25/01/2021	Ruth Joanna Davis (UNIVR), Stefania Vitali (UNIVR)
0.2	26/01/2021	Evelina Tacconelli (UNIVR)
0.3	31/01/2021	Stefania Vitali (UNIVR)

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101016167.



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Glossary of terms

AP	Advisory Panel
DCU	Data Coordination Unit
CFS	Certificate on the financial statements
DMP	Data Management Plan
EB	Ethics Board
EC FO	European Commission Financial Officer
EC PO	European Commission Project Officer
ECDC	European Centre for Disease Prevention and Control
EMA	European Medicines Agency
GA	General Assembly
Participant Portal	European Commission electronic platform for contract management
Project Coordinator	University of Verona
Project Beneficiary	Project partner who is signatory to the Grant Agreement
PMU	Project Management Unit – dedicated unit within the structure of the Project Coordinator



Executive summary

This document is the deliverable “D1.1 – Project Management Guidelines” of the European project “ORCHESTRA – Connecting European Cohorts to Increase Common and Effective response to SARS-CoV-2 Pandemic: ORCHESTRA”. It is issued by UNIVR as deliverable of WP1 (Coordination).

The purpose of the Project Management Guidelines is to provide guidance and direction to project beneficiaries on specific management activities, namely: monitoring of progress of work packages, sharing and storing of documents, communication among consortium members, scheduling of meetings and quality control of project deliverables.

This document is based on the terms and conditions established in the **Grant Agreement** and its Annexes, as well as on the **Consortium Agreement** specifications and requirements. For the avoidance of doubt, in case of ambiguity of interpretation between official EC documents and these Guidelines, the latter takes a subordinate role.

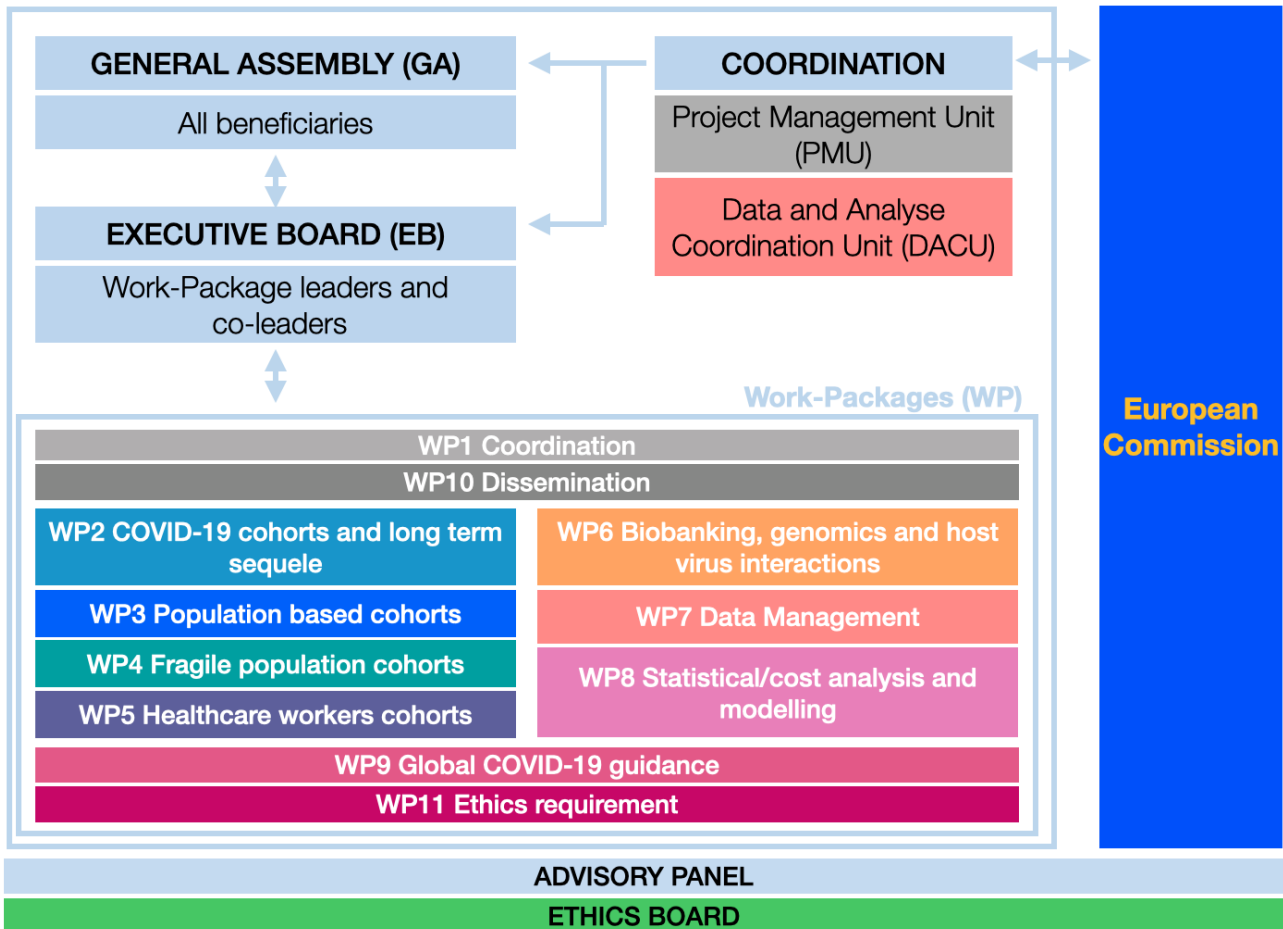
In addition, the Project Management guidelines will be complemented by other project deliverables, namely:

- D10.1 Communication and dissemination strategy plan and website online (31/01/2021)
- D10.2 Social media accounts created and accredited (31/01/2021)
- D9.1 Working Plan (31/01/2021)

Finally, the intended audience of the ORCHESTRA Project Management Guidelines consists of beneficiaries of the ORCHESTRA project and the European Commission Project Officer.

1. Project management

1.1. Governance structure



1.2. Project Management Unit (PMU)

The Project Management Unit (PMU) is a dedicated unit that has been set up within the premises of the Coordinator organisation (UNIVR) for the overall management of the ORCHESTRA project. It is staffed with a Project Officer, a Project Manager, a Financial Officer, a Legal Officer and an Ethics Officer.

The main tasks of the PMU as per Grant Agreement are as follows:

- Establishment of the ORCHESTRA management bodies (Executive Board, General Assembly, Advisory Panel, Ethics Board)
- Organisation of formal meetings of management bodies
- Development and maintenance of the ORCHESTRA project management guidelines (PMGs)
- Coordination of the financial and technical reporting to the European Commission
- Distribution of EC advance payments and interim payments.
- Coordination and monitoring of the WP progress, quality and deadlines (milestones and deliverables)

1.3. Data Coordination Unit (DCU)



The Data Coordination Unit aims to facilitate the creation of a proper design and documentation of data, taking into account not only the data-formulation and encoding (activity coordinated by WP7), but also data semantic (known best by clinicians or scientists involved in data collection). The activity of the DCU would then favour the statistical and machine learning analysis and ensure the reproducibility of the results.

The DCU is coordinated by WP1 and WP6 in collaboration with WP7 and it comprises one (1) representative member from each WP. The DCU meets according to the project needs. In the initial phase of the project one meeting every 2-3 weeks is desirable.

1.4. Executive Board

The Executive Board is the supervisory body for the execution of the Project. The Executive Board consists of one representative of each Work Package. (See Table 1)

Table 1: List of Executive Board Members

WP No	ORCHESTRA Members	
WP1	UNIVR	Università di Verona
	Evelina Tacconelli	
WP2	INSERM	Institut National de la Sente et de la Recherche Medicale
	France Mentre	
WP3	LMU	Ludwig-Maximilians - Universität Muenchen
	Michael Hoelscher	
WP4	UNIBO	Università di Bologna
	Maddalena Giannella	
WP5	UNIBO	Università di Bologna
	Paolo Boffetta	
WP6	UANTWERPEN	Universiteit Antwerpen
	Surbhi Malhotra-Kumar	
WP7	CINECA	Cineca Consorzio Interuniversitario
	Gabriella Scipione	
WP8	HMGU	Helmutz centrum Muenchen Deutsches Forschungszentrum Fuer Gesundheit und Umwelt
	Jan Hasenauer	
WP9	UMCG	Academisch Ziekenhuis Groningen
	Alex Friedrich	
WP10	UHC	Klinikum der Universitaet Zu Koeln
	Jörg Vehreschild	
WP11	UNIVR	Università di Verona
	Elda Righi	

The Executive Board shall meet at least quarterly or at any time upon written request of any Member of the Executive Board.

The Project Coordinator shall chair all meetings of the Executive Board, unless decided otherwise by a majority of two-thirds of the Members.

In order for Executive Board Meetings to be quorate, 75 percent of its members need to participate. Decisions will be taken by simple majority. Each Board member will have one vote. The minutes of the Executive Board meetings are prepared by the PMU and – within 10 working days after the meeting - disseminated to the General Assembly members. The minutes shall be considered as accepted if, within 15 calendar days from sending, no Member has sent an objection in writing to the



chairperson with respect to the accuracy of the draft of the minutes. Final minutes will be made available to the Executive Board members and the General Assembly members via the ORCHESTRA restricted web platform or on request to the PMU.

To further increase collaboration and the exchange of knowledge and ideas, the Executive Board members will meet with the EC Project Officer and the Advisory Panel every 3 months.

1.5. General Assembly

The General Assembly is the decision-making body of the ORCHESTRA Project. The General Assembly will decide on issues that affect the consortium composition (e.g. new beneficiaries, replacement of beneficiaries, defaulting beneficiaries) and/or the Grant Agreement (e.g. major shifts in goals, activities or budgets). The General Assembly will be made up of one representative nominated by each of the Beneficiaries (See Table 2).

Table 2: List of General Assembly Members

	Beneficiary	Representative
1	UNIVR	Evelina Tacconelli
2	UNIBO	Pierluigi Viale
3	INSERM	Laurence Meyer
4	SAS	Jesús Rodríguez Baño
5	CINECA	Gabriella Scipione
6	LIH	Rejko Krüger
7	APHP	France Mentré
8	RER-ASSR	Maria Luisa Moro
9	ISGlobal	Elisa Sicuri
10	LMU	Michael Hoelscher
11	UANWERPEN	Surbhi Malhotra-Kumar
12	HMGU	Jan Hasenauer
13	UHC	Jörg Vehreschild
14	PENTA	Carlo Giaquinto
15	USTUTT	Björn Schembera
16	CERMEL	Selidji Agnandji
17	RAPH BB	Radovan Lapunik
18	CHARITE	Eugenia Rinaldi
19	UMCG	Corinna Glasner
20	CINES	Florian Piffet
21	UNIOVI	Adonina Tardon
22	UBA	Gabriel Levy Hara
23	INSP-NIPH	Dana Mates
24	UKHD	Thomas Jaenisch
25	REG VEN	Michele Tonon
26	FCRM	Francine Ntoumi

In order for a General Assembly meeting to be quorate, at least 75 percent of the General Assembly representatives must attend. Each beneficiary will, through its representative, have one vote in the General Assembly.



The General Assembly meets at least every twelve months or at any time upon written request of the Executive Board or 1/3 of the Members of the General Assembly. The meetings are prepared by the PMU. They are chaired by the Project Coordinator.

The minutes of the General Assembly meetings are prepared by the PMU and – within 10 working days after the meeting - disseminated to the General Assembly members. The minutes shall be considered as accepted if, within 15 calendar days from sending, no Member has sent an objection in writing to the chairperson with respect to the accuracy of the draft of the minutes. Final minutes will be made available to the Executive Board members and the General Assembly members via the ORCHESTRA restricted web platform or on request to the PMU.

1.6. Advisory Panel

The Advisory Panel is set up to assist and contribute to scientific and technical discussion during the three-year project period. In addition to the representatives from the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) who will sit in the Panel, an additional five members are to be appointed by the ORCHESTRA Executive Board.

The tasks of the Advisory Panel are as follows:

- provide feedback on draft deliverables and main project outputs;
- review the progress of research presented during the meetings;
- guide the project participants on potential new project developments and their future applications.

Specific Terms of Reference have been drawn up for the members of the Advisory Panel detailing tasks and required involvement (see Appendix 1).

The Project Coordinator will be the main point of contact with the Advisory Panel.

As per the Consortium Agreement, the Project Coordinator will execute, on behalf of the Consortium, a non-disclosure agreement with each member of Advisory Panel.

The Board members are invited to attend to the ORCHESTRA project meetings in accordance with the schedule below. The frequency of these meetings may be adjusted in accordance with the project needs or in case of specific requests by the Consortium or the European Commission. Additional meetings may also be organised on an *ad hoc* basis, according to the same premise as described in the previous point.

MEETINGS	FREQUENCY	AP
Executive Board and European Commission	Every 3 months	<input checked="" type="checkbox"/>
Partner Assembly	Every 6 months	<input checked="" type="checkbox"/>
General Assembly	1 per year	<input checked="" type="checkbox"/>

✓ - Participation required - Participation optional

1.7. Ethics Board

The Ethics Board is set up to oversee and advise on ethical issues. This Board is composed of three experts and is nominated by the ORCHESTRA General Assembly.

The tasks of the Ethics Board are as follows:



- monitor the compliance with all relevant international guidelines, conventions, and ethical requirements applicable to ORCHESTRA;
- advise the consortium on activities concerning vulnerable populations;
- advise the consortium on issues related to the development of clinical decision-making algorithms, profiling and secondary use of data;
- contribute to a report on the status of ethical approvals in accordance with WP11 (to be presented at month 18 and 36, as a deliverable).

The composition of the Ethics Board will be confirmed at the 1st General Assembly meeting.

Specific Terms of Reference has been drawn up for the members of the Ethics Board detailing tasks and required involvement (see Appendix 1).

The Project Coordinator will be the main point of contact with the Ethics Board.

As per the Consortium Agreement, the Project Coordinator will execute, on behalf of the Consortium, a non-disclosure agreement with each member of the Ethics Board.

The Board members are invited to attend to the ORCHESTRA project meetings in accordance with the schedule below. The frequency of these meetings may be adjusted in accordance with the project needs or in case of specific requests by the Consortium or the European Commission. Additional meetings may also be organised on an *ad hoc* basis, according to the same premise as described in the previous point.

MEETINGS	FREQUENCY	EB
Executive Board and European Commission	Every 3 months	<input checked="" type="checkbox"/>
Partner Assembly	Every 6 months	<input checked="" type="checkbox"/>
General Assembly	1 per year	<input checked="" type="checkbox"/>

✓ - Participation required - Participation optional

2. Communication

The Project Coordinator is responsible for communication between the Project and the EC.

2.1. Internal communication

The ORCHESTRA project uses several mechanisms for ensuring open and frequent communications amongst its members: e-mail and mailing lists; conference calls; face-to-face meetings (when it will be possible); ORCHESTRA website dedicated area with restricted access.

2.1.1. Internal mailing lists

Day-to-day communication will be based on e-mails. To facilitate rapid e-mailing and ensure the correct inclusion of involved persons, on the basis of a shared contact form per WP the following mailing lists have been created:

- orchestra@orchestra-cohort.eu for all people involved
- executive-board@orchestra-cohort.eu for the Executive Board members
- general-assembly@orchestra-cohort.eu for the General Assembly members
- wp-leaders@orchestra-cohort.eu for all WP leaders/co-leaders/coordinators
- wp1@orchestra-cohort.eu for all WP1 participants
- wp2@orchestra-cohort.eu for all WP2 participants
- wp3@orchestra-cohort.eu for all WP3 participants



- wp4@orchestra-cohort.eu for all WP4 participants
- wp5@orchestra-cohort.eu for all WP5 participants
- wp6@orchestra-cohort.eu for all WP6 participants
- wp7@orchestra-cohort.eu for all WP7 participants
- wp8@orchestra-cohort.eu for all WP8 participants
- wp9@orchestra-cohort.eu for all WP9 participants
- wp10@orchestra-cohort.eu for all WP10 participants
- wp11@orchestra-cohort.eu for all WP11 participants

In order to ensure proper coordination, Coordinator contacts are included in each mailing list.

In addition to the above, three e-mail accounts have been set up to facilitate communication with the coordinating partner and the technical support:

- info@orchestra-cohort.eu for general communication;
- pmu@orchestra-cohort.eu for communication with the project management unit;
- support@orchestra-cohort.eu for technical questions.

A current list of the members of each list is uploaded on the ORCHESTRA restricted web platform.

The mailing lists are set up and maintained by WP10. It is the responsibility of each Partner to actively and timely inform the WP10 Team (support@orchestra-cohort.eu, luise.wolf@orchestra-cohort.eu) of changes to contact details or additional persons involved.

2.1.2. Website and restricted area for members only

The partners can access all the project official and working documents in the ORCHESTRA platform accessible through a link on the project external website <https://orchestra-cohort.eu>.

The access is available to registered members of the project consortium only and it will be monitored by the WP10 IT team.

The restricted platform features, as a minimum, the following items:

- File and documents repository in cloud with collaboration tool;
- Chat function by groups;
- Shared calendar with all the project events and meetings;
- Project Management tool.

Additional features are added by WP10 according to the Consortium need.

The directory tree is structured as follows:

- **Official documents**

This area may be edited by PMU and WP10 Team only but all partners can read and download the documents.

It contains the following sub-directories:

- Administration: containing project administrative documents such as guidelines, etc.;
- Communication package: containing all project communication material for partner reuse (e.g. logos, press releases, visuals and images, templates, etc.);
- Contracts: containing all official project contracts (Grant Agreement and Consortium Agreement), their annexes and eventual official amendments;
- Deliverables – containing the finalised versions of all project deliverables;
- Milestones - containing the finalised versions of all project milestones;
- Events: containing agenda, presentations and minutes list of all project events and official meetings;

- **Working documents**

This working and collaboration area can be edited by all project members.



It includes 11 sub-folders, one per each WP and one subfolder. Each WP leader will be in charge of managing the respective folder and is free to set it up as best suited to the WP needs.

Additional folders and subfolders can be created upon request to the PMU.

2.2. External communication

2.2.1. Project website

The project website url is: www.orchestra-cohort.eu.

It is developed and maintained by WP10, while the content is defined and updated by WP10 and WP1 in collaboration with all WPs.

2.2.2. Logo, templates and brand guide

The creation of ORCHESTRA brand through the creation of a logo and MS Office templates is a crucial part of the project's communication strategy. To ensure consistent use of the ORCHESTRA brand across all communication efforts a brand guide, a set of elaborated instructions on the usage of the logo, including associated colours and fonts, is developed by WP10. These communication tools will be made available to all project partners via the restricted area on the ORCHESTRA web platform.

2.2.3. Social media

Social media accounts are created for the ORCHESTRA project in Facebook, Twitter and Instagram. The rules for a correct communication in these channels is provided by WP10.

2.3. Meetings

Regular meetings are essential for good communication. The formal meeting schedule is as follows:

Table 3: Schedule of Meetings

MEETINGS	Frequency
WP internal	Every 1-2 weeks
WP leader and Co-leader	Every month
Data Coordination Unit (DCU)	Every 2-3 weeks
Executive Board and European Commission	Every 3 months
Partner Assembly	Every 6 months
General Assembly	1 per year

Members of the Advisory Panel and Executive Board are will be invited to attend the Partner and General Assembly meetings and other meetings to be decided on an ad hoc basis according with project needs (See Sections 1.6, 1.7).

It is the responsibility of the WP leader to add the internal WP meeting dates on the **shared calendar** on the restricted area of the Orchestra web platform. The PMU is responsible for adding the dates of all the other ORCHESTRA project meetings.

3. Workpackages, milestones and deliverables

3.1. Workpackages

WP N°	TITLE	Leader	Co-Leader
WP1	Coordination	UNIVR	

WP2	COVID-19 cohorts and long-term sequelae	UNIVR	UHC, INSERM
WP3	Population-based cohorts	INSERM	LMU
WP4	Fragile population cohorts	UNIBO	SAS
WP5	Healthcare workers cohorts	UNIBO	INSP
WP6	Biobanking, genomics and virus-host interactions	UANTWERPEN	UNIBO
WP7	Data management	CINECA	CINES, USTUTT
WP8	Statistical/cost analysis and modelling	HMGU	ISGLOBAL
WP9	Global COVID-19 guidance	UMCG	UNIVR
WP10	Dissemination	UHC	UNIVR
WP11	Ethics requirements	UNIVR	

3.2. Milestones

Milestones are project check points that help to measure and monitor the project progress. 58 milestones have been identified within the ORCHESTRA project to be accomplished along the 36-month implementation. The milestones are listed in Table 1.3.4 of Annex 1A of the Grant Agreement and the beneficiary responsible for the achievement of the milestone is included in this table. It is the responsibility of the listed beneficiary to ensure the timely achievement of the milestones. The leader of the WP under which the milestone foreseen is responsible for:

- following up with the beneficiary to check the status of the milestone
- checking the milestone report to be submitted to the PMU(see below)

In case of potential delays, it is the duty of the lead beneficiary responsible for the milestone to promptly inform the Project Coordinator of a delay as soon as possible, at least 3 or 6 months before the due date. The Project coordinator will work with the responsible lead beneficiary and WP leader to develop a contingency plan. Acute delays will be brought to the attention of the Executive Board and of the Project Officer.

Once a milestone has been reached, the responsible beneficiary should inform the PMU specifying the exact date of delivery and providing a short report on the milestone achievement. The milestone template report is provided in the dedicated Template section in the ORCHESTRA portal. The PMU is responsible for recording the accomplishment of the milestone on the EC participant portal.

3.3. Deliverables

Deliverables are outcomes of the project that are produced during the project's course linked to the WPs tasks. The project counts 65 deliverables along the 36-months. The deliverables are listed in Table 1.3.2 of Annex 1A of the Grant Agreement and the beneficiary responsible for the achievement of the deliverable is included in this table. It is the responsibility of the listed beneficiary to ensure the timely achievement of the deliverable. The revision process of the deliverable is described below in section 3.3.2.

In case of potential delays, it is duty of the lead beneficiary responsible for the deliverable to promptly inform the Project Coordinator of a delay as soon as possible, at least 3 or 6 months before the due date. The Project coordinator will work with the lead beneficiary and responsible WP leader to develop a contingency plan. Acute delays will be brought to the attention of the Executive Board and of the Project Officer.

3.3.1. Deliverable structure

Deliverable name:

- Produce the document with the name as follows

Draft: DeliverableNo_yyyymmdd_v1.0; e.g. D1.1_20210131_v1.0

Final: DeliverableNo_yyyymmdd_final; e.g. D1.1_20210131_final

Deliverable template:

- Use the appropriate ORCHESTRA template.

Deliverable format:

- The final version of the deliverables must be submitted to the Project Coordinator in Word and pdf formats.
- The pdf is the electronic format requested by the EC for the submission of all the deliverables/documents elaborated during the project.

Deliverable content (indications):

- The contribution of the deliverable to the WP and the overall goals of ORCHESTRA should be clearly stated;
- The objectives of the deliverable should be clearly expressed. Specifically, the deliverable should feature a short 1-2 paragraphs introduction that clearly states the role and duty of said document, in the scope of ORCHESTRA (Executive summary);
- The deliverable should be clearly related to previous and future deliverables in the WP and – if applicable – to deliverables from other WPs;
- The relation / additions / differences to previous deliverables in the same work package (i.e. in the case the deliverable is an improved version of a previous one) should be clearly stated;
- The deliverable should be a self-contained document, which can be understood without knowledge of the other documents or previous deliverables;
- The deliverable contents should be consistent with its description in the Grant Agreement; if not, the deviation should be explained;
- The deliverable should be cohesive and concise
- The deliverable should not contain any claims that are not proven or supported by references
- The deliverable should include acknowledgments where appropriate (e.g. in case of input/feedback from advisory panel or other stakeholders)

3.3.2. Deliverable monitoring and control

The monitoring process should envisage in advance possible problems connected to the development of tasks and the production of deliverables. To facilitate communicating progress on each deliverable, each WP leader will report on the status of deliverables during the monthly leader/co-leader meetings.

A formal quality control process has been developed by the ORCHESTRA project to ensure that the quality of deliverables generated meets the requirements of the European Commission and that any potential risks affecting the project are properly managed. (See Table 4)

Each project deliverable will be the target of a peer revision **by the Project Coordinator and by 1 internal reviewer**. In addition, the Project Coordinator may request 1 or more (depending on the deliverable) members of the Advisory Panel to review the deliverable.

The limit date for reception of comments of 7-10 working days should be considered.

During the review the PMU will check if the deliverable meets the formal requirements regarding the file format, naming and versioning schemes.



The beneficiary responsible for the deliverable is in charge of the update of a document after internal review. They will receive the comments from the reviewers, provide an answer to all the comments and take into account the accepted ones.

The PMU is responsible for the upload of the final pdf of the deliverable on the Participant Portal.

Table 4: Overview Deliverable Drafting and Revision process

Time	Action	Actor
3 months before due date	Reminder to partners of upcoming deliverable	PMU
1 month before due date		
2 weeks before due date	Submission to Reviewer and Coordinator for quality and compliance check	Lead beneficiary
1 week before due date	Revision report and eventual edits	Reviewers
Due date	Final approval and submission to the EC	PMU

Note that Table 4 is an indicative timeline for the revision process. The review time may change according to the nature and relevance of the deliverable.

4. Reporting

4.1. Continuous reporting

Continuous Reporting is a new functionality in the Participant Portal. It is activated at the start of the project and it is continuously open to submit deliverables, to report on progress in achieving milestones, and to follow up on critical risks, publications and communication activities.

Continuous Reporting will be a fixed item on the agenda of the monthly Work Package meetings, so that the Coordination Team remains fully informed about the progress made, allowing the PMU to regularly update the information about the milestones, deliverables, critical risks, publications and communication activities in the Participant Portal.

4.2. Periodic reports

According to art. 20 of the Grant Agreement, the Consortium must submit 2 reports covering the 2 reporting periods as follows:

Reporting Period	Covering the Period	Covering Dates	Due Date
RP1	from month 1 to month 18	01.12.2020 – 31.05.2022	31.07.2022
RP2	from month 19 to month 36	01.06.2022 – 30.11.2023	31.01.2024

The Periodic reports are due 60 days after the end of each reporting period. Periodic reports consist of two parts, namely a technical report and a financial report.

The PMU is in charge of collecting the information necessary for the technical report whereas each beneficiary is responsible for submitting the information for the financial report on the Participant Portal (following a verification by the PMU).

In order to respect the reporting deadlines and to ensure that the PMU has sufficient time to compile all the information necessary from all the different beneficiaries, the following schedule for submitting the required information is foreseen.

ACTION	Deadlines for RP1 (M18)	Deadlines for RP2 (M36)
--------	-------------------------	-------------------------

PMU reminds beneficiaries of upcoming deadlines and provides reporting templates and instructions	1.05.2022 (Internal Deadline)	1.11.2023 (Internal Deadline)
Beneficiaries provide technical and financial content (Form C) to the PMU	20.06.2022 (Internal Deadline)	20.12.2023 (Internal Deadline)
Financial report: The PMU checks if financial documentation (Form C) is correct and confirms to the beneficiary that they can proceed with filling in the same financial information on the participant portal.	11.07.2022 (Internal Deadline)	11.01.2024 (Internal Deadline)
Technical report: The PMU compiles the information received from the beneficiaries in a single report and circulates the draft to the beneficiaries	11.07.2022 (Internal Deadline)	11.01.2024 (Internal Deadline)
The PMU finalises the technical report on the basis of the feedback received and submits to the European Commission	31.07. 2022 (EC Deadline)	31.01.2024 (EC Deadline)
The PMU checks if the financial information on the portal corresponds to the form C. If yes, the PMU will close the Financial report of each Beneficiary on the Participant Portal.	31.07. 2022 (EC Deadline)	31.01.2024 (EC Deadline)
The EC approves the report on the Participant Portal. (unless any clarifications are requested).	N/A	N/A

For the final report, those beneficiaries who claim more than 325.000€ as Direct costs must also submit a certificate on the financial statements (CFS). The certificate must be issued by an external auditor, using the template in Annex 5 of the Grant Agreement.

4.3. Interim activity report

In accordance with the Grant Agreement, an Interim Activity Report (Deliverable D1.5) is foreseen at **month 6**. This is a technical report and will provide an overview of milestones and deliverable achieved by month 6. It will be prepared by the PMU on the basis of feedback provided by the WP leaders and co-leaders. Instructions for the completion of this report will be sent to partners at **month 5**.

4.4 Interim financial report

In accordance with the Consortium Agreement, all project beneficiaries are required to submit an internal financial report at **month 12**. In this report, beneficiaries must be able to claim expenditures for at least 70% of pre-financing payment received (60%). Once this report has been checked by the PMU, the remaining 40% of the pre-financing statement can be processed. For this report, beneficiaries will be asked to submit the documentation similar to that requested for the first periodic financial report. Instructions for the completion of this report will be sent to partners at **month 11**. This will be a good test exercise for partners in preparation for the formal report due to the European Commission.

5. Publication rules

5.1. General publication and presentations rules

As per art. 38.1.2. of the GA, any communication activity related to the ORCHESTRA (including in electronic form, via social media, etc.) must:

- (a) display the EU emblem and
- (b) include the following text: *“This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 101016167”*.

When displayed together with another logo, the EU emblem must have appropriate prominence.

As described in section 2.2.2.(Logo, templates and brand guide), presentations (in whatever form) should use the ORCHESTRA templates provided.

Each partner must keep track of all their publications and dissemination activities related to ORCHESTRA and report them to the PMU (in cc WP10 leader). The PMU will maintain the overall list of publications and dissemination activities and ensure that this list is updated on the EU Participant Portal. WP10 leader will be responsible for updating the ORCHESTRA website.

5.2. Review and approval process

In accordance with the Consortium Agreement, if a beneficiary intends to publish results in the framework of ORCHESTRA he/she must inform the other beneficiaries via the PMU at least 30 days before the actual dissemination. Any objection to the planned publication must be made in writing to the disseminating party or parties within 21 days from the date of the notification. If no objection is made within this time frame, the publication is permitted. A fast-track procedure is foreseen for abstracts, presentations, press releases, newsletters, posters, leaflets, which shall be sent to the PMU for approval 15 calendar days prior to the submission deadline. Confidentiality obligations must be considered, and no information or work must be published that may be the property of another partner without their prior written approval.

5.3. Open access

Open access can be defined as the practice of providing on-line access to scientific information that is free of charge to the reader. In the context of R&D, open access typically focuses on access to 'scientific information' or 'research results', which refers to two main categories:

- Peer-reviewed scientific research articles (primarily published in academic journals)
- Research data

5.3.1. Open access to publications

Under Horizon 2020, **each beneficiary must ensure open access to all peer-reviewed scientific publications relating to ORCHESTRA results.**

Beneficiaries can freely choose between the most appropriate route towards open access for them:

- Self-archiving (also referred to as 'green' open access) means that a published article or the final peer-reviewed manuscript is archived (deposited) in an online repository before, alongside or after its publication. Repository software usually allows authors to delay access to the article ('embargo period') If this route is chosen beneficiaries must ensure open access to the publication within a maximum of six months (twelve months for publications in the social sciences and humanities).
- Open access publishing (also referred to as 'gold' open access) means that an article is immediately provided in open access mode (on the publisher/journal website). Publishers sometimes charge so called Article Processing Charges (or APCs) to make articles open. Such costs are eligible for reimbursement during the duration of the project as part of the overall project budget.

In the case of gold open access publishing, open access must be granted at the latest on the date of publication and a copy must also be deposited in a repository.

For more information, please refer to [Open access - H2020 Online Manual \(europa.eu\)](https://europe.europa.eu)

5.3.2. Open access to research data

Access procedures to ORCHESTRA Research Data are governed by the Data Management Plan (DMP)





Appendix

Advisory Panel and Ethics Board Terms of Reference

1. Introduction

The ORCHESTRA project

ORCHESTRA provides an **innovative approach** to learn from the pandemic SARS-CoV-2 crisis and **to propose recommendations** for further **management of COVID-19** and to be prepared for possible future pandemic waves. The ORCHESTRA project aims to respond to this need through the **creation of a new pan-European cohort** built on existing and new large-scale population cohorts in European and non-European countries. This three-year international research project is led by the University of Verona and involves **26 partners** (which extends to 37 partners when considering the wider network) from **15 countries** (Argentina, Belgium, Brazil, Congo, France, Gabon, Germany, India, Italy, Luxemburg, Netherlands, Romania, Slovakia, Spain, Venezuela).

The project structure foresees the establishment of **two independent Boards** to ensure **scientific excellence** and **compliance with ethical requirements**, respectively.

The purpose of this document is to define tasks, roles and organisation for these Boards. A single document has been prepared for both Boards so that each Board is informed of the boundaries of their remit.

2. Roles of the Advisory Panel and of the Ethics Board

Advisory Panel (AP)

As foreseen by the ORCHESTRA Grant Agreement (GA) the **Independent Advisory Panel** will be established at the outset of the project to **assist and contribute** to **scientific and technical discussion** during the three-year project period. In addition to the representatives from ECDC (European Center for Disease Prevention and Control) and EMA (European Medicine Agency) who will sit in the Board, an additional **five members** will be appointed by the **ORCHESTRA Executive Board**. Nominees have been proposed by the Project Partners and the European Commission and have been selected according to a majority vote.

The role of the AP is to:

- i. **provide feedback** on draft deliverables and main project outputs;
- ii. **review** the progress of research presented during the meetings (see point 4.2);
- iii. **guide** the project participants on potential new project developments and their future applications.

Ethics Board (EB)

Also foreseen in the ORCHESTRA GA is the independent **Ethics Board** established to **oversee and advise on ethical issues**. This Board is composed of **three experts** and is nominated by the **ORCHESTRA General Assembly**. Nominees have been proposed by the Project Partners.

The role of the EB is to:

- i. monitor the compliance with all relevant international guidelines, conventions, and ethical requirements applicable to ORCHESTRA;
- ii. advise the consortium on activities concerning vulnerable populations;
- iii. advise the consortium on issues related to the development of clinical decision-making algorithms, profiling and secondary use of data;
- iv. contribute to a report on the status of ethical approvals in accordance with WP11 (to be presented at month 18 and 36, as a deliverable).

3. Members

The Board members will have in-depth experience in at least one of the following fields: infectious diseases, virology and microbiology, public and environmental health, health economics, epidemiology, big data management and should not have any involvement as partners in the project. The participation is on a voluntary basis and remuneration for participation is not foreseen.



Reimbursement of travel, accommodation and subsistence is foreseen in case of participation in on-site meetings (see point 5).

The Boards may designate a **leading chair** responsible for the moderation of the discussion, deliberations and reporting to the Executive Board.

The Project Coordinator will execute with each member of the Ethics Board and Advisory Panel a **non-disclosure agreement**, which shall be concluded no later than thirty (30) calendar days after nomination or before any confidential information will be exchanged, whichever date is earlier.

4. Organisation and Resources

Meetings plan

The Board members are invited to attend to the ORCHESTRA project meetings in accordance with the schedule below. The frequency of these meetings may be adjusted in accordance with the project needs or in case of specific requests by the Consortium or the European Commission. Additional meetings for each Board may also be organised on an *ad hoc* basis, according to the same premise as described in the previous point.

MEETINGS	FREQUENCY	AP	EB
Executive Board and European Commission	Every 3 months	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Partner Assembly	Every 6 months	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
General Assembly	1 per year	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

✓ - Participation required - Participation optional

Reporting

The **Advisory Panel** will be asked to produce a **short written report** after the General Assembly (GA), with recommendations addressed to each work package.

The **Ethics Board** will be asked to contribute to the writing of a report on the status of the **project ethics approvals** that will be submitted to the EC as a deliverable (M18, M36).

All the members are expected to **protect the confidentiality** of the information discussed during each meeting, as specified in the confidentiality agreement signed by each board member and the Coordinator.

5. Travel and expenses

Clerical support will be provided to the Board members by the **ORCHESTRA PMU**. Reimbursement for expenses related to travel, subsistence and accommodation incurred for participation in ORCHESTRA on-site meetings is foreseen. Conditions for reimbursement rates will be in-line with the usual practice on travel of the Coordinator University of Verona.



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101016167