



## D1.1 Project handbook, quality manual

<b>Project acronym</b>	ONELAB
<b>Project number</b>	101073924
<b>Project Title</b>	Orchestrating next-generation mobile modular laboratories for pandemic monitoring preparedness
<b>Call/Topic identifier</b>	HORIZON-CL3-2021-DRS-01-05
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<b>Lead beneficiary</b>	AMC
<b>Other contributors</b>	
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# 1 Glossary

CA	Consortium Agreement
D	Deliverable
DoA	Description of the Action
DoW	Description of Work
GA	Grant Agreement
GAss	General Assembly
HE	Horizon Europe
PM	Person Month
PHB	Project Handbook
WPL	Work Package Leaders
EB	Executive Board
PO	Project Officer (European Commission)
QA	Quality Assurance
WP	Work Package

## 2 Executive summary

The Project Handbook and quality manual (PHB) describes the project organisation and internal procedures of the ONELAB project with regard to day-to-day communication and progress towards the timely delivery of the deliverables and within budget. It shall be used by all partners for all deliverables to the European Commission and for deliverables between partners. Quality of the work will be continuously monitored by and will follow specific guidelines throughout the entire duration of the project; The Handbook describes the following procedures in the project: documentation management, repository management, project communication mechanisms, project management, tracking system for actions. The documentation management procedure defines the standard rules and procedures with regard to the production of documentation that all partners need to apply throughout the project. It also outlines the procedure for the publication of peer reviewed publications. The generic document template is described.

Dedicated mailing lists are in place to facilitate the communication within the consortium. We organise regular face to face consortium meetings bi-annually and teleconferences.

The governance of ONELAB consists of four bodies which are assisted by a project advisory, ethics and safety board. The latter three boards are not management bodies but provide solicited and unsolicited advice on the overall progress and ethics related topics within the project.

The bodies of the Project Management structure are:

- General Assembly (GAss)
- Executive Board (EB), formed by Work Package Leaders (WPL)
- Project Support Team (PST)
- project management office (PMO), consisting of:
  - Project Coordinator
  - Project Manager

- Project Controller
- Security Advisory Board (SAB)
- External Ethics Board (EEB)
- Project Advisory Board (PAB)

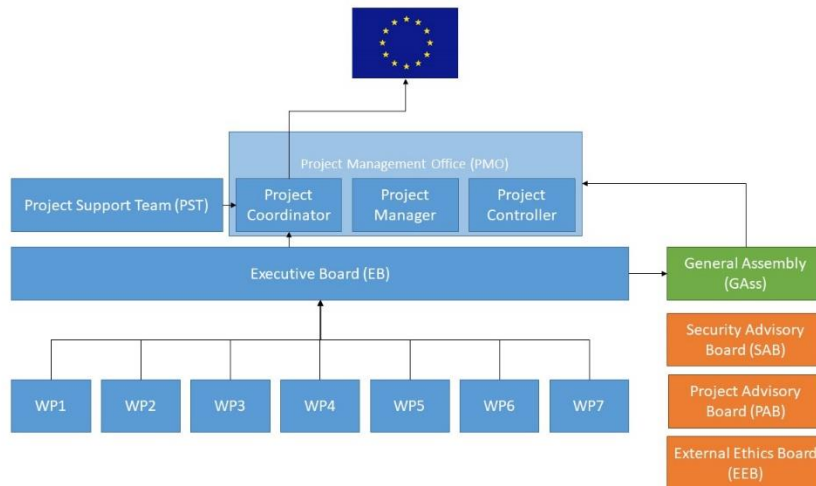


Figure 1: Diagram of the ONELAB Governance structure.

Access Rights are regulated by Article 9 of the ONELAB Consortium Agreement and Article 16 of the HE Grant Agreement Annex II. The Project Manager will track the budget and deliverables. It is vital that potential problems are identified early and dealt with. To this end, conflict resolution procedures are in place, as well as procedures for dealing with changes in the consortium. The project handbook is a work in progress; based on experiences and needs in the consortium, we will continue to adapt and update the document. Best practices will be incorporated and used to constantly improve the management of the project.

## 3 Main body of the handbook

### 3.1 Introduction

#### 3.1.1 Purpose

The Project Handbook and quality manual (PHB) describes the project organisation and internal procedures of the project with regard to day-to-day communication and progress towards the timely delivery of the deliverables and within budget. The PHB establishes the management structures and monitoring of progress, administrative and financial management and periodic reporting and internal and external communication and exchange of data. The project management will ensure that the deliverables and milestones are reached under the direction of the General Assembly and ensure procedures leading to the preparation of a standardized template for reports, early planning of deliverable release and document management. This document thus provides the information needed to facilitate the monitoring of the overall progress and the communication between project partners and the European Commission.

The PHB shall be used:

- By all partners;
- For all deliverables to the European Commission;
- And for reports between partners.

The Consortium Partners will supervise and check the work performed by the consortium in the work package meetings (§3.3.2) and as described for the deliverables in §3.2.5 and §3.6.1.

#### 3.1.2 Reference documents

The reference documents used to create this handbook are listed below:

- ONELAB Grant Agreement (GA)
- ONELAB Description of Work (DoA/ Annex I)
- ONELAB Consortium Agreement (CA)

### 3.2 Documentation Management

#### 3.2.1 Introduction

This chapter describes the documentation management procedure in the ONELAB project. It defines the standard rules and procedures with regard to the production of documentation that all partners need to apply throughout the project.

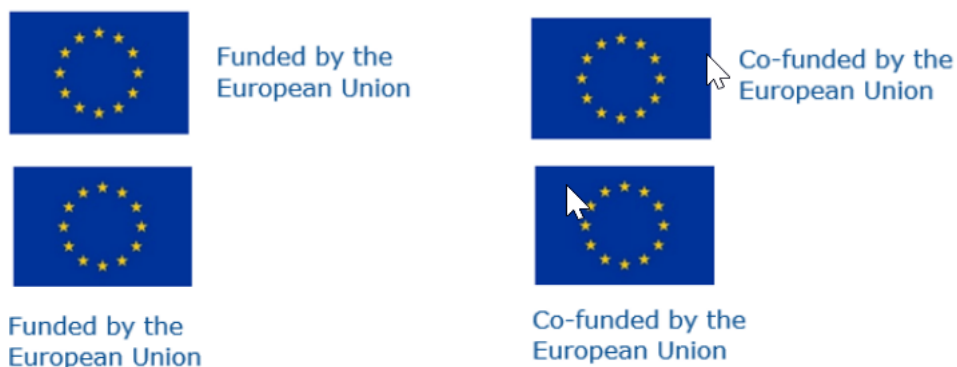
The documentation management procedure is to be used:

- By all partners;
- for all deliverables documents to European Commission;
- for documents exchanged between partners.

### 3.2.2 Documentation publication rules

The Project Manager will ensure the adherence to the requirements of the Grant Agreement and acknowledge the financial contribution of the European Commission. All publications and any other dissemination material relating to results of ONELAB should include a statement to indicate that this result was generated with the assistance of financial support from the European Union.

- Communication activities of the beneficiaries related to the action (including media relations, conferences, seminars, information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via traditional or social media, etc.), dissemination activities and any infrastructure, equipment, vehicles, supplies or major result funded by the grant must acknowledge EU support and display the European flag (emblem) and funding statement (translated into local languages, where appropriate):



- Include the following acknowledgement: “This (project/work/article) has received funding from the European Union’s Horizon Europe innovative action under grant agreement No 101073924 (ONELAB project)”.
- Any communication or dissemination activity related to the action must use factually accurate information. Moreover, it must indicate the following disclaimer (translated into local languages where appropriate):  
*“Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or [name of the granting authority]. Neither the European Union nor the granting authority can be held responsible for them.”*
- Draft papers and articles shall be placed in the password protected ONELAB surfdrive environment for the whole consortium.
- The document’s owner shall invite and solicit contributions from the whole consortium when applicable.
- The contributors and authors of the publication shall abide by clause 8.4.2.1 of the Consortium Agreement allowing the Consortium to be notified of the planned publication **at least 30 days before the publication date**.
- Any objections on the publication of specific results (i.e. in case such result is susceptible to breach Intellectual Property Rights of another party within the consortium) shall be made to the Coordinator by the party raising the objection.

- The coordinator shall notify the consortium.
- Any objections and resolutions shall be dealt with in accordance with the ONELAB consortium agreement.

### 3.2.3 Document layout

All partners will use standard document templates in order to apply a consistent look for all project documents. One generic document template will be provided and several specific templates for particular documents such as deliverables, Periodic Report etc. The templates are available from the ONELAB intranet.

The generic document template will follow guidelines given by the EU and contains the following:

- Layout of the title page
- Layout of headers and footers
- Styles that are to be used in the documents

Templates available:

- Template for the Periodic Report
- Template for the deliverables

Document elements

Each document for reporting and for deliverables shall follow the guidelines given by the European Commission and shall have the following elements (present in the template):

- Project logo
- Project number
- Project Acronym
- Project title
- Title of Report
- Dissemination level (i.e.: public or confidential)
- Date of preparation
- Authors
- Revision

### 3.2.4 File naming conventions

Each document shall be uniquely identifiable together with its version. See the table below for the way to name files. Other document types should adapt the similar logic.

File naming conventions

Document Type	ID	Convention	File Name example
Deliverables	D	D[WP#].[D#]_[Short Title]_[lead partner] .[version#]_[DDMMYYYY].[extension]	D1.1_ProjectHandbook_AMC_ v1.0_10022023.doc
(Draft) Meeting Minutes	(D)MM	[DDMMYYYY]-(D)MM-[type of meeting, e.g. EAB, MT or WPL#].[extension]	10022023-MM-WPL.doc



Meeting Agenda	MM	[DDMMYYYY]-Agenda-[type of meeting, e.g. EAB, MT or WPL#].[extension]	10022023-Agenda-WPL.doc
Periodic Report	PR	PR[period#]-[version#]. [extension]	PR1-v0.0.doc

### 3.2.5 Deliverables

All the publicly available deliverables will be made available in the in the password protected ONELAB surfdrive environment WP1-Management/Deliverables. The deliverables are written in the format below:

1. Executive summary/objective (Target Audience: Project Officer, reviewers, consortium)
2. List of contributors, their role, and description of on-going work.
3. Main body of the report (Target Audience: reviewers, consortium)
4. Conclusions
5. Appendices: contain all the technical details, or a paper, a software manual, or other detailed material. (Target Audience: consortium (but also distributed to reviewers and PO))

Length: No limit

By reading the executive summary and main body, reviewers must be able to assess the content of the deliverable, and must also be able to assess that the deliverable reflects the contractual obligations as laid down in the DoA. If needed, the reviewer can choose to read the full appendix to assess all details.

### 3.2.6 Document repository

The password protected ONELAB surfdrive environment accessible to the members of the ONELAB consortium. Others do not get access.

The public website at <https://onelab-project.eu/> hosts the public repository intended for the published publications and all other dissemination materials.

## 3.3 Project Communication Mechanisms

All partners will inform the Project Manager of changes of their contact details or contact persons, or of changes in any other information needed for executing the project.

### 3.3.1 Mailing Lists

Dedicated mailing lists have been set up to support the project communication.

To prevent an avalanche of unsolicited messages, senders are obliged to target their messages carefully to the narrowest audience as reasonably possible.

### 3.3.2 ONELAB meetings and teleconferences

Within the ONELAB project the following meeting structure is in place:

1. A fixed scheme of online meetings (teleconferences):
  - a. PST meetings, twice a week:

- Monday, 11:00-12:00 (CET)
  - Thursday, 11:00-12:00 (CET)
- b. Intra-WP meetings (organized by the WP leads):
    - WP2 - 2<sup>nd</sup> Tuesday of the month; 11:00 (CET)
    - WP3 - 2<sup>nd</sup> Wednesday of the month; 12:00 (CET)
    - WP4 - 1<sup>st</sup> Friday of the month; 09:00 (CET)
    - WP5 - 3<sup>rd</sup> Tuesday of the month; 12:00 (CET)
    - WP6 - 1<sup>st</sup> Wednesday of the month; 12:00 (CET) [NOTE: starts at a later stage]
    - Additionally; task specific meetings are organized by task leads in case required
  - c. WP1/Management team – 2<sup>nd</sup> Friday of the month; 09:00 (CET) [NOTE: these meetings will start soon, so far, they were ad-hoc meetings, due to the focus on starting other activities], the project manager and the coordinator are in contact on an ad hoc basis, when necessary, any time.
  - d. Monthly telcos between Work Package Leaders, currently 1<sup>st</sup> Friday of the month, 11:00 (CET)
2. Operational meetings:
    - Design of clinical trial; March'23 Innsbruck
    - Field Training Exercises (FTX); D16 (Task 5.2) + D17 (Task 5.3) – date & location(s) TBD
    - Additionally; workshops organized on a specific subject when deemed necessary.
  3. Consortium meetings; once a year over 2 days, including a GAss meeting, tentative schedule:
    - Fall 2022: Kick off meeting, The Netherlands
    - Fall 2023: Location TBD
    - Fall 2024: Location TBD
    - Final meeting 2025: Location TBD

We have not yet defined the date of the future meetings, but will do so during the teleconference of the EB (Work Package Leads) in May'23.

### 3.3.3 Financing of meetings

The Consortium meeting will be yearly. The location should be within easy reach of an airport. These meetings shall be run as internal workshops. The costs incurred by the beneficiaries for travel and accommodation shall be claimed as part of Other Direct Costs of the beneficiary's budget. AMC will take charge in calling the meeting and will decide on the venue together with the WPL. Once decided the member of the partner hosting the meeting will work with AMC to manage the logistics. The hosting partner will ask a contribution in the costs for the meeting rooms, catering (including lunch) and one joint dinner from the ONELAB partners from their own project budget.

## 3.4 Project Management

In this section the Project Management structure of the project is described.

### 3.4.1 Project Management

#### **General Assembly (GAss)**

The GAss represents all partners in the project and has the final managerial and decisive power. It is concerned with the overall strategic direction of the project.

The **General Assembly** is the highest level of management and the board for strategic direction of the project and consists of one representative per partner in the consortium. The Project Coordinator chairs the General Assembly. The General Assembly is the only body within the project that decides on contractual issues, including the budget, timescales, deliverables, and reallocation of effort. The General Assembly takes responsibility for the total content and quality of the ONELAB project and the composition of the consortium (entry or exit of beneficiaries), takes final decisions in case of conflict or defaulting partners, decides on whether milestones and deliverables (including planning) are reached, reviews and approves proposals made by the Executive Board for the adjustment of the project's plan whenever necessary in consultation with the European Commission, takes final decisions on the exploitation of project results (intellectual property rights), initiates and maintains the consortium agreement between the ONELAB beneficiaries, and takes decisions on the dissemination of project results. Decisions are taken by a majority vote, with each member of the General Assembly having one vote. All further details will be arranged in the Consortium Agreement. The General Assembly will meet formally once per year. The General Assembly delegates daily execution and management to the Executive Board. Besides the chair and his substitute, the GAss consists of 1 representative per beneficiary.

#### **Security advisory board (SAB) and the Project Advisory Board (PAB)**

Due to the trans-disciplinary nature of ONELAB, two bodies of consultative experts and stakeholders specifically addressing scientific progress, exploitation measures, patient safety and societal interests will be constituted at the very beginning of the project; the PAB and the SAB. The SAB will advise the Consortium on security sensitive issues and will review the sensitivity of deliverables to be marked as EU Classified Information, as well as all publications before their submission. They will ensure that outputs comply with the regulations about EU Classified Information (EUCI). The PAB will be appointed to assess the scientific progress of the project and advise the WPL.

The PAB members will be asked to sign a confidentiality agreement regarding the non-disclosure of foreground. They will be invited to join the plenary session of the ONELAB Project Meeting, and their expenses will be covered from the Management budget of the project, held by AMC.

The PAB will only have an advisory role to the GAss and will not take part in the decision-making processes of the project. In more detail, the AB will:

- Increase interest in and awareness of the research within the scientific, policy and industrial communities;
- Facilitate access to additional relevant organizations and stakeholders;
- Offer scientific, technological and strategic guidance to the project;

- Monitor the adequate implementation of the proposed dissemination and exploitation measures.
- Take the multidisciplinary nature of ethical issues (e.g. animal issues, clinical cohorts, data protection) arising in the conduct of the project into account;
- Monitor gender equality measures during the execution of the project.

At the moment we have one member, Anke-Hilse Maitland-van der zee, but we are in contact with (and will add) at other external advisors. The members that have already agreed to be a member of the Safety Advisory Board are Dr. Georgios Kioumourtzis (chair), Prof. Dr. Chris A. Mayhew and Dr. Kelly Feytens.

### **Project Coordinator (PC) and Project Manager (PM)**

At the coordinating partner the project management office (PMO) is located, consisting of the Project Coordinator, Dr. Paul Brinkman, AMC. the Project Manager (Dr. Laurian Jongejan) and the project financial controller (Ruud Nok) to professionally handle all consortium management issues. They are supported by the local Project support team. The GAss delegates executive management of ONELAB to the PC and PM, who are thus responsible for the day-to-day operations of the project. Only the PC and PM shall have direct communication with the Project Officer at the European Commission.

The Project Coordinator will coordinate research and innovation activities, monitor progress, coordinate reporting to the European Commission, and act as a link between the ONELAB project and the Advisory Board, and other related projects, initiatives and commercial bodies. The Project Coordinator executes all decisions made by the Executive Board and can in turn delegate this to the appropriate manager or work package leader.

The Project Manager (Laurian Jongejan) will interface with the European Commission and assist the Finance Manager (Ruud Nok) in all administrative, legal and financial matters to ensure that the project program, milestones, and timescales are carried out efficiently. The Project Manager will control the quality assurance procedures (WP1), identify bottlenecks and control the risks in implementation. The Project Manager, Task 1.3 partners Telesto & IANUS and Paul Brinkman (coordinator/WP1, will ensure that all Intellectual Property Rights used or generated by the project are managed in accordance with the Consortium Agreement during the contract preparation phase and the legal requirements of the partners (also especially described in Task 1.3 IPR and Innovation management. On a 6-monthly basis they will be in touch with the WP leads in order to monitor progress and new developments. The Finance Manager is responsible for all contractual financial reporting.

### **Executive Board (EB)**

The members of the EB are composed of the project coordinator (Paul Brinkman (coordinator/WP1), the project manager (Dr. Laurian Jongejan), and the 5 scientific WP leaders; Andria Hadjithekli (IANUS, WP2), Kathleen van Heuverswyn (JUR, WP3), Christopher Mayhew (UIBK, WP4), Simon Bittner (JOAFG, WP5) and Paul Thomas (BIOX, WP6).

The executive board ensures efficient daily management of ONELAB. It will also ensure the operation of the overall communication lines inside and outside the Project's remit. The Project Manager will

handle all consortium management issues. The EB will establish detailed research and technical planning and control of the activities bridging the WPs (inter-WPs), identify key clinical, scientific or technical issues that require final approval by the GAss to adjust planning and necessary tasks re-allocation, review risks related to the project and propose mitigation strategies and risk contingency, and implement and execute all required procedures for quality assurance of all deliverables of the project.

### **Ethics board (EthB)**

Oversight of our ethics is embedded into ONELAB's governance (see figure 1), where the PMO will receive regular reports from our internal/local ethics managers (partner level), and the project's Ethics advisor (Dr. Marina Andeva, expert on legal sociology, data protection and privacy, ISIG) will be heavily involved in the initiation and support of the External Ethics Board (EEB).

## **3.5 Open Science**

ONELAB will implement open science practices as an integral part of the proposed scientific approach. The subsequent principles will be followed:

### **3.5.1 Open data**

ONELAB's research data will be publicly available (respecting privacy and fundamental rights as to be detailed in the Data Management Plan. ONELAB will adhere to common data standards and formats ensuring reusability and exploitation of the produced data, including joint exploitation with existing datasets.

### **3.5.2 Open access**

Gold Open Access journals or transformative journals committed to transform into fully Open Access journals will be targeted for the research outputs. Pre-print repositories will be used enabling *early and open sharing* of the project's results. A Zenodo community, linked to trusted repositories such as OpenAire, will be created for public and open non-security sensible datasets will be disseminated using a Creative Commons license CC BY 4.0. Capacity development deliverables such as D2.1, D2.5, D3.1, D6.1, and D6.2 will also be disseminated using a Creative Commons license CC BY 4.0.

### **3.5.3 Open Science tools**

Open Repositories for data, code and research results will be supported by ONELAB. Consortium partners are also encouraged to use Open Workflow tools (e.g., GitHub, Notebooks) to facilitate collaboration and cross fertilization of research activities.

### **3.5.4 Open peer-review**

The participation of first responders and local authorities as partners in ONELAB Consortium increases the versatility of outcomes of the research and innovation process. Early sharing enabling open peer review within the consortium along with the participation of expert contributors from the worldwide

pandemic community-testing forum (WPCTF) in T2.4. will involve all necessary and relevant knowledge for objective and subjective assessments. Publications to OpenReview conferences will be encouraged.

### ***3.6 List of contacts***

An overview of the contact persons and roles in the ONELAB project will be listed in the file ONELAB\_contacts.xls on the intranet/surfdrive repository.

#### **Project Officer**

Patricia Elena Rischitor

#### **Reviewers**

(not known currently)

### ***3.7 IPR and access rights***

Access Rights are regulated by Article 9 of the ONELAB Consortium Agreement and Article 16 of the Horizon 2020 Grant Agreement Annex II. For best practice every use by any partner of software or components related to the background knowledge of a partner for the implementation of the technical work in ONELAB should be recorded in writing or at least by email exchange between parties.

### ***3.8 Quality Assurance (QA) Plan for Project Deliverables***

1. The first step in the QA Procedure is the check by the Corresponding Deliverable Editor of the quality of the content of the deliverable. The Deliverable Editor is appointed by the lead beneficiary of that deliverable. The Deliverable Editor will check the following points:

- The deliverable covers the stated objectives;
- The quality of the work described in the deliverable is of high standard and is in accord with what is expected;
- The quality of the writing of the document is of high standard with respect to style, errors and organisation; readability; and illustrations. This is described in the Project Handbook.
- The deliverable is complete, i.e. there are no missing parts, missing references, missing explanations of concepts;
- The deliverable is clearly written and understandable by its potential readers.

2. The Deliverable should be written in Word unless otherwise agreed with the consortium. The deliverable editor must provide the consortium with a version which is readable for all and use the provided deliverable template. The format for the title is described in §3.2.4.

3. Next, to ensure that these standards of quality are achieved, each deliverable will be submitted for project-internal peer review two weeks before the delivery date of the deliverable. The peer reviewers will be at least two members of the consortium, who have not been directly involved in the work described in the deliverable. They will be selected by the Project Coordinator and Project Manager at least 3 weeks before the delivery date. They will read the submitted deliverable and

suggest changes where necessary. During the review, the deliverable draft should also be accessible by all project members through the repository.

4. The assessments of the peer reviewers are sent by email to the Deliverable Editor a week before the delivery date of the deliverable. The Deliverable Editor has one week for the revision of the deliverable.

5. The Deliverable Editor will send the revised version of the deliverable to the Reviewers to check whether the comments have been adequately addressed, if possible, within two days. The reviewer's comments and recommendations will be sent to the Project Manager and the Executive Board (EB) few days before the delivery date. The EB leader will ensure that the Deliverable Editor takes into account the suggestions of the reviewers in preparing the final document.

6. The Deliverable Editor will send the final version of the deliverable to the Project Manager before the delivery date.

### 3.9 Risk analysis and contingency planning

The following risks associated with the QA procedure can be identified:

Deliverable is not submitted to a project-internal peer review one month before the delivery date of the deliverable.

Probability	medium
Impact	Minor
Risk assessment	medium
Mitigation	Deliverable Editor to update WP leader and Coordinator about the progress of the deliverable. PM will start reminding Deliverable Editors 2 months before the delivery date of the deliverable.

Peer reviewers do not complete their review of the deliverable within one week

Probability	Medium
Impact	Minor
Risk assessment	Minor
Mitigation	Project Coordinator to ensure timely appointment of reviewers. Project Manager to remind reviewers one week before submission that deliverable is due for submission, and to monitor the progress of the review.

Major problems with the deliverable are discovered by the peer reviewers

Probability	Small
Impact	Medium
Risk assessment	Minor-Medium
Mitigation	Progress of the deliverables will be checked regularly internally within the work packages through intra-WP meetings and teleconferences, and through the WP leader teleconferences.

## *3.10 Tracking of Person months and of Budget*

### 3.10.1 Person months

The Project Coordinator and Project Manager will monitor:

- Technical work per WP
- Actions from meetings

The Project Coordinator and Project Manager will monitor the list of staff members working within the consortium. Every partner will communicate the list of staff working for the ONELAB Project throughout the lifetime of the Project to the Project Manager. The workforce may change but the current Person Months (PM) will be strictly adhered to by each of the partners in the WPs they are dealing with.

Tasks attributions to WP leaders will be governed by the WP1 leader and reported as part of the WPL meetings.

### 3.10.2 Budget

An internal assessment of the expenditure per partner is reviewed every 12 months; this includes the reporting of person months per WP; reporting of costs and explanation of the use of resources when regarded necessary.

The Project Management (WP1) will have direct communication with the financial and administrative officer at each of the beneficiaries to collect the EC required information and possibly additional information for monitoring expenditure in the course of the project and to prepare periodic reporting.

## *3.11 Conflict resolution procedures*

It is vital that potential problems are identified early and dealt with. Potential problems can be of the following nature:

### **Technical Problems**

Sometimes, as a result of work undertaken in the project, it becomes obvious that for technical reasons the original goal is unachievable to the point it is a waste of effort to continue. A procedure must be followed for the swift continuation of the Project:

- First any technical issues within a work package must be brought to the attention of the Work Package leader.
- If the problem can be solved within the work package such as for example: the technical issues can be fixed by another partner without change of budget, the WP leader will take the final decision and report to the coordinator.
- If necessary, the issue shall be escalated to the WPL group, who shall take the final decision. The GAss shall be notified.
- Any member of the GAss can object to the proposed solution.
- Ultimately any changes in the DoA shall be dealt with and approved by the GAss, before an official amendment request will be made to the EU.



## **Partners**

- A partner wishing to leave the consortium must inform the Project Coordinator at least 4 months before he wishes to do so. Defaulting partners will be dealt with in accordance with the consortium agreement.

## **Safe space**

- ONELAB pursues a safe working environment for everyone. We will treat one another with equality, politeness and respect at all times. In case of issues related to this topic, ONELAB members can consult one of the members of the PST, who will listen and deal with the problem in the necessary confidence.

## **4 Conclusions**

This document has set out the practical organisation and procedures of the ONELAB project. It is a reference document for the consortium members that they should read and familiarise themselves with. The Project Handbook is work in progress; based on experiences and needs in the consortium; the document will be continuously adapted and updated. Best practice will be incorporated and used to constantly improve the management of the project. The most recent version will be available on the repository, in the WP1 Project Management folder.