Contract no. 101057548

EPIVINF

Epigenetic regulation of host factors in viral infections

ACTION: Research & Innovation Action (RIA)

CALL: HORIZON-HLTH-2021-DISEASE-04

TOPIC: HORIZON-HLTH-2021-DISEASE-04-07

Deliverable D7.1: Project Handbook of Management

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Deliverable leading partner	IRSICAIXA	Author	Christian Brander
WP Nº	WP7	WP Title	Management, Communication and Exploitation

Project starting date	01/09/2022	Project Duration	60 months

Dissemination Level	PU	Public	X
	PP	Restricted to other program participants (including the Commission Services)	
	RE	Restricted to a group specified by the consortium (including Commission Services)	
	CO	Confidential, only for members of the consortium (including Commission Services)	

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1 GLOSSARY

- CA: Consortium Agreement
- CFS: Certificate on the Financial Statement
- CV: Curriculum Vitae
- DL: Deliverable Leader
- DOA: Description of Action
- EC: European Commission
- ESC: General Assembly
- EU: European Union
- FMEA: Failure Mode Effects Analysis
- GA: Grant Agreement
- IP: Intellectual Property
- IPR: Intellectual Property Rights
- PC: Project Coordinator
- PLSIGN: Project Legal Signatory
- RTD: Research and Technical (or Technological) Development
- SAB: Scientific Advisory Board
- SO: Scientific Objectives
- WPL: Work Package Leader

2 INTRODUCTION

The Handbook on Management is intended to support partners in the effective and efficient administration and procedural management of the project.

It focuses on project implementation procedures, structures, and coordination and sets out key responsibilities for EU engagement and interaction. It is intended to support the achievement of project objectives, the effective management of partner progress, and the timely delivery of project results. The Handbook on Management is supplemented and supported by a series of project management procedures - including half-yearly technical progress reports.

3 STRUCTURE OF THE DOCUMENT

The Work package 7 "Management, Communication and Exploitation" aims at ensuring the monitoring of the project and that the project objectives are completed in a timely and proper manner. Regarding management, the specific objectives of this work package include:

- the research project is carried out according to the established time schedule and budget
- the objectives are efficiently achieved
- a system to provide continuous evaluation feedback and constant project monitoring is created
- an effective coordinated structure is created and maintained
- the project is managed according to the contract between the Consortium and the EC, maintaining a continuous link with the EC
- overall legal, contractual, ethical, financial, and administrative management of the project

The present EPIVINF Handbook on Management summarizes all the required knowledge for the good management of the project focusing mainly on procedures.

The main sections to be found in this document are:

1. Project management structure. This part is based on information gathered from the Consortium Agreement and it encompasses not only the governance structure but also its decision-making procedure and its meeting procedure.
2. Management Procedures. This part has been developed to make the coordinator and partners know how to proceed and deal with each case such as deliverable submission, and amendment request, among others.
3. Annexes. In this section, templates used for the management procedures are included.

4 PROJECT MANAGEMENT STRUCTURE

In order to establish well-organized interactions between all partners, the consortium will employ a flexible management structure. Project management will consist of three committees (General Assembly, External Advisory Board (EAB, Technical Committee, and Dissemination, IPR), and The Exploitation and Dissemination Board (EDB).

The organizational structure of the Consortium shall comprise the following Consortium Bodies:

- General Assembly (ESC) is the decision-making body of the consortium
- The Coordinator (CO) is the legal entity acting as the intermediary between the Parties and the Granting Authority. The coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement.
- External Advisory Board (EAB) The EAB shall assist and facilitate the decisions made by the General Assembly. The Coordinator will ensure that a non-disclosure agreement and MTA are executed between all Parties and each EAB member.
- The Technical Committee supervises the technical and scientific work and comprises work package leaders who are responsible for achieving the goals of their specific topic and tasks.
- The Exploitation and Dissemination Board (EDB), will be responsible for all exploitation and dissemination activities

4.1 Project Coordinator

The coordinator, Dr. Christian Brander, IRSICAIXA, is the primary contact person for the European Commission and will head the General Assembly. The role of the Coordinator will be to co-Chair meetings of the Technical Committee; Coordinate the overall financial, administrative, and contractual activities of the project, including monitoring and maintaining the overall adherence to the financial budgets; act as liaison to the European Commission on behalf of the group in all verbal and written communication; initiate, prepare and preside over regular project progress meetings and the dissemination of information to all partners pertaining to these meetings; disseminate information from consortium bodies to all partners; propose to the General Assembly all measures needed to ensure the proper implementation of the project; report to the General Assembly and disseminate minutes to all partners pertaining to these meetings.

Apart from his role as liaison between the consortium and European Commission, the coordinator shall establish, through participation in the committees, a permanent communication link ensuring that these bodies are working synchronously; he will also be in charge of coordinating the work of each committee. Signed meeting protocols will be compiled for all committee meetings in order to record major decisions and provide traceable documentation for test and validation procedures of the planned project goals. It is the duty of the coordinator to distribute these documents to the consortium.

4.2 The General Assembly

The General Assembly is the ultimate governing body of the project. It shall consist of the Coordinator and the persons appointed by the partners. The Coordinator shall chair all meetings of the General Assembly.

The General Assembly shall monitor the effective and efficient implementation of the Project.

In addition, the General Assembly shall collect information at least every 6 months on the progress of the Project, examine that information to assess the compliance of the Project with the Consortium Plan and, if necessary, propose modifications of the Consortium Plan to the General Assembly.

The General Assembly shall:

- agree on the Members of the Management Support Team, upon a proposal by the Coordinator.
- support the Coordinator in preparing meetings with the Funding Authority and in preparing related data and deliverables.
- prepare the content and timing of press releases and joint publications by the consortium or proposed by the Funding Authority in respect of the procedures of the Grant Agreement Article 29.
- Accept, reject, or modify any decision taken in other consortium bodies.

4.3 External Advisory Board (EAB)

An External Expert Advisory Board (EAB) will be appointed and steered by the General Assembly. The EAB shall assist and facilitate the decisions made by the General Assembly.

The Coordinator will ensure that a non-disclosure agreement is executed between all Parties and each EAB member. Its terms shall be not less stringent than those stipulated in the Consortium Agreement, and it shall be concluded no later than 30 days after their nomination or before any confidential information will be exchanged/disclosed, whichever date is earlier.

The Coordinator shall write the minutes of the EAB meetings and submit them to the General Assembly. The EAB members shall be allowed to participate in General Assembly meetings upon invitation but have not any voting rights.

4.4 Technical Commiittee

Supervises the technical and scientific work and comprises work package leaders who are responsible for achieving the goals of their specific topic and tasks. It will meet frequently (every 6 months), both personally or by electronic means.

Role of Work package (WP) Coordinators:

Work Package Coordinators are responsible for coordinating the partners and subcontractors carrying out the individual experimental elements to ensure scientific objectives are delivered on schedule. They will:

- manage the respective work packages;
- be responsible for the necessary resources within the work package and liaise with contributing partner institutions;
- assure the quality of the work within the specific work package;
- manage the work package in such a way that key objectives and milestones are reached in a timely fashion; and
- discuss the approach and methodologies taken with other Work Package Coordinators as appropriate.

They are also responsible for preparing progress reports. All Work-package coordinators will attend technical committee meetings.

4.5 Management Support Team

The Management Support Team shall be proposed by the coordinator. It shall be appointed by the Executive Board and shall assist and facilitate the work of the Executive Board and the Coordinator for executing the decisions of the General Assembly as well as the day-to-day management of the Project.

The management support team will be in charge of:

- Managing the financial aspects: to support the consortium in all financial questions during the project, i.e., a) to monitor the eligibility of costs, b) to check partners 'financial statements, c) to support the coordinator during the audit, d) to support in the release of the payments to the partners, among others.
- Managing the consortium coordination: prepare templates of basic documentation that will be used during the project, check the reporting documentation developed by the coordinator and partners, monitor the tasks are carried out properly, to be in continuous touch with partners in order to help them to solve doubts or any issues, to support the preparation of the Technical Review Meetings, among others.
- Managing the communication issues: to support internal and external communication activities such as convening a meeting, sending agendas and minutes, developing the Handbook on Management, developing the Dissemination and Communication Plan, etc.

4.6 The Exploitation and Dissemination Board (EDB)

The EDB is responsible for all exploitation and dissemination activities (working closely with the project coordinator). Through the appointment of an exploitation manager, this committee monitors internal and external exploitation opportunities. The exploitation manager (Dr. Christian Brander) heads the committee and his tasks will be to identify and manage foreground IP within EPIVINF while also monitoring the IP outside of the consortium in relevant areas (with the help of an external IP specialized consultancy firm). An appropriate person will represent each partner in this committee.

The EDB meets every 6 months. Apart from the obvious tasks of dissemination, it also monitors IPR and exploitation opportunities. Specific tasks are a) to review and manage dissemination plans and deliverables¡, b) To identify and protect valuable intellectual property, e.g., patents, created within the project. c) To review the state-of-the-art and current patent situation, d) To identify opportunities to exploit the results of the project, and e) submitting the dissemination and exploitation plan as part of the project completion.

The outcomes of EPIVINF are promising and may result in reasonable social and industrial impact. Most of the participants already have considerable pre-existing know-how in various fields, from basic science to novel biomarkers and personalized profiles to guide clinical management and improve prognosis. Still, it is critical that each EPIVINF participant is able:

- To valorise its pre-existing know-how through the results of the project.
- To identify contractually its pre-existing know-how.
- Not do disclose the part of its pre-existing know-how that is not necessary for the implementation of the project.
- To benefit from the generated intellectual property for any future development beyond EPIVINF.

In addition to the contractual rules, set up by the European Commission, the Consortium Agreement addresses IPR issues, according to the rules set forth in the DOA and allows a higher level of protection for all participants both individually and collectively; the clauses are detailed in the Consortium Agreement.

In order to ensure the best possible economic success of the project outcomes, the following basic rules have been agreed on between the consortium partners:

- Every partner is requested to appropriately protect the intellectual property, gained in his/her project parts, especially to file patent applications,
- The intention is to create or strengthen a patent portfolio, which shall give as much protection as possible for the exploitation field described in the project,
- Every partner is responsible for the continuous analysis of the patent situation in his/her specific field of work.

The dissemination and exploitation manager, supported by a specialized firm will support the partners while conducting the above tasks.

4.7 Decision process

Each Consortium Body shall not deliberate and decide validly unless two-thirds (2/3) of its Members are present or represented (quorum). If the quorum is not reached, the chairperson of the Consortium Body shall convene another ordinary meeting within 15 calendar days. If in this meeting the quorum is not reached once more, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if fewer than the quorum of Members are present or represented.

The ESC is the ultimate decision-making body of the Consortium.

The ESC will include the Coordinator and one senior representative from each partner organization who has the authority from his or her contributing organization to take any necessary corrective action. Each GA Member present or represented will bear one vote.

The ESC shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures that will be set out in the Consortium Agreement. In addition, all proposals made by the Technical Committee and the IPR, Exploitation, and Dissemination committee shall also be considered and decided upon by the General Assembly. As the final decision-making body, the General Assembly will be able to accept, reject or modify any decision taken by other consortium bodies.

In case of conflicts, those will be submitted to the Coordinator for mediation and resolution. The Coordinator will employ a fact-finding exercise to investigate the circumstances and prepare and submit an objective report to the involved parties. Investigations will consist of both individual interviews and group processes to be able to develop a composite understanding of the conflict. Based on that report, the parties will be asked to decide whether or not a dispute exists and take steps to resolve it if it does.

Any dispute that may arise in other Committees or between the partners and that cannot be solved through the coordinator will be presented to the ESC in order to reach a final decision. Its decision will be definitive.

In the case of any major dispute, controversy, or claim that cannot be tackled in the ESC, it shall be submitted to mediation by the partners involved in the dispute, or alternatively, by the coordinator under the mandate of the ESC.

5 MEETINGS

In the EPIVINF project, according to the Consortium Agreement, any Party which is a member of a Consortium Body:

- should be represented at any meeting of such Consortium Body;
- may appoint a substitute or a proxy to attend and vote at any meeting;
- shall participate in a cooperative manner in the meetings.

The chairperson of a Consortium Body shall convene meetings of its Consortium Body. The frequency where meetings will take place has already been fixed, being the ESC one at least twice a year; the Technical Committee one at least every 6 months, and; linked to issues related to dissemination, IPR, and exploitation once every 6 months. Otherwise, extraordinary meetings could be requested.

Each time a meeting is called, the chairperson of a Consortium Body shall give notice in writing of it to each Member of that Consortium Body no later than the minimum number of days preceding the meeting as stated in the Consortium Agreement.

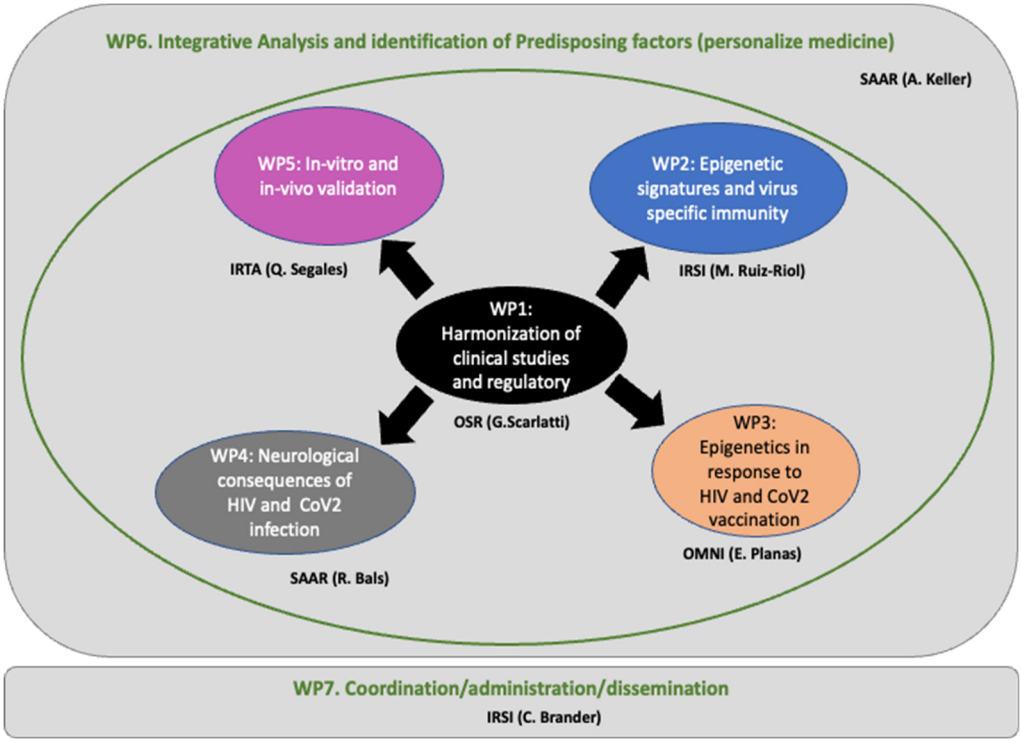
Once the meeting has taken place, the chairperson of a Consortium Body shall produce written minutes of each meeting and send the draft minutes to all Members. These shall be considered as accepted if no Member has sent an objection in writing to the chairperson within 15 days.

6 WORKPLAN

The EPIVINF project is structured into 7 work packages, which are highly inter-related through the following diagram:

1) A central work package (WP1) that forms the basis for controlled patient recruitment, optimal study group composition and sample storage and covers all ethical and regulatory aspects related to human and animal studies.

2) A second work package (WP2), where the epigenetics marks after HIV and SARS-CoV-2 infection are being studied, validated by transcriptomics and proteomics analyses, and related to the virus-specific host immunity.
3) A third work package (WP3), where the infection-induced host epigenetic alterations are being put in context with the immune response to HIV and SARS-CoV-2 vaccination.
4) The fourth work package (WP4), which will investigate how the epigenetic dysregulation of HIV or SARS-CoV-2 infection impacts the long-term neurological disease observed with these infections.
5) A work package 5 (WP5) dedicated to the in-vitro exploration of epigenetic mechanisms and their validation and experimental modulation in animal models of SARS-CoV-2 infection.
6) An overarching WP6, which will integrate the data generated in WP1 to WP5 related to clinical,



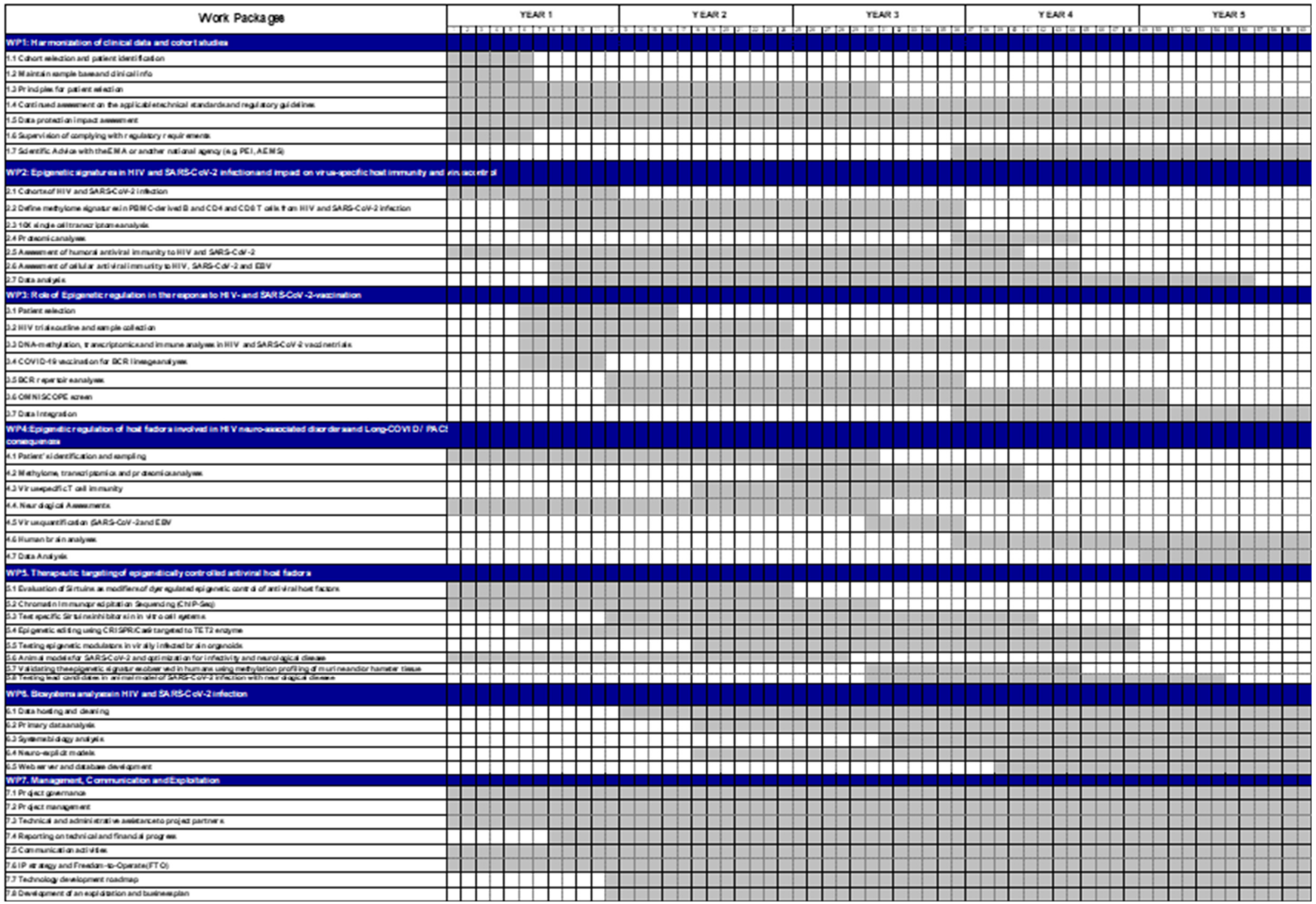
immunological, virological, and neurological data and will identify the similarities and differences of host epigenetic regulation in HIV and SARS-CoV-2 infection.
7) Work package 7 (WP7), containing all tasks related to project coordination, administration and results, and knowledge dissemination.

6.1 List of Work Packages

In order to carry out successful management of the project, the following table indicates how the work packages are interconnected with their respective leaders and their duration:

No.	Title	Leader	Start	End
WP1	Harmonization of clinical data and cohort studies	OSR	M1	M60
WP2	Epigenetic signatures in HIV and SARS-CoV-2 infection and impact on virus-	IRSI	M1	M44
WP3	Role of Epigenetic Regulation in the Response to HIV- and SARS-CoV-2-vaccination	OMNI	M6	M60
WP4	Epigenetic regulation of host factors involved in HIV neuro-associated disorders	IRSI	M1	M60
WP5.	Therapeutic targeting of epigenetically controlled antiviral host factors	IRTA	M1	M60
WP6	Biosystems analyses in HIV and SARS-CoV-2 infection	USAAR	M1	M60
WP7	Management, Communication, and Exploitation	IRSI	M1	M60

The project Gantt chart can be founded in the table below:


Work Package
YEAR 1
YEAR 2
YEAR 3
YEAR 4
YEAR 5
WP1: Harmonization of clinical data and cohort studies
1.1 Cohort selection and patient identification
1.2 Maintain sample base and clinical info
1.3 Principles for patient selection
1.4 Continued assessment on the applicable technical standards and regulatory guidelines
1.5 Data protection impact assessment
1.6 Supervision of complying with regulatory requirements
1.7 Scientific Advice with the EMA or another national agency (e.g. PEI, AEMS)
WP2: Epigenetic signatures in HIV and SARS-CoV-2 infection and impact on virus-specific host immunity and viral control
2.1 Cohort of HIV and SARS-CoV-2 infection
2.2 Define methylome signature in PBMC-derived B and CD4 and CD8 T cells from HIV and SARS-CoV-2 infection
2.3 10X single cell transcriptome analysis
2.4 Proteomic analyses
2.5 Assessment of humoral antiviral immunity to HIV and SARS-CoV-2
2.6 Assessment of cellular antiviral immunity to HIV, SARS-CoV-2 and EBV
2.7 Data analysis
WP3: Role of Epigenetic regulation in the response to HIV- and SARS-CoV-2-vaccination
3.1 Patient selection
3.2 HIV trial outline and sample collection
3.3 DNA-methylation, transcriptomics and immune analyses in HIV and SARS-CoV-2 vaccinetrials
3.4 COVID-19 vaccination for BCR lineage analyses
3.5 BCR repertoir analyses
3.6 OMNISCOPE screen
3.7 Data Integration
WP4: Epigenetic regulation of host factors involved in HIV neuro-associated disorders and Long-COVID/ PACS consequences
4.1 Patient´s identification and sampling
4.2 Methylome, transcriptomics and proteomic analyses
4.3 Virus-specific T cell immunity
4.4. Neurological Assessments
4.5 Virus quantification (SARS-CoV-2 and EBV
4.6 Human brain analyses
4.7 Data Analysis
WP5. Therapeutic targeting of epigenetically controlled antiviral host factors
5.1 Evaluation of Sirtuins as modifiers of dysregulated epigenetic control of anti-viral host factors
5.2 Chromatin Immunoprecipitation Sequencing (ChIP-Seq)
5.3 Test specific Sirtuin inhibitors in in vitro cell systems
5.4 Epigenetic editing using CRISPR/Cas9 targeted to TET2 enzyme
5.5 Testing epigenetic modulators in virally infected brain organoids
5.6 Animal models for SARS-CoV-2 and optimization for infectivity and neurological disease
5.7 Validating the epigenetic signature observed in humans using methylation profiling of murine and/or hamster tissue
5.8 Testing lead candidates in animal model of SARS-CoV-2 infection with neurological disease
WP6. Biosystems analyses in HIV and SARS-CoV-2 infection
6.1 Data hosting and cleaning
6.2 Primary data analysis
6.3 Systems biology analysis
6.4 Neuro-explicit models
6.5 Web server and database development
WP7. Management, Communication and Exploitation
7.1 Project governance
7.2 Project management
7.3 Technical and administrative assistance to project partners
7.4 Reporting on technical and financial progress
7.5 Communication activities
7.6 IP strategy and Freedom-to-Operate (FTO)
7.7 Technology development roadmap
7.8 Development of an exploitation and business plan

6.2 Risk Management

The proposed approach to minimize risks during the project includes:

- Excellence of the Consortium: the involved principal investigators are among the best in Europe in their fields. This excellence brings knowledge and experience to the consortium and will ensure that objectives are met on time.
- The work plan has been proactively assessed and adjusted for any risk eventuality before its implementation. Alternative tasks of the contingency plan have been identified in order to react in the case of a required adaptation of the work plan.

A Risk & Contingency management plan will be enabled through the application of Failure Mode Effects Analysis (FMEA) techniques to individual WPs, as well as across the inter-dependencies between them. For this purpose, specific potential critical risks have been preliminary identified in the management risk table, together with the proposed mitigation measures.

Then FMEA approach will also be used to assess cumulative risk build-up within the inter-relationships between deliverables. An evaluation of performance regarding deliverables has been scheduled on a six-month basis, enabling an assessment of the cumulative effect of each failure or delay upon the final set of project objectives.

In all cases, the Coordinator will make sure that the goals and objectives are clear, and the participants of each work package will be made aware of the resources available and actions needed to complete the task on time, with high quality, and within budget. All members will be informed about their required actions, foreseen timelines and the milestones and deliverables to be factored into the work. They will also be informed about the appropriate communication channels to use if external adverse risks enter into the project so that the work plan can be adjusted properly.

Generally speaking, the procedure to be implemented will be as follows:

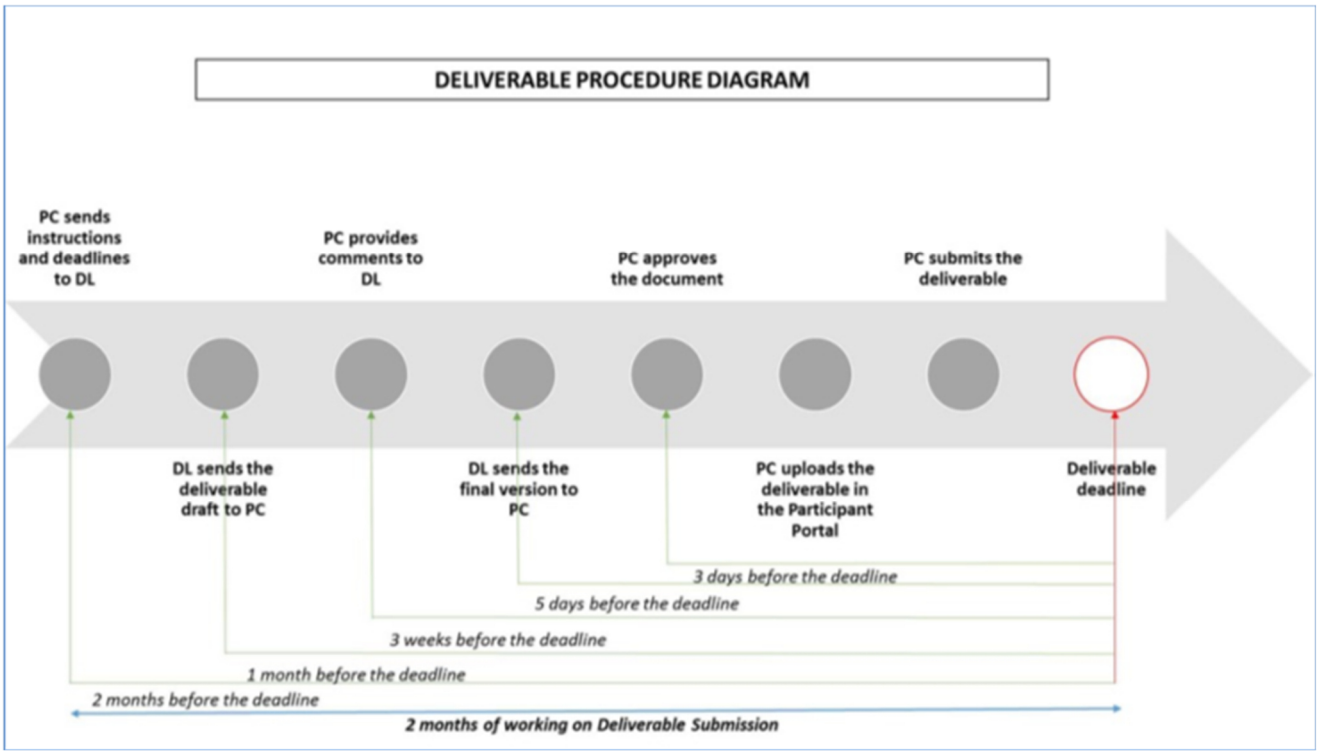
- Any partner or member of the project (including those on the external Boards) who is able to identify a potential risk within the project shall immediately inform the Coordinator.
- Coordinator will assess the dimension of the issue and its impact on the milestones and deliverables of the project. The Coordinator, together with the partners involved and, if needed, with the work package leaders, will define potential mitigation measures and will submit them to obtain ESC approval. In case those measures were urgently needed and the ESC decision could not be rapidly obtained, Coordinator would implement the mitigation measures before ESC approval.

The coordinator may also initiate the breach procedure before the ESC if one partner is responsible for a severe failure in fulfilling its responsibilities within the project. The Consortium Agreement will define the number of votes needed within the ESC to declare a partner's breach.

7 DELIVERABLES

Deliverables are project outputs that must be delivered at a given moment during the action. The coordinator must submit the deliverables identified in Annex 1 of the Grant Agreement, in accordance with the timing and conditions set out in the Grant Agreement. The procedure to be followed in order to submit them successfully consists of these steps:

1. Project Coordinator (PC) will send by mail the deliverable template together with instructions and deadlines to the Deliverable Leader (DL), at least two months before the submission deadline.
2. DL will send a first draft to the PC in order to have it checked by the project coordinator. The revision will be focused on the content and the quality of the information provided. This draft has to be sent to the project coordinator one month before the deadline for its submission.
3. PC will have one week to provide comments to the DL.
4. DL will have three additional weeks to implement the requested modifications and send the document back to PC.
5. Approval of the deliverable by PC will take place at least 3 days before the submission deadline.
6. Once the deliverable is ready, the PC will upload and submit the final document in the Participant Portal. These steps are described in the following diagram:



8 TECHNICAL PROJECT PROGRESS

An active periodic monitorization is key in the project management. A project needs to have an efficient management in order to avoid failures and finish successfully. For this reason, it is necessary to carry out a thorough planification and organization along all the stages of the project where the resources, schedules and costs are assessed.

Once the project starts, the coordinator focuses all his efforts on assessing periodically (every 6 months) its advance by monitoring that all tasks, deliverables, milestones and costs are being fulfilled without any deviation or that mitigation actions are implemented if needed. The document that will gather the progress of the project every 6 months will be the Technical Project Progress.

This document will be sent by the project coordinator to all Workpackage Leaders aiming to:

1. Have an overall overview of the project progress, specifically regarding ongoing tasks, issues that occurred, and potential deviations.
2. Have up-to-date information that will allow us to make decisions to overcome any issue that might arise during the project implementation.
3. Update the continuous reporting modules of the electronic exchange system in the Participant Portal, thus providing an accurate project situation to the European Commission.

The information required will encompass:

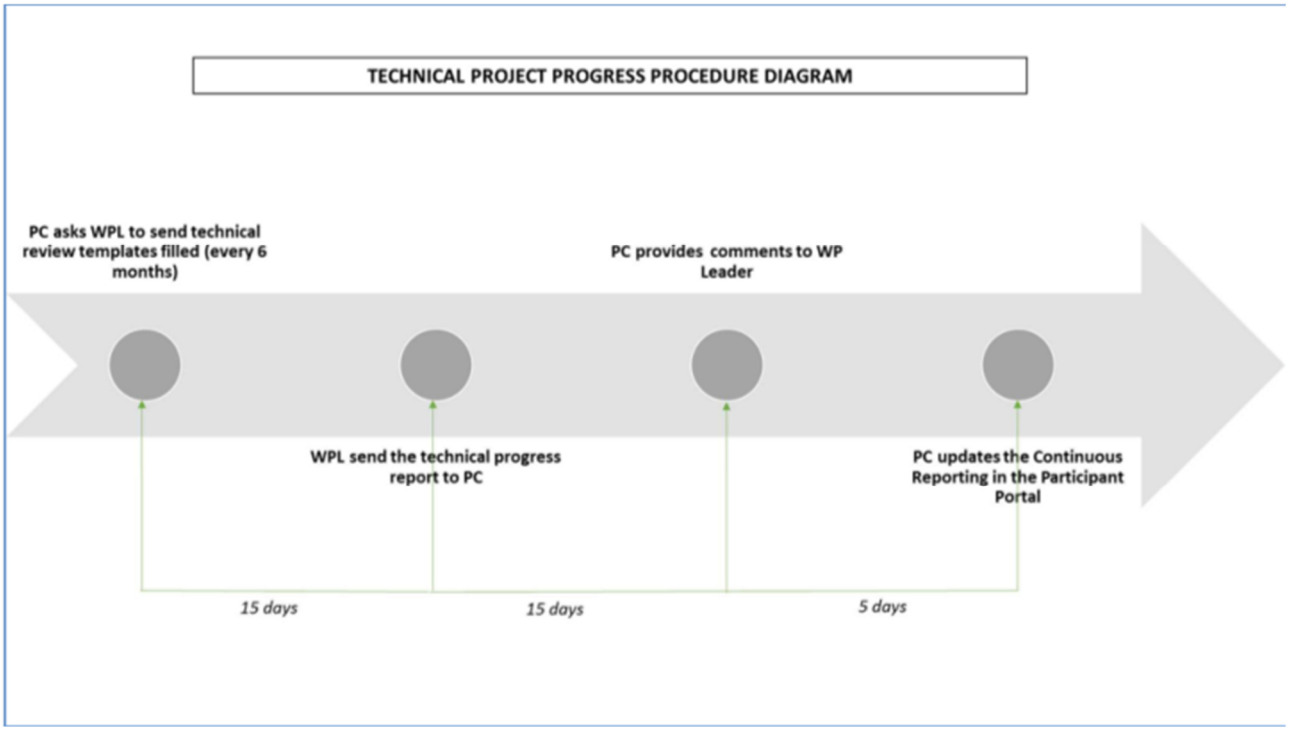
- Deliverables
- Progress in achieving milestones
- Updates to the publishable summary
- Responses to critical risks, publications, communications activities, IPRs

Individual partners will provide a written progress report (1-2 pages plus supporting data) to their respective Work Package Leader every 6 months. On the basis of these reports, the Work Package Leader will monitor progress and take any necessary action to ensure the work package remains on schedule.

Any potential difficulties will be identified and discussed with the partners responsible to prevent an adverse impact on the work package and the project as a whole. These reports will be organized in such a way that it can easily be assessed whether planned milestones and deliverables have been achieved. The reports will be discussed by the Work Package Leaders in a conference call and/or face-to-face at project meetings.

In the case of problems being identified in a work package, the Coordinator will discuss the issue with the individual Work Package Leader and project scientists involved and will take appropriate measures. The ESC will use the interim and annual reports as the basis for their discussions in their meetings.

- The status of the project will be updated by the Project Coordinator in the “Continuous reporting” area of the Participant Portal on following these steps:
- Project coordinator (PC) will ask Work Package Leaders (WPL) to send Technical Project Progress Templates filled every 6 months.
- WPL will have 15 days to gather the information, write it down and send it to the PC.
- PC will have another 15 days to provide comments to the WPL.
- After 5 days, PC will inform every partner about what information should be uploaded in the Continuous Reporting area of the Participant Portal.



9 AMENDMENTS

9.1 When is it necessary?

An amendment is mandatory to include any significant modification in the GA (i.e., its 'Terms and Conditions' and/or the Annexes). It is compulsory in the following cases:

	Cause of amendment	Description
1	Changes involving beneficiaries & linked third parties	Addition of a new beneficiary Deletion of a beneficiary whose participation has been terminated because: • it has not signed the grant agreement • it has not provided a declaration on joint & several liability as requested • for some other reason Change of beneficiary due to 'partial takeover' Deletion or addition of linked third party Specific case: if a beneficiary's participation is terminated at the initiative of other beneficiaries
2	Change involving the coordinator/principal beneficiary	Change of coordinator Change in the coordinator's bank account used for payments Change in the 'authorisation to administer' option
3	Changes affecting the project or its implementation	Change to Annex 1 Change in the title of the project or its acronym, starting date, duration or reporting periods Resumption of project activities after a temporary suspension
4	Changes involving the financial aspects of the grant	Change to Annex 2 or 2a Change in the maximum grant amount, reimbursement rate(s), the estimated eligible costs of the project, the amount of pre-financing or the contribution to the Guarantee Fund Change concerning specific cost categories ('internal invoice")

9.2 Amendment request procedure

Once a potential amendment has been identified it is recommended to start the procedure as soon as possible due to fact that it takes time.

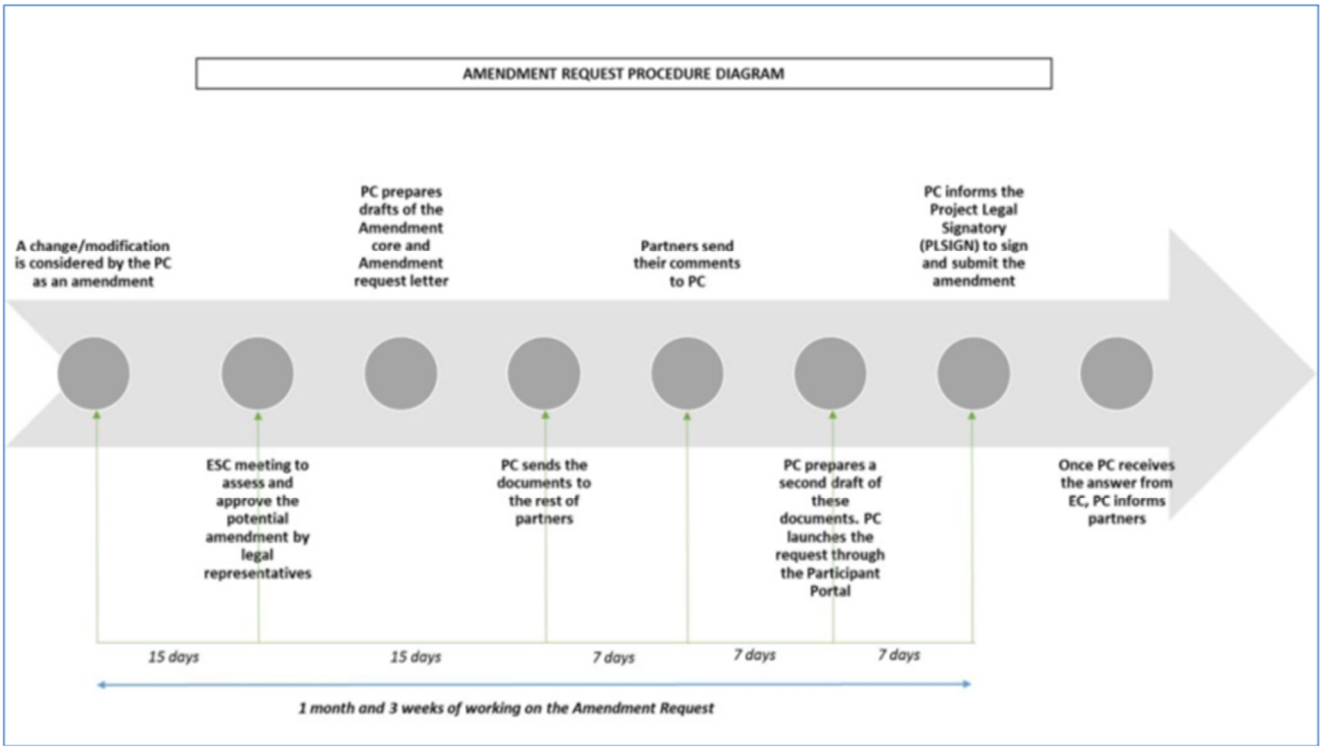
The amendment process would consist of:

1. Once a change or a modification is considered as an amendment by the project coordinator (PC), a General Assembly (ESC) meeting will be organized.
2. The amendment will be evaluated by principal investigators and legal representatives, who will grant permission to the coordinator to proceed.

At this point, PC will undertake the preparation of the following documents1:

- The letter requesting an amendment, which provides justification for the request. The request is assessed on the basis of whatever information and explanations the coordinator provides.
- The amendment itself, which is the legal document containing the amendments to the Grant Agreement. It is legally binding and will be incorporated into the agreement.

- Once these drafts are prepared, PC will send these documents to rest of partners in order to get their approval.
- Partners will have one week to look over them and send their comments to PC.
- From the information and comments gathered, the PC will elaborate the final draft of these documents and introduce the amendment data into the system2.
- PC will launch the request through the Participant Portal and complete all amendment data.
- Once the amendment is ready, the PC informs the Project Legal Signatory (PLSIGN) to sign and submit the amendment.
- Once PC receives the answer from European Commission (EC), PC will inform partners.



10 TECHNICAL AND FINANCIAL PERIODIC REPORTING

10.1 Main Content

The Commission will monitor the activities of the project in order to assess and verify:

- that beneficiaries implement the project as described in Annex 1 of the Grant Agreement (GA) (Description of the action – DoA).
- the eligibility of the costs claimed.

In order for the Commission to verify that the project is implemented properly, beneficiaries must submit any information requested, in particular the deliverables and reports detailed in the GA.

Monitoring project implementation is a continuous task that can take place at any moment during the active period of the project (and beyond), but there are key contractual tasks that make project monitoring most relevant at certain moments, in particular after each reporting period at the time of payments.

Partners project reporting obligations are the following:

1. Deliverables (as described in DoA)
2. Periodic Report (within 60 days following the end of each reporting period)
    a. Periodic technical report
    b. Periodic financial report
3. Final Report (in addition to the periodic report for the last reporting period)
    a. Final technical report – summary for publication
    b. Final financial report – CFSs

The Periodic Technical Report consists of:

1. Part A – This part will be updated from the technical project progress report delivered to WPL every 6 months
    - Publishable summary
    - Deliverables, milestones, risks, etc.

This information for this part should have previously been gathered every 6 months in Technical Project Progress.

2. Part B – narrative part – This part will be written by the coordinator from the information provided by WPL in the Periodic Technical Report.
    - Explanation of the work carried out by the beneficiaries and overview of progress
    - Update of the plan for exploitation and dissemination of results
    - Explanations on deviations from DoA

Regarding the information for financial reporting:

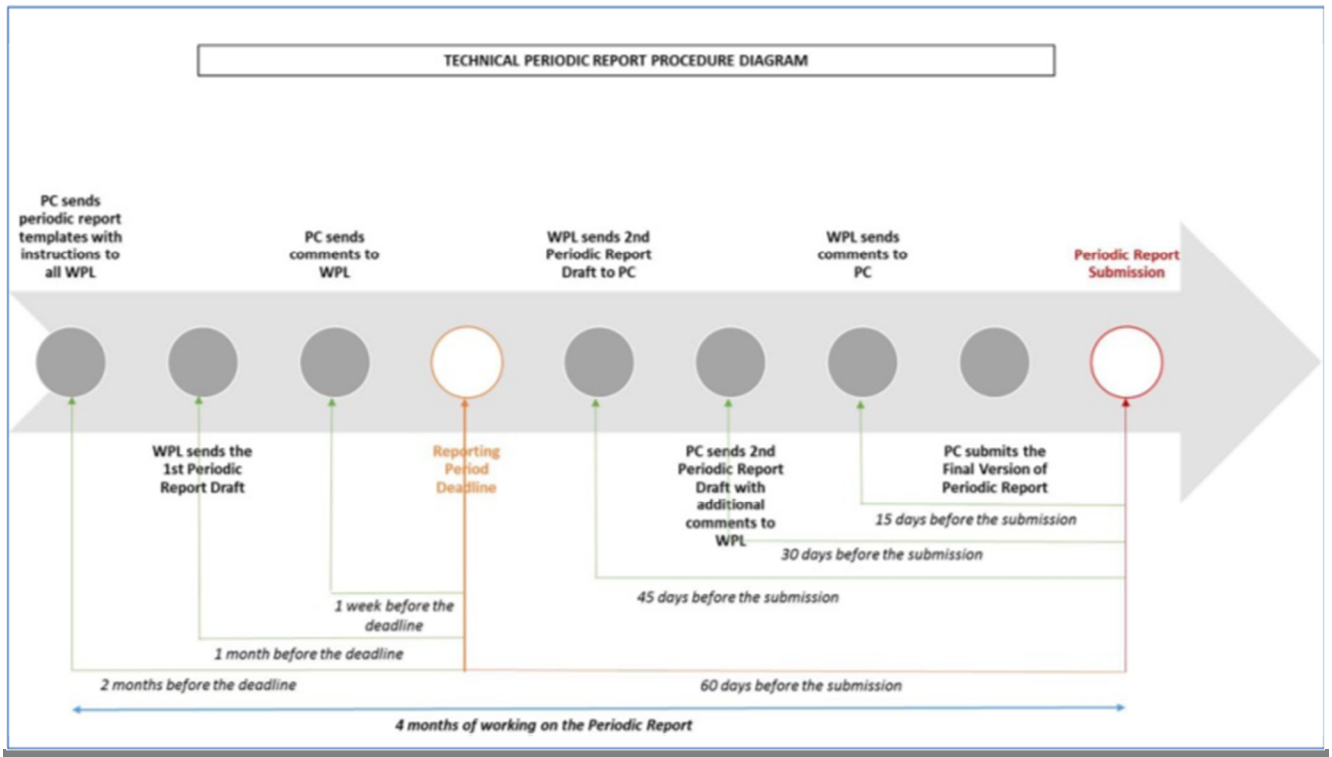
Financial Statement – This part is provided by each beneficiary electronically, and it will be signed and submitted by the Project Financial Signatory.

The periodic report must be submitted by the coordinator within 60 days following the end of each reporting period.

10.2 Preparation Procedure Technical Part

Timelines for the technical periodic reporting will be as follows:

- 2 months before the Reporting Period deadline and 4 months before its submission, the Project Coordinator (PC) will send to every Work Package Leader (WPL) the technical periodic template with instructions.
- 1 month later (1 month before the end of the reporting period), the WPL will send the PC the first Technical Periodic Report Draft.
- The PC will have 3 weeks to check it and send comments to the WPL.
- WPL will have 3 weeks to prepare the second draft and send it to the PC.
- Then, the PC will have 15 days to send that 2nd draft with additional comments to WPL.
- 15 days before the submission, WPL will send comments to the PC in order to finish the Final Version of the Technical Periodic Report.
- PC will be in charge of submitting Part B in the Participant Portal.



10.3 Financial Periodic Reporting

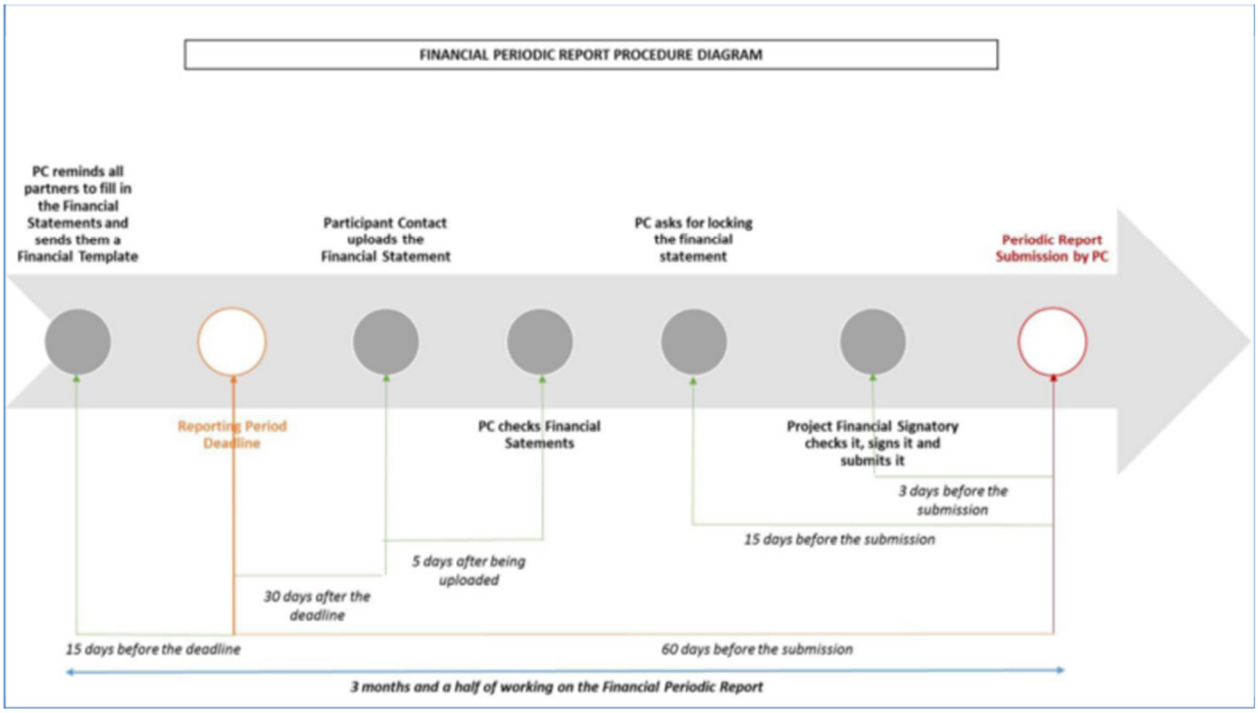
The Financial Report consists of structured forms from the grant management system, including:

- Individual Financial Statements for each beneficiary (and third parties).
- Explanation of the use of resources and the information on subcontracting and in-kind contributions provided by third parties, from each beneficiary for the reporting period concerned.
- Periodic summary financial statement including the request for interim payment.

All beneficiaries - including the coordinator - must fill in their own financial statement, electronically sign it and submit it to the coordinator.

Nevertheless, beneficiaries should provide to the EU services detailed information on the use of resources, which means that a procedure to gather all financial information from the partners should be set up. This procedure is expected to take approximately 3 months:

- 15 days before the Reporting Period deadline, the Project Coordinator (PC) will remind all partners to complete their Financial Statements on a standard template. The PC will gather all the information related to the Use of Resources and the latest updates about the financial progress of the project.
- Each beneficiary will have up to 30 days to fill and upload their own financial statement to SyGMa.
- The PC will check all Financial Statements.
- 15 days before the submission deadline, the PC will ask the Project Financial Signatories (PFSIGN) to lock their financial statements.
- Each Project Financial Signatory (PFSIGN) will have approximately 12 days to check, sign and submit the Financial Statement.
- Once all Financial Statements4 and Technical Periodic Reports have been uploaded, Project Coordinator will be able to submit the report.



Each participant will be able to complete online its own Financial Statement (and the financial report of its Third Parties, if any) including explanations on the use of resources.

Two types of users will be able to participate in this process:

- Users who can fill in the statement: Participant Contacts, Project Financial Signatories, and Task Managers.
- Users who can electronically sign & submit the statement: Project Financial Signatory (PFSIGN).

In order to carry out this task successfully, the following steps will be followed:

1. Participant Contacts usually draft the financial statement (also users with Project Financial Signatories, Coordinator Contacts, Primary Coordinator Contacts, and Task Managers roles can perform this action).
2. Participant Contacts usually “Lock for review” (also users with Coordinator Contact or Primary Coordinator Contact roles can perform this action). This action prevents participants from further editing and generates a pdf document.
3. Project Financial Signatories (PFSIGN) review the Financial Statement. Once reviewed, the Financial Statement can be unlocked ("Unlock to draft") for further editing or electronically signed & submitted ("Sign and Submit") to the coordinator.

11 MAIN CONCLUSIONS

The objectives of this Handbook on Management are as follows:

- To define the procedures and standards to be used in the EPIVINF project.
- To define key roles and responsibilities.
- To demonstrate how the project will be carried out, measured, monitored, accounted for, and safeguarded during the project.

Furthermore, during the project implementation, the consortium will prepare several deliverables that complement the Handbook on Management:

- IP strategy plan and Freedom-to-operate report.
- Exploitation Plan. It will be prepared and updated on a periodical basis.
- Dissemination and Communication Plan.
- Data Management Plan

With this document, the partners will have useful information during project implementation in order to deal with administrative issues. Continuous support on these issues will be given to project partners by the Coordinator.