
Biomarker and AI-supported FX06 therapy to prevent progression from mild and moderate to severe stages of COVID-19

Project No. 101045956

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|---|---|
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| **Deliverable Title** | COVend Governance Report |
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| **Lead Participant** | accelCH |
| **Contributors** | Jeanette Müller (accelCH), Géraldine Messmer (accelCH), Andreia Cruz (accelCH) |
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# Partner short names

| | |
|---|---|
| GUF | Johann Wolfgang Goethe Universität Frankfurt am Main |
| accelCH | accelopment Schweiz AG |
| F4 | F4 Pharma GmbH |

# Abbreviations

| | |
|---|---|
| D | Deliverable |
| EC | European Commission |
| HE | Horizon Europe |
| M | Month |
| MS | Milestone |
| P-DMP | Project Data Management Plan |
| WP | Work Package |

## Revision history

| Date | Authors | Revision |
|---|---|---|
| 12.10.2021 | Jeanette Müller (accelCH) | Draft version |
| 19.10.2021 | Géraldine Messmer (accelCH) | First version |
| 22.10.2021 | Andreia Cruz (accelCH) | Revision |
| 29.10.2021 | Benjamin Ginski (GUF) | Final version |

# Executive Summary

The Governance Report (Deliverable D1.1 of the COVend Research and Innovation Action) defines the organisation, processes and procedures of the COVend project coordination and management, as well as the roles and responsibilities of the consortium bodies. The purpose of the Governance Report is to provide guidelines for all project partners and consortium members related to internal and external communication (in collaboration with WP8 Communication, Dissemination and Exploitation), quality assurance aspects as well as risk management and contingency planning across all work packages for efficient and effective project implementation. As the data governance will be covered by the Project Data Management Plan (Deliverable D1.3), data management related rules are not defined in this report. However, the Governance Report goes beyond the consortium internal features and covers the cooperation and collaborations with other COVID-19 initiatives, relevant authorities and networks that are foreseen in this project.

The contents of the Governance Report are based on 1) the experience of some of the COVend partners` participation in previous EU Framework Programme projects, such as ENVISION, led by Goethe University Frankfurt (GUF), and EURO SHOCK, managed by accelopment Switzerland AG (accelCH), 2) the rules of the EC Model Grant Agreement, notably Art. 17-18, 25.1, and 36.1, 3) the Consortium Agreement (Section 6) using the DESCA model Version 1.2.4, October 2017 and 4) good project management practices according to the PM2 methodology.

The deliverable D1.1 is part of **Work Package 1: Project management and collaboration with other initiatives** and confirms that the different consortium bodies are established, emphasizes which tasks and responsibilities each board fulfils and provide all partners easy guidance on all important aspects of taking part in such a collaborative project on European scale.

# 1. Organisational structure

## 1.1 Contractual framework

The COVend governance plan follows two main contracts: the Grant Agreement (GA) and the Consortium Agreement (CA). The GA will be signed by the European Union, represented by the European Commission, and the Coordinator and all the other Beneficiaries. The GA includes a standard contract and some project specific Annexes, namely the Description of Action (DoA) with its Part A and Part B. As at this stage the GA as not been signed, the consortium follows the "Grant Agreement Core" available in the EC portal. The CA is being concluded between all project partners, i.e. Beneficiaries, only. It is based on the DESCA Horizon 2020 Model Consortium Agreement (currently being updated for Horizon Europe) and it covers for example the detailed management procedures, IP related issues and publication rules. Additionally, the coordinator may sign Non-Disclosure Agreements (NDAs) with external advisors, on behalf of the consortium. Nevertheless, whatever contracts are signed, the GA always supersedes all other agreements.

## 1.2 Roles and responsibilities

The COVend project management structure and procedures are intended to support the project activities in the most effective way based on the governance structure recommended for EU projects. The actual management tasks are primarily carried out in WP1 and cover administrative, financial and legal aspects, the coordination of the work plan and reporting as well as data and risk management.

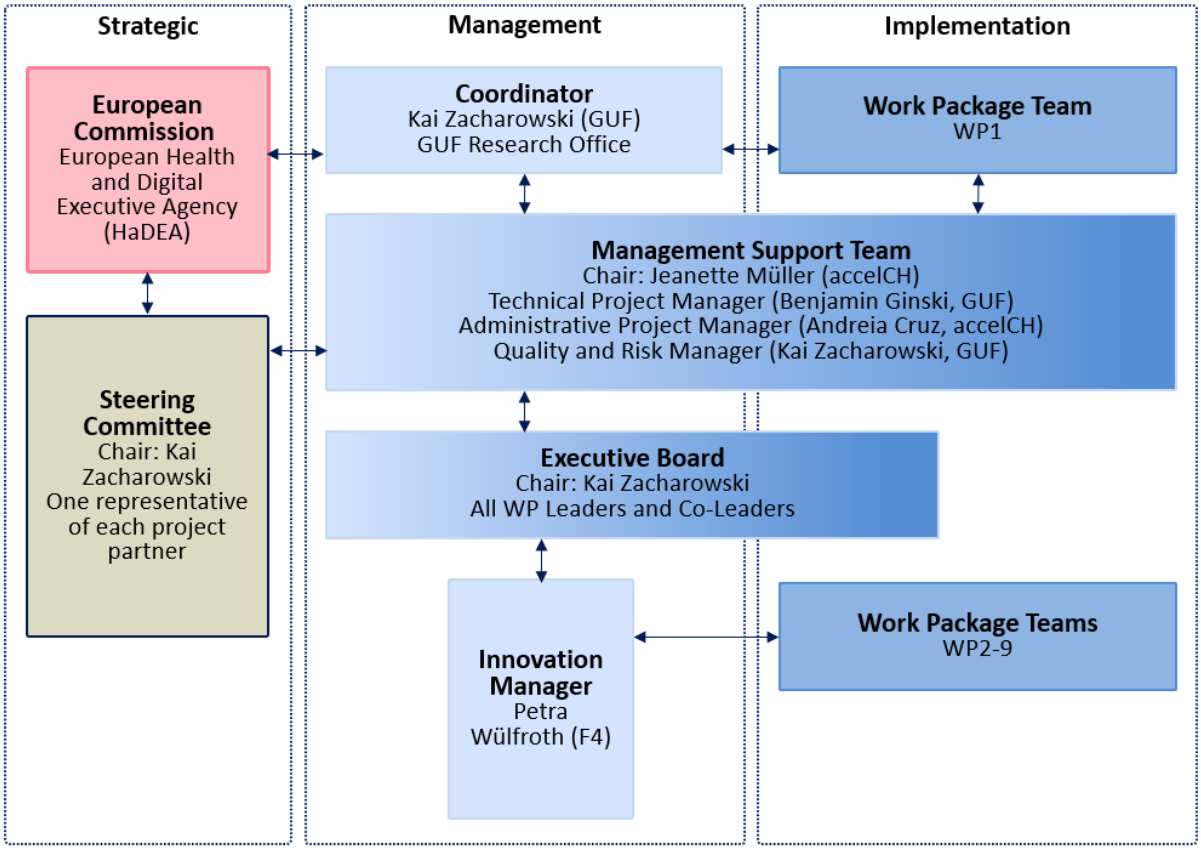



*Figure 1. Organisational chart*

The overall coordination of the project is the responsibility of GUF as the legal entity responsible for all contractual arrangements with the European Commission (EC). The ***Scientific Coordinator*** of the

COVend project, Professor Kai Zacharowski, has more than 25 years of experience in project management. Since January 2020, he is the President of the European Society of Anaesthesiology and Intensive Care (ESAIC). The main responsibilities of the Coordinator are to:

- monitor compliance by the project participants with their obligations;
- review and submit reports and deliverables (including financial statements and related certifications) and specific requested documents to HaDEA and the European Commission);
- transmitting documents and information related to the Project but were exclusively received by the Coordinator to any other Parties concerned;
- administer the financial contribution of the Funding Authority.

The Coordinator will primarily be supported by the ***Management support team*** led by Jeanette Müller (accelCH), including the ***Technical Project Manager*** (Benjamin Ginski, GUF) and the ***Administrative Project Manager*** (Andreia Cruz, accelCH). The ***Innovation Manager*** (Petra Wülfroth, F4) will guide the coordinator and remaining partners in exploiting the project results. Additional support is provided by GUF's Finance Office and Research Office to ensure adequate institutional support for the successful delivery of the project goals. The organisational structure is shown in Figure 1 while the role of the consortium bodies and their obligations are detailed in Table 1.

*Table 1. Overview of project bodies and committees*

| Consortium Bodies | Responsibilities |
|---|---|
| **Steering Committee (SC)**<br>*Chair:* Kai Zacharowski<br>*Members:* One representative of each project partner | The Steering Committee refers to the General Assembly and is the ultimate decision-making body of the consortium. All partners have agreed to abide by all decisions made by the Steering Committee. This does not prevent partners from submitting a dispute for resolution in accordance with provisions for the settlement of disputes as described below. |
| **Executive Board (EB)**<br>*Chair:* Kai Zacharowski<br>*Members*: All WP leaders and WP co-leaders | The Executive Board is the supervisory body for the execution of the Project which shall report to and be accountable to the Steering Committee. The EB is responsible for:<br>• Monitoring the progress of work in the WPs and their interactions<br>• Preparing all decisions to be taken by the Steering Committee and executing its decisions<br>• Facilitating collaboration with external stakeholders |
| **Management Support Team**<br>*Chair*: Jeanette Müller<br>*Members*: Technical Project Manager, Administrative Project Manager | The Management Support Team provides daily operational and implementation support to the Coordinator and all consortium bodies on all management related tasks:<br>• Implementing innovation and quality and risk management with dedicated tools<br>• Collecting input for regular reports and finances following standardised processes<br>• Monitoring and tracking of deliverables with dedicated tools<br>• Organising meetings and preparing minutes using EU project proven templates<br>• Facilitating knowledge and document sharing on a secure web-based tool<br>• Advising the Executive Board on management related issues and necessary measures<br>Detailed activities of its members are described in chapter 2. |
| **Work Package Teams**<br>*Lead*: WP leader and WP co-leaders | The WP Teams are responsible for delivering their respective tasks. Their leaders and co-leaders will monitor their timely execution and oversee the |

| Consortium Bodies | Responsibilities |
|---|---|
| *Members*: WP participants | planned activities to ensure quality of work, achievement of deliverables and contribution to reports. |

Each Party undertakes to take part in the efficient implementation of the Project, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under the Grant Agreement and the Consortium Agreement.

## 1.3 Communication

Communications within the COVend consortium will build on three pillars: consortium and WP meetings, web conferences, and several online discussions. GUF will be responsible for the overall coordination of the consortium meetings and the WP leaders will lead the meetings for their respective WPs. COVID-19 and the limitations it brought in terms of travel led to a greater flow of online discussions, but the consortium is aware that maintaining physical contact is important. Therefore, physical meetings will be planned in different places throughout the project. GUF, supported by accelCH, will jointly organise the physical consortium meetings with the host partner. At least one representative of each partner is expected to attend. Table 2 shows the meeting plan of each consortium body (see more info in section 5.3).

*Table 2. Ordinary and extraordinary meetings*

| Consortium body | Ordinary meeting | Extraordinary meeting |
|---|---|---|
| Steering Committee | At least twice a year | At any time upon written request of the Executive Board or 1/3 of the Members of the Steering Committee. |
| Executive Board | At least monthly (face-to-face and web conference) | At any time upon written request of any Member of the Executive Board. |
| Management Support Team | At least monthly (web conference) | At any time upon written request of any Member of the Management Support Team. |
| Work Package Teams | At least monthly (web conference) | At any time upon written request of any Member of the Work Package Teams. |

Discussions and negotiations will generally take place during the ordinary and ad-hoc meetings between the relevant partners. If a problem persists and no solution can be found, then: (1) The partner concerned will inform the WP Leader. If no solution is achieved on WP level, then; (2) The WP Leader will inform the Coordinator who will mediate between relevant partner(s), with the support of the External Advisors (if deemed appropriate). If no solution is achieved, then; (3) The Steering Committee will be required to hold an ad-hoc meeting within 14 days. If the conflict can still not be resolved or if it significantly affects the viability or scope of the project, then; (4) the coordinator will additionally seek advice from the EU Project Officer.

**Remark**: Each Party undertakes to notify promptly, in accordance with the governance structure of the Project, any significant information, fact, problem or delay likely to affect the Project.

# 2. Deliverables and Milestones

## 2.1 Deliverables

The progress of all deliverables is tracked by the Coordinator and by accelCH using an Excel-based monitoring tool. The file contains the list of all project deliverables with a number of details, such as their due dates, assigned internal reviewer and the current status of the deliverable. The file named *COVend_Deliverables_tracking.xls* is stored in the cloud-based document management system accelCLOUD and is regularly updated by GUF and accelCH. The status of upcoming and pending deliverables is checked in a weekly basis and discussed during the meetings and conference calls of the Executive Board as well as in personal communication between the Coordinator and the WP leaders. Any problems or expected delays should be flagged immediately to the Management Support team.

Each deliverable, regardless of its actual nature (e.g., report or data), requires a formal deliverable document in PDF format to be submitted to the EU Participant Portal. To facilitate the preparation of deliverables, a template is readily available in accelCLOUD. This Word template is named COVend-_*Deliverables_Template.docx* and stored under Templates. The template is mandatory to use for all project partners when preparing deliverables.

The due date of a deliverable is specified as a project month, with month 1 (M1) representing the first month of the project. This means that a deliverable need to be submitted to the EC at latest on the last day of the respective month in which the deliverable is due. The deliverable tracking file also contains the calendar date for ease of use. In order to ensure a timely submission of high-quality deliverable documents the following procedure will be followed:

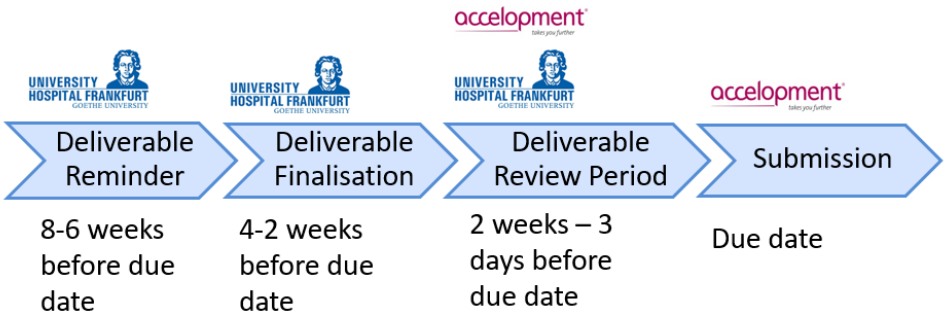



*Figure 2. Deliverables – schedule until submission*

GUF will remind all partners of the deliverable 8-6 weeks before the due date. Its responsible and the internal reviewer need to send the document to the technical manager for final revision 4-2 weeks before the due date. GUF with the support of accelCH will revise the document and accelCH will upload it in the EC portal.

## 2.2 Milestones

Milestones are control points in the project that help monitor the progress of work and identify potential risks early. Milestones often correspond to the completion of a key deliverable, allowing the next phase of the work to begin, or are needed at intermediary points. Similar to the deliverables, the Milestones are defined in the Description of Action (DoA). However, and in contrast to the deliverables, it is not required to submit a formal document for a Milestone to the European Commission (EC). In the EU

Participant Portal, the technical manager or accelCH will indicate whether a Milestone has been achieved (yes/no), the actual date of achievement and any comments. This ongoing report directly made in the EC Portal will be validated and will constitute part of the periodic report (Part A, see chapter 3). The achievement of Milestones is discussed in the regular Steering Committee and Executive Board meetings. In total, 22 Milestones have been defined for COVend and their progress can be seen in the file named *COVend_Milestones_tracking.xls* available in accelCLOUD.

**Support & Tips**

- When preparing the deliverable, use the template available in accelCLOUD;

- The deliverables and milestones must be achieved in the period set out in the DoA;

- Send the document to the technical project manager in good time (Figure 2);

- The granting authority may — during the action or afterwards — check the proper implementation of the action: the coordinator or beneficiary concerned must cooperate diligently and provide — within the deadline requested — any information and data in addition to deliverables already submitted.

# 3. Reporting

As part of its contractual obligation towards the EC, the Consortium will deliver periodic reports within 60 days after the end of each reporting periods (Figure 3). Additionally, and for internal monitoring purposes, the partners have agreed to produce ***9-monthly internal progress reports*** to identify any risks at an early stage (M9, M27). The Periodic Report (PR) consists of the Periodic Technical Report (Part A and Part B) and a Periodic Financial Report.

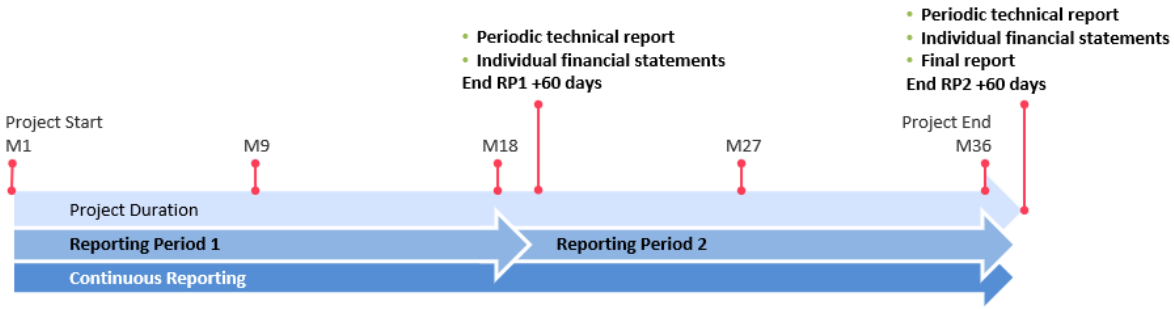



*Figure 3. COVend reporting periods*

Part A of the Periodic Technical Report is generated by the IT system. It is based on the information entered by the participants through the Periodic Report and continuous reporting modules of the electronic exchange system in the Participant Portal. Part B of the Periodic Technical Report is the narrative part that includes explanations of the work carried out by the Beneficiaries during the RP and is uploaded as a PDF document.

As part of the Periodic Report, Beneficiaries are asked to complete their individual Financial Statement. It provides information on the use of resources, subcontracting and in-kind contributions provided by third parties. Only users with the role as Project Financial Signatory (PFSIGN) can sign and submit the Beneficiaries' Financial Statement. All Financial Statements combined create the Periodic Financial Report. The management support team will assist all partners during this process.

**In case of delays, that are consequences…**

In case the Consortium is late (no report on time):

- The EC will send a reminder;
- The payment is suspended;
- If still not submitted after 30 days, the EC may terminate the grant agreement.

In case one beneficiary is late (but the report is ready):

- The Coordinator may decide to submit the reports without that beneficiary;
- Beneficiary's costs will be considered "zero" for this reporting period, but it can declare its costs with the next reporting period.

# 4. Finances

The Coordinator (GUF) will be responsible for the overall financial management and the timely distribution of the EU contribution. The overall budget, including planned costs and requested EU contribution, is shown in the EC Portal and in Annex 2 of the Grant Agreement (to be available soon). An overview of the staff efforts and some direct costs is provided in Part B of the Description of Action (DoA). The pre-payment will be made to each organisation as soon as the pre-financing is transfered to the coordinator. The expected amount is € 7,199,033.13, equalling 72% of the total planned EU funding for the entire project. This amount will be distributed to all partners following the terms defined in the CA. All **interim payments** will be made by the EU after the Periodic Reports have been approved by the EC (see Figure 3). The actual payment usually occurs within 3 months upon submission of each Periodic Report. The EC retains at least 5% of the maximum grant amount until the end of the project (mutual insurance mechanism). The **final payment of the balance** will be made by the EU after the second Periodic Report and the Final Report have been approved by the EC. The actual final payment occurs within 3 months upon submission of the Final Report.

**Remark**: The financial unit of each partner is solely responsible for administering expenses and all project costs, i.e., all costs that can be directly attributed to COVend. These include timesheets to calculate personnel costs, invoices for consumables purchased and receipt for travel and other expenses. Each time worked for the beneficiary under the action must be supported by declarations signed monthly by the person and their supervisor, unless another reliable time-record system is in place. The EC may accept alternative evidence supporting the time worked for the action declared, if it considers that it offers an adequate level of assurance.

**Support & Tips**

- In case of any questions please contact the Management Support Team;
- Timesheets: Not needed if working full time on COVend (in this case only one declaration is needed);
- Keep documentation (boarding passes, all receipts) from all expenses occurred within the project;
- Plan necessary audit a few months in advance;
- Keep you financial status updated!

# 5. Quality assurance

A quality assurance process is necessary to ensure consistent and/or increasing high quality in the preparation and submission of deliverables and to record the general rules in the project, roles and responsibilities of each partner, the general project procedures, templates, meeting planning and other subjects.

## 5.1 Documentation

Documents such as deliverables, reports, study protocols, data management plans, software specifications etc. are issued by the assigned partner as specified in the DoA. The document management is controlled through a well-defined process flow including document issue, update requests sent by email to the document owner, draft reviews following a defined workflow, approval for release and implementation into practises. Document review and approval involves accountability and individuals are responsible for the accuracy and verification of the information, the absence of conflicts with other documents and compliance to regulatory and other legal requirements. Periodic review and revisions of critical documents (such as requirement specifications, design documents, study protocols, SOPs) is necessary to ensure their continuing suitability. Where changes are necessary, updated documents are drafted, issued, reviewed and approved following the same procedure as the standard document control process. Changes are captured into a history record and version control is applicable. All deliverables reports and critical documents will be uploaded and archived in accelCLOUD.

## 5.2 Mailing lists

Two main mailing addresses are currently used within the project. Only participants that are subscribed to the list can use the email address to send emails to the respective groups. accelCH maintains the lists and subscribes the required consortium members.

**Steering Committee:** consortium@list.covend-project.eu

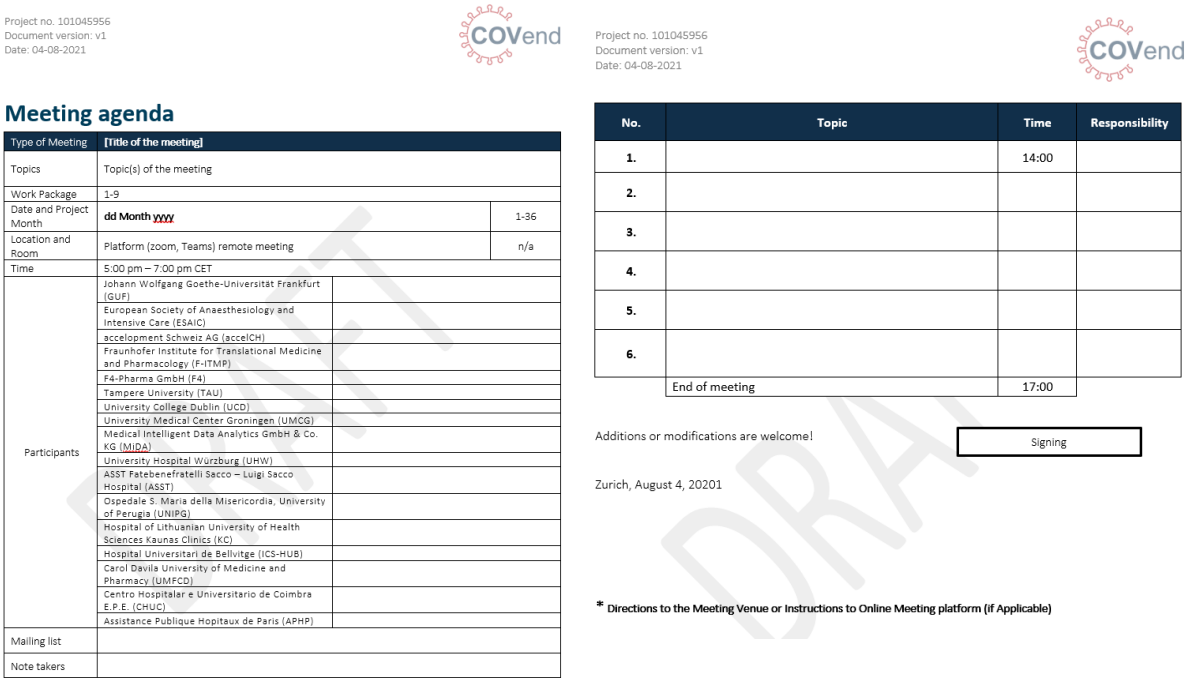
The SC mailing list includes all participants in the project. The email address is used to notify all participants at once on project-related issues that concern all partners, such as SC meetings or general project updates.

**Executive Board:** eb@list.covend-project.eu

This list comprises all the WP leaders, including the technical and administrative project managers. This list is mainly used for GUF and the R&D partners since no clinical partner (except GUF) is in charge of a WP.

## 5.3 Meetings

In order to guarantee regular meeting appointments and the regularities of the Grant Agreement (section 1.3), meeting schedules are created by the technical and administrative project managers for a period of three months each and made available to all parties on the accelCLOUD. For each scheduled meeting, the leader of the meeting, as defined in the schedule, provides a draft meeting agenda to all participants. The agenda entails the topics to be discussed within the meeting. The participants have the chance to add additional discussion points to the agenda within one week of distribution.



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**Meeting agenda**

| Type of Meeting | [Title of the meeting] | |
|---|---|---|
| Topics | Topic(s) of the meeting | |
| Work Package | 1-9 | |
| Date and Project Month | dd Month yyyy | 1-36 |
| Location and Room | Platform (zoom, Teams) remote meeting | n/a |
| Time | 5:00 pm – 7:00 pm CET | |
| Participants | Johann Wolfgang Goethe-Universität Frankfurt (GUF) | |
| | European Society of Anaesthesiology and Intensive Care (ESAIC) | |
| | accelopment Schweiz AG (accelCH) | |
| | Fraunhofer Institute for Translational Medicine and Pharmacology (F-ITMP) | |
| | F4-Pharma GmbH (F4) | |
| | Tampere University (TAU) | |
| | University College Dublin (UCD) | |
| | University Medical Center Groningen (UMCG) | |
| | Medical Intelligent Data Analytics GmbH & Co. KG (MIDA) | |
| | University Hospital Würzburg (UHW) | |
| | ASST Fatebenefratelli Sacco – Luigi Sacco Hospital (ASST) | |
| | Ospedale S. Maria della Misericordia, University of Perugia (UNIPG) | |
| | Hospital of Lithuanian University of Health Sciences Kaunas Clinics (KC) | |
| | Hospital Universitari de Bellvitge (ICS-HUB) | |
| | Carol Davila University of Medicine and Pharmacy (UMFCD) | |
| | Centro Hospitalar e Universitario de Coimbra E.P.E. (CHUC) | |
| | Assistance Publique Hopitaux de Paris (APHP) | |
| Mailing list | | |
| Note takers | | |

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| No. | Topic | Time | Responsibility |
|---|---|---|---|
| 1. | | 14:00 | |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |
| 6. | | | |
| | End of meeting | 17:00 | |

Additions or modifications are welcome!

Signing

Zurich, August 4, 20201

* Directions to the Meeting Venue or Instructions to Online Meeting platform (if Applicable)

*Figure 4. Template of the meeting agenda*

Unless otherwise agreed, the chairperson of the consortium body of the respective meeting shall produce written minutes of each meeting which shall be the formal record of all decisions taken. He/she shall send the draft minutes to all project partners within 10 calendar days of the meeting. The minutes shall be considered as accepted if, within 15 calendar days from sending, no member has sent an objection in writing.

## 5.4 Project management practices

Project management within COVend includes activities such planning, organising, securing, monitoring and managing the resources and work necessary to deliver the project objectives in an effective way. The Management Support Team has planned the Kick-off meetings to officially start the project and organised the project work plan using the accelCOCKPIT®. Besides overseeing all the SC and EB meetings, this team will perform regular quality assurance activities, support the coordination of the project and resources, resolve conflicts and other issues and will handle the deliverables and reports. Assessing project performance against project plans is also one of the main tasks to be performed and corrective actions to address deviations will be identified.

## 5.5 Research management

Themes relating to ethics and integrity in research, diversity, gender equality, and cultures in a research environment cannot be dismissed. COVend brings together 17 partners from 13 countries, leading to an inclusive setting that requires all participants to respect each other's distinctness. The Management Support Team plays an important role to make communication easier. Because of the complexity of organized science, management is increasingly indispensable to ensure the social, cognitive, and material preconditions of research. The goal of research management is the production of selective couplings between organisational elements, disciplines and across organisational boundaries. By tightening loose couplings up, the capacity of researchers can be increased.

Research is a continuous process, where ideas, data gathering, and documentation are closely interlinked. It's why a Data Management Plan (DMP) is mandatory in Horizon Europe, to not only cover the type of data/research outputs and how they are processed but also to outline the measures that will be taken to maximize access and re-use of the data for further purposes and applications. COVend partners will follow the HE DMP template and will submit the first version of the project DMP by M6. Due to the clinical study, a separate DMP covering the clinical data will be prepared as a separate deliverable. Any of these documents are static, meaning that there will be quite a few updated versions during the course of the project.

## 5.6 Ethics and data protection

According to the described project objectives, COVend will be targeted to patients with mild to moderate COVID-19. For that reason, COVend will carefully consider the ethical aspects of the project with the aim to ensure at every moment and in every situation the adequate protection of the privacy and the personal rights of the participants (for more details, please consult Chapter 4 and 5 of the DoA-Part B). Safety of patients is the key priority within the project. This aim will also affect the limitations and regulations that must be applied to every project activity: research, development, testing, evaluation and dissemination. **Ethics Advisory Boards** have been defined to supervise ethics within COVend. National legal and ethical requirements will be fulfilled for each country participating in the project through the research ethics governance in place within that country. A **Data Safety Monitoring Board** (DSMB) will also be assembled to ensure the safety of the patients and the high-quality conduct of the study.

The participants of the consortium have conducted the ethics self-assessment and identified the ethics issues relevant to the project. The consortium members are aware of the required ethics approvals prior to initiation of any procedure involving participation of humans and of the need of a sound informed consent. Ethical approval is being handled at the moment, considering the finalisation of the study protocol last month (September 2021).

Data generated will only be used within the scope of the informed consent form signed by the subjects and in a totally anonymized manner. It is not planned to reuse data that will not be generated within the project, nevertheless, the consortium will fuel the European **COVID-19 data portal** with the data generated in the project.

# 6. Risk management and contingency plan

Risk management is an important element in project management in general. It is even more important in the management of research projects, which have a higher degree of unpredictability due to the very nature of research. Accordingly, the COVend risk assessment is carried out as part of the project management WP1, where it constitutes the main part of Task 1.3. The main objective of this task is to ensure that all potential risks are identified and assessed and that appropriate contingency plans are in place or are executed, when necessary. The activities in risk management typically comprise the following four phases:

- **Risk identification**: During risk identification, the sources of risk, potential risk events, and symptoms of risk are identified.

- **Risk analysis**: During risk analysis, the value of opportunities to pursue *vs*. the threats to respond to, and the opportunities to ignore vs. the threats to accept are assessed.

- **Response planning**: During response planning, risk management and contingency plans are developed.

- **Risk monitoring & control**: During risk monitoring and control, corrective action plans are developed, implemented, and monitored.

Following this process helps project partners and notably those with leading or managing roles to plan, monitor and assess potential risks and coordinate the implementation of contingencies. The project risks are listed in an excel-based tool managed by the technical and administrative project managers. During each Steering Committee meeting, the technical project manager gives a forecast of whether the risks have changed in their frequency or severity and of any new risks that may arise. This is approved by the respective representative of the respective parties and the result is noted in the corresponding minutes.

| Risk Assessment | | | | | | | | | Risk Mitigation |
|---|---|---|---|---|---|---|---|---|---|
| Risk Nr. | Description | WPs involved | Identification | Risk type | Probability | Impact | Score | Risk level | Measures |
| 1 | Partner leaving the project | WP1 | Foreseen | Management | 0.1 | 0.2 | 0.02 | LOW | Consortium partners have a large mutual drive to work together. In the unlikely event, a partner leaves the consortium, all partners will be responsible for seeking a new partner that has similar capabilities and is able to finish the work. |
| 2 | External alignment not successful | WP1 | Foreseen | Management | 0.5 | 0.05 | 0.025 | LOW | A structured planning and implementation of each external collaboration is necessary. |
| 3 | Manufacturing FX06 fails | WP2 | Foreseen | Technical | 0.1 | 0.8 | 0.08 | MEDIUM | Have alternative manufacturer |
| 4 | Toxicity concern from rat study | WP2 | Foreseen | Technical | 0.1 | 0.2 | 0.02 | LOW | Consider other species in addition (dog) |
| 5 | Recruitment sufficient patients is slowed | WP3 | Foreseen | Technical | 0.5 | 0.8 | 0.4 | HIGH | GUF will increase training and personal contact, further sites will be selected, non-recruiting sites will be closed |
| 6 | Study will not be approved in planned country | WP3 | Foreseen | Technical | 0.1 | 0.2 | 0.02 | LOW | GUF, F4, Fraunhofer and ESAIC will cooperate in select other suitable countries |
| 7 | Safety signals arise | WP3 | Foreseen | Technical | 0.1 | 0.2 | 0.02 | LOW | Independent safety board will be involved in review of safety data and will advise regarding conduct of study |
| 8 | Data collection is delayed | WP3 | Foreseen | Technical | 0.5 | 0.2 | 0.1 | MEDIUM | Frequency of monitoring visits will be increased as well as direct contact to site to support timely and correct data entry in eCRF |

*Figure 5. Extract from the monitoring tool*

# 7. Collaborations and external cooperation

A plan for dissemination including communication activities (D8.3) will be developed until M6 to specify the activities and time plan for outreach matters. The dissemination measures will contribute towards the exploitation of IP and results, targeting different stakeholder groups. A roadmap for exploitation is considered in the DoA as deliverable D8.6 (M30). The Innovation Manager will support the project partners exploiting results commercially and non-commercially.

A virtual meeting will be set up by DG RTD in coordination with HaDEA between the projects working on COVID-19 therapeutics funded under the Horizon Europe call "HORIZON-HLTH-2021-CORONA-01" at the beginning of the projects' life-time (D1.6, planned to M3). This meeting is to introduce each project to each other and to identify areas for potential collaboration. A report on collaborations and impact assessment is also planned, including the main outcomes from the meeting with the European COVID-19 clinical trial network for therapeutics (D1.8, M6). Several workshops are also considered (D8.4, M12) and a final cluster event between the different EU-funded initiatives will be prepared at the final stages of the project.