
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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**Abstract – The COVend Project**

About 14% of COVID-19 patients with mild or moderate disease develop severe symptoms and are eventually admitted to the intensive care unit.

The main goal of the COVend project is to reduce the number of COVID-19 patients in hospitals and thereby reduce the burden on patients and their families, hospital staff, and the healthcare sector. The specific objectives are, first, to enrich the current portfolio of SARS-CoV-2/COVID-19 prophylactics and therapeutics by clinically testing FX06 as a promising drug candidate.

Second, to provide effective therapy against SARS-CoV-2 by using innovative immune biomarker profiling, endothelial cell assessment methods, and artificial intelligence-driven models for decision support for clinical treatment of COVID19 disease. This is expected to prevent a progression to severe disease and subsequent hospitalisation. Endothelial cells are the main regulators of vascular homeostasis (dynamic equilibrium), as they interact with both circulating cells and cells present in the vessel wall. When endothelial function deteriorates, vascular homeostasis is impaired, leading to increased permeability for blood and its components as well as inflammation of the endothelium.

FX06 has shown to have a protective effect on the endothelium by reducing the inflammatory process. This way, the disease progress will be interrupted, resulting in faster recovery of the patients and less admissions to intensive care units.

# Table of Contents

# Partner short names

| | |
|---|---|
| GUF | Johann Wolfgang Goethe Universität Frankfurt am Main |
| accelCH | accelopment Schweiz AG |
| ESAIC | European Society of Anaesthesiology and Intensive Care |
| F-ITMP | Fraunhofer Institute for Translational Medicine and Pharmacology ITMP |
| F4 | F4 Pharma GmbH |
| TAU | Tampereen Korkeakoulusaatio SR |
| UCD | University College Dublin |
| UMCG | Universitair Medisch Centrum Groningen |
| MiDA | Medical Intelligent Data Analytics GmbH |
| UHW | University Hospital Würzburg |
| ASST | ASST Fatebenefratelli Sacco – Luigi Sacco Hospital |
| UNIPG | Universita degli Studi di Perugia |
| KC | Lietuvos Sveikatos Mokslu Universiteto Ligonine Kauno Klinikos |
| ICS-HUB | Hospital Universitari de Bellvitge |
| UMFCD | Universitatea de Medicina si Farmacie Carol Davila din Bucuresti |
| CHUC | Centro Hospitalar e Universitario de Coimbra E.P.E. |
| APHP | Assistance Publique – Hôpitaux de Paris |

# Abbreviations

| | |
|---|---|
| CRA | Clinical Research Associate |
| D | Deliverable |
| EU | European Union |
| eCRF | Electronic Case Report Form |
| M | Month |
| SIV | Site Initiation Visit |
| WP | Work Package |

# Revision history

| Date | Authors | Revision |
|---|---|---|
| 25.10.2021 | Raquel Hernandez (ESAIC) | Draft version |
| 26.10.2021 | Raquel Hernandez (ESAIC) | Revision 1 |
| 26.10.2021 | Jocelyne Dewulf (ESAIC) | Revision 2 |
| 28.10.2021 | Cathy Weynants (ESAIC) | Revision 3 |
| 28.10.2021 | Raquel Hernandez (ESAIC) | Final version |

# Executive Summary

The COVend project partners are committed to an open science approach complying with the EU's Open Science policy and aims to maximise the impact of its project results by disseminating and exploiting its research results as widely and as open as possible.

The main goal of the present deliverable D8.2 – Training Material is to describe which training material will be developed for local site initiation as part of the COVend study to inform and train the clinical staff involved on the COVend study, how to provide verification of the study data and ensure patients' safety.

The developed training material as well as the clinical guidelines will be made public, to facilitate clinical sites in the adoption, implementation and uptake of the new therapy and clinical guidelines on a national and European level.

**Related deliverables**

- D8.4: European trial networks workshops collaboration plan with other initiatives defined and first workshop implemented;

# 1. Introduction

Although diverse vaccines in many European countries are already available, a third of all European citizens are still reluctant to be vaccinated and the risk of severe COVID-19 cases is high, especially due to new SARS-CoV-2 variants. In this regard, FX06 promises a unique therapy to prevent progression of COVID-19. FX06 has already been successfully tested in animal experiments as well as in critically ill COVID-19 patients by COVend consortium member Patrick Meybohm, University Hospital Würzburg in 2020, and, therefore, represents a very promising candidate for a controlled, randomized Phase II/III clinical trial. In total, 309 COVID-19 patients are planned to be recruited in this clinical study.

## 1.1 Purpose of the deliverable

The present deliverable D8.2 – Training Material is closely linked to two activities of Task 3.5: Set-up and coordinate sites during study described as following in the Description of the Action (DoA, Version 6.0 01 Sep 2021):

- Selected and approved sites will be initiated by the CRA from ESAIC and F-ITMP to inform and train them on study protocol and study procedures incl., e-CRF. Qualified sites will be opened for recruitment upon fulfilling all start-up requirements;
- Throughout study conduct, the CRA will verify the patient's data and ensure adherence to protocol by on-site and remote visits in accordance with the monitoring plan. The CRA reports will be reviewed by F-ITMP and ESAIC respectively, deviations will be escalated to F4 (Sponsor).

# 2. Strategy

The overall intention of the COVend partners is to start the clinical study as fast as possible. The clinical sites to initiate as a priority are GUF, UHW (Germany) and UMFCD (Romania).

The strategy to develop the training material is described as follows:

- Gather the final study documents and clinical guidelines from the clinical partners: study protocol, Investigator Brochure, Inform Consent Form, monitoring plan, eCRF user guidelines, randomization guidelines, SAE reporting and flow, logistics for laboratory and sample collection guidelines;
- Develop a draft study training PowerPoint slide deck;

- Quality review of the draft study training PowerPoint slide deck by project partners;
- Update the draft study training PowerPoint slide deck based on partner's feedback;
- Pilot training with CRAs to validate training material;
- Update (if applicable) based on feedback from CRAs;
- Release training material on the project website;
- Plan SIVs to deliver training to the clinical sites;
- Execute SIVs and communicate to site staff the availability of training material from the project website.

**Table 1**: Overview of the European clinical sites participating in the clinical study of the COVend project

| | |
|---|---|
| **Germany** | |
| University Hospital Würzburg (UHW)<br>clinical trial led by Dr. Patrick Meybohm | |
| Goethe University Frankfurt am Main<br>clinical trial led by Prof. Dr. Dr. Kai Zacharowski | |
| **Italy** | |
| ASST Fatabenefratelli Sacco – Luigi Sacco Hospital<br>clinical trial led by Dr. Maddalena Wu | |
| Universita degli Studi di Perugia (UNIPG)<br>clinical trial led by Prof. Edoardo de Robertis | |
| **Lithuania** | |
| Lietuvos Sveikatos Mokslu Universiteto Ligonine Kauno Klinikos (KC)<br>clinical trial led by Prof. Dr. Andrius Macas | |
| **Spain** | |
| Hospital Universitari de Bellvitge IDIBELL (ICS-HUB)<br>clinical trial led by Dr. Antoni Riera Mestre | |
| **Romania** | |
| Universitatea de Medicina si Farmacie Carol Davila din Bucuresti (UMFCD)<br>clinical trial led by Dr. Dana Tomescu | |
| **Portugal** | |
| Centro Hospitalar e Universitario de Coimbra E.P.E (CHUC)<br>clinical trial led by Dr. Francisco Maio Matos | |
| **France** | |
| Assistance Publique - Hôpitaux de Paris (AP-HP)<br>clinical trial led by Prof. Francis Bonnet | |

## COVend Digital presence:

COVend's digital presence will be ensured by the project website from accelCH to enhance the impact of its communication and dissemination activities.

Such online presence will ensure an effective and efficient communication of COVend news, results and events, in order to maximise the project's impact, reach and involve the widest audience possible throughout its conduction.

COVend Newsletters:

There will be a regular COVend e-newsletter to help communication and dissemination with the COVend partners and the COVend community. The newsletter will be in English and it will be published every month, starting after the first Ethics Committee approval.

Every edition will provide information about activities related to the clinical study (e.g., study highlights, partner in the spotlight, recruitment status).

### 2.1 Site Initiation Visit

The SIV is an opportunity for the clinical staff involved on the COVend study to ask questions on the study protocol, on how the study should be executed and to obtain clarity on the procedures and interventions to guarantee effective study delivery while ensuring patients safety and reliability of study results.

Site Initiation Visits are most successful when they are hold as face-to-face meetings. As the overall intention of the COVend partners is to initiate the clinical sites as fast as possible and move forward without delay, an SIV in remote format may be proposed to the clinical sites if the COVID-19 pandemic and social distancing persists.

## 3. Result and summary

Besides the goal of training the clinical staff involved on the COVend study during the SIV this deliverable presented will be used as set of instruments for the project partners to disseminate COVend and maximize its impact.

The development of the training material has been started but it is not yet completed as we are in the process of gathering and consolidation technical information from the clinical partners to get the final study documents and guidelines.

## 4. Outlook

It is expected that the final training material will be available by M5-M6 however this will not have an impact on the overall project timelines because the training material is due before the first SIV (once all agreements with the clinical site(s) are fully executed and the study is fully approved by both Ethics Committee and Competent Authorities) which is expected to end in M7 (Figure 1).

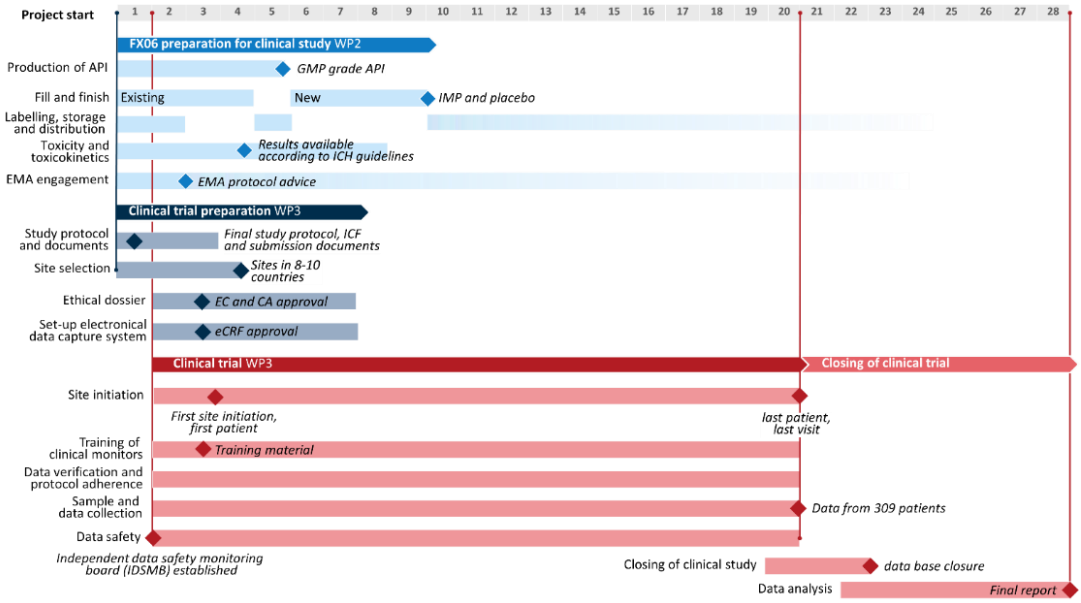


**Figure 1:** Study Schedule