

Project No. **101045956****Biomarker and AI-supported FX06 therapy to prevent
progression from mild and moderate to severe stages of COVID-19**

Deliverable 8.4

European trial networks workshops

WP8 – Communication, dissemination & exploitation

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Partner short names

GUF	Johann Wolfgang Goethe Universität Frankfurt am Main
accelCH	accelopment Schweiz AG
ESAIC	European Society of Anaesthesiology and Intensive Care
Fraunhofer	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
UNIPG	Università 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
MUMC	Maastricht University Medical Center+

Abbreviations

D	Deliverable
EC	European Commission
EU	European Union
HEU	Horizon Europe
M	Month
MS	Milestone
WHO	World Health Organisation
KPI	Key Performance Indicator

Executive Summary

COVend implements a structured synergistic approach to implementing all dissemination measures. The COVend partners are committed to an open science approach complying with the EC's Open Science policy and aim to maximise the impact of its project results by disseminating and exploiting its research results as widely and as open as possible.

The present document represents Deliverable 8.4 – European trial networks workshops and has been developed as part of WP8 – Communication, dissemination & exploitation, Task 8.2: Dissemination of scientific and technological results.

The main goal of this deliverable is to describe the preparation, implementation and follow-up of the planned workshops with the European COVID-19 clinical trial network. The developed plan will be used for further implementation of the mentioned collaboration activities with other initiatives.

Once the initial results are available, the implementation of the European trial network workshops, a planned dissemination activity serving the vital purpose of the COVend project results sharing and facilitating knowledge transfer to the scientific community, will be initiated according to this plan.

By implementing this activity, the COVend consortium expects to provide a platform through which the invited coordinators and members of the European network for COVID-19 therapeutic trials as well as EU-funded COVID-19 clinical trials can exchange ideas, share knowledge, and develop best practices for the successful implementation and conduct of clinical trials. It is anticipated that the topics raised during discussions will serve to identify any potential challenges and areas of improvement that can be addressed through further collaboration. Finally, the successful implementation of the planned workshops will provide involved stakeholders with the opportunity to learn from each other's successes and challenges, as well as discover creative solutions to issues that they encounter.

Related deliverables

- D8.2 Training material
- D1.6 Report on virtual meeting with the other successful projects working on COVID-19 therapeutics funded under the Horizon Europe call "HORIZONHLTH-2021-CORONA-01".
- D8.3 Plan for dissemination, including communication activities

1 Introduction

The COVID-19 pandemic has been a global health crisis that has caused much disruption to the lives of people around the world. However, the number of cases is decreasing, hence the number of patients available for recruitment to clinical trials has also reduced significantly. According to the World Health Organisation (WHO), globally, the number of new COVID-19 cases and deaths has continued to decline since the end of March 2022.¹ As the IXION clinical trial is at the heart of the work in COVend, to deliver FX06 as a viable therapy against COVID-19, the COVend project and especially the patient recruitment process have been hampered strongly by this fact. The lack of patients has been a major blow to the COVend research as the shortage of patients has delayed the progress of the trial resulting in the lack of data to properly evaluate the safety and efficacy of the FX06 therapy. This has led to temporary delays in the delivery of some of the project's results.

Despite the above-described circumstances, the COVend consortium is committed to continuing the efforts to pursue the best outcome from the IXION study. Once the initial results are available, the COVend project will disseminate them through the planned dissemination activities, such as collaboration with clinical trial networks. The workshops with the existing COVID-19 clinical trial networks will be put into motion following the plan outlined in more detail below.

The objectives of Deliverable 8.4 – European trial networks workshops - are to ensure the successful execution of the planned workshops with the European clinical trial networks. Specifically, the document will provide a detailed plan for the preparation, implementation and follow-up of the workshops, which will be used to facilitate collaboration activities with other initiatives. This deliverable will also provide an overview of the planned objectives, strategy and outcomes of the workshops, which will hopefully be used to evaluate their success and to implement future collaboration activities.

2 Objectives

The primary objective of the planned workshops is to facilitate the transfer of knowledge and experience between European trial networks. The workshops will provide a platform for researchers to share best practices, discuss common challenges and identify solutions to those challenges. Through these workshops, the COVend project aims to develop a comprehensive and harmonised approach to trial networks interaction in Europe in order to optimise the quality and effectiveness of the trials conducted and to ensure that the results of the trials are applicable across Europe. The workshops will also contribute to the development of a comprehensive European trial network database, which will help to ensure the traceability and reproducibility of results.

¹ World Health Organisation, COVID-19 Weekly Epidemiological Update, Edition 91, 11 May 2022

3 Strategy

In order to successfully implement the workshops with other initiatives and achieve the goals, a detailed strategy (Figure 1) has been developed, comprising three main stages: preparation, implementation and evaluation. Several adjustments to the strategy are possible during the implementation stage of the described activity to ensure that the goals set are met. The lead partners responsible for the organisation and implementation of the activity are accelCH and GUF.

3.1 Preparation

Minimum two workshops are envisioned for implementation, as it will ensure comprehensive coverage of the topics raised as well as a greater number of those that can be discussed in depth. By having multiple workshops, a variety of topics related to clinical studies can be brought upon, allowing participants to build upon the knowledge gained in the previous workshop and deepen their understanding of the topics raised. Additionally, having two and more workshops allows for the inclusion of different stakeholders and perspectives, leading to a more collaborative and productive experience. The first step in implementing a successful strategy for the workshops with the European clinical trial networks is to establish clear definitions for the following aspects:

- **Identifying target audience:** This should include the coordinators and members of the European network for COVID-19 therapeutic trials, the EU-funded COVID-19 clinical trial projects and other related initiatives.
- **Delivery format:** online
- **Key messages:**
 - It is of utmost importance to increase the number of best practices for conducting clinical trials as much as possible in order to reach robust results in a more timely manner and, ultimately, to better support the clinical management of COVID-19 patients.
 - The workshops organised by the COVend consortium are an excellent opportunity for the participants to facilitate knowledge transfer and peer feedback through interactive and constructive dialogue.
 - Participants will gain valuable insights into the peculiarities of the projects' trial infrastructure, as well as provide valuable input on the challenges encountered and

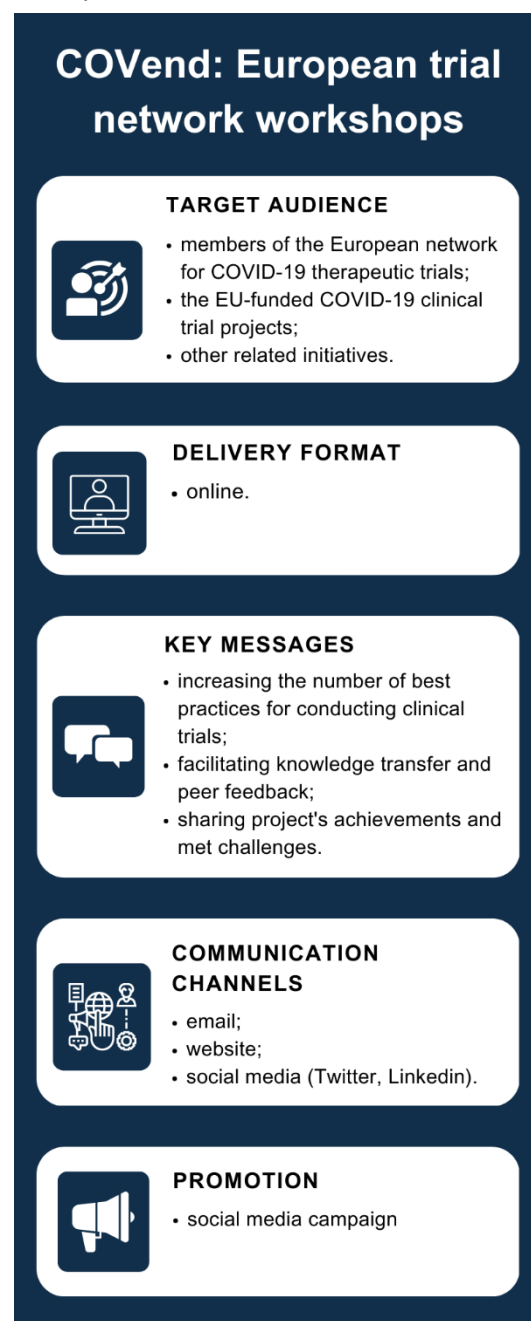


Figure 1. The key components of the COVend communication strategy for the implementation of the European trial network workshops

potential solutions to effectively implement clinical trials and better understand the COVID-19 pandemic.

- The COVend project is transferring its results to the scientific community to make the best use of them and maximise the impact of research, enabling the value of results to be potentially wider than the original focus.

3.2. Implementation

Upon reaching the implementation stage of the planned activity, the COVend consortium will ensure that the following steps are adhered to:

- **Establishing contact with the potential participants of the workshops:** This includes the representatives of the European network for COVID-19 therapeutic trials, the EU-funded COVID-19 clinical trial projects and other related initiatives. Figure 2 below contains the list of potential participants to be contacted by COVend consortium partners.
- **Developing an agenda for workshop sessions:** The agenda will include a mix of presentations, discussions, and interactive sessions. accelCH will ensure that the agenda and all materials are prepared and distributed among the participants, including any slides, digital handouts, etc.
- **Outlining the content of the workshops according to the agenda:** The workshops should include presentations from key participants, outlining the topics that are to be covered; contributions to the discussions and sessions on the commonly experienced hurdles for the implementation of clinical trials as well as sharing the ways of tackling these. The representatives of the invited organisations or projects are expected to hold presentations.
- **Providing a workshop facilitator:** The workshops will be facilitated by an experienced professional who has a good understanding of the topics raised and the goals of the workshops, such as Project Coordinator Prof. Dr. Kai Zacharowski, Project Innovation Manager Dr. Petra Wüllfroth, Clinical Scientists Dr. Jan Kloka and Dr. Benjamin Friedrichson.
- **Technical realisation:** COVend consortium partners, namely accelCH will ensure the implementation of all technical aspects required for a successful run of the planned activity (e.g. event registration, online meeting invitation, Zoom event management, event recording, etc.)
- **Follow-up activities:** After the workshops, follow-up activities will be implemented to ensure that the objectives of the workshops have been met (media highlights, post-event survey, etc.).
- **Communication channels**
 - Email: All communication with the participants of the workshops will be supported through an email campaign, which includes all relevant information (e.g. invitation, follow-up emails, etc.)
 - Social Media: The project will use its own social media platforms, such as [Twitter](#) and [LinkedIn](#) to advertise the workshops and their outcomes to a wide audience.
 - Website: The [project website](#) will be used to provide information about the workshops and to promote them.
- **Promotion**

- A specially tailored social media campaign for COVend social media channels will be implemented for the promotion of the workshops. All COVend partners are to make reposts, shares and retweets to achieve a wider reach. In addition, the workshop participants will be kindly requested to share information about the COVend workshops through their networks using social media channels and websites of their organisations/projects.



Figure 2. The list of potential collaborators in the European trial network workshops organised by COVend

3.3 Evaluation

Establishing clear and measurable goals (Figure 3) is key to evaluating the success of the planned workshops. The Key Performance Indicator (KPI) for this activity is the number of attendees and audience feedback. The success of the implemented workshops will be evaluated with the help of collecting data on the number of registrations and a post-workshop feedback survey distributed among attendees after the event.

Activity	KPI	Method	Target
European trial network workshops	<ul style="list-style-type: none"> Audience feedback Number of attendees 	<ul style="list-style-type: none"> Registrations Feedback survey 	<ul style="list-style-type: none"> 80% positive feedback 5-10 attendees at each workshop

Figure 3. Evaluation plan for the workshops

Finally, a report that describes the implementation of the activity summarises the findings from the evaluation and identifies any areas for improvement will be created.

4 Outcomes

The purpose of these workshops is to share knowledge, insights and best practices from the networks for COVID-19 therapeutic trials and EU-funded COVID-19 clinical trial projects in order to strengthen the research community and facilitate the development of new solutions. The expected outcome of the European trial network workshops implemented by the COVend consortium will be to provide a platform for the invited coordinators and members of the European network for COVID-19 therapeutic trials and EU-funded COVID-19 clinical trial projects to exchange ideas, share knowledge, and thus develop best practices for the successful implementation and conduction of the clinical trials. The workshops will also help to identify any potential challenges and areas of improvement that can be addressed through further collaboration. Additionally, the workshops will enable the participants to learn from each other's successes and challenges and to develop creative solutions to the difficulties encountered. Ultimately, the workshops are expected to lead to a more successful and efficient implementation of the COVend project results.

Specific outcomes of the planned activity are the following:

- more informed and connected European trial network community, who are better equipped to develop new solutions to the challenges posed by COVID-19;
- gaining a deeper understanding of the clinical trial infrastructure, methodology and its conduction;
- fostering collaboration among clinical trial projects, exchange of ideas and the development of new and innovative solutions to the challenges posed by the pandemic;
- a better understanding of the impact of COVID-19 on research and the current state of clinical trials, and a greater understanding of the importance of collaboration between networks;

A concise workshop report covering the main conclusions will be shared with all participants afterwards.