IMI2 Project ID 101005077

CARE – Corona Accelerated R&D in Europe

WP 7 – Clinical evaluation of repurposed or novel SARS-CoV-2 antivirals or antibodies

D7.17: Setup of the Clinical Trial Platform:Implementation of representation concept completed

Lead contributor	8 - Goethe University Frankfurt (GUF)

Other contributors	1 - Institut National de la Santé et de la Recherche Médicale (Inserm) 5 - Centre Hospitalier Universitaire Vaudois (CHUV) 6 - Eurovacc Foundation (EVF) 12 - Academisch Ziekenhuis Leiden (LUMC) 13 - Servicio Madrileno De Salud (SERMAS)

Document History

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V0.1	28.09.2021	1st Draft by GUF

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Abstract

In order to prepare the CARE I – III clinical trials, under the guidance of GUF, all contributors are working together to set up a clinical trial platform. As a first step towards establishment of the platform, a representation concept needed to be implemented within Work Package (WP) 7. In a bottom-up process, a clinical development team was identified among members of WP7. Members of this team are experts in the diagnosis and treatment of COVID-19, as well as in the design and conduct of clinical trials. They will represent the clinical trial platform under the guidance of the WP leaders and serve as a contact for any clinical questions that may arise in the others WPs over the course of the CARE project. Furthermore, they are responsible for the completion of a range of sub-tasks needed to provide different services from the areas quality assurance, fast track processes, patient information/access and representation via the clinical trial platform. Overall, deliverable D7.17 could be implemented within the allocated timeframe and serves as a basis for further role out of the clinical trial platform.

Introduction

In order to prepare the CARE I – III clinical trials, under the guidance of GUF, all contributors are working together to set up a clinical trial platform. The clinical trial platform will cover the following overarching service topics:

1. Quality assurance
2. Fast track processes
3. Patient information/access
4. Representation

As a first step towards establishment of the platform, a representation concept needed to be implemented within WP7. This concept should enable all academic partners to contribute effectively and in an interactive fashion to the aims of the platform.

Methods

A designated WP meeting was announced and partners were asked to support the development of a representation concept through suggestions on how to implement a bottom-up process for representation of the different partners in the platform and their contributions to it. During the meeting, different suggestions of the partners were discussed in the group and the best option identified. In the same meeting, sub-tasks for completion of the platform were identified through discussion and responsible persons designated within the group.

Results

Prior to and during the designated WP meeting, a broad range of suggestions concerning the set-up and the contribution of partners to the platform, as well as the representation of partner sites within the platform and on its website were received. It

was proposed that WP7 and CARE in its entirety would profit from a designated team of experts in the diagnosis and treatment of COVID-19, as well as in the design and conduct of clinical trials. This "clinical development team" would set up and represent the clinical trial platform under the guidance of the WP leaders and serve as a contact for any clinical questions that may arise in the others WPs over the course of the CARE project. Each WP7 partner thus designated a suitable candidate and the following group was agreed on to form the clinical development team:

- Linda Wittkop (INSERM)
- Giuseppe Pantaleo (CHUV)
- Song Ding (EVF)
- Maria Vehreschild (GUF)
- Anna Roukens (LUMC)
- Alberto Borobia (SERMAS)

In a next step, different sub-tasks necessary to implement the platform were proposed and discussed in depth. For each sub-task, one responsible member of the clinical development team was identified, as well as contributing members. The sub-tasks sorted by main topics are:

1. Quality assurance
    a. Assessment of current standards and infrastructures at study sites
    b. Creation of common standard operating procedures (SOPs) for clinical COVID-19 trials (e.g. specimen collection, storage and shipment, PBMC collection, storage and shipment, assessment of transmission potential, long-COVID assessment, patient related outcomes tools)
    c. Training program for implementation of SOPs
2. Fast track processes
    a. Data safety monitoring board (DSMB) and data review committee (DRC) preparation
    b. Protocol template creation
    c. Establishment ethics fast track
    d. Establishment contracting fast track
    e. Conduct EMA (European Medicines Agency) Innovative Task Force Meeting
3. Patient information/access
    a. Provision of information on clinical trials in COVID-19 to patients
    b. Outreach to potential study subjects
    c. Identification of specific patient populations at different study sites (e.g. hematology/oncology, solid organ transplantation, rheumatology)
4. Representation
    a. Presentation of platform on CARE Website
    b. Establishment of connections and synergisms with other platforms

Conclusion

Deliverable D7.17 could be implemented within the allocated timeframe and serves as a basis for further role out of the clinical trial platform.