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

D7.16: Setup of Clinical Trial Platform: Fast track process set up

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Document History

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V2.0	20.10.2021	Report Deliverable D7.16

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Table of Contents

Abstract

In order to prepare the CARE I – III clinical trials (CARE I&II: phase 1 trials, CARE III: phase 2 trial) under the guidance of GUF, all contributors are working together to set up a clinical trial platform. Rapid design and conduct of clinical trials are key to the successful development of a novel therapeutic in the context of this pandemic and beyond. Therefore, as a key service of the platform, a fast-track process for submission and review of trial documents to the ethics committees and contracts to the legal departments of the participating partner sites needed to be implemented within WP7. At a local level, discussions with the responsible organizations (ethics committees and legal departments) were carried out to ensure high efficiency of local processes. Finally, a survey was performed to collect the respective information from all sites. Results of the survey were analyzed and used to inform a GANTT chart depicting the overall duration of CARE I. Overall, deliverable D7.16 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

To ensure rapid initiation of clinical trials at the platform partner sites, a fast track process for submission and review of trial documents to the ethics committees and contracts to the legal departments needed to be implemented. Establishment of these processes will enable all academic partners to contribute effectively and in a timely manner to the aims of the platform.

Methods

In a first step, all partners were asked to enter to enter discussions with their local ethics committees and legal departments, in order to optimize timely submission and processing of trial-associated documents and contracts, respectively.
In a second step, a survey was carried out to assess the result of these local discussion. Finally, the results of the survey were analysed to inform the completion of a GANTT chart that will be used to give an overview on the timelines that are required to set up and complete CARE I.

Results

At all sites, satisfactory processes and timelines for submission and processing of trial documents and contracts could be set up in cooperation with the local ethics committees and legal departments. Table 1 gives an overview on the survey results.

Table 1: Results of survey on timelines

	Average weeks (range)	Dependencies
Average time for EC approval	7.8 (1-12)	At LUMC and CHUV, contract signature is needed before ethics approval is issued
Average total time for EC approval if queries	11 (2-18)	
Average time for contracts	6 (4-12)	Concurrent process, however, at LUMC and CHUV, contract signature is needed before ethics approval is issued
Additional approvals needed?	Yes in 3/5 sites	Concurrent processes

The results of the survey were integrated into a GANTT chart (Table 2) used to assess the overall duration of CARE I, as the first trial to be planned by WP7.

Table 2: Simplified example GANTT chart of CARE I (starting date will be adjusted)

Essential Work Packages	Task/Milestone	Planned starting date	Planned duration (working days)
Contract Management Sites	Task	15.10.2021	80
Milestone Contract Sites final	Milestone	04.02.2022	1
Preparation Trial Protocol	Task	15.10.2021	90
Preparation CRF	Task	15.10.2021	90
Milestone CRF final	Milestone	18.02.2022	1
Milestone Trial Protocol final	Milestone	18.02.2022	1
Initial EC submission preparation	Milestone	01.02.2022	30
Initial CA submission preparation	Meilenstein	01.02.2022	60
EC approval	Milestone	15.06.2022	1
CA approval	Milestone	15.06.2022	1
Initiation Visits	Task	20.06.2022	7
Study Duration (FPI-LPO)	Task	25.06.2022	
Milestone FPI	Milestone	10.07.2022	1
Milestone 25% recruited	Milestone	20.07.2022	1
Milestone 50% recruited	Milestone	30.07.2022	1
Milestone 75% recruited	Milestone	10.08.2022	1
Milestone LPI (100% recruited)	Milestone	20.08.2022	1
Milestone LPO (effective end date)	Milestone	30.08.2022	1
Data Cleaning	Task	01.09.2022	90
Milestone DB lock	Milestone	05.01.2023	1
Tables, Listings, Graphs	Task	06.01.2023	60
Milestone Trial Report final	Milestone	01.04.2023	1

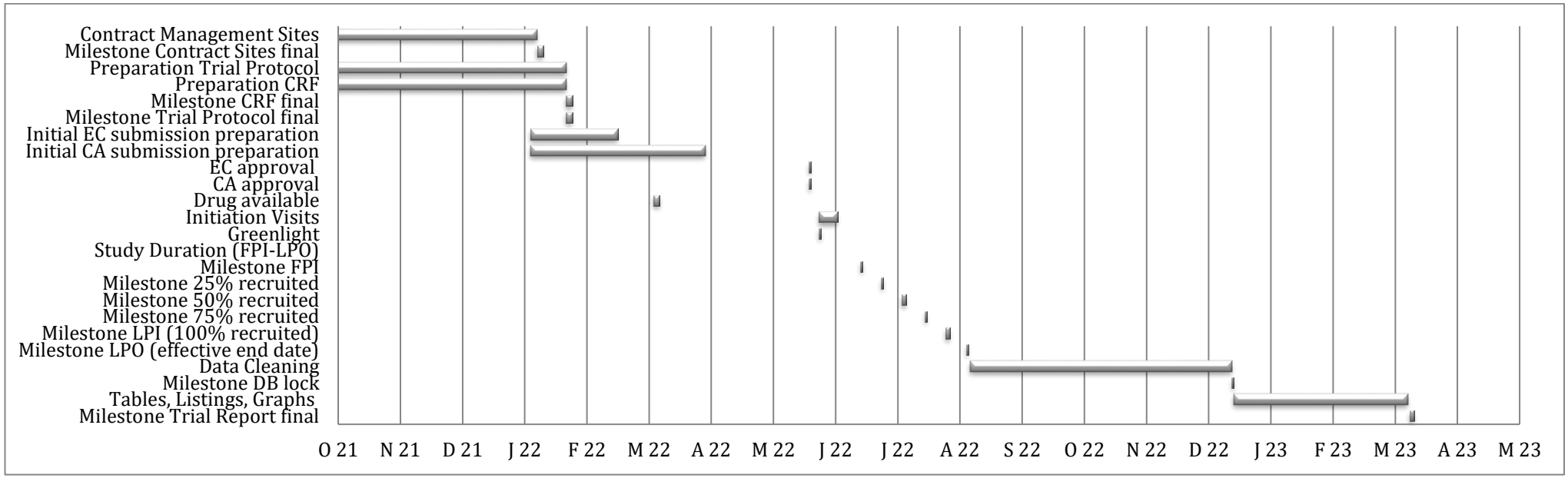

Figure 1: Illustration of example timelines for CARE I (starting date will be adjusted)

Conclusion

Deliverable D7.16 could be carried out within the allocated timeframe and helps to inform and accelerate the further roll out of the clinical trials CARE I-III.