DRAGON

innovative medicines initiative

IMI2 Project 101005122 - DRAGON

The RapiD and SecuRe AI enhAnced DiaGnosis, Precision Medicine and Patient EmpOwerment Centered Decision Support System for Coronavirus PaNdemics

WP8 – Fast track clinical studies

D8.1 Report on ethical approval and informed consent for the secondary use of data from the Remdesivir clinical trial

Lead contributor	UNILIV
Other contributors	
Deliverable submission date	17-12-2020
Deliverable type	Report
Dissemination level	Public

Abstract

Deliverable D8.1 is defined as a report on ethical approval and informed consent for the secondary use of data from the following clinical trial: Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants With Moderate Coronavirus Disease (COVID-19) Compared to Standard of Care Treatment (ClinicalTrials.gov Identifier: NCT04292730). This clinical trial was performed by UNILIV outside the DRAGON project activities, therefore samples and associated data (blood and nasopharyngeal samples and transcriptomics data from 500 patients) will be provided at month 6 (deliverable D8.2) free of cost, as well as free of GDPR and IP restrictions to the DRAGON consortium.

Partner UNILIV, represented by Dr. Julian Hiscox, was responsible to obtain all the necessary ethical approvals before the start of the trial. The attached letter signed by Dr. Hiscox, certifies that all the required ethical approvals for the above mentioned clinical trial were obtained and can be shared with the IMI project officer if required. Furthermore, the ethical approval available allows for the secondary use of patient data and samples for the purpose of the Dragon consortium.Methods

UNIVERSITY OF LIVERPOOL

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Dear IMI office and DRAGON project officer,

D8.1 Report on ethical approval and informed consent for the secondary use of data from the Remdesivir clinical trial (UNILIV)

As a representative of the University of Liverpool I hereby confirm that we have acquired and can provide all the required ethical approvals for the clinical trial: Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants With Moderate Coronavirus Disease (COVID-19) Compared to Standard of Care Treatment (ClinicalTrials.gov Identifier: NCT04292730). Furthermore we confirm that the ethical approval available allows for the secondary use of patient data and samples for the purpose of the Dragon consortium.

Yours sincerely

Julian A. Hiscox.

Prof. Julian A Hiscox
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