D4.2 Data Management System

116019 - RESCEU

REspiratory Syncytial virus Consortium in EUrope

WP4 – Prospective data collection

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Definitions

Participants of the RESCEU Consortium are referred to herein according to the following codes:

UEDIN. University of Edinburgh (United Kingdom)

UA. Universiteit Antwerpen (Belgium)

UMCU. University Medical Centre Utrecht (Netherlands)

UOXF. The Chancellor, Masters and Scholars of the University of Oxford (United Kingdom)

SYNAPSE. Synapse Research Management Partners S.L. (Spain)

Imperial. Imperial College of Science, Technology and Medicine (United Kingdom)

SERGAS. Servicio Galego de Saúde (Spain)

TUCH. Varsinais-Suomen sairaanhoitopiirin kuntayhtymä (Finland)

RIVM. Rijksinstituut voor Volksgezondheid en Milieu - National Institute for Public Health and the Environment (Netherlands)

SSI. Statens Serum Institut (Denmark)

UMCG. Academisch Ziekenhuis Groningenand (Netherlands)

PENTA. Fondazione PENTA for the treatment and care of children with HIV-ONLUS (Italy)

AZ. Astrazeneca AB (Sweden)

Pfizer. Pfizer Limited (United Kingdom)

GSK Bio. GlaxoSmithKline Biologicals S.A. (Belgium)

SP. Sanofi Pasteur (France)

JPNV. Janssen Pharmaceutica, N.V (Belgium)

Novavax. Novavax Inc. (United States of America)

Grant Agreement. The agreement signed between the beneficiaries and the IMI JU for the undertaking of the RESCEU project (116019).
Project. The sum of all activities carried out in the framework of the Grant Agreement.
Work plan. Schedule of tasks, deliverables, efforts, dates and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.
Consortium. The RESCEU Consortium, comprising the above-mentioned legal entities.
Consortium Agreement. Agreement concluded amongst RESCEU participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.

Publishable Summary

Data management of the clinical studies will be performed by a professional and experienced data management team from the Julius Center, Utrecht, the Netherlands. This team will coordinate and implement a high quality IT-infrastructure which will be necessary for the collection, controlling and reporting of the research data of this study. All study subjects will be identified with a participant identification code in order to safeguard the identity of the participants. The de-identified data will be stored on secure servers.

A GCP compliant electronic data capture (EDC) system, Research Online, will be used to guarantee a correct, complete and consistent data collection. Web-based case report forms will be developed and implemented on the EDC system. By using comprehensive data validation checks within these forms, only data of high quality will be submitted to the study database. The forms, integrated into the EDC system, will easily be accessed by a standard web browser.

The data management system will facilitate the collection of data, support the monitoring processes and provide real time progress reports for the management of the study. After the last patient recruitment and follow up has been completed, the database can rapidly be closed and data made available for further analysis and publication purposes. No interim database locks are planned, but if needed, interim database locks can be requested by the study team.

The system will meet all GCP guidelines for electronic data collection in terms of protecting data integrity and securing the information collected. This means, among other things, that users will get a role based access to the system after they have logged-in using their own username and password. The system will log all data entry steps with timestamps, update reasons and user information. The role based access to the system will avoid unauthorised data access and prevents users from performing actions that they are not allowed to carry out. Data from the EDC system will be transferred over the internet using secure data communication protocols. Data will be stored automatically with regular back-ups to ensure no data loss at any stage. Databases and web servers will be hosted in data centres that meet the highest possible security requirements.

1. Introduction

Starting July 2017, RESCEU will begin data collection from the prospective clinical studies which will continue for over 3 years until September 2020. To ensure high quality data collection, handling and storage, we will make use of a GCP compliant electronic data capture (EDC) system; Research Online. Full data management will be performed by Julius Center, based in the Netherlands. The data management team has been involved in large-scale international clinical studies since 2006. Research Online has been or is being used in 210 clinical trials and cohort studies in 42 countries (https://www.researchonline.info/en-us/). The following document provides information on the specifications of Research Online and will cover various topics such as data collection, data storage and data security.

2. Methods

Full data management will be performed by Julius Center in Utrecht, the Netherlands. Frank Leus is the Manager Data Management for the Julius Center and responsible for database security and governance (contact details in Annex 1). The EDC system, Research Online, in which the data will be entered, is a web based system. Data that is submitted will be stored in cloud based databases. The data center of this cloud based database is located in the European Union (Amsterdam). Databases and web servers are hosted in data centers that meet the highest possible security requirements. The EDC system is developed and maintained on the Mendix development platform. Mendix is hosting this platform, including the applications and databases in secure data centers. Research Online makes use of one data center (based in Amsterdam, as stated above). This data center is yearly audited according to ISAE 3402 type 2 report. All relevant topics related to the security of the systems are element of this type of audit (e.g. security of operations, user access, logical security, data handling, physical security, change management, incident handling etc.).

The EDC system, Research Online, will only capture anonymised patient data. Only unique study identifiers will be used to identify the subjects in the eCRF database. Local teams will log patient identifiable data (like name, contact data and date of birth) in a separate document to link the subject to the correct eCRF ID number. These documents, that are only available for the local study team, are stored at a secured location on site. In this way there will be no direct link between personal data and clinical research data.

Data management will be performed by a professional and experienced data management team. This team will coordinate and implement a high quality IT-infrastructure which will be necessary for the collection, controlling and reporting of the research data of this study. The data management department maintains SOPs for using these systems. The SOPs cover, among other things, system setup, installation and use. The SOPs also describe system validation and functionality testing, data collection and handling, system maintenance, change control, data backup and recovery and user management. When needed a list of the SOPs can be provided.

The EDC system, Research Online, meets all ICH-GCP, EMA (annex 11) and FDA (21CFR part 11) guidelines. The systems are being developed and maintained according to GAMP 5 system validation procedures. The system meets all GCP guidelines for electronic data collection in terms of protecting data integrity and securing the information collected. This means, among other things, that users will get a role based access to the system after they have logged-in using their own username and password. The role based access to the system will avoid unauthorised data access and prevents that users perform actions that they are not allowed to do. The system will log all data entry steps with timestamps, update reasons and user information and are designed in such a way that data changes are documented and that there is no deletion of entered data (an audit trail will be maintained). If needed, it will be possible to grant access rights to the system, on different levels, for EFPIA partners. For instance CRA's of EFPIA partners can be granted the rights of the 'monitor' role. Using this role, it will be possible to perform source data verification and query management.

Data from the EDC system will be transferred over the internet with secured encrypted data communication using the Secure Socket Layer cryptographic protocol.

Data will be stored immediate and automatic in the cloud based databases located in Amsterdam and regular back-ups will ensure against any loss of data.

3. Results

D4.2. Data management system (M6)

> *Single user-friendly cloud-based data platform gathering all the RESCEU data (including clinical, microbiological and biomarker data), and being accessible to all interested stakeholders, in compliance with European and local data protection norms.*

The Research Online EDC system is currently being built by the data management team of Julius Center and is expected to be ready before the start of the clinical studies. The questionnaires and eCRFs for the Infant birth cohort study, which have already been discussed extensively by the various work packages involved (WP3-4-5), will be tested by the various clinical partners involved in the clinical studies, before being translated into the different languages of the participating centers. Similar procedures are being followed for the questionnaires and CRFs for the elderly cohort study and the COPD cohort study.

4. Conclusion and next steps

Full data management of the clinical cohort studies will be provided by Julius Center in the Netherlands. Research Online, a GCP compliant electronic data capture (EDC) system, will be used to guarantee correct, complete and consistent data collection. The databases and patient registration modules are currently being prepared to ensure completion before the clinical studies start.

ANNEXES

ANNEX I. contact data manager data management Julius Center

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