

101034339 – PROMISE

Preparing for RSV Immunisation and Surveillance in Europe

WP3 –Clinical validation studies

## D3.2 Database development for patient recruitment, characterisation and sample allocation

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## Definitions

- **Participants** of the PROMISE Consortium are referred to herein according to the following acronyms:
  1. **UEDIN.** The University of Edinburgh (United Kingdom)
  2. **UMCU.** Universitair Medisch Centrum Utrecht (Netherlands)
  3. **UA.** Universiteit Antwerpen (Belgium)
  4. **Imperial.** Imperial College of Science, Technology and Medicine (United Kingdom)
  5. **UOXF.** The Chancellor, Masters and Scholars of the University of Oxford (United Kingdom)
  6. **THL.** Terveysten Ja Hyvinvoinnin Laitos (Finland)
  7. **RIVM.** Rijksinstituut voor Volksgezondheid en Milieu (Netherlands)
  8. **NIVEL.** Stichting Nedelands Instituut voor Onderzoek van de Gezondheidszorg (Netherlands)
  9. **TUCH.** Varsinais-Suomen Sairaanhoidopiirin Kuntayhtymä (Finland)
  10. **TEAMIT.** TEAM IT Research, S.L. (Spain)
  11. **ReSViNET.** Stichting Resvinet (Netherlands)
  12. **SSI.** Statens Serum Institut (Denmark)
  13. **SERGAS.** Servizo Galego de Saúde (Spain)
  14. **PENTA.** Fondazione PENTA - For the treatment and care of children with HIV and related diseases - ONLUS (Italy)
  15. **FISABIO.** Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (Spain)
  16. **MLU.** Martin-Luther-Universitaet Halle-Wittenberg (Germany)
  17. **SP.** Sanofi Pasteur, S.A. (France)
  18. **GSK.** GlaxoSmithKline Biologicals, S.A. (Belgium)
  19. **JANSSEN.** Janssen Pharmaceutica, N.V (Belgium)
  20. **Novavax.** Novavax Inc. (United States)
  21. **Pfizer.** Pfizer Limited (United Kingdom)
  22. **AZ.** AstraZeneca AB (Sweden)
  
- **Grant Agreement.** (Including its annexes and any amendments) The agreement signed between the beneficiaries of the action and the IMI2 JU for the undertaking of the PROMISE project (Grant Agreement No. 101034339).
- **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 PROMISE Consortium, comprising the above-mentioned participants.
- **Consortium Agreement.** The agreement concluded amongst PROMISE participants for the implementation of the Grant Agreement. The agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.

## Abbreviations

<b>Acronym / Abbreviation</b>	<b>Meaning</b>
<b>GCP</b>	Good Clinical Practice
<b>GDPR</b>	General Data Protection Regulation
<b>EDC</b>	Electronic Data Capture
<b>WP</b>	Work Package
<b>eCRF</b>	electronic Case Report Form

## Abstract

A user-friendly, GCP and GDPR compliant electronic data capture (EDC) system, Castor EDC, will be used to guarantee correct, complete and consistent data collection of the clinical studies of PROMISE Work Package (WP3). Electronic case report forms (eCRFs) 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 be easily accessible by a standard web browser.

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. Local teams will log patient identifiable data in a separate secure document to link the subject to the correct ID number noted on the eCRF.

The system will meet all GCP and GDPR guidelines for electronic data collection in terms of protecting data integrity and securing the information collected.

## 1. Introduction

Prospective data will be collected in the PROMISE infant case-control validation study and extended follow-up of eligible children of the RESCEU infant cohort study and infant case-control study. To ensure high quality data collection, handling and storage, we will make use of a GCP and GDPR compliant electronic data capture (EDC) system; Castor EDC. Castor EDC is user-friendly, allowing researchers to develop a database themselves, and is supported by the UMC Utrecht data management team.

## 2. Methods

For collection and storage of data from the PROMISE infant case-control validation study and the extended follow-up of eligible children of the RESCEU infant studies, Castor EDC will be used. Castor is a web-based EDC system; data that is submitted will be stored in cloud based databases. Databases and web servers are hosted in data centers that meet the highest possible security requirements.

Castor EDC will only capture data without subject identifiable data. Only unique study identifiers will be used to identify the subjects in the eCRF database. The database will be checked by the UMC Utrecht data management team before data are entered. Local teams will log subject identifiable data (for example, name, contact data and date of birth) in a separate document to link the subject to the correct ID number noted on the eCRF. This document will only be accessible for local researchers and will be stored locally in a secure, password protected file and/or locked cabinet. In this way there will be no direct link between personal data and clinical research data.

Castor EDC fulfils all legal and privacy requirements (amongst others GDPR and European legislation). This means, among other things, that users will get 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 will prevent users from performing actions that they are not authorised to perform. Furthermore, 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.

### 3. Results

The database is currently being built in the Castor EDC system by the researchers with support from the UMC Utrecht data management team. The researchers have undergone training on database development in Castor. The eCRFs and questionnaires of the PROMISE infant case-control validation study are similar to the questionnaires and eCRFs of the RESCEU infant case-control study to allow comparison of clinical characteristics between these two studies. Sample collection information (for example sample collection date/time, volume, physical location) will be added to the database to allow easy localization of available samples.

The database for the questionnaire based follow-up study of eligible children of the RESCEU infant cohort and infant case-control study at age 4, 5 and 6 will also be built in the Castor EDC system. With Castor it is also possible to request electronic consent; it is currently being evaluated whether this would be suitable for use in the PROMISE follow-up study and infant case-control validation study.

## 4. Conclusion and next steps

Castor EDC, a user-friendly GCP and GDPR compliant EDC system, will be used for data collection, including information about collected samples, for the PROMISE infant case-control validation study and for data collection and storage of the long-term follow-up of eligible children of the RESCEU infant cohort study and the infant case-control study. These databases are currently being built.

## ANNEXES

### ANNEX I. Link to EDC system information

More information about the Castor EDC system can be found on:

<https://www.castoredc.com/>