25/06/2020

TREATMENT OF CRITICALLY ILL PATIENTS WITH COVID-19 WITH CONVALESCENT PLASMA

NCT04468009

STATISTICAL ANALYSIS PLAN

DATA COLLECTION METHOD AND STATISTICAL ANALYSIS PLAN

Database design and data collection form

The main source documents for this research project will be the subjects' medical records (clinical history). If researchers maintain separate research records, both the medical records and the research records will be considered source documents for the purpose of auditing the study.

The investigator will allow monitoring and auditing of this data, and will allow regulatory authorities to access the original documents. The investigator is responsible for ensuring that the data collected is complete, accurate and recorded in a timely manner.

Source documentation (the initial information recording point) must support the data collected and entered into the research project database / form (CRF). The research project data will be recorded in electronic case report forms (CRF).

If corrections in the CRF are required, they will be made by an investigator or an authorised designated person. Those changes, as well as the identity of the person making them and the date in which they are made, will be recorded.

All submitted data must be reviewed by the centre investigator and signed as necessary with a written or electronic signature, as appropriate.

Data entered into the research project's database will either be collected directly or extracted from the subjects' medical records. The participation in this clinical trial and what medications (with dosage and frequency) or other medical interventions or treatments were administered, as well as any adverse event experienced during the clinical trial, must be recorded in the subjects' medical records.

A designated professional ir responsible for retaining all essential documents from the clinical trial. The clinical trial records will be kept for a certain time, determined by the regulatory authority.