

## Project group 17

### Case: Platform for performing electronic Case Report Forms

The platform for performing electronic Case Report Forms case is focused on developing a user-friendly web application that supports study definition, data collection and some basic statistical analysis using eCRF's. A Case Report Form (CRF) is a specialized protocol driven document for clinical research, an eCRF is an electronic version. In this case we focus particularly on a CRF developed by the World Health Organization (WHO) for COVID-19. The main purpose of using the same CRF worldwide is to ensure standardized clinical data collection for healthcare facilities. The goal is to provide a web application that addresses the dynamic aspects of CRFs, it must enable changes in the form over time, consider answers as controlled vocabulary (e.g. through check/radio/combo boxes) and support free text answers. In order to provide this the system must be able to make changes in the CRF structure at runtime and provide a list of previous versions. During the COVID-19 epidemic and in earlier occasions, we have seen severely suboptimal data management solutions that do not support Findability, Accessibility, Interoperability and Reusability (FAIR) for humans and machines. User-friendly eCRF web systems, such as the Castor EDC application, support healthcare professionals to perform the two first phases of a typical clinical diagnostic workflow: study definition and data collection. In order for our system to be able to be deployed on a global scale we need to ensure our system supports FAIR. Preferably, the system must follow the 3-tier architecture communicating with a database through a service and the data stored in a relational database and/or a knowledge graph database. Additionally because clinical data is privacy sensitive data the system must be secured using role based administration. Furthermore, this system must support identity management with an identification authority solution to assure the global uniqueness of the identity of the person under recording