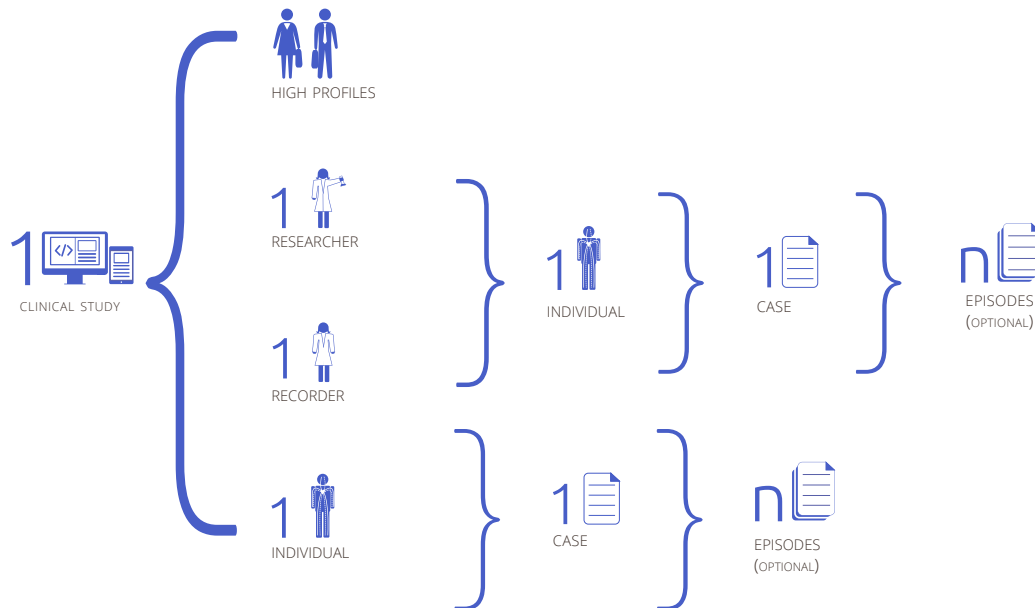


1 CLINICAL STUDY SETUP

uEDC solution provides a flexible setup of a clinical study, in accordance with an established protocol defined by the study promotor. Each clinical study has several intervenient actors which by default, are organised by the following disposal:



If needed, it is possible to have the site concept, where any researcher associated to a certain community can edit a case from that site. A clinical study can have different sites associated.

2 PROFILE AND USER MANAGEMENT

uEDC solution allows to the responsible for the clinical study – the promotor – to manage profiles and users.

1. Profile management. Provided by the technical responsible – iUZ – it is possible to set permissions associated to each profile, carefully selected with the study promotor.
2. User administration. Depending on the level of permissions given to a specific profile or user, it is possible to:
 - Manage users (by registering, modification or/and elimination)
 - Option to activate a user account, and to resend access credentials to a specific user
 - Uploading data of new users
 - Data export
3. For each clinical study is possible to have different standard profile types, previously loaded through the profile manager:





Electronic Data Capture

STANDARD FEATURE LIST - BUILDING BLOCKS

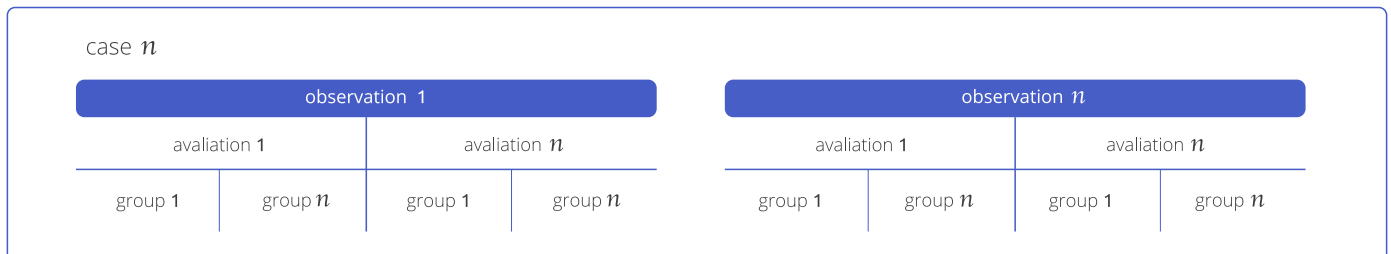
2 PROFILE AND USER MANAGEMENT

- Platform manager, is the technical responsible for the information system that configures the study and CRF
- Data Manager: Responsible for the process quality and for the collected data. This profile can create and manage users; export data; view cases from the study and their details; dismiss cases; manage the study characteristics (eg, update the expiration date), and make Audit Trails
- Study Coordinator: Responsible to examine and monitor data, as well as the creation of users, depending on the level of permissions given to the profile
- Researcher: Responsible for a case. This profile can view, create, manage and submit cases or episodes. It is also possible for the researcher to be associated to a certain site, where any researcher from his community can edit his cases
- Recorder: Assistant associated to a specific researcher, which depending on the permissions given to the profile can start, fill out and/or submit a case or episode
- Individual: Responsible for completing his case. Depending on the permissions given to the profile is possible to start, fill out and/or submit the case or episode

3 DATA ENTRY

The organization of the CRF (Case Report Form) is realized according to the rule, established by iUZ:

study 1



In the CRF organization ensured by iUZ, it is possible to:

- Setup the observations' sequencing
- Define continuous evaluations
- Define types of answers
- Help elements
- Engine outputs
- Filling forms
- And, the existence of movement questions

Each observation can assume innumerable forms of sequencing, such as:

1. All observations are available and the user can choose the desired order





Electronic Data Capture

STANDARD FEATURE LIST - BUILDING BLOCKS

3 DATA ENTRY

2. After observation x is completed, unlocks a specific observation (not necessarily the subsequent)
3. After observation x is filled out and without errors (not necessarily concluded), unlocks a specific observation (not necessarily the subsequent)
4. After the conclusion of the previous observations, moves to the subsequent observation
5. Along with the previous observation

Regarding the existence of continuous evaluations, it can be specify the number of times a given evaluation is performed, delayed or not in time.

There is a range of response types that can be associated to a particular question, namely:

1. Single choice ('yes or no', radio button, drop down list)
2. Multiple choice (check box)
3. Continuous or range scale
4. Text
5. Dates (simple or complex (if the subject does not know a specific date it is possible to enter the year and/or month and/or day, or none))
6. Master & Details (simple or complex), blocks and sub-blocks of questions
7. Movements, which depending on the answer to a question, may show or hide another question or group of questions

Through the study it may appear different assistance elements, such as:

- Enlightening pictures, with the presentation of an image along a particular group of questions
- Introduction texts to a group or to a question
- Subtitles
- Mechanisms for auto-fill responses

During the study it can occur exit mechanisms triggered by blocking responses (eg. the subject has an age lower than x).

Throughout the study there may exist different ways of completing the CRF with the possibility of:

- Save the evaluation in a temporary or permanent way, such as, when the user makes a partial filling, it is allowed to continue the evaluation later
- The evaluation is saved automatically, with the possibility to recover answers

4 DATA VALIDATION

uEDC solution is able to have several data validation types, at the time of response to a given question, like:





Electronic Data Capture

STANDARD FEATURE LIST - BUILDING BLOCKS

4 DATA VALIDATION

- Mandatory
- Mandatory, depending to the response to another variable
- Compare dates (full, monthly or annually)
- Compare responses between Groups, Evaluations and/or Observations
- Validate answers given by a user
- Limited amount of characters

If the user does not fulfil the predefined validation, is sent a feedback message and is possible to obtain an indication of the non-compliance issue level, the group or the evaluation, with the following types of feedback, through the display of messages:

- Advisory: Grey message, non-blocking
- Warning: Yellow message, non-blocking
- Error:
 - Red message, blocking the user, allowing to navigate in the case, but it is not possible to submit it
 - Red message, blocking the user, not being allowed to go through the case, forcing the user to leave the event immediately
- Double confirmation response: Pop-up mechanism

If the study promotor requests, it is possible for the user when submitting the case, to be prompted his signature, through a pop-up mechanism for confirmation of his answers.

5 DATA MANAGEMENT

According to the permission level of the user profile, it is possible to manage the data case, like:

- Discard cases manually
- Consultation of the CRF data:
 - 'View Responses' mode: List of the questions and answers given to the user, prepared for printing
 - 'Read-only' mode: List of the questions and answers given to the user in 'read-only' mode
 - Case Summary: Displays the status of fulfilment of each observation

6 CALIBRATION

Support for calibration procedures between researchers:

- Standard case definition
- Report for comparison between the specific case and the standard case
- To print the report of a specific calibration (1 specific case and 1 standard case)



Electronic Data Capture

STANDARD FEATURE LIST - BUILDING BLOCKS

7 DATA EXPORT

Depending on the user permission level, it is possible to export data for further study treatment, such as export data from the study to an excel sheet data, and, send the exported data by email to the user.

8 NOTIFICATIONS

During the user's presence on the platform, there are pre-set notifications sent by email, including:

- Platform registration
- Access credentials (new or forwarded)
- Results of exporting data

9 AUDIT TRAIL

uEDC solution is aligned with IHE Profile – ATNA (Audit Trail and Node Authentication) and RFC 3881 protocol (Security Audit and Access Accountability Message XML Data Definitions for Healthcare Applications), which enables a continuous recording of audit logs.

Subsequently allows the consultation of Audit Logs through:

- Mechanisms for consult audit records
- Mechanisms to export audit records for a standard file - PDF

10 NON-FUNCTIONAL REQUISITES

uEDC solution lies in an application execution environment based on http and https, with the interface available to users through an internet browser (by default, it is not a cross platform) and is optimized for the latest versions of the following browsers, on the date of contract signature:

- Google Chrome
- Mozilla Firefox
- Internet Explorer

11 ASSOCIATED SERVICES

The setup of uEDC platform is made by iUZ.