Setting up a Project

Definitions

- A database is called a **project.**
- Variables are called **fields.**
- Fields have **names and labels** (descriptive name).
- All data connected to a single subject is called a **record.**
- CRFs/ forms/ surveys are called **data collection instruments.**
- An instrument that is repeated on an ad hoc basis is called a **repeating instrument** (these instruments must be designated to an **ad hoc event**).
- Data collection points or assessments are called **events.**

CCRH Project Default Settings

- Main project settings: enable surveys and longitudinal mode (use longitudinal mode even if the project only has one event in case future events are added).
- Optional modules; enable the following:
    - repeatable instruments
    - scheduling
    - data resolution workflow
    - data history widget
    - today / now button
    - DAG switcher
- The first variable on the first instrument is the participant ID ("record ID"); the field name and label can be changed (e.g., "Screening ID" or "Study ID" for field name).
- In the screening database use NHI as second unique identifier (to prevent same individual being screened twice).
- The first instrument in the project should not be a survey, unless the project only contains a single survey (note custom record ID is not permitted in surveys).
- Turn off "auto-numbering for records" for trial databases (Study ID will be assigned at randomisation and imported to the trial database).
- Note that reports can only be constructed from a single event; assign instruments that will be reported together to a single event. Ad hoc instruments are reported one instance per row.
- Suggested events: first event is "enrolment" and the last is "ad hoc" (SAE, protocol deviation); other events should be in order of assessments. Place all instruments that will be combined in reports on the enrolment event (including withdrawal).
- DAGs should be set up by site in screening and then imported to trial database. Ensure DAG switcher options are completed before production and higher level users have access to all DAGs.
- Status fields should be created for the following:
    - each study phase
    - the intervention (as per definition of minimum)
    - primary outcome data availability

CCRH Instrument Default Settings

- In general, avoid using field numbers as it makes reports look messy and queries should be managed via the data resolution workflow. However, this may be required for paper based studies or with complex instruments / surveys.
- Avoid putting comments in the field labels as this makes reports look messy; instructions are best placed in the field note (don't use parentheses as these are automatically inserted if exported to pdf).
- Macrons and other special characters can be inserted by pasting from word but these characters are best avoided as they will be lost when the project is uploaded from the data dictionary.
- Calculated fields do not update automatically but are updated when an instrument is opened and saved. Calculated fields should be placed at the end of an instrument after "For admin use" heading. These can be hidden from survey view with the @HIDDEN-SURVEY tag.
- Ensure instruments have the following fields, where appropriate:
    - completion date (usually at the top of the instrument)
    - examiner name
    - completion status: (1) completed (minimum data); (2) incomplete; (3) not done.
- If additional identification or demographic information is needed on instruments, use piping. Never duplicate data fields.
- A management instrument can be added to the enrolment event to monitor and report study progress. Calculations can run across multiple events but will require manual updating.

Fields

Use default yes/ no binary fields as calculated fields only work on numerals (code with suffix <_bn>)

Essential variables

- Intervention status
- Primary outcome status
- Assessment status at any other key events
- Instrument status for monitoring secondary outcomes / data completeness