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**UNIVERSITÄT
BERN**

Faculty of Medicine
CTU Bern

REDCap Light User Manual

18.01.2023

Revision Index

Version	Chapter	Summary of changes	Reason for change(s)
03	N/A	first version of controlled document	N/A
04/5.0.0	N/A	see latest version of document	N/A
6.0.0	2.2.11	Additional information on new SAE templates	Implementation of new SAE templates in REDCap
	2.2.13	Clarification on randomization process	
	2.2.6	Addition on File upload	
	9.2.2	Additional note on export of audit trail	
6.0.1	---	Technical change in ORCA only, as incorrect file was uploaded	Technical change in ORCA.
7.0.0	2.1	Removal of information on external multi-lingual module	Updated due to new REDCap version
	2.2.3	Additional information on HTML tags	
	2.2.5	Additional information on action tag	
	2.2.8	Additional information on form display logic	
	2.2.9	Rewrite information on HTML tags	
	2.2.10	New multi-language management tool	
	7.2	Additional information on export rights	
	9.	Additional information after process revision Additional information after process revision	New DB Lock Process / SOP update

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Abbreviations

Abbreviation	Term
AE	Adverse Event
(e)CRF	(electronic) Case Report Form
(C)EC approval	(Cantonal) Ethics Committee approval
IC	Informed Consent
PID	Patient ID
SAE	Serious Adverse Event

Definitions

Term	Definition	Reference
N/A		

1. Finalizing design / requirements of study database

Before you start to implement the study, check that the specifications (e.g. study protocol, visit plan, list of variables, randomization requirements (if applicable),...) are complete and that the documents are in alignment with the study protocol.

Check also that the study endpoints are defined in the study protocol and that they are present and consistent throughout all documents (e.g. list of variables). Verify that you are able to assess the study endpoints with the chosen variables.

You can use the template “Submission: Study_protocol_DM_text template_REDCap”¹ for the data management section in the study protocol.

It might be helpful to create a codebook (see CTU codebook template¹).

- ✓ If applicable, check that the following data is being collected and is consistent throughout the study specification:
 - Eligibility criteria
 - Informed consent (including date of informed consent)
 - (Serious) Adverse Events
 - End of study data
- ✓ If the CTU **SAE template** is not being used, check that crucial information (e.g. SAE start date, SAE description, severity,...) is collected.
- ✓ If **identifiers** (e.g. first name, last name, initials, postal address, internal patient IDs, etc.) are being collected, check that the **CEC has approved** the collection of this information. Year of Birth and Age (collected as integer) are not considered as identifying data and thus are not subject to approval.
- ✓ If **surveys** are going to be sent to participants, clarify if the Sponsor has received EC approval to collect and store email addresses in the REDCap database. If not, email addresses should be collected at a different location (e.g. the patient log).
- ✓ Check that **unique data** (eg. Sex, Year of Birth, Age, Date of Informed Consent,...) is collected only once to avoid discrepancies during data entry.
- ✓ If **special roles, reports or additional information** is needed (e.g. restricted access to eCRFs with identifying data), **define and document these requirements**.
- ✓ If a **multilingual system** is needed, check that the **translation for all fields** is available in all required languages.

¹ * available on «CTU_Library of REDCap Light Documents»

2. Implementing the study database

2.1. General Settings of the new project Accessing the database

You can access your database(s) by logging in at <https://redcap.ctu.unibe.ch>. An additional REDCap installation of the Inselspital will follow at a later stage.

Project Setup Page

The screenshot displays the REDCap Project Setup Page. The sidebar on the left includes sections for 'Data Collection' (with sub-items: Scheduling, Record Status Dashboard, Add / Edit Records), 'Applications' (File Repository, Resolve Issues), 'Project Bookmarks' (CTU Bern Website), and 'Help & Information' (Help & FAQ, Video Tutorials, Suggest a New Feature, Contact REDCap administrator). The main content area shows the project status as 'Development' and 'Completed steps 0 of 9'. It features four main sections: 'Main project settings' (Not started), 'Design your data collection instruments & enable your surveys' (Not started), 'Define your events and designate instruments for them' (In progress), and 'Enable optional modules and customizations' (Optional). Red boxes highlight 'Data Collection' in the sidebar, 'Help & FAQ' and 'Video Tutorials' in the sidebar, and 'Online Designer', 'Data Dictionary', 'Define My Events', and 'Designate Instruments for My Events' in the main content area.

Main project settings

Enter basic project information:

- ✓ **Is data collection longitudinal** (i.e. are specific forms going to be used multiple times during different visits)?
- ✓ Are **eSurveys** going to be used?
- ✓ Enter **project title and further information** (e.g. purpose and basic project information)

Optional modules and customizations:

- ✓ Enable or disable **repeatable instruments and events** to use visit-independent forms (e.g. for Adverse Events) multiple times or repeat events with the same structure (e.g. unscheduled visits)
- ✓ **Always leave 'Auto-numbering for records' enabled!**
- ✓ Enable/Disable **Randomization**
- ✓ Enable/Disable **scheduling module** (use of REDCap internal calendar)

Additional customizations:

Configure additional customizations like

- Custom record label
- Secondary unique field
- Data Resolution Workflow or Field Comment Log
- Missing data codes

These settings can be set/changed at any time. If you are unsure if and how you want to configure them, please refer to the REDCap FAQs.

Missing data codes

Custom '**Missing Data Codes**' can be used to mark fields that have a **blank/missing value**. Using these missing codes helps in data analysis and monitoring by specifying why a field is missing a value. CTU recommends using the code -999 for 'missing'.

Please note that the **missing code should be deactivated** for fields like **eligibility criteria, strata, endpoints and important fields in the SAE form**. This can be done by using the **action tag '@NOMISSING'** in the field annotation for the respective fields. This action tag will disable the 'missing data code' functionality for the given fields and hide the M icon next to the field.

The use of missing codes in numeric fields should also be considered carefully. It might falsify calculation if not handled correctly (e.g. falsify the calculation of mean values)

For more information on missing data codes, consult the REDCap FAQs and the explanations in the additional customizations section in Project Setup.

Double data entry

As a preventive measure, REDCap prevents users from entering duplicate records. However, some projects may need to enter data twice for each record as a means of ensuring quality data collection by comparing the records. This can be done using the **Double Data Entry Module**." If you want to use **double data entry**, please inform CTU Bern Data Management. We will activate it for your study.

For more information concerning double data entry, consult the REDCap FAQs.

Change system language for your project

German or **French** can be set up as a language for user interfaces (e.g. menu, many help texts and options) with the **Multi-language Management tool** in REDCap. See instruction on how to activate these languages in chapter 2.2.10. If you want to have a different language for user interfaces, you can contact CTU Bern Data Management to check if these translations are available.

Since these translations are not directly provided and reviewed by Vanderbilt (the provider of the REDCap system), the correctness and completeness of the translations cannot be guaranteed.

2.2. eCRFs Creation (Online Designer or/and Data Dictionary)

2.2.1. General Considerations

- ✓ **Create short and well-structured eCRFs.** Use **Section headers** to structure longer eCRFs.
To insert a Section header, click on “add field” and in field type choose: “Begin New Section (with optional text)”
- ✓ Do not collect any **identifying data** (full name, birthdate, email address, ...) unless necessary for the analysis or study conduct (sending out patient questionnaires). The collection of identifying data has to be approved by the CEC.
Restrict the access to personal data to the study personnel who is working directly with it. This can be done by collecting all identifying data on one separate instrument to which only very few people have access to
- ✓ Use **terminology familiar** to data entry personnel. This is of special importance when patient-completed questionnaires are being used!
- ✓ **Phrase all fields positively** (e.g. “Patient is Swiss” rather than “Patient is not Swiss”)
- ✓ **Avoid open ended questions** (i.e. non-validated text fields)
Only use comment fields if needed and provide clear data entry instructions
- ✓ Always indicate **clear time frames**: e.g. Quality of Life: data related to the last 14 days

- ✓ **A form can be used for several visits.**
 If similar forms (difference < 10 fields) are being used at different visits (e.g. laboratory), the same form should be used.
The visibility of single fields at certain visits (e.g. if “gender” is only documented at Baseline) **can be controlled via Branching Logic**, using the Smart Variables [event_name] and [event_label].
 See “REDCap FAQ and Help” for further information.
- ✓ Create an **Eligibility form**
 CTU Bern recommends to collect at least the Informed Consent decision as well as the date of Informed Consent signature
- ✓ For prospective studies, create an **End of study form** to collect information regarding at which date and under which circumstances the patient left the study
- ✓ For prospective studies, create a **(Serious) Adverse Event (=SAE) form** (if applicable)

2.2.2. Identifying Data

Identifying data are:

- full name
- full birthdate
- eMail address
- full postal address
- telephone number
- patient IDs
- images showing the face of a patient or images which contain any of the data mentioned above
- other data which might directly identify a patient

Identifying data should only be collected in the study database if absolutely necessary for the data analysis or the study conduct. In any other case identifying data should be collected externally, e.g. on an Excel sheet which is stored on a secured study drive with restricted access.

The collection of identifying data **always** has to be approved by the Cantonal Ethics Committee.

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If identifying data has to be collected in the study database, the access should be restricted to study personnel that is directly working with them, e.g. sending out patient questionnaires or doing telephone interviews. For this reason, identifying data should be collected on (a) separate instrument(s). That way other study personnel can be restricted from accessing these instruments.

Fields that collect identifying data should always be marked as “identifier”, so that these fields can be excluded from data exports.

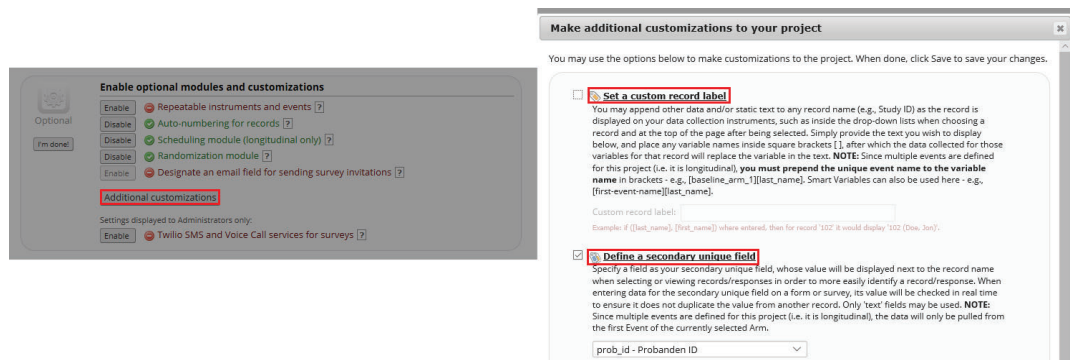
2.2.3. eCRFs Setup

IMPORTANT:

- ✓ Never change the name of the **first field of the first form (record_id)**! The **Record-ID** is a system variable which is used by the REDCap system.



If you want to use a **study specific Patient ID**, create an additional text field below the REDCap record_id and indicate its format in the field note (e.g., Bern-0001, 1957-M-001). You can set this field as a secondary unique field or custom record label in the additional customizations tab to prevent that the same patient is entered twice by mistake.



This information will then be visible next to the Record ID in the Record Status Dashboard:

Record ID
<u>1</u> (Probanden ID Bern-0001)
<u>2</u> (Probanden ID 1957-M-001)

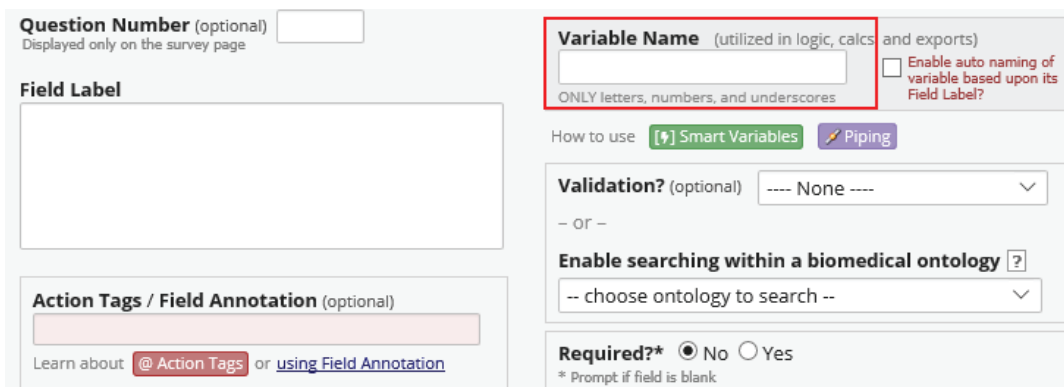
Field creation – Predefined field types

- Text Box, validated
 - Numeric fields (validation required)
 - Dates (validation required)
- **Text Box, unvalidated***: single-line text box
- **Notes Box***: large text box for longer text
- Dropdown List / Radio Buttons: multiple choices, single answer
- **Checkboxes***: multiple answers possible
- **Calculated Fields***: perform calculations (numbers/dates only)
- File Upload: document upload, e.g. PDF file (small and coded files only)
- Slider / Visual Analogue Scale: coded from 0 to 100

* avoid if possible

Field definition

- ✓ Click on “add field” at the position where you want to add a field, the following popup window opens:



The screenshot shows a field definition popup window with the following sections:

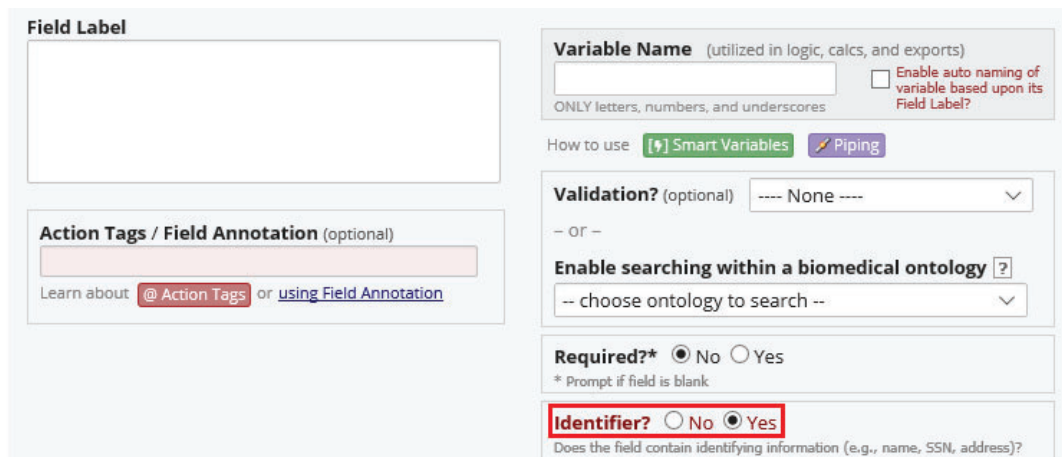
- Question Number (optional)**: A text input field with a note "Displayed only on the survey page".
- Field Label**: A large text area for entering the field label.
- Action Tags / Field Annotation (optional)**: A text input field with a note "Learn about @ Action Tags or using Field Annotation".
- Variable Name (utilized in logic, calcs and exports)**: A text input field with a red border and a note "ONLY letters, numbers, and underscores". There is a checkbox "Enable auto naming of variable based upon its Field Label?".
- How to use**: Two buttons: "Smart Variables" and "Piping".
- Validation? (optional)**: A dropdown menu with "None" selected.
- Enable searching within a biomedical ontology**: A dropdown menu with "-- choose ontology to search --" selected.
- Required?***: Radio buttons for "No" (selected) and "Yes". A note below says "* Prompt if field is blank".

- ✓ Define field label: if possible, try to avoid using HTML tags or other formatting in the labels
- ✓ Define **variable names**:
 - First character must be a lowercase letter

- Only lowercase letters, numbers and underscores can be used

Variable names should be short (not more than 25 characters) and concise

- ✓ Define **mandatory fields** and set them as **required** (e.g. eligibility criteria, primary endpoints, etc.).
Fields that depend on other fields (e.g. pregnancy test only for women) should not be set as required, unless branching logic is used.
- ✓ **No identifying field** (e.g. first name, last name, initials, postal address, internal patient IDs, etc.) should be collected in your REDCap database unless approved by the ethics committee.
Identifying data should be collected rather in an Excel sheet that will be kept in a well-protected study drive.
In case **identifying data** (e.g. email addresses) must be collected in the REDCap database and you have the approval of the ethics committee, put the fields on a separate form/instrument with restricted access: only the users who are working with this data should be able to see and edit information on this form.
- ✓ Mark the field containing identifying data with “Identifier” Yes:



The screenshot shows the REDCap field configuration interface. The 'Identifier?' checkbox is checked and highlighted with a red box. Other options include 'Required?*' (No selected), 'Validation?' (None), and 'Enable searching within a biomedical ontology?'.

This will make sure that these data can be excluded from exports, reports etc.

- ✓ Add a date field “**Visit Date**” or “**Date of Assessment**” on top of the form when needed (e.g. study and follow-up visits, laboratory data, questionnaires, etc.)
- ✓ Use Field Embedding to change the layout of fields and put them next to each other.

1. Create a descriptive field and use the Rich Text Editor to embed fields (e.g., in table form) in curly brackets (e.g., {field_name})
2. Use {field_name:icons} to show icons for missing codes, field comments and queries.

- ✓ Copy, move or delete multiple fields at once by clicking on them while pressing “Ctrl”

2.2.4. Single- and Multiple-Answer Multiple choice fields

- ✓ In **single-answer multiple choice fields** (i.e. radio buttons and dropdown lists), add a choice “**Not available**” (coded as 99) if missing data is expected.
- ✓ In **single- and multiple-answer multiple choice fields** (i.e. radio buttons, dropdown lists and checkboxes), add a choice “**Other**” (coded as 88) so that possibilities which you don’t foresee can be entered. Create an **additional text field** where the choice “Other” can be specified.

- ✓ **Code first choice as 1** and increment by 1 for each additional choice:

- ✓ CTU Bern standard **coding of special values** is:

0 = no/false/negative/absent/abnormal, 1 = yes/true/positive/present/normal
 1 = male, 2 = female
 88 = other
 99 = not available / unknown

Keep the codes consistent throughout the database.

- ✓ **Important multiple-answer multiple choice fields** (e.g. checkboxes related to primary/secondary endpoints) **should be replaced by matrices of yes/no fields** (e.g. Symptoms: Headache yes/no, Diarrhea yes/no, Rash yes/no, etc.)

Matrix Header Text (optional)
Symptoms

Expand

Matrix Rows
Each row represents a different field with its own label and variable name.

Enable auto naming of variable based upon its Field Label

Field Label	Variable Name <small>ONLY letters, numbers, and underscores</small>	Required** <small>Field Annotation</small>
Headache		<input type="checkbox"/>
Diarrhea		<input type="checkbox"/>
Rash		<input type="checkbox"/>
...		<input type="checkbox"/>

[Add another row](#)

Matrix Column Choices
Choices (one choice per line)
0, no
1, yes

[How do I manually code the choices?](#)

Other Matrix Info
Answer Format: [Single Answer \(Radio Buttons\)](#)

Ranking: [What is a ranked matrix of fields?](#)
 Allow only 1 choice to be selected per column (radio buttons only)

Matrix group name: ONLY letters, numbers, and underscore
[What is a matrix group name?](#)

Field Type: [Checkboxes \(Multiple Answers\)](#)

Field Label: Symptoms

Variable Name (utilized in logic, calcs, and exports)
ONLY letters, numbers, and underscores Enable auto n Variable based Field Label?

How to use: [Smart Variables](#) [Piping](#)

Choices (one choice per line) [Copy existing choices](#)

1, Headache
2, Diarrhea
3, Rash
4, ...

[How do I manually code the choices?](#)

Required? No Yes
* Strong if field is blank

Identifier? No Yes
Does the field contain identifying information (e.g., name, SSN, add

Custom Alignment: [Right / Vertical \(RV\)](#)
Align the position of the field on the page

Action Tags / Field Annotation (optional)

[Learn about: \[Action Tags\]\(#\) or \[using Field Annotation\]\(#\)](#)

Field Note (optional)
Small reminder text displayed underneath field

2.2.5. Numeric Fields

- ✓ **Numeric fields are text fields that are validated as numeric fields.**

Several numeric field validation formats are available:

number: any number

integer: whole number, never contains decimal places

1 decimal place number: always contains exactly 1 decimal

2 decimal places number: always contains exactly 2 decimals

- ✓ Indicate the **unit** (e.g. [mL]) in field label
- ✓ Provide **minimum and maximum range values**

Important:

If an entered value is **outside the range**, a **warning** is given **but the value can still be saved!**

Note: The action tag **@FORCE-MINMAX** can be used on numeric fields that have a min or max validation range defined so that no one will be able to enter a value into the field unless it is within the field's specified validation range (**hard check**).

- ✓ Indicate the **field validation format** as well as the **minimum and maximum range values in field note** (e.g. 1-decimal number, min=0.0, max=100.0) in order to improve the data quality.

---- None ----

Date (D-M-Y)

Date (Y-M-D)

Datetime (D-M-Y H:M)

Datetime (Y-M-D H:M)

Datetime w/ seconds (D-M-Y H:M:S)

Datetime w/ seconds (Y-M-D H:M:S)

Email

Integer

Letters only

Number

Number (1 decimal place)

Number (2 decimal places)

Number (3 decimal places)

Number (4 decimal places)

Patient ID (HCC)

Patient ID (IHR)

Phone (Switzerland)

Pseudonym

Time (HH:MM)

Time (MM:SS)

Time w/ hours & seconds (H:M:S)

Zimb date range + error code

Edit Field ✕

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: Text Box (Short Text, Number, Date/Time, ...) ▾

Field Label

Weight [kg]

Variable Name (utilized in logic, calcs, and exports)

weight Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

How to use [Smart Variables](#) [Piping](#)

Action Tags / Field Annotation (optional)

Learn about [@ Action Tags](#) or [using Field Annotation](#)

Validation? (optional) Number (1 decimal place) ▾

Minimum: 15.0

Maximum: 70.0

– or –

Enable searching within a biomedical ontology ?

-- choose ontology to search -- ▾

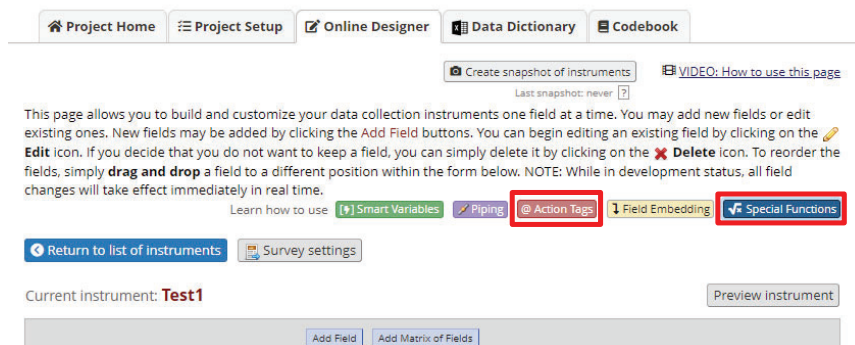
Required?* No Yes
* Prompt: if field is blank

Identifier? No Yes
Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Right / Vertical (RV) ▾
Align the position of the field on the page

Field Note (optional) in kg, min=15.0, max=70.0
Small reminder text displayed underneath field

- ✓ **Add calculated fields only if necessary and avoid complex calculations** in REDCap; These should be done during the statistical analysis phase using Excel or any other statistics software (e.g. Stata, SAS, R).
If you use calculated fields in REDCap, make sure to put single or double quotes around numbers in the equation when using =, != or <> (e.g. [field_name] = '1'). When you are using a comparison operator (<, <=, >, or >=), be sure to use the numerical values WITHOUT quotes or double quotes (e.g. [field_name] > 4).
- ✓ You can use **pipng** to show values that were already entered e.g. age at enrolment collected at baseline can be piped and shown at a later visit
- ✓ There are some special features you can add to the field using **action tags** (e.g. hiding fields, choices, default values), **special functions with numbers** (e.g., round, mean) or **special string functions** (e.g., starts_with, contains, length). But we advise you to carefully reflect what functionalities you want to use. **In clinical trials you shouldn't work with default values** since this could lead to data entry bias, e.g. missing values are set to the default value and are easily forgotten to be changed. Click on the help texts on top of the online designer to learn more.



2.2.6. File upload

- ✓ REDCap is not designed to store big amounts of images like DICOM. There are dedicated systems imaging platform for this that also handle anonymization of DICOM images etc. Please talk to your local IT to see what option they can provide.
- ✓ If you plan to use REDCap's file upload functionality on patient level for small amounts of documents/images, please inform CTU Bern data management as this has an influence on disk space used for your project as well as on the costs.
- ✓ The sponsor should make sure that the files which are uploaded are **coded** This can be done through a predefined process & training and can be assured by a central monitor that checks regularly if the process has been followed.
No identifying information should be visible on documents/images etc.

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2.2.7. Branching Logic

- ✓ Implement branching logic in fields that must be displayed only when **specific conditions** are met (e.g. pregnancy test only for women).
- ✓ In longitudinal studies, always add the **REDCap event name** to the field name in branching logic rules or calculated fields when they refer to a **field not belonging to the current event**:
e.g. to calculate the age at randomization use [baseline_arm1][yob] instead of [yob].


All REDCap **event names** for your project can be found at the **event definition page**.

Important:

Remember that if you change the event names on the event definition page, branching logics using this event name have to be adapted as well.

If you update branching logic that is used by multiple fields, you can choose to automatically update all the branching logic for all those fields. Use caution when using this option since you cannot check before which fields are going to be updated!

- ✓ Do not implement Branching logic which refers to **calculated, empty date or empty text fields**.
- ✓ **Smart Variables:**
Branching Logic can also use **meta data of the project** (e.g. site name), the so-called Smart Variables.
Please refer to the help in the Online Designer for further information:



Design your data collection instruments

Add or edit fields on your data collection instruments. This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). Quick links: [Download PDF of all instruments](#) OR [Download the current Data Dictionary](#).

Go to Online Designer or Data Dictionary Explore the REDCap Shared Library

Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been tagged?

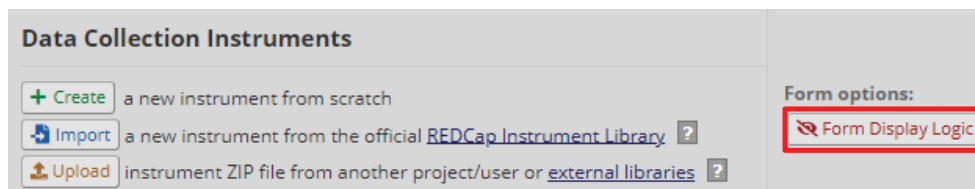
Learn how to use Smart Variables Piping Action Tags

- ✓ When using the Advanced Branching Logic Syntax make sure to ALWAYS put single or double quotes around numbers in the equation UNLESS you are using the comparison operators <, <=, >, and >=
E.g., [field] = '0' BUT [field] > 0

- ✓ **Test branching logic thoroughly!**
Note: To test a branching logic, you need to create a new record and enter test data. It is not possible to test a branching logic in the instrument preview!

2.2.8. Form Display Logic

- ✓ Implement Form Display Logic in the Online Designer e.g., when forms need only to be displayed for a certain group.
- ✓ In longitudinal studies, add the **REDCap event name** before the field name for the display of logic rules or calculated fields when they refer to a **field not belonging to the current event**.
- ✓ **Test** the form display logic **thoroughly**.
- ✓ **Note:** The Form Display Logic does not impact data imports but only operates in the data entry user interface to enable/disable forms. Additionally, Form Display Logic is not utilized by the Survey Queue at all but can affect the behaviour of the Survey Auto-Continue feature if the checkbox for it is enabled.



2.2.9. Defining eCRFs using the REDCap data dictionary

For experienced REDCap users, defining eCRFs might be faster using the data dictionary than using the online designer.

- ✓ Check that csv-files you save in Excel are separated by comma. If necessary, change the **format in the region and language settings (Control Panel of your computer)** to English (USA) while you are working on the data dictionary

- ✓ **Download the current data dictionary** from REDCap and save it as a CSV file (“save” copy)
- ✓ **Save the file again under a different name** to get a “work” copy. Open the “work” copy in Excel **and implement your changes**.
- ✓ If you **copy & paste** anything (e.g. variable names) from another document, make sure you **remove the formatting** (e.g. Microsoft Word line breaks, paragraphs etc.). REDCap might run into troubles later while uploading the data dictionary
- ✓ If possible, try to avoid using **HTML tags** and other formatting in field labels.
- ✓ Check that **dates** (e.g. as range values) are formatted in “DD-MM-YYYY” or “YYYY-MM-DD” and not in “DD.MM.YYYY” or “YYYY.MM.DD” format. Also check that **numerical range values** follow the **expected format**, e.g. for a 2 decimal places number: 5.70 and not 5.7.

Note:

Excel automatically removes leading and trailing zeros (0). To make sure that the zeros are kept, format the range columns “Text Validation Min» and «Text Validation Max» as “text” and check that all ranges are entered in the correct format, before you upload the data dictionary.

- ✓ **Save your updated data dictionary as a CSV file.**
- ✓ **Convert** (not encode!) **your updated CSV data dictionary to UTF8** and save it. E.g. by using the freeware Notepad++

This step has to be done in order that characters like umlauts (ä, ü, ö) and special characters are handled correctly by REDCap.

- ✓ **Upload your UTF-8-converted CSV data dictionary back to REDCap**

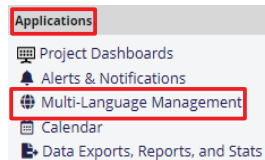
Keep in mind:

The newly uploaded data dictionary overwrites the previous data dictionary. The updated data dictionary must therefore always contain all the eCRFs.

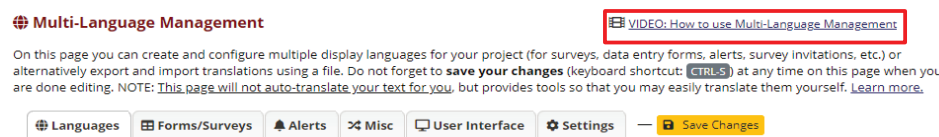
Please do not work simultaneously with the online designer and the data dictionary. Whenever a data dictionary is uploaded, all the changes done in the online designer since the download of the data dictionary will be overwritten.

2.2.10. Multi-language management

Instruments in REDCap can be set up in multiple languages with the feature “Multi-Language Management”.



To set up your items for multiple languages, follow the instructions in the REDCap training video in REDCap.



Manage the available languages in this project using the table and options by following these steps:

- ✓ Create your **default language** (e.g., English, i.e., used when creating your fields, instruments, etc.). This will serve as the reference for the other languages.
- ✓ Add **other languages** that you wish to offer as a translation of the default language. Click ‘+Add a new language’.

Add New Language

Language ID

A unique identifier for this language. It is recommended to use the ISO code, such as 'en' or 'en-US' for English, or 'es' for Spanish. Use only letters and hyphen. [View list of ISO codes](#)

Language Display Name

This is the name of the language as shown in the language selectors. This should be entered in its language, such as 'English' or 'Deutsch' (for German).

Sort Override (optional)

If set, this will be used instead of the display name for determining the sort order of languages in language selectors.

To use **German** or **French** also as languages for user interface, click ‘Import from file or system’ and choose from available system languages, then ‘Import’.

Add New Language

Import language data ...

from a file (JSON, CSV, or INI)

Choose or drop file...

Include the following:

Translations of user interface items

Translations of project-specific items*

*These include: fields, survey settings, ASIs, alerts, missing data code labels, ...

- or -

from available system languages

Deutsch

- ✓ Set the languages to **active**. Note that only active languages will be available for selection.
- ✓ Always remember to save the changes.

Multi-Language Management

[VIDEO: How to use Multi-Language Management](#)

On this page you can create and configure multiple display languages for your project (for surveys, data entry forms, alerts, survey invitations, etc.) or alternatively export and import translations using a file. Do not forget to **save your changes** (keyboard shortcut: **CTRL+S**) at any time on this page when you are done editing. NOTE: This page will not auto-translate your text for you, but provides tools so that you may easily translate them yourself. [Learn more](#).

Manage the available languages in this project using the table and options below by following these steps:

1. Create your default language (i.e., used when creating your fields, instruments, etc.). This will serve as the reference for the other languages.
2. Add other languages that you wish to offer as a translation of the default language.
3. Translate your default text into different languages by clicking the tabs above or the icons to the right of each language below.
4. Test your translations by switching back and forth between languages on your data entry forms and/or surveys. Note that only active languages will be available for selection on those places.
5. Learn how to implement some language-related action tags, such as `@LANGUAGE-SET`, if desired. Learn about them here: [@ Action Tags](#)

Export or import general settings

ID	Display Name	Active	Default	Fallback	RTL <input type="checkbox"/>	Actions
de	Deutsch	<input checked="" type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="button" value="✎"/> <input type="button" value="📄"/> <input type="button" value="📁"/> <input type="button" value="🔊"/> <input type="button" value="🗑️"/>
en	English	<input checked="" type="checkbox"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="button" value="✎"/> <input type="button" value="📄"/> <input type="button" value="📁"/> <input type="button" value="🔊"/> <input type="button" value="🗑️"/>

- ✓ Translate your default text into different languages by clicking the tab “Forms/Surveys”, select the language and click “**Translate**”. Save the changes.

Multi-Language Management

On this page you can create and configure multiple display languages for your project (for s alternatively export and import translations using a file. Do not forget to **save your change** are done editing. NOTE: This page will not auto-translate your text for you, but provides toc



Click a button below to select a language to translate:



Use this page to manage which instruments will be translated, separately in data entry a sub-pages, such as field exclusions (default language only), or translations of field items emails.

Instrument	Data Entry	Fields	Export
Eligibility	<input type="checkbox"/>	<input checked="" type="checkbox"/> Translate	
Rando	<input type="checkbox"/>	<input checked="" type="checkbox"/> Translate	

- ✓ Test your translations by switching on the instruments/surveys for ‘**Data entry**’ so that the language button will appear above the form.
- ✓ Additional translations can be provided, e.g., for alerts, user interface (messages, warnings etc.), Missing Data Codes.

2.2.11. Events Grid (for longitudinal studies only)

- ✓ Enable “**Longitudinal data collection**” in the “Main Project Settings”
- ✓ **Define the events of the project**, the custom event label is optional

Define your events and designate instruments for them

Create events for re-using data collection instruments and/or set up scheduling.

Go to Define My Events or Designate Instruments for My Events

I'm done!

- ✓ If **different event grids** (=visit schedules) are going to be used, create every event grid in a different arm (**these are NOT randomization arms!!**)
- ✓ Make sure that **time points of events are well described** (e.g. Follow-up 3M, Follow-up 6M)

- ✓ **Allocate eCRFs to events**
- ✓ If the **scheduling module** is going to be used:
Specify accepted deviations (= Offset Range) for every event

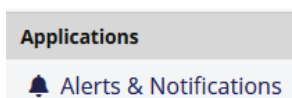
Begin Editing Save Select All | Deselect All

Data Collection Instrument	Screening (1)	T0 (2)	T1 (3)	T2 (4)	T3 (5)	T4 (6)	End of Study (7)	Serious Adverse Event (8)
Eignungskriterien	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Randomisierung	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Assessment	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Zufriedenheitsumfrage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CTU Template End of Study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

2.2.12. Alerts and Notifications

Alerts and notifications can be used to send out an email, e.g. when a specific form is completed or a condition is fulfilled, e.g. a patient is randomized.

- ✓ Go to “Alerts and Notifications” in the left hand menu:



- ✓ Create a new alert and enter all relevant data for:
 - 1) Condition when a notification should be send out
 - 2) When and how many times a notification should be send out
 - 3) The recipient(s) and the content of the notification email
NOTE:
 if possible, send email notifications only to secure email addresses (e.g. HIN secured), especially if you pipe links or patient information in the email content or header
 - 4) If there is an expiration date of the notification
- ✓ In the notification email subject, content field values and Smart Variables can be inserted (=piped) to indicate directly, e.g. for which record, site,... an email is send

NOTE

If you include Smart Variables into the notification email, always write them by hand and **DO NOT COPY** them from the Smart Variable help page, otherwise the values will not appear in the email!

Test the alerts and notifications carefully before starting data entry

2.2.13. Eligibility Form

- ✓ **Inclusion and exclusion criteria** are collected
- ✓ **Informed Consent** decision as well as the **Date of Informed Consent** signature are collected
- ✓ **Age at inclusion** (without decimals) or **Year of Birth** is collected
- ✓ An **eligibility decision** (eligible/not eligible) is calculated (if applicable)

2.2.14. (Serious) Adverse Event Form

As part of the CTU template database, CTU Bern provides a template for (serious) adverse event (S)AE documentation, reporting, and sponsor review for open label clinical trials with investigational medicinal products (IMP).

The templates reflect the current (regulatory) requirements for event documentation, reporting, and sponsor review in open label clinical trials with an IMP and should not be modified without very good reason.

Furthermore, CTU Bern provides (S)AE and sponsor assessment templates for the following trial types:

- Blinded clinical trial with IMP
- Other clinical trial according to ClinO Chapter 4
- Medical device trial (including device deficiency reporting form)

These forms are not included in the CTU template database but can be downloaded from the file repository of the database "CTU_Library of REDCap Light documents":

https://redcap.ctu.unibe.ch/redcap_v12.4.12/FileRepository/index.php?pid=654

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Setup of CTU Template (S)AE for IMP Trial

The person responsible for the database setup adjusts the **(S)AE** and **SAE, Sponsor assessment** eCRFs according to the needs of the study protocol. The blue remarks are recommendations from CTU Bern data management regarding form setup. These notes can be deleted in the process of setting up the forms.

Piping/smart variables are used to auto-fill general information in the (S)AE eCRF and to feed in the information of the SAE form into the SAE, Sponsor assessment form. Both forms are highly linked. **Therefore, care should be taken when changing variable names or branching logic.**

- ✓ **Adjust** the CTU (S)AE template and SAE, Sponsor assessment form according to the study requirements
- ✓ Define a new **event** e.g. **(S)AE**
- ✓ Designate **(S)AE** and **SAE, Sponsor assessment** instruments to this event
- ✓ Set this event as a **repeatable event** in the project setup under **Enable optional modules and customizations** and **Repeatable instruments and events**
- ✓ Setup email notifications under **Alerts and Notifications** if the reporting functionality should be used

Reporting

The SAE form contains an SAE reporting workflow under the section 'SAE version history'. The site can state here if reporting to the sponsor should be initiated for the initial report and several follow up reports. To use this option, email notifications need to be set up under 'Alerts & Notifications' in REDCap. We recommend setting up one rule-based email alert per report to the sponsor.

- ✓ In case of a Serious Adverse Event, the site completes the (S)AE eCRF
- ✓ Site informs the sponsor (e.g. by using the version history of the SAE form and the REDCap alert functionality)
- ✓ Sponsor completes SAE, Sponsor assessment eCRF (i.e. re-evaluation of the SAE for seriousness and causality and assessment of expectedness)
- ✓ Follow up SAE report: SAE form is updated by the site
- ✓

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- ✓ Site informs the sponsor about the follow up (e.g. by using the version history of the SAE form and the REDCap alert functionality)
- Sponsor receives email about follow up report and updates the SAE, Sponsor assessment form if necessary

Blinded studies

For blinded studies, the investigator should **assess the causality** with the IMP/medical device/intervention **for each study arm** (control/intervention/etc.). Please **adapt the appropriate CTU (S)AE template** according to the study needs. For blinded IMP trials, a CTU (S)AE template is also available (see above link to "CTU_Library of REDCap Light documents").


2.2.15. Randomization

Setup of randomization in REDCap

Please keep in mind that the **allocation of medipacks** to patients **should not be implemented using the randomization module of REDCap**. The reason for that is because you will run into troubles when the medipacks expire, are damaged or lost since the randomization list cannot be changed while collecting data (production mode). Therefore, **the randomization list for medipacks should rather be stored on a well-protected study drive**.

CTU Bern Data Management recommends the randomization lists for the development & productive environments **to be created by CTU Bern Statistics**. The reason is that these randomization lists should be created by an **independent statistician** and not by the study statistician. Moreover, creating a randomization list is a core part of a randomized trial and it is crucial that no error occurs. In case the randomization list is provided by the CTU Bern: To allow sufficient time to create the randomization list and perform quality checks, please inform the data management at CTU Bern at least 2-3 weeks before the database should be put into production.

✓ Enable Randomization Module


 Optional

Enable optional modules and customizations

Modify
✔ Repeatable instruments and events ?

Disable
✔ Auto-numbering for records ?

Enable
✘ Scheduling module (longitudinal only) ?


Disable
✔ Randomization module ?

Disable
✔ Designate an email field for sending survey invitations ?
Field currently designated: e_mail ("Studien E-Mail Adresse")

Additional customizations

Settings displayed to Administrators only:

Enable
✘ Twilio SMS and Voice Call services for surveys ?


 Not started

Set up a randomization model

The randomization module will help you implement a defined randomization model within your project, allowing you to randomize your subjects (i.e. records in your project).

Go to Set up randomization

✓ Set up randomization (see item 'Randomization' in the left hand menu)

- strata and/or site (as applicable)
- randomization result field

- ✓ **Upload two different randomization lists**, one for the test and one for the productive environment
- ✓ **Test randomization**

Workflow if CTU Bern is providing the randomization lists

Set up your project. Create one instrument for the randomization of the patient. Configure the randomization on the Project Setup page, section 'Enable optional modules and customizations'

- A) Choose your strata in the randomization model
- B) If you want to randomize by site, create DAGs with the sites you wish to include (you will see how many sites you have created). If you want to randomize by other groups, select an existing field to designate each group/site.

IMPORTANT: If you want to add additional sites to your study *after* moving to production (e.g. due to an amendment), it is very important to inform CTU Bern that the randomization table needs to be appended with allocation results for the new site(s). If you want to randomize by other groups, select an existing field to designate each group/site.

- C) Choose your randomization field: The randomization button will appear there once the randomization list is uploaded. The result of the randomization will be saved and stored there.

✓

STEP 1: Define your randomization model

This step will allow you to define the randomization model you will be implementing and all its parameters, which includes defining strata (if applicable) and optionally randomizing subjects per group/site (if a multi-site study).

A) Use stratified randomization?

It is often necessary to ensure equal treatment among a number of factors. Stratified randomization is the solution to achieve balance within one or more subgroups, such as gender, race, diabetics/non-diabetics, etc. By choosing strata (multiple choice criteria fields), you may then be able to ensure balance within those subgroups. [Tell me more](#)

Choose strata (criteria fields used for stratification; may specify up to 14 multiple choice fields)

- select a field - for Screening

[Add another stratum](#)

B) Randomize by group/site?

If this is a multi-center/multi-site project (or something similar), you may want to stratify the randomization by each group/site. You can select an existing multiple choice field that represents the groups/sites, OR you can use Data Access Groups to stratify by group/site.

Use Data Access Groups to designate each group/site (3 groups currently exist)

Use an existing field to designate each group/site

- select a field - for

C) Choose your randomization field

This is the field where the allocated randomization (treatment) group will be saved and stored, and is where the Randomize button will appear on your data collection form.

- select a field - for Screening

[Save randomization model](#) [Erase randomization model](#)

✓

After you defined your randomization model, download the template “Example #3 (5x all possible combos)” and send it to CTU Bern with the request to create the randomization lists. Include **the latest version of the protocol**, where the statistician will retrieve the details of the randomization.

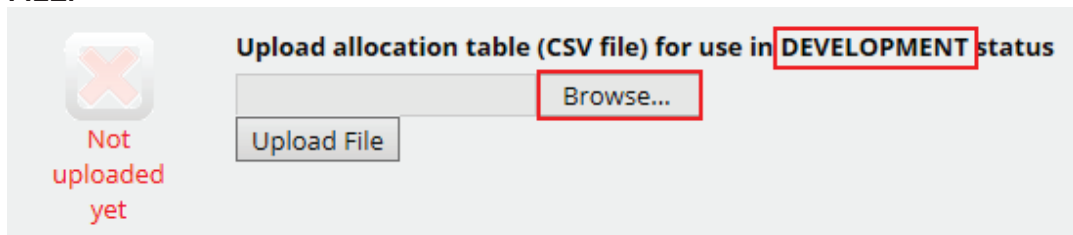
It is important that **you do not modify the variable names** of variables used in the randomization model, after having sent the template to CTU Bern. The randomization list provided by CTU Bern will use the names you provided and will not match if you make changes.

STEP 2: Download template allocation tables (as Excel/CSV files)

Below are some example files that you may download to get a general idea for how you may structure your own randomization table. You do not have to use any of these. In fact, **we recommend that you NOT use these exact templates** but instead recommend that you merely use them as an example or baseline to start from in order to create your own custom allocation file. After uploading your allocation table in Step 3 below, it will then be used as a lookup table to perform assignments when subjects are being randomized. **NOTE:** Record names (e.g., study ID) should NOT be included as a column in your allocation table, but only the fields listed in the example files below. [More details](#)

[Example #1 \(basic\)](#) [Example #2 \(all possible combos\)](#) [Example #3 \(5x all possible combos\)](#)

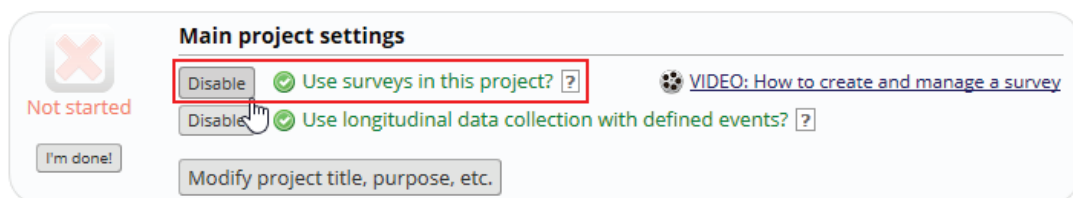
- ✓ CTU Bern will send you a randomization report containing information about stratification factors, block sizes and allocation ratio. After the Sponsor has confirmed correctness of the report, CTU Bern will then upload the test randomization list as a csv file for use in DEVELOPMENT status. **DO NOT DOWNLOAD OR MODIFY THIS FILE.**



- ✓ After CTU Bern has confirmed the upload of the file, you can test data entry with randomization and **test** the use of the randomization button.
- ✓ CTU Bern will upload the randomization list for use in PRODUCTION status, once the project is **ready to be moved to production**. Please remember that changes in the project setting (e.g. addition of a study center/site) will have an effect on the randomization including randomization list. Inform the CTU as soon as you plan such an amendment so that they can plan the amendment of the list. Please also remember that when a project is moved to production, **all test data will be deleted**.

2.2.16. eSurveys

- ✓ Define **survey distribution** (public link vs. participant list)
- ✓ Enable Surveys in the main project settings:



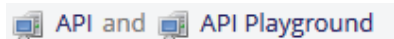
- ✓ Set **survey settings**:
 - Online Designer: enable as survey, survey options, survey settings or survey queue
 - Project Setup (Enable optional modules and customizations)



- To designate an e-mail field for sending survey invitations you first need to create a text field in an instrument with the validation “e-mail”.
- ✓ **Don’t set fields as ‘required’** unless it is absolutely necessary: missing required fields prevent participants from saving and submitting the survey!
 - ✓ **Test** survey distribution, options, and settings

2.2.17. API

You can use the API functionality to create customized imports and exports of data. The necessary information can be found in REDCap Help and FAQ, the API documentation (<https://redcap.ctu.unibe.ch/api/help/>) and in the API section within your project:



By default, super users have API access rights but to be able to use an API connection, you’ll have to request an API token from the REDCap administrators – which can be done within the API module:

Obtain API token for "CTU_API_TEST"

Use the button below to request an API token for this project from your REDCap administrator. You will need a different token for each project you would like to access. Please note that your REDCap administrator is emailed every time a token is requested.

[Request API token](#)

If other users in your project should be able to use API as well, you need to give them the rights for API export and / or API import and they will have to request an API token from the REDCap administrator as described above.

3. Testing the study database

Test your study database thoroughly. Keep in mind to document the tests

- ✓ **Print the REDCap codebook** of your database (-> Project Home -> Codebook) and compare to the latest version of the study protocol: Have all variables been implemented? Double check for primary/secondary endpoint fields
- ✓ Check that no **identifying data** is collected, unless necessary for the study conduct (e.g. survey invitations, telephone interviews,...) or analysis (e.g. full birthdate). If identifying data is collected, check if the concerning fields are marked as identifiers and that they are on separate instruments. Only study personnel working with identifying data should be able to access these instruments
- ✓ **Test all fields of your database by entering plausible data.** Check if REDCap correctly accepts plausible data
- ✓ **Test all fields of your database by entering erroneous data.** Check if REDCap shows correct error messages
- ✓ Focus especially on **primary and secondary outcomes** and **complex branching logics**
- ✓ if applicable: **Test randomization**
- if applicable: **Test alerts and notifications**
- ✓ **Test data export** and ask your statistician to approve the current version of the Database

4. Plan Data Entry Phase

Before data entry can start, define the Data Entry Workflow:

- ✓ Who enters data and when?
- ✓ How are the different data entry status used and defined?:

For each data entry form the status “incomplete”, “unverified” and “complete” are applicable. The status field does not have to be used and the status have no influence on the data entry process. But their different symbols make it easier in the Record Status Dashboard to see instantly which forms have been completed – and to what extent.

- ✓ Who is setting which status? E.g. to green “data entry (for this form) is completed”?

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- ✓ Is the locking status used, if yes: who locks the records and when?
- ✓ Is anyone cross-checking the data?
- ✓ For multi-centric studies: is someone overseeing the accrual and the data entry of all sites?

5. Plan Monitoring / Data Quality Process

If you want to set a monitoring process in place, clarify the following questions:

- ✓ Do you need a Monitoring system that's able to generate queries (Data Resolution Workflow)? Or is only a commenting module needed (Field Comment Log)? Only one of the two can be used in a project.
- ✓ Who is monitoring the data? If Data Resolution Workflow is used, who is opening, responding to and closing queries?
- ✓ At which time point should the data be checked (e.g. after a given number of patients have been enrolled)? Or is someone continuously checking the data?
- ✓ Which data should be checked (e.g. all data, only endpoints)? Are all records monitored? Or is only a random sample of records monitored?
- ✓ For multi-centric studies: is on-site monitoring needed or is central data monitoring sufficient?

6. Deployment of the database

Deployment is the transition from the database implementation/test phase to the productive phase where real data is collected.

6.1. Prerequisites

Before any real data is collected, the following tasks must be fulfilled:

- ✓ A positive decision or **approval from the (main) Ethics committee** must be obtained.
If **identifying data** is collected, the (main) Ethics committee must be informed accordingly and has to consent.
- ✓ The **study database must be tested**, the tests must be documented
- ✓ **Inform involved parties** about the planned deployment.
- ✓ **Training:** All study team members who will be working with the study database have to be trained on how to use the system in general and how to enter data in this specific study database.
The training has to be documented. You can use the CTU CDMS Training Log which can be found in the CTU_Library of REDCap Light Documents
- ✓ **Access rights:** Fill out the Database Access List (a template can be found in the CTU_Library of REDCap Light Documents). If the study is multicentric, there must be a separate Database Access List for every center.
Please remember that the sponsor has to authorize all users by signing the Database Access list – and each row in the table needs to be signed if single users are added later. A Sponsor is authorized to delegate this responsibility to the PI; CTU DM requires a written and signed statement from the sponsor, which confirms the delegation.
- ✓ Make sure that you created **user roles for all access types** (e.g. data entry, monitoring, database setup and changes,...) and verify that all roles settings are accurate; check also the detail page of each role
- ✓ Check that forms with **identifying data** can only be accessed by very few users; create a special role and restrict all other roles from accessing this form / these forms
- ✓ **Verify that all users who can access the project are assigned to a role.** If there are users that are not assigned to a role, assign them to the correct role

6.2. Deployment

- ✓ In 'Project Setup', move Project to production status.
You then have the option to choose whether CTU Bern should be requested to keep ("Keep ALL data saved so far.") or delete ("Delete ALL data in the project") your test data when moving the project to production!
For randomized trials, test data should always be deleted to ensure that the randomization will work properly.

Move your project to production status

Move the project to production status so that real data may be collected. Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will be auto-approved or else might need to be approved by a REDCap administrator before taking effect.

Go to Move project to production

Request Admin to Move to Production Status? ✕

Are you sure you wish to leave the DEVELOPMENT stage? If you proceed, the project will be moved to PRODUCTION status so that real data may be collected. If you select the 'Delete ALL data' option below, all current collected data, calendar events, and uploaded documents will be deleted, otherwise all will remain untouched as the project is moved to production.

★ Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been tagged?

Keep existing data or delete?

Keep ALL data saved so far. **(10 records)**

Delete ALL data in the project (including any survey responses), calendar events, documents uploaded onto forms/surveys, and all archived data export files stored in the File Repository, and any logged events that pertain to data collection.

Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will be auto-approved or else might need to be approved by a REDCap administrator before taking effect.

NOTE:
Since only REDCap administrators can move a project to production, clicking the button below will send a request to a REDCap admin, who will move it to production status for you. An email will be sent to your address (dominik.guentensperger@ctu.unibe.ch) when this has been done.

Yes, Request Admin to Move to Production Status
Cancel

- ✓ For multi-centric studies: Create Data Access Groups (DAG) for every Center (see REDCap Training Video "Data Access Groups for multi-site projects" for more details)
- ✓ Send request for new database users to CTU Bern. Once the logins are created, assign all new users to the correct role. Delete the roles which are not relevant for the study.
- ✓ Prepare a note to file for the TMF documenting the location of the (electronic) data dictionary (see template CTU_DM_TEM-28_NoteToFile_TMF_DataDictionary in the CTU_Library of REDCap Light Documents).
- ✓ Inform all involved parties that the database is productive

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- ✓ Read the checklist for PI tasks during data collection (Section 8.1)

7. User management

With REDCap Light, the management of users, roles and centers is done exclusively by the study team, i.e. by the 'project super user' of the study database. The study team is therefore responsible for the assignment of all users to their research project's database. In case a new user account is required for a given user, this can be requested at CTU Bern data management.

Nevertheless, new user logins should always be authorized and requested in writing by the sponsor. The requests for new users – or for the deactivation of existing accounts - should be documented in order to show which users had which kind of access during which time period.

This can either be done by saving the emails in question in a dedicated folder or use the database access list template which is provided in the CTU_Library of REDCap Light Documents.

If database access lists are used, make sure that the sponsor always signs, e.g. on the same line, on the same day or before a new access is requested.

7.1. Standard roles

The CTU has defined a set of standard roles. They are explained below.

In REDCap (<https://redcap.ctu.unibe.ch>) you will find a detailed overview of all rights of every role.

Standard roles are:

- **Analysis:** Standard role for the statistician
- **Data Entry:** Standard role for the study nurse
- **Monitoring:** Standard role for central data monitoring and for on-site monitoring
- **Super User:** The project super user has the maximum rights on his study database. He can manage user rights, roles, DAGs, he can deploy his study database.
- **Project setup:** Design study database: create eCRFs, visit plan, reports, enter test data
- **Sponsor/PI:** standard role for the sponsor and/or PI

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7.2. Management of roles

All roles are study database specific. If you add a role or adapt a role, it will have no effect on other study databases.

We recommend using the CTU Standard roles. Make sure that the data viewing rights and data export rights are setup correctly for each role. However, if the standard roles do not correspond to the needs of your study database, you might adapt them or create new roles. Please be aware that this might be risky, e.g., a statistician could be unblinded if the role allows a complete data export. Data export rights can be adapted on instrument level.

Add new users: Give them custom user rights or assign them to a role.

— OR —

Create new roles: Add new user roles to which users may be assigned.

(e.g., Project Manager, Data Entry Person)

7.2.1. Adding a role

If you need to add a role, ask your project super user to do it. You do not need to ask the CTU to do this.

7.2.2. Adaptation of a role

If you need to adapt a role, we recommend that you copy an existing CTU Standard role, and give it a meaningful name (e.g. “Data entry & Export”). Do not adapt CTU Template roles while keeping the same name as this might lead to confusion. Be careful with adapting roles, make sure that people do not get access to data they are not allowed to see!

Editing existing user role "Data Entry"

You may set the rights for the user below by checking the boxes next to the application tools to which you wish to grant them access. You may also grant them or deny them access to individual data collection instruments, if so desired. To save your selections, click the "Save Changes" button at the bottom of the page.

Editing existing user role "Data Entry"

Basic Privileges

Role name:

Highest level privileges:

- Project Design and Setup
- User Rights
- Data Access Groups

Other privileges:

- Calendar
- Add/Edit/Organize
- Reports**
Also allows user to view ALL reports (but not necessarily all data in the reports)
- Stats & Charts
- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository
- Randomization
[What is randomization?](#)
- Data Quality
[What is Data Quality?](#)
- Data Resolution
[What is Data Resolution Workflow?](#)
- Workflow**
 - No Access
 - View only
 - Open queries only
 - Respond only to opened queries
 - Open and respond to queries
 - Open, close, and respond to queries
- API
[What is the REDCap API?](#)
- Setup
- Dashboard
- Randomize
- Create & edit rules
- Execute rules
- API Export
- API Import/Update

Settings pertaining to project records: [Explain these settings](#)

- Create Records
- Rename Records
- Delete Records
* Includes ability to delete all data on an instrument or on a repeating event.

Settings pertaining to record locking and E-signatures:

- Record Locking Customization
- Lock/Unlock Records (instrument level)
 - Disabled
 - Locking / Unlocking
 - Locking / Unlocking with E-signature authority
[What is an E-signature?](#)
- Lock/Unlock *Entire* Records (record level)

NOTE: It is important to note that instrument level locking and record level locking are independent features that are governed by separate user privileges (as seen above). You must have explicit permission to either one in order to perform that specific locking action. Also, record locking is a higher-level locking than instrument locking, which means that an entire record may be locked or unlocked while one or more instruments are currently locked, but an instrument cannot be locked or unlocked while the entire record is locked.

Privileges for Viewing and Exporting Data

Data Viewing Rights pertain to a user's ability to view or edit data on pages in the project (e.g., data entry forms, reports). Users with 'No Access' Data Viewing Rights for a given instrument will not be able to view that instrument for any record, nor will they be able to view fields from that instrument on a report. Data Export Rights pertain to a user's ability to export data from the project, whether through the Data Exports page, API, Mobile App, or in PDFs of instruments containing record data. Note: Data Viewing Rights and Data Export Rights are completely separate and do not impact one another.

	Data Viewing Rights			Data Export Rights			
	No Access (hidden)	Read Only	View & Edit	No Access	De-Identified*	Remove All Identifier Fields	Full Data Set
Eligibility	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Rando	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labor	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
new form	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
FU	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
CTU Template End of Study	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
CTU Template Concomitant Medication	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

* De-identified means that all free-form text fields will be removed, as well as any date/time fields and Identifier fields.

External Modules: Configuration Permissions

Privileges may be defined regarding whether the user can set or modify the configuration of an External Module that has been enabled on this project. Below are the currently enabled modules. NOTE: Only administrators may modify the module configuration permissions here.

- Multilingual*

*Permissions based on user's Project Design/Setup rights

Please note:

Changes to a role have an immediate effect on all users assigned to this role.

Role name <small>(click role name to edit role)</small>	Username or users assigned to a role <small>(click username to edit or assign to role)</small>	Expiration <small>(click expiration to edit)</small>	Project Design and Setup	User Rights	Data Access Groups	Data Export Tool	Reports & Report Builder	Graphical Data View & Stats	Calendar	Data Import Tool	Data Comparison Tool	Logging	File Repository	Record Locking Customization	Lock/Unlock Records	Randomization	Data Quality (create/edit rules)	Data Quality (execute rules)	Data Resolution Workflow	API	Create Records	Rename Records	Delete Records
Analysis	(No users assigned)		X	X	X	Remove all tagged Identifier fields	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Edit role privileges	aredmann (Annetta Redmann) epelzer (Christiane Felzer)	never never	✓	✓	✓	Full Data Set	✓	✓	✓	✓	✓	✓	✓	✓	✓	Setup Dashboard Randomize	✓	✓	Open close and respond to queries Export Import		✓	✓	✓
Data Entry	aredmann_ess (Annetta Luiza Redmann)	never	X	X	X	X	X	X	X	X	X	X	✓	X	X	Randomize	X	X	Respond only to opened queries Open close and respond to queries	X	✓	X	X
Monitoring	(No users assigned)		X	X	X	X	✓	✓	X	X	X	✓	✓	X	✓	X	X	✓	Open close and respond to queries View only	X	X	X	X
PI	(No users assigned)		X	X	X	Full Data Set	X	✓	X	X	X	✓	✓	X	X	X	X	✓	View only	X	X	X	X
Project Setup	(No users assigned)		✓	X	X	Full Data Set	✓	X	X	X	X	X	✓	X	X	Randomize	✓	✓	X	X	✓	X	X

7.2.3. Identifying Data

If you are collecting identifying data, make sure that only people who need them and have authorization to see them have access to these identifying data (e.g. normally, the statistician is not allowed to have access to identifying data). Create a special role for the study team members who need to access the identifying data.

How to prevent the statistician (role 'Analysis') to access identifying data:

1. If possible, collect all identifying data in one separate eCRF that does not contain any other data.
2. In the eCRFs, mark all variables with identifying data as 'identifying'.
3. Go to role 'Analysis' and set the 'Data Export Rights' to 'De-Identified*' or 'Remove all tagged Identifier fields' for all instruments with identifying data and the 'Data Viewing Rights' to 'No access' for all instruments containing identifying data.
4. Create a special role e.g., 'Data entry + ID data' for the study team members who need to access the identifying data. Go to role 'Data Entry', copy the role and adapt the role name, set the 'Data Viewing Rights' to 'Read-only' or 'View & Edit' to all eCRFs containing identifying data.

For all roles that **do not need** access to identifying data: e.g. select the role, set the 'Data Export Rights' to 'De-Identified*' or 'Remove all tagged Identifier fields' for all instruments with identifying data or for 'Data Entry', set 'No Access' for 'Data Viewing Rights' and 'Data Export Rights' to all eCRFs containing identifying data.

7.2.4. Blinded studies

If your study database is blinded you can implement the entire study database as blinded (=only blinded information in study database). However, it might be necessary to show the randomization result to some people of the study team. In this case, the unblinded data should be implemented exactly as described above for identifying data:

1. If possible, collect all variables with treatment information in one separate eCRF that does not contain any other data, except maybe for randomization strata. You can show (via piping) the value of the strata on other forms if necessary.
2. In the eCRFs, mark all variables with treatment information as 'identifying'.
3. For all exporting roles that are blinded, select the role under user rights, set the 'Data Export Rights' to 'De-Identified*' or 'Remove all tagged Identifier fields' and the 'Data Viewing Rights' to 'No Access'.
4. For all other roles that are blinded, e.g., 'Data Entry', set 'No Access' for 'Data Viewing Rights' and 'Data Export Rights' to all eCRFs containing variables with treatment information.
- 5.

7.3. Management of Centers / Sites (DAGs)

For each center / site a separate Data Access Group (DAG) should be created. DAGs organize the data according to each site and prevent the sites from seeing each other's data.

User Rights and Permissions

Optional

You may grant other users access to this project or edit the user privileges of current users on this project by navigating to the User Rights page. Additionally, if you wish to limit user access to certain records/responses for this project, you may want to use Data Access Groups, in which only users within a given Data Access Group can access records created by users within that group.

I'm done!

Go to User Rights or Data Access Groups

The management of DAGs is explained in the training video 'Data Access Groups for multi-site projects'.

IMPORTANT:

As a "Project Super User", you should never assign yourself to a DAG! As soon as you are assigned to a DAG, you will lose your permission to manage DAGs and will have to contact CTU Bern data management in order to get this permission back again.

If a project super user needs to create records and enter data for a DAG during the study conduct, please request a second login which can then be used for data entry.

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Users can be assigned to more than one DAG using the “DAG Switcher”.

DAG Switcher: Enable multiple Data Access Groups for users Display options: Rows are DAGs
 Rows are Users

Users assigned to Data Access Groups (DAGs) can optionally be assigned to multiple *potential* DAGs, in which they may be given the privilege of switching in and out of specific DAGs on their own whenever they wish. To assign a user to multiple DAGs, check the checkboxes below for that user. At least two DAGs must be checked for a user in order for them to use the DAG Switcher. NOTE: This does not override a user's current DAG assignment, as set above or on the User Rights page.

Show entries

The users can then switch the DAG to enter data.

The screenshot shows the REDCap interface. At the top, a notification bar indicates the current Data Access Group is 'DAG_test2' with a 'Switch' button. A modal dialog box titled 'Switch Data Access Group' is open, prompting the user to 'Select the Data Access Group to which you would like to switch:'. The dropdown menu in the dialog shows 'DAG_test' selected. Below the dialog, the 'Current Users' table is visible, listing users like 'aredmann (Annetta Redmann)', 'dguentensperger (Dominik Güntersp', and 'dguentensperger_c (Dominik Güntersp'. To the right, the 'Project Statistics' section shows 'Records in project: Total: 10 / In group: 0', 'Most recent activity: 23-02-2021 09:55', and 'Space usage for docs: 0.24 MB'.

7.4. Management of Users

All users of the study database must be documented in the Database Access List, which is signed by the sponsor. Without the documented (=written) approval of the sponsor, no user should get access to a study database.

All users should be assigned to a role, we recommend that you do not create users without assigning them to a role.

There are two ways of providing access to REDCap: LDAP & table-based.

- Users on the CTU Bern REDCap - Installation can only use the table based option.
- LDAP should be used on the Inselspital REDCap Installation for all users who have an Insel identifier (I-Number/U-Number/E-Number).

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The two methods are explained below:

7.4.1. LDAP (using I-/U-/E-Number)

Only applicable for projects on the REDCap installation at Inselspital (<https://redcap.insel.ch>)

- ✓ Based on the Database Access List* completed and signed by the sponsor, check if the LDAP users already exist in REDCap.
- ✓ For all LDAP users that do not yet exist in the Insel REDCap system, ask them to perform a one-time LDAP account activation:
 1. The user has to log in to REDCap using his/her I-/U-/E-number and his/her Insel password.
 2. They will be redirected to the REDCap 'Basic User Information Page' where they will be asked to enter their first name, last name and email address.
 3. REDCap sends a verification email to the user with a link.
 4. The user has to confirm the email by clicking on the link.The LDAP user is now activated on the Insel REDCap and can be added to your study database. This process only happens once for every user, no matter how many studies the user is involved in.
- ✓ Assign the LDAP users to your study database by assigning them to their role (and if applicable, to the respective DAG).

7.4.2. Table-based

- ✓ Based on the Database Access List* completed and signed by the sponsor, check if the users already exist in REDCap.
- ✓ Ask the CTU to create all user logins which do not yet exist in REDCap (datamanagement@ctu.unibe.ch). You might do so by sending a copy of the Database Access list. If you don't want to send the Database Access list, provide the following information:
 - First name
 - Last name
 - Email address

* available on «CTU_Library of REDCap Light Documents»

* available on «CTU_Library of REDCap Light Documents»

The CTU creates the user(s) in REDCap and informs the person who requested the login.

The user(s) receive(s) an email informing them that a REDCap account has been created. The user does not have access to your study database yet.

- ✓ Assign the user(s) to your study database by assigning them to their role (and if applicable, their respective DAG).

8. Database in Production

8.1. Sponsor tasks during data collection

Below you will find a checklist with processes that occur during the productive phase of a study. The project super user is responsible for user management and database changes. CTU Bern is responsible for creating new users (except for LDAP users), setting database changes productive (for the CTU REDCap Installation) as well as for data security and backups.

8.1.1. Monitor Data Entry

- ✓ Using 'Data Exports, Reports, and Stats'
Go to REDCap menu item 'Data Exports, Reports, and Stats', 'My Reports & Exports'. Choose an eCRF/instrument in section B, 'Selected instruments' and click on 'Stats & Charts'. REDCap provides you with a visual overview of the data entered as well as the distribution and the amount of missing values.
- ✓ Check form completion: Form status (last field of each data entry form) should be updated by data entry staff according to previously defined instructions (not complete = red; unverified = yellow; complete = green). At the end, all forms should have a green icon.
- ✓ Form Locking, if applicable: certain users (e.g. monitor, PI taking over monitoring role), lock forms after individual form or patient completion (according to pre-defined locking process).
- ✓ Data Export: Export data and carefully check both data quality and quantity.

8.1.2. Check for Missing Data

- ✓ Using 'Data Exports, Reports, and Stats'
Go to REDCap menu item 'Data Exports, Reports, and Stats', 'My Reports & Exports'. Choose an eCRF/instrument in section B, 'Selected instruments' and click on 'Stats & Charts'. REDCap provides you with a visual overview of the data entered as well as the amount of missing data.
- ✓ Using Data Quality Rules:
Go to REDCap menu item "Data Quality". Data quality rules A and B show you all missing data.
However, keep in mind, that REDCap shows all missing data of all events/visits, where data entry has started. It does not take into account the state of a form (not complete and not verified forms are included in the report).

8.1.3. User Management during Production

- ✓ Requests for new user accounts must be sent to CTU Bern.
Use the template provided by the CTU Bern or write an email. All new requests have to be coordinated with the sponsor. If a study nurse is requesting new users, the sponsor must be copied in the email.
- ✓ Users who leave the study team must be reported to the sponsor/PI/project super user and CTU Bern, so that their access to the database is removed as soon as their involvement in the project ends.

8.1.4. Randomization Error

If you by mistake randomised a patient using the wrong stratification group, do the following:

- ✓ Do not try to redo the randomization. Leave the patient as he/she was randomized.
- ✓ Document the error that happened during randomization. This can be done by creating a note to file for the study folder.
- ✓ Inform the statistician who is going to analyse the study about the wrong stratification group.

8.2. Changes in a productive database

8.2.1. General


Before implementing changes in a productive database, make sure to consider the impact on the database, especially on already entered data, but also on documents and processes outside the database:

- ✓ For complex, possibly risky changes (e.g. inclusion / exclusion criteria, randomization, complex branching logics,...), identify possible risks and evaluate possibilities how to decrease or avoid them, e.g. back-up of current database and data, have the CTU create a work copy of the current database to test changes before they are released into production, let a second person check the changes for correctness,...
Re-check the changes and the correct implementation after they have been released on the productive database
- ✓ Consider the impact of the changes on
 - Regular imports
 - Auxiliary systems to the database
- ✓ To make changes, change to Draft Mode:
Under 'Project Home and Design' choose 'Designer', then click 'Enter Draft Mode'.
- ✓ While in draft mode, the study team can still enter data and already collected data will not be deleted.
- ✓ Implement the changes (see below: Adding new fields or forms / Change of existing fields or forms). Be very careful not to corrupt or delete existing fields where data has already been collected.
At present, the changes are only visible in the design mode. They are not visible neither for data entry nor for analysis.
- ✓ Ask someone to review your changes and confirm that the change does not affect existing data. If the second person identifies a risky change, clarify this issue and choose a less risky option
- ✓ Remember to document changes in case discrepancies or questions emerge later on. The easiest way to do this is to copy the summary of changes into an Excel file, with either the change date in the first column or one sheet for each change date:

Since this project is currently in PRODUCTION, changes will not be made in real time. [Tell me more](#)

Fields to be added: **1** / Total resulting field count: **604**
Fields to be deleted: **0** / Existing field count: **603**

[Remove all drafted changes](#)

 [View detailed summary of all drafted changes](#)

Change Date	Variable Name	Section Header	Field Type	Field Label	Choices or Calculations
19.03.2019	note_box_new		notes	New Notes Box!	

(careful: this summary does not include deleted fields or new forms)

- ✓ Update documentation, e.g. study protocol, paper CRFs, manuals, work instructions, guidelines,...
- ✓ Inform other users / sites about the changes, especially when already entered forms have to be updated
- ✓ For projects on **the CTU REDCap installation**, ask CTU Data Management to release the changes for you: press the button 'Commit changes'. Note: CTU Data Management will NOT review your changes!
On the **Inselspital REDCap installation** you can release changes yourself by committing and confirming the changes.

8.2.2. Adding new fields or forms

- ✓ If new fields are added: remember to update already entered forms or add a branching logic from which date on the field will be visible, e.g. only if the entry in "infcondef_dtc" (=Informed Consent Date) is later than 01.07.2017:

Advanced Branching Logic Syntax How to use [Branching Logic](#) [Smart Variables](#)

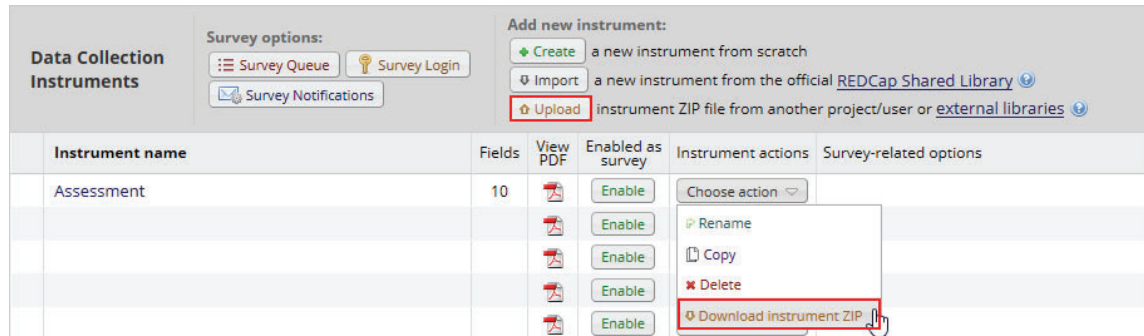
Show the field ONLY if...

```
datediff([infcondef_dtc], "01-07-2017", "d", "dmy", true) <= 0
```

NOTE:

Fields with calculations can be updated after changes by using a data quality rule. After the change was committed successfully, enter the data quality module and execute data quality rule H. Please note that with this rule only ALL effected calculated fields can be updated. There is no possibility to exclude certain records.

- ✓ To develop and test a new form, you can request a copy of the database (without real data and users), create and test new forms, fields and branching logics there. When the changes and tests are complete, the form can be downloaded as a zip-file. The zip-file can then be uploaded directly into the productive database. The test database will be deleted when the productive database is closed.



- ✓ After the form is released into production, check all user roles and ensure that the access rights for the new form are correct.
- ✓ The new form must also be added to the instrument-event mapping after it was released into production.

Please note: User rights have to be checked and updated after new forms are released into production.

8.2.3. Change of existing fields or forms

- ✓ Avoid deletion and changes of already entered data! Better use the “@hide” action tag (the data will still be in the system and part of the data exports)
- ✓ Is any data going to be hidden by a changed branching logic? This will bring up warnings whenever a form with hidden data is opened
- ✓ Are there dependent fields on the changed field (e.g. yes/no fields) which have to be changed or adapted
- ✓ Remember that if you change the label in a dropdown field, this will affect all data, also data which have already been entered
If you want to remove an option (e.g. Aspirin) of a dropdown or multiple choice field from further use, use the action tag @HIDECHOICE. Entries which already have that option used, will still store and show the correct value but for new entries the option will be hidden.
- ✓ If a calculation is changed, remember to use the data quality rule H to update all existing calculated fields
For more information about the Data Quality Module, consult the REDCap FAQs (<https://redcap.ctu.unibe.ch/index.php?action=help>)
- ✓ If you change event names, remember to adapt branching logics which use the SmartVariables “event-name” and “event-label” to the new name

- ✓ For complex changes, we recommend copying the project and implement and test the changes on the work copy first; new forms can be downloaded as a zip-file and uploaded with all information (e.g. branching logics,...) into the productive environment
- ✓ If regular imports are taking place, remember to adapt them to the changed fields

9. Project completion

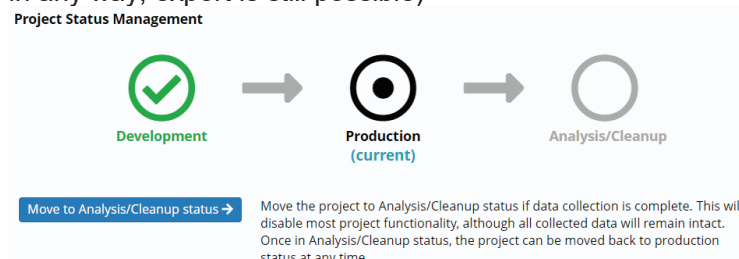
9.1. Process for Disabling Participants' Inclusion in Database

- ✓ If enrolment has been completed or stopped prematurely, go to 'User rights', copy & paste the entire table with user rights into Excel and save it as a PDF or create a screenshot of the overview of user rights. In addition, create a screenshot of the 'privileges for viewing and exporting data' for each role.
- ✓ Disable inclusion for all sites. In 'User rights', adapt the role 'Data entry'. Remove the rights to create new records. If other roles have rights to create new records, remove the right also for these roles.

9.2. Partial Database lock

If data collection is complete and all queries are closed, the DB Lock procedure can start:

- ✓ Save the official confirmation from the Sponsor to partially lock the database in the study (database) folder
- ✓ Remove all data editing rights from all user roles
- ✓ If the study contains participant-filled questionnaires, make sure that the access to the questionnaires is permanently deactivated: set survey(s) Status to "offline" in the survey settings
- ✓ Move project to "Analysis/Cleanup": Go to "Project Home"- "Other Functionality" – "Move to Analysis/Cleanup status" – "set all project data as Read-only / Locked' (If set to Read-only/Locked mode, then no data in the project will be able to be modified in any way, export is still possible)



The data in this project is currently: **Read-only / Locked** [Modify](#)

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- ✓ Remember to cite the REDCap publication from Vanderbilt University (<https://projectredcap.org/resources/citations/>) for any publications involving data captured in REDCap.
- ✓ Document and communicate to other sites (if applicable) that the database has been locked

9.2.1. Unlocking of the partially locked database – exceptional cases only-

- ✓ Note: unlocking is not recommended and should if possibly be avoided.
- ✓ If the unlocking of the database should be necessary, save the written request from the sponsor stating the reason for the unlocking in the study (database) folder
- ✓ Create a new data entry role called 'Data entry for reopened DB' with the necessary access rights and add the person(s) who need(s) to do modifications during this phase.
- ✓ Go to "Project Home"-“Other Functionality” and move the project back into "production" status
- ✓ Export Roles: Go to 'User rights', copy & paste the entire table with user rights into Excel and save it as a PDF or create a screenshot of the overview of user rights. In addition, create a screenshot of the 'privileges for viewing and exporting data' for each role.
- ✓ Close the database again as soon as the necessary changes have been conducted

9.2.2. Final Database Lock

Anonymization of data due to consent revocation

If a participant in Switzerland revoked their informed consent, the health-related personal data of the person concerned must be anonymized after data evaluation has been completed (see ClinO, Art. 9, HRO, Art.10). For other countries, please follow the local legal regulations.

This step can be skipped, if it is stated in the informed consent that data will not be anonymized after consent revocation.

- ✓ Check if there are patients with consent revocation (see 'end of study' form).
- ✓ If there are patients with consent revocation: Discuss the method of de-identifying data of these patients with the statistician. The method must ensure that proper

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statistical preparation and evaluation of data is feasible. - For coded data, identifying data may only consist in the code of the patient. - For non-coded data, more fields may need to be changed in order to anonymize the data.
 Change all identifying data of the person concerned. Replace identifying text fields with non-identifying data (e.g. 'revoked'). If the database setup allows for it, include 'rev' or 'revoke' in the new ID of the patient

- ✓ Make sure the same is done with the Patient Log and all other documentation containing identifying information.

Final export of study data and meta data

- ✓ Create a final export folder in your electronic study folder
- ✓ We recommend exporting the data in the following formats to allow data access by different tools in the future and to comply with the regulations (e.g. GCP):
 - All empty eCRFs as pdf: Project Setup / Design your data collection instruments / Download PDF of all instruments
 - All versions of the Data Dictionary: Project Revision History
 - Data exports (Export data) in:
 - o csv, raw data
 - o Stata
 - o xml
 - o the format you use for the analysis
 - o all completed pdfs: Other export options
 - the whole project (data and metadata) in REDCap.xml format: Other export options
 - the visit plan:
 export format is Excel, we recommend setting the Excel-file to "read-only" to avoid accidental changes: right click on the file: Properties, activate write protection
 - users, roles, and centers: save screenshots to document the different access types, their access rights and the role allocation of users
 - Audit trail: export the complete Logging file (all pages)
 The export format is csv, so make sure to activate the write protection to prevent unintended changes in the audit trail. **Attention:** the audit trail that is exported using the REDCap user interface does not contain all information of meta data changes (e.g., changes in user roles). To have the entire audit trail, please ask the CTU Data management to extract the audit trail directly from the database
 - If applicable, all uploaded files: File repository
- ✓ Create a password protected zip-file to prevent unauthorized access to the data, delete the original unprotected export file

Step by Step Instruction for export:

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On the left side, in Applications, choose “Data Exports, Reports and Stats”. For a complete export choose A (All Data) and click on “Export Data”.

My Reports & Exports		
	Report name	View/Export Options
A	All data (all records and fields)	<input type="button" value="View Report"/> <input type="button" value="Export Data"/> <input type="button" value="Stats & Charts"/>
B	Selected instruments (all records)	<input type="button" value="Make custom selections"/>
<input type="button" value="+ Create New Report"/>		

The following window pops up and asks you to define:

- on the left: which format you wish to export in
- on the right: some possibilities to eventually de-identify the database/ avoid exporting free text fields or date and date/time fields.

Exporting "All data (all records and fields)" ✕

Select your export settings, which includes the export format (Excel/CSV, SAS, SPSS, R, Stata) and if you wish to perform de-identification on the data set.

<p>Choose export format</p> <p><input type="radio"/> CSV / Microsoft Excel (raw data)</p> <p><input type="radio"/> CSV / Microsoft Excel (labels)</p> <p><input type="radio"/> SPSS Statistical Software</p> <p><input type="radio"/> SAS Statistical Software</p> <p><input type="radio"/> R Statistical Software</p> <p><input type="radio"/> Stata Statistical Software</p> <p><input type="radio"/> CDISC ODM (XML)</p>	<p>De-identification options (optional)</p> <p>The options below allow you to limit the amount of sensitive information that you are exporting out of the project. Check all that apply.</p> <p>Known Identifiers:</p> <p><input type="checkbox"/> Remove all tagged Identifier fields (tagged in Data Dictionary)</p> <p><input type="checkbox"/> Hash the Record ID field (converts record name to an unrecognizable value)</p> <p>Free-form text:</p> <p><input type="checkbox"/> Remove unvalidated Text fields (i.e. Text fields other than dates, numbers, etc.)</p> <p><input type="checkbox"/> Remove Notes/Essay box fields</p> <p>Date and datetime fields:</p> <p><input type="checkbox"/> Remove all date and datetime fields — OR —</p> <p><input type="checkbox"/> Shift all dates by value between 0 and 364 days (shifted amount determined by algorithm for each record) What is date shifting?</p> <p><input type="checkbox"/> Also shift all survey completion timestamps by value between 0 and 364 days (shifted amount determined by algorithm for each record)</p> <p>Deselect all options</p>	<p>Additional export options</p> <p><input checked="" type="checkbox"/> Export Data Access Group name for each record (if record is in a group?)</p> <p><input checked="" type="checkbox"/> Export survey identifier field and survey timestamp field(s)?</p> <p>Advanced data formatting options</p> <p>Set CSV delimiter character Set the delimiter used to separate values in the CSV data file (only valid for CSV Raw Data and CSV Labels export formats): <input (comma)="" -="" default<="" p="" type="text" value=","/> <p>Force all numbers into a specified decimal format? You may choose to force all data values containing a decimal to have a specified decimal character (comma or period/full stop). This will be applied to all calculations and number-validated text values in the export file. <input type="text" value="Use fields' native decimal format (default)"/></p> <p><small>NOTE: Your data formatting selections above will be remembered in the future and will be pre-selected upon your next export.</small></p> </p>
---	---	---

Export in csv:

The .csv file format is readable by most statistical software packages but it is better to use the other export features specific to the statistical software package you have as it will take into consideration the labelling of the data, which will considerably save time for statistical analysis.

When you export in csv, you can choose between 2 possibilities, either raw data or labelled data:

- “Raw data” means that the coding behind each variable will be displayed. This is applicable for dropdown lists and checkboxes. For instance, if a question is coded as 1/Yes, 0/No and 99/Unknown, the csv file will display either 1, 0 or 99 in this column. In order to do analysis, raw data are always easier to use.
- If “labels” is chosen, Yes, No and Unknown will be displayed in this column.



To export as .csv, click on:

REDCap exports csv using comma as separators which is very common in the US but not so much in Europe. If your data is displayed incorrectly in Excel you can change the delimiter during the export. In European countries it is mostly semi-colon:

Advanced data formatting options

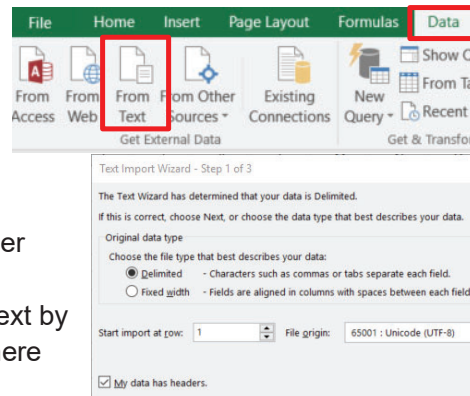
Set CSV delimiter character

Set the delimiter used to separate values in the CSV data file (only valid for CSV Raw Data and CSV Labels export formats):

; (semi-colon)

To import the data into Excel:

- open a new and empty Excel file
- go to “Data/From Text”, choose the exported file
- select “Delimited”, “UTF-8” and check the box “My data has headers”
- choose “comma” as delimiter, unselect any other delimiters
- format at least the first column (record_id) as text by marking the column and clicking on “Text”, if there are more text fields proceed the same way
- we recommend that you also import date and datetime fields as text, so that the format isn’t automatically changed by Excel during the import.
- finish the import by selecting A1 as starting cell and confirm the import settings
- After the import, check that all columns were imported in the correct format.
- If columns are still not displayed correctly, try to import the data again and import these columns also as Text columns.
- If you want to work on this file in Excel later on, we recommend you to save it as an xlsx-file (instead of csv).




Export in SPSS/SAS:

What is practical in using the feature to export data for a specific statistical software is that a script is built in order to integrate the codebook directly inside the exported database: the script

imports the raw data but labels all variables according to the data dictionary, which saves lots of time for statistical analysis.

Steps to export in SPSS:

- download the 3 files within the same directory by clicking and using “Save as” (without opening the files).
- Double-click on the file “Pathway Mapper”
- Open the .sps file in SPSS, Select all (Ctrl+A), and click on  to run the script.
- File, Save Data as to save you labelled database to be used directly for data analysis.

Export in R

- Click and Save as the 2 files (.r and .csv).
- Open R and open the script .r you just downloaded.
- You have to precise in the script the path of the directory where you saved the .csv file on the 7th line of the script: `data=read.csv('C:/Users/...')`. Please be careful to specify the path using / and not \ otherwise R will not understand where the data are.
- Run the entire script
- Save the database

Export in Stata

- Click and Save as the 2 files (.do and .csv).
- Open Stata
- Open the .do file in Notepad and select all (Ctrl+A) and copy (Ctrl+C).
- Paste (Ctrl+V) in the dofile editor of Stata. You could open the .do file directly in Stata but there is a risk of getting strange signs if your labels contain special characters (accents ü, ä..)
- At the end of the third line - command “insheet” - specify at the end of the line the path of the directory where you stored the csv file.
- Run the entire script
- Save the database

9.3. Archiving of the database

- ✓ Go to 'Project Home', 'Other Functionality' and 'mark project as completed' (This will take the project offline, and you and other users will no longer be able to access it. The project and its data will remain in the system and cannot be modified. Only a REDCap administrator may return the project back to its previous status.).
- ✓ Archive all study documents according to your institution's guidelines
- ✓ Contact CTU Bern and inform data management that the database is locked and archived and can be removed from the server.

10. Help / Support

10.1. REDCap functionalities

In case you need help or additional information about a REDCap feature, check the information buttons directly on the Project Setup Page (e.g. SmartVariables, Piping, Action tags,...).

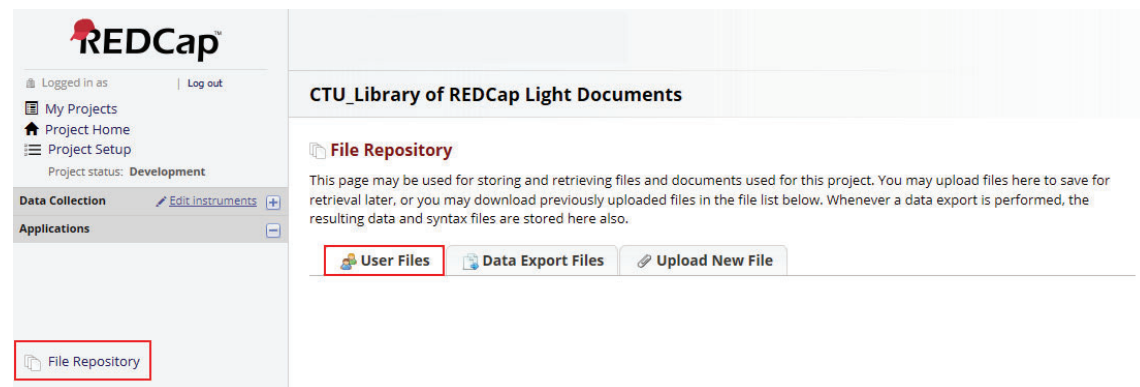
If you don't find the required information there, consult the REDCap video tutorials and the "Help and FAQ" page: <https://redcap.ctu.unibe.ch/index.php?action=help> .

10.2. Technical problems

In case technical problems occur (e.g. database not accessible, log in not working,...), please contact support@ctu.unibe.ch

11. Additional Documents

As a Project Super User, you can find all above-mentioned documents in the REDCap project «CTU_Library of REDCap Light Documents» which is accessible on https://redcap.ctu.unibe.ch/redcap_v12.4.12/FileRepository/index.php?pid=654 (for the CTU REDCap installation):



Protocol:

- Template for data management section in study protocol (Submission: Study_protocol_DM_text_template_REDCap)

Set up:

- CTU Template Codebook (CTU_DM_TEM-26_TemplateCodebook)

Deployment:

- Deployment: REDCap Training Log (CTU_DM_TEM-16_CDMS_TrainingLog)
- Deployment: Database Access List for CTU REDCap /Insel REDCap (CTU_DM_TEM-14_DatabaseAccessList)
- Deployment: TMF Note to file location of codebook & CRFs (CTU_DM_TEM-28_NoteToFile_TMF_DataDictionary)

DB Lock:

- DB Lock: Data complete Confirmation from PI (CTU_DM_TEM-29_Data_Complete_Confirmation_PI)
- DB Lock: Sponsor Approval - DB Lock & Pre-lock Checks (CTU_DM_TEM-42_Sponsor Approval – DB Lock &Pre-lock Checks)

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12. Software Updates

If users set up their own study databases (e.g. REDCap Light), it lies in their responsibility to make sure that the project specific functionalities (e.g. branching logics, calculations) are still working correctly after a software update.

Appendix A: Overview of CTU Bern Data Management Services

The table below shows the different services the CTU Bern is providing as well as the responsibilities of the different tasks. You received this document from the CTU Bern because you have chosen REDCap Light.

	REDCap Light	Full Services
Finalizing specifications of study database	Sponsor	Sponsor
Project creation	CTU	CTU
Training on database implementation	CTU	n.a.
Support during implementation	(CTU)	n.a.
Database Implementation & Testing	Sponsor	CTU/Sponsor
Database Review	(CTU)	n.a.
Deployment	Sponsor	CTU
User creation	CTU	CTU
Management of Users/Roles/Centers	Sponsor	CTU
Implementation Database Changes	Sponsor	CTU
Review Database Changes	(CTU)	n.a.
Database Closure/Archiving	Sponsor	CTU
Clinical Data Management System	REDCap	REDCap secuTrial

(CTU) = if requested/agreed in costing

Appendix B: Creative Commons License



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