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1. List of Abbreviations

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**

2. 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 template[1]).

- ✓ 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»

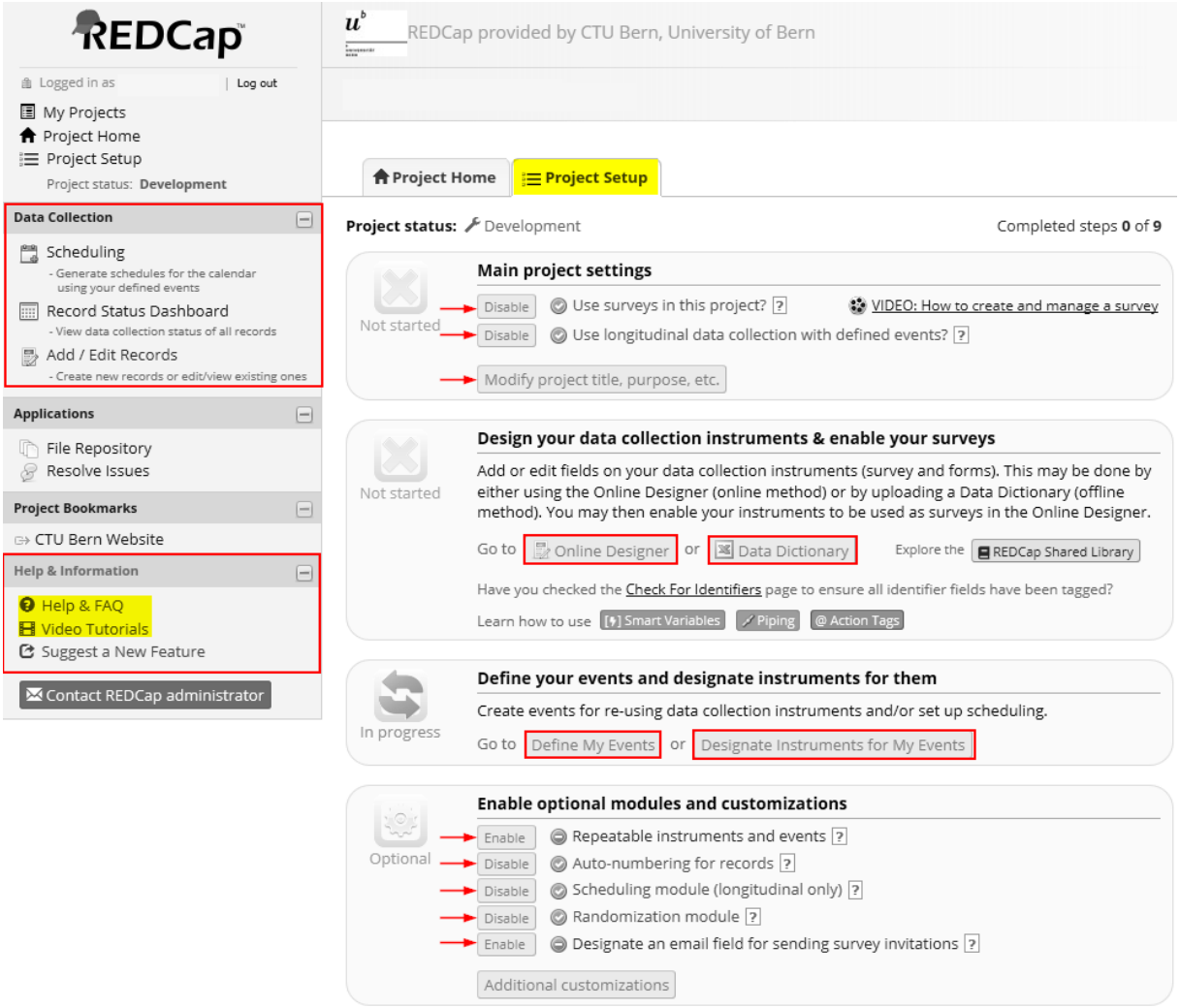
3. Implementing the study database

3.1. 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.

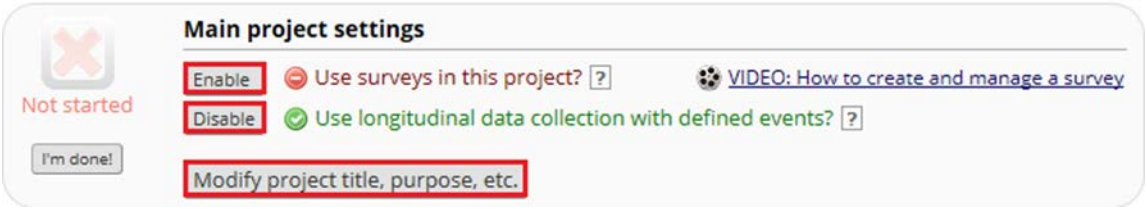
Project Setup Page



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)



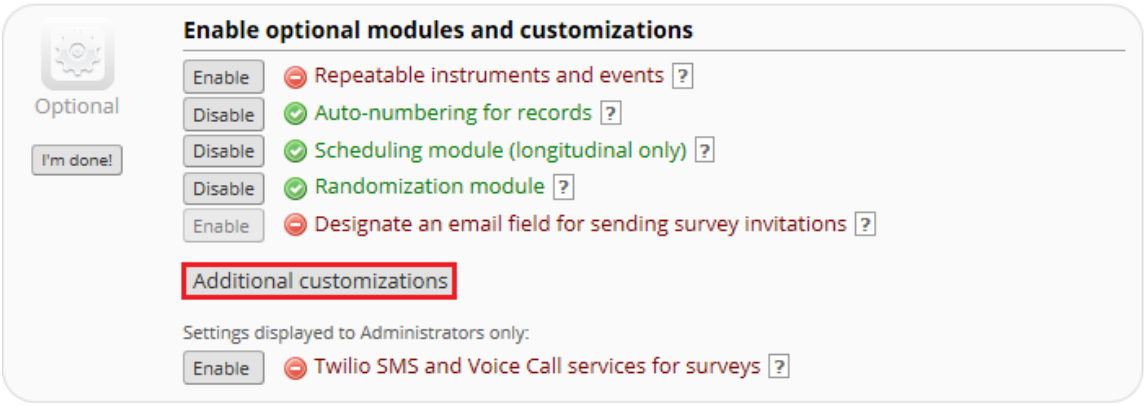
Optional modules and customizations:

✓ 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

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.

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.

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

3.2.1. 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)"

- ✓ 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

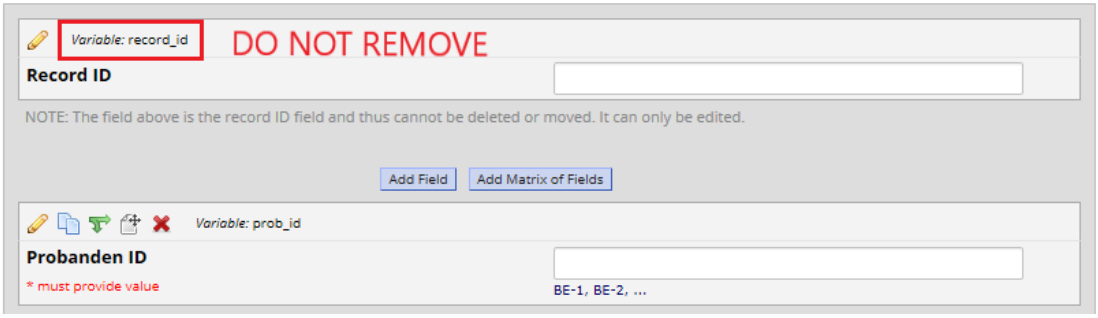
- ✓ For prospective studies, create an **End of study form** to collect information regarding at which date and under which circumstances the patient left the study

- ✓ For prospective studies, create a **(Serious) Adverse Event** (=SAE) **form** (if applicable)

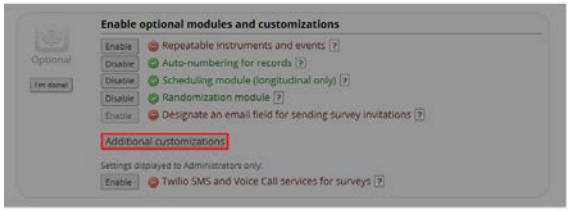
3.2.2. eCRFs Setup

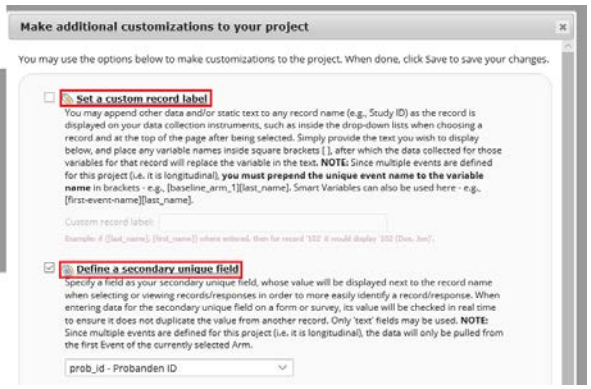
IMPORTANT:

✓ 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.

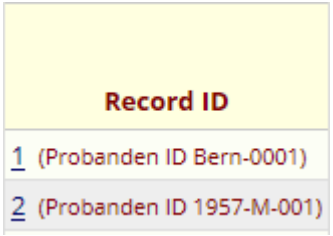


If you want to use a **study specific Patient ID**, create an additional text field below the REDCap record_id and indicate its format in the field note (e.g., Bern-0001, 1957-M-001). You can set this field as a secondary unique field or custom record label in the additional customizations tab to prevent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



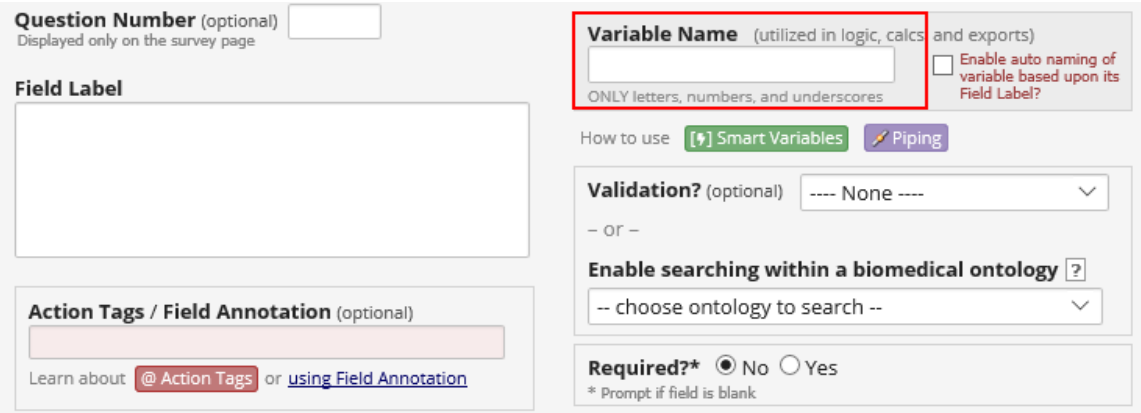


This information will then be visible next to the Record ID in the Record Status Dashboard:



Field definition

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



✓ Define **variable names**:

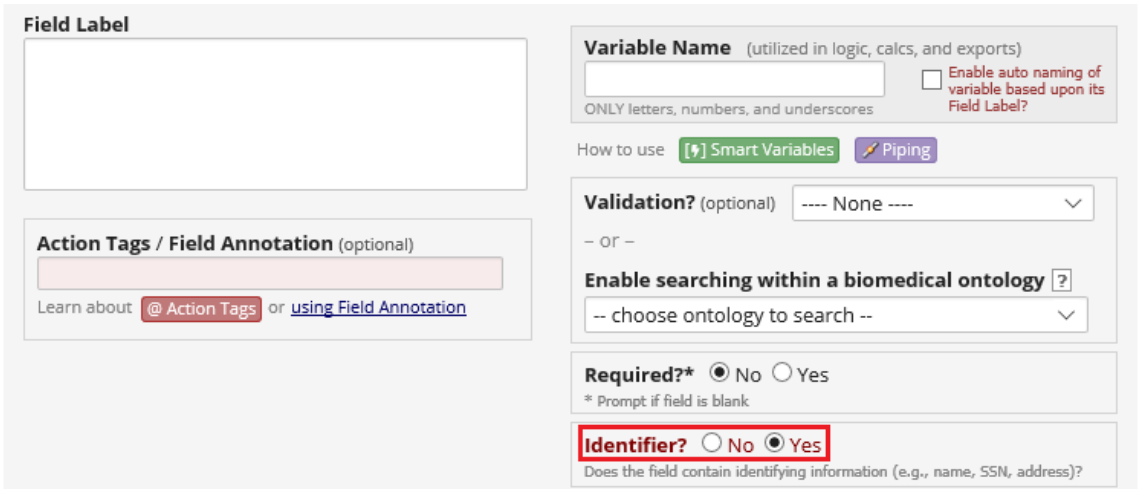
- First character must be a lowercase letter
- Only lowercase letters, numbers and underscores can be used

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:



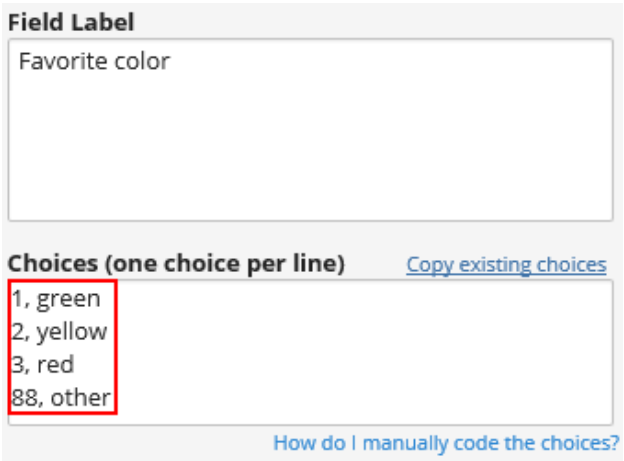
✓ Add a date field "**Visit Date**" or "**Date of Assessment**" on top of the form when needed (e.g. study and follow-up visits, laboratory data, questionnaires, etc.)

3.2.3. 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:

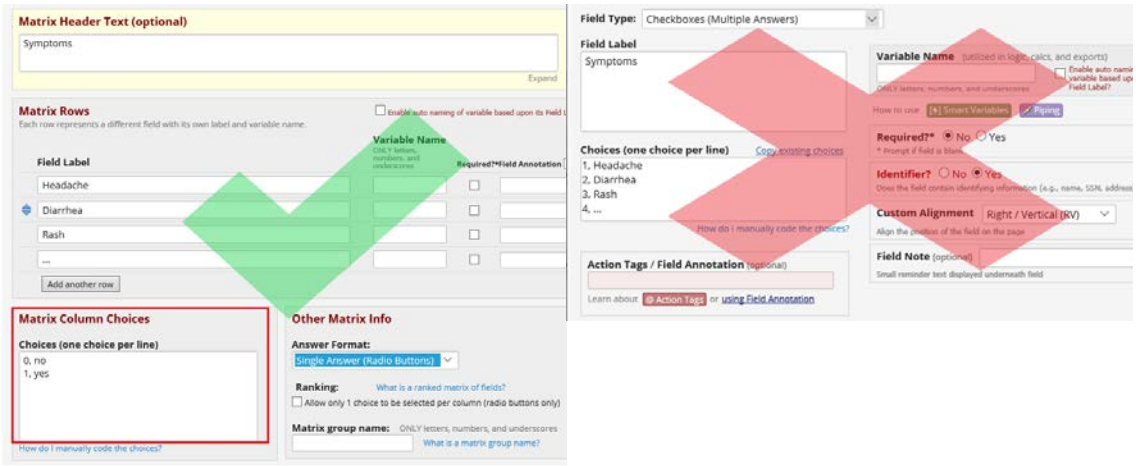


- ✓ CTU Bern standard **coding of special values** is:

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.)

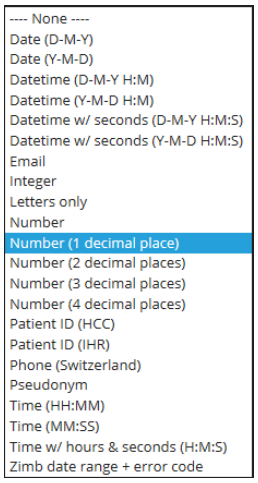


3.2.4. Numeric Fields

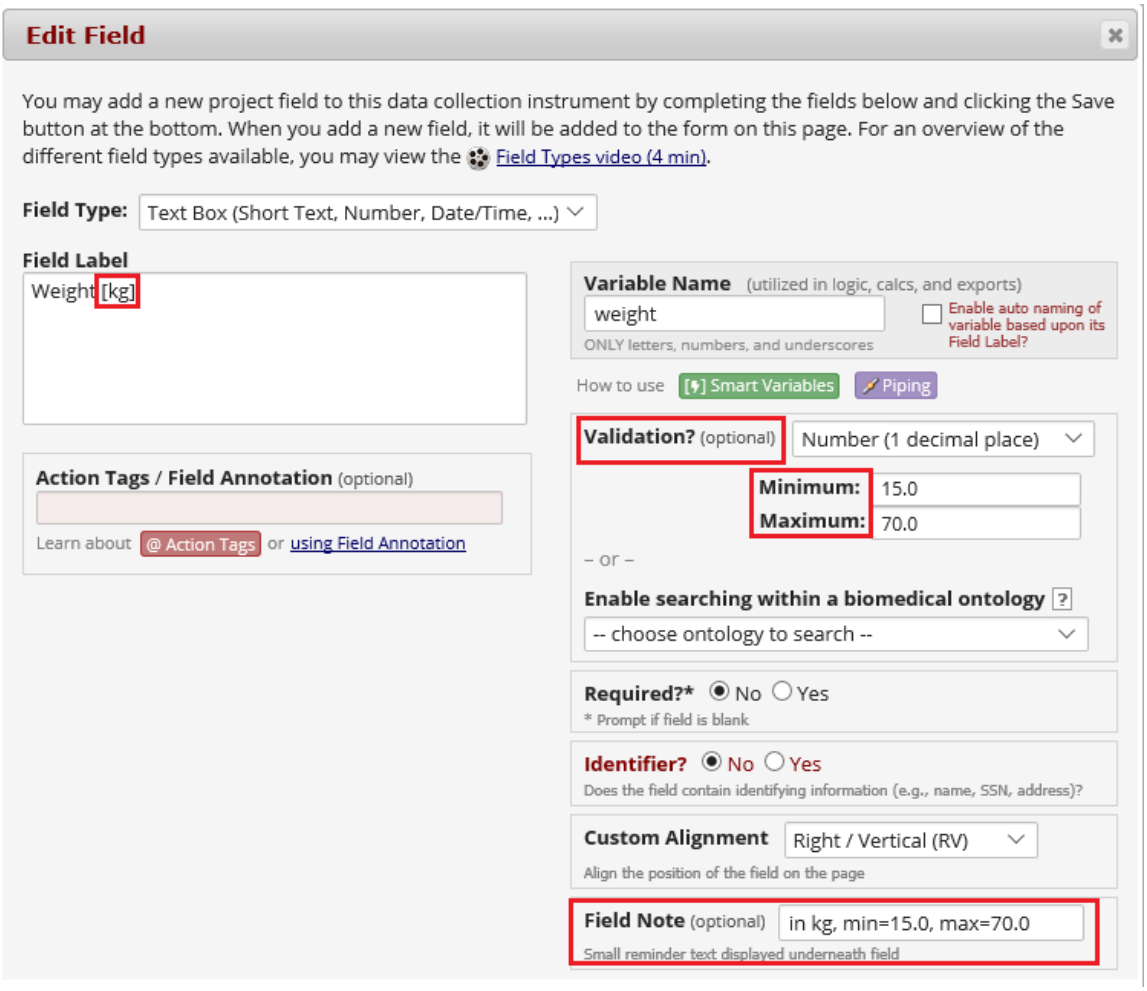
- ✓ **Numeric fields are text fields that are validated as numeric fields**.
  Several numeric field validation formats are available:
  number: any number
  integer: whole number, never contains decimal places
  1 decimal place number: always contains exactly 1 decimal
  2 decimal places number: always 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**!



✓ 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.



✓ **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)

✓ You can use **piping** 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,…). 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.

3.2.5. Branching Logic

- ✓ Implement branching logic in fields that must be displayed only when **specific conditions** are met (e.g. pregnancy test only for women).

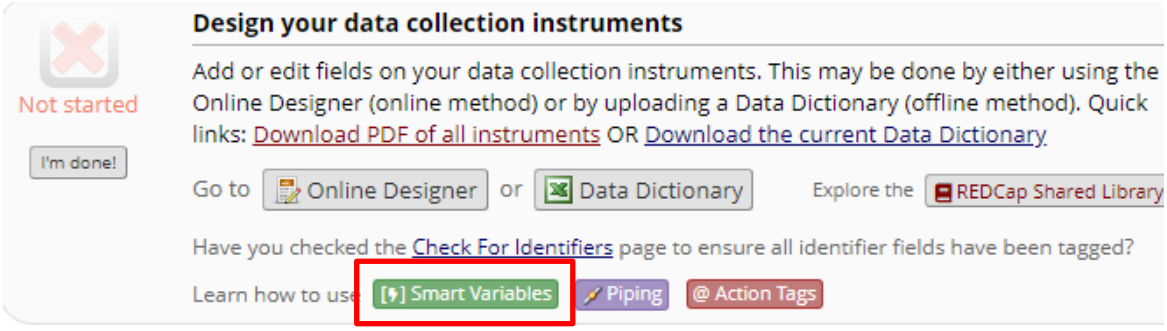
- ✓ In longitudinal studies, always add the **REDCap event name** to the field name in branching logic rules or calculated fields when they refer to a **field not belonging to the current event:**
  e.g. to calculate the age at randomisation use [baseline_arm1][yob] instead of [yob].

  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.

- ✓ 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:



- ✓ **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!

3.2.6. 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
- ✓ Be careful when using **HTML tags** in field labels. Test first in a simple example if you can upload the data dictionary when using your HTML tags
- ✓ 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. And that **numerical range values** follow the **expected format**, e.g. for a 2 decimal places number: 5.70 and not 5.7.
- ✓ **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**

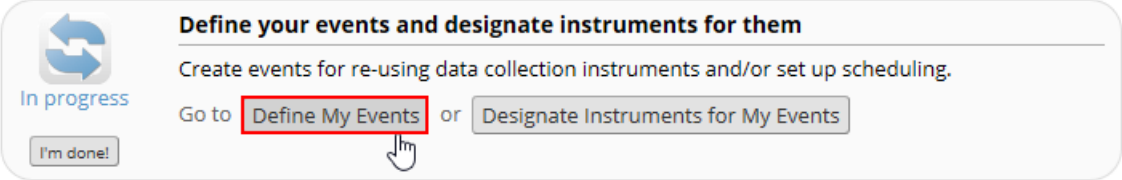
Keep in mind:

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.

3.2.7. 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



- ✓ If **different event grids** (=visit schedules) are going to be used, create every event grid in a different arm **(these are NOT randomisation 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	☑	☐	☐	☐	☐	☐	☐	☐
Randomisierung	☑	☐	☐	☐	☐	☐	☐	☐
Assessment	☐	☑	☑	☑	☑	☐	☐	☐
Zufriedenheitsumfrage	☐	☐	☐	☐	☐	☑	☐	☐
CTU Template End of Study	☐	☐	☐	☐	☐	☐	☑	☐

3.2.8. 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)

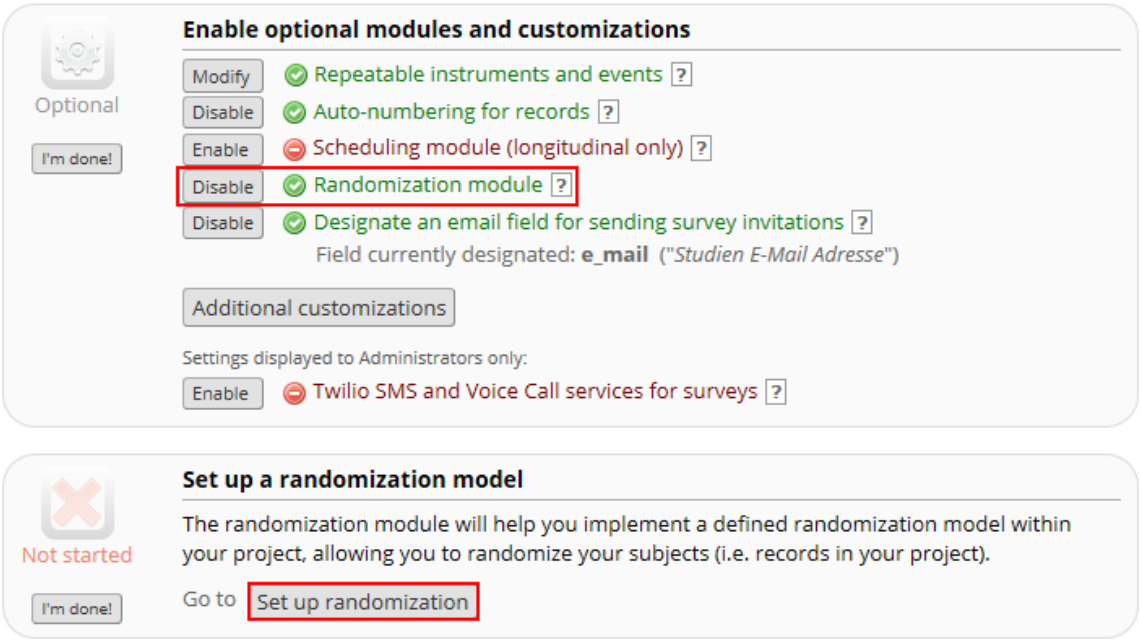
3.2.9. Randomisation

Setup of randomisation in REDCap

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

CTU Bern Data Management recommends the randomisation lists for the development & productive environments **to be created by CTU Bern Statistics**. The reason is that these randomisation lists should be created by an **independent statistician** and not by the study statistician. Moreover, creating a randomisation list is a core part of a randomised trial and it is crucial that no error occurs.

- ✓ **Enable Randomisation Module**

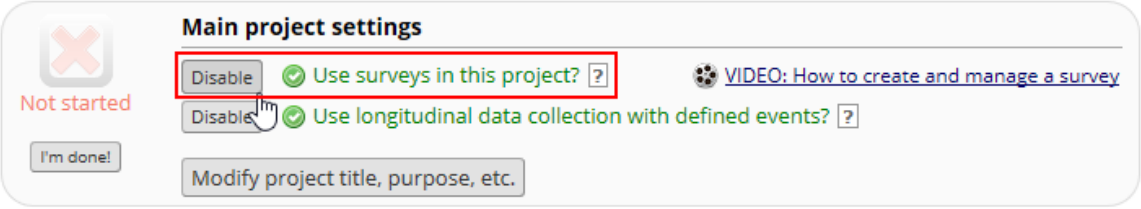


- ✓ **Set up randomisation** (see item 'Randomisation' in the left hand menu)
  - strata and/or site (as applicable)
  - randomisation result field
- ✓ **Upload two different randomisation lists**, one for the test and one for the productive environment
- ✓ **Test randomisation**

3.2.10. eSurveys

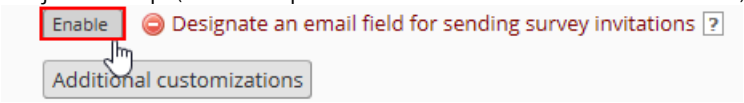
✓ Define **survey distribution** (public link vs. participant list)

✓ 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)



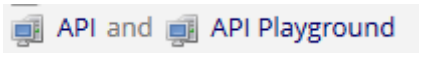
- To designate an e-mail field for sending survey invitations you first need to create a text field in an instrument with the validation "e-mail".

✓ **Don't set fields as 'required'** unless it is absolutely necessary: missing required fields prevent participants from saving and submitting the survey!

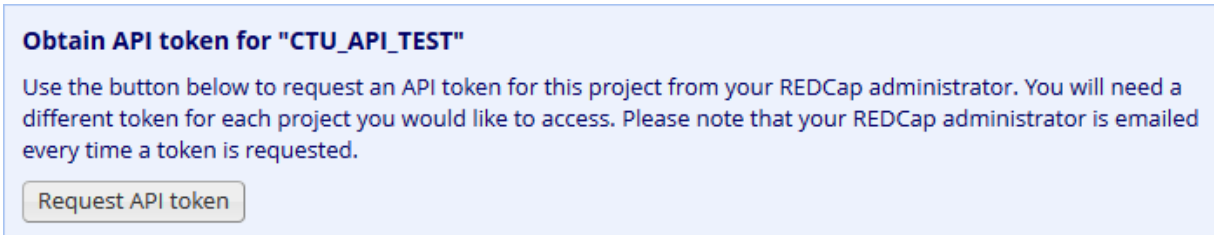
✓ **Test** survey distribution, options, and settings

[redacted]

[redacted]



[redacted]



[redacted]

4. 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
- ✓ **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 randomisation**
- ✓ **Test data export** and ask your statistician to approve the current version of the Database

5. 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"?
- ✓ 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?

6. 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?

7. Deployment of the database

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

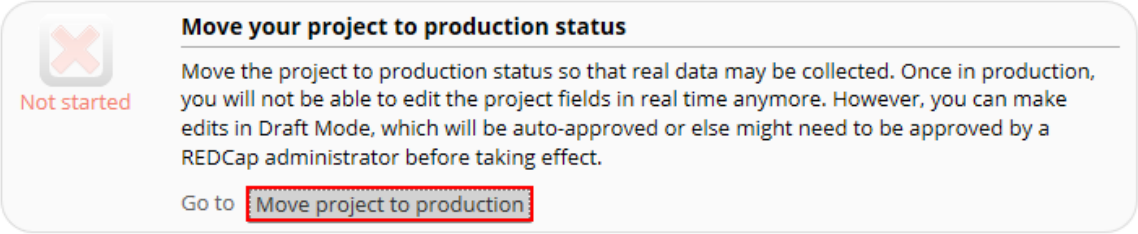
7.1. Prerequisites

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.
- ✓ 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 local PI 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
- ✓ 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

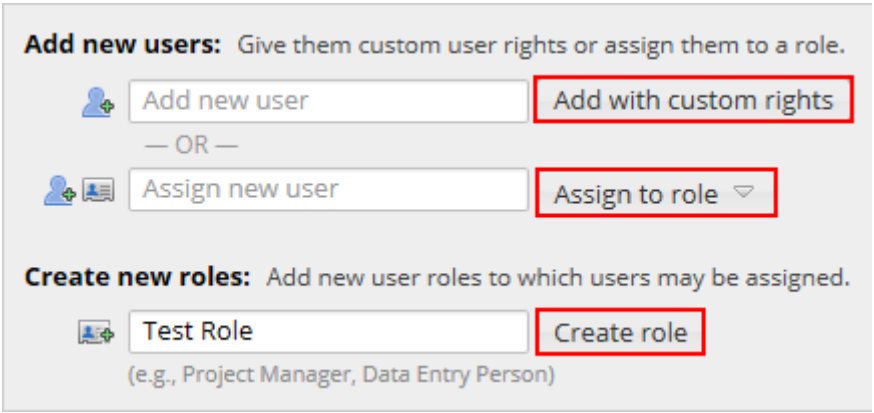
7.2. Deployment

- ✓ In 'Project Setup', move Project to production status. Confirm that all test data already entered in the database are deleted.
  For **projects at the CTU REDCap installation**, ask the CTU datamanagement team to deploy the project for you.



- ✓ 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.
- ✓ Prepare a note to file for the TMF documenting the location of the (electronic) data dictionary (see template CS_DMA_TEM-28_NoteToFile_TMF_DataDictionary in the CTU_Library of REDCap Light Documents).
- ✓ Inform all involved parties that the database is productive
- ✓ Read the checklist for PI tasks during data collection (Section 9.1)

[redacted]



[redacted]

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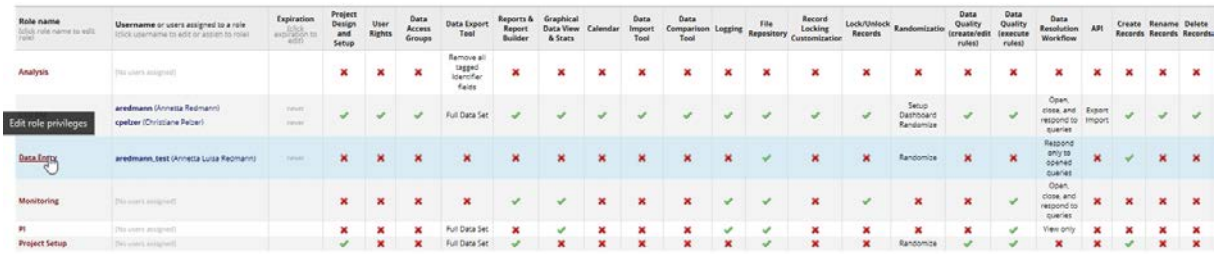


8.2.3. Identifying Data

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. Create a special role for the study team members who need to access the identifying data. Go to 'Data Entry rights', set 'Read-only' or 'View & Edit' to all eCRFs containing identifying data.

For all roles that do not need access to identifying data: go to basic rights, set the 'Data Export' right to 'De-Identified*' or 'Remove all tagged Identifier fields'. Then go to 'Data Entry rights' and set 'No Access' to all eCRFs containing identifying data.

8.2.4. Blinded studies

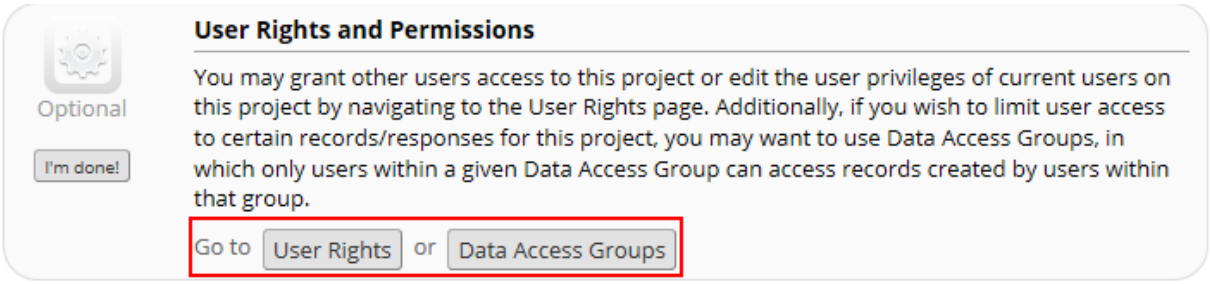
If your study database is blinded you can implement the entire study database as blinded (=only blinded information in study database). However, it might be necessary to show the randomization result to some people of the study team. In this case, the unblinded data should be implemented exactly as described 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 randomisation 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 roles that are blinded, go to basic rights, set the 'Data Export' right to 'De-Identified*' or 'Remove all tagged Identifier fields'

For all roles that are blinded, go to 'Data Entry rights', set 'No Access' to all eCRFs containing variables with treatment information.

8.3. 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.



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

8.4. Management of Users

All users of the study database must be documented in the Database Access List, which is signed by the PI. Without the documented (=written) approval of the PI, 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).

The two methods are explained below:

8.4.1. 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/PI, 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.

* available on «CTU_Library of REDCap Light Documents»

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).

8.4.2. Table-based

✓ Based on the Database Access List* completed and signed by the sponsor/PI, 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
- Access rights

The CTU creates the user(s) in REDCap.

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).

* available on «CTU_Library of REDCap Light Documents»

9. Database in Production

9.1. PI 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.

9.1.1. 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.

9.1.2. 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).

9.1.3. User Management during Production

- ✓ Users who leave the study team must be reported to the 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.

9.1.4. Randomization Error

- ✓ 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.

9.2. Changes in a productive database

9.2.1. General

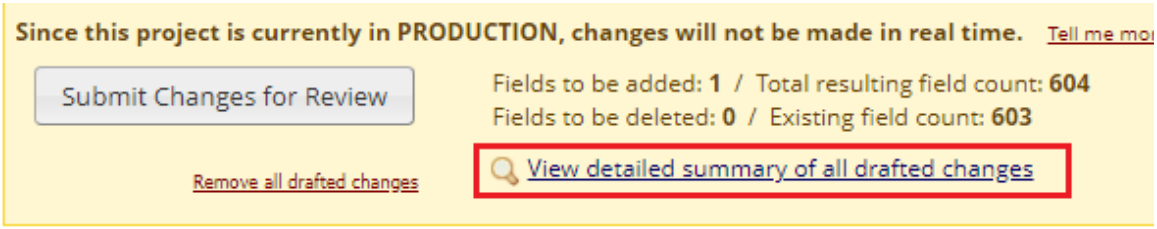
Before implementing changes in a productive database, make sure to consider the impact on the database, especially on already entered data, but also on documents and processes outside the database:

- ✓ For complex, possibly risky changes (e.g. inclusion / exclusion criteria, randomisation, complex branching logics,…), identify possible risks and evaluate possibilities how to decrease or avoid them, e.g. back-up of current database and data, 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:
  On the REDCap project setup page, go to the bottom and choose 'Online Designer' in the section 'Modify your data collection instruments in Draft Mode'.
- ✓ Confirm that you want to enter Draft Mode

- ✓ 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:



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)

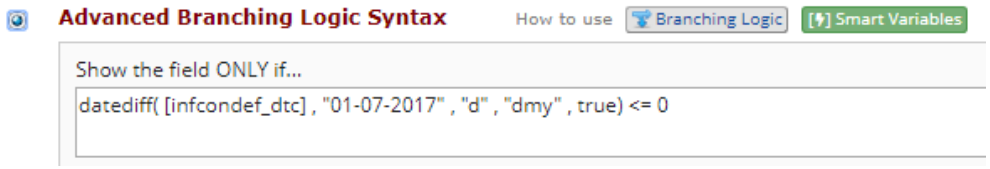
- ✓ Update documentation, e.g. study protocol, paper CRFs, manuals, work instructions, guidelines,…

- ✓ Inform other users / sites about the changes, especially when already entered forms have to be updated

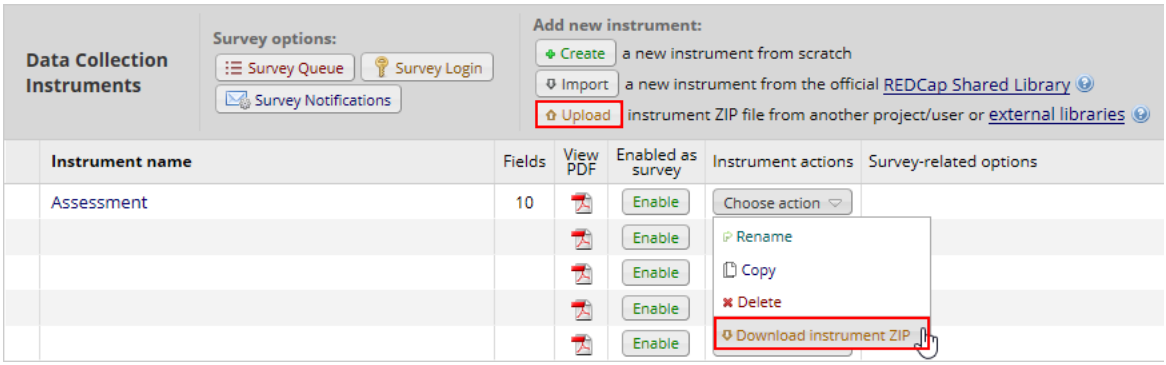
- ✓ For projects on **the CTU REDCap installation**, ask CTU Data Management to release the changes for you: press the button 'Commit changes'. Note: CTU Data Management will NOT review your changes!
  On the **Inselspital REDCap installation** you can release changes yourself by committing and confirming the changes.

9.2.2. 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:



- ✓ To develop and test a new form, you can copy the database (without real data and users), create and test the form there and download it as a zip-file. The zip-file can later be uploaded directly into the productive database



- ✓ If you add a new form, remember to add it into the instrument-event mapping after the form is released into production

- ✓ After the form is released into production, check all user roles and ensure that the access rights for the new form are correct

9.2.3. 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 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

10. Project completion

10.1. Closure of patient recruitment

- ✓ If patient inclusion is complete or stopped, remove the right to create new records from all concerned user roles

10.2. 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 lock the database in the study (database) folder
- ✓ Remove all data editing rights from all user roles
- ✓ If the study contains patient-filled questionnaires, make sure that the access to the questionnaires is permanently de-activated: set survey(s) to "offline"
- ✓ Move project to "inactive status": "Project Home"- "Other Functionality"
  In inactive status, data can still be read and exported but data changes can no longer be conducted
- ✓ 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

10.2.1. Reopening the database

- ✓ If the re-opening of the database should be necessary, save the written request from the sponsor stating the reason for the re-opening in the study (database) folder
- ✓ Log in to REDCap, go to "Project Home"-"Other Functionality" and move the project back into "active" status
- ✓ 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.
- ✓ Close the database again as soon as the necessary changes have been conducted

10.2.2. Final Export of Study Data and Metadata

Anonymization of data due to consent revocation

If a subject 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 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 to export 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:
    - Csv, raw data
    - Stata
    - xml
    - the format you use for the analysis
    - 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 to set 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: Logging

The export format is csv, so make sure to activate the write protection to prevent unintended changes in the audit trail
- 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

10.3. Archiving the database

✓ Log in to REDCap, Project Setup, Other functionalities and archive the project

✓ Archive all study documents according to your institution's guidelines

11. Help / Support

11.1. REDCap funtionalities

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,…).

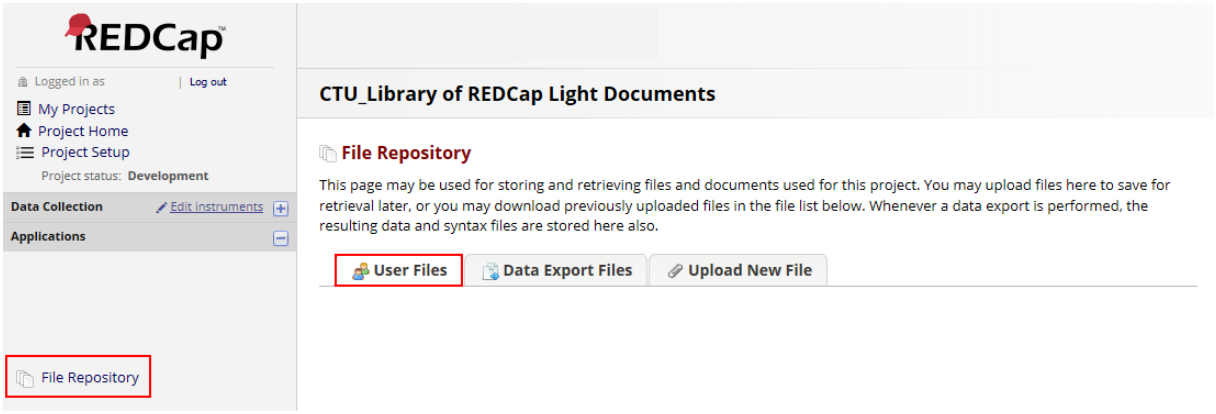
If you don't find the required information there, consult the REDCap video tutorials and the "Help and FAQ" page: https://redcap.ctu.unibe.ch/index.php?action=help .

11.2. Technical problems

In case technical problems occur (e.g. database not accessible, log in not working,…), please contact [redacted] datamanager.CRC@hcuge.ch

12. 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_v8.5.19/ProjectSetup/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 (CS_DMA_TEM-26_TemplateCodebook)

Deployment:

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

DB Lock:

- DB Lock: Data complete Confirmation from PI (CS_DMA_TEM-29_Data_Complete_Confirmation_PI)
- DB Lock: DB Lock request from Sponsor (CS_DMA_TEM-30_DBLock_Request_Sponsor)

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	**PI**	**PI**
Project creation	**CTU**	**CTU**
Training on database implementation	**CTU**	**n.a.**
Support during implementation	**(CTU)**	**n.a.**
Database Implementation & Testing	**PI**	**CTU/PI**
Database Review	**(CTU)**	**n.a.**
Deployment	**PI**	**CTU**
User creation	**CTU**	**CTU**
Management of Users/Roles/Centers	**PI**	**CTU**
Implementation Database Changes	**PI**	**CTU**
Review Database Changes	**(CTU)**	**n.a.**
Database Closure/Archiving	**PI**	**CTU**
Clinical Data Management System	REDCap	REDCap secuTrial

(CTU) = if requested/agreed in costing

Appendix B: Creative Commons License