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# REDCap Database Setup: An Introduction


**CTU Bern**

**Data Management**

# Content

1. **Human Research Act (HRA)**
2. Clinical Data Management Systems (CDMS)
3. REDCap Services Models at CTU Bern
4. REDCap: how it works…step by step
5. Principles of CRF Design

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# Requirements arising from the HRA

**Human Research Act, HRA** ClinO, Art. 18.1 / HRO Art. 5.1

- Restrict the handling of the health-related personal data to those persons who require this data to fulfil their duties
  **=> Personalized login**

- Prevent unauthorised or accidental disclosure, alteration, deletion and copying of the health-related personal data
  **=> Access control**

- Document all processing operations which are essential to ensure traceability
  **=> Audit trail**

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# Data Management solutions that are NOT compliant with Swiss law

Current Excel / Access / SPSS solutions:

=> no login, no access control, no audit trail, no multi-user capability etc.

Survey Monkey or similar survey systems:

(not subject to Swiss Data Protection Law)
=> collected participant data must be stored on servers your institution owns or for which your institution has a written privacy/data protection/ownership agreement

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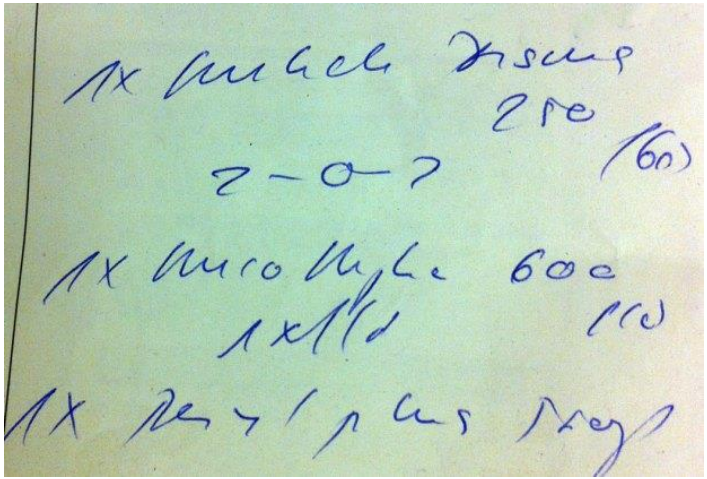
– Computerized system designed for the collection of clinical data (i.e. CRF data) in electronic format.



Use of a CDMS improves data quality and leads to more reliable research results

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# CDMS Advantages

- Defined data types => controlled data entry
- Real-time validation (fewer errors and thus fewer queries!)
- Standardized process of data collection (data entry, completeness, query system, data lock, archiving)
- Record status overview (close observation of data, early discovery of systematic mistakes)
- Highly structured data in various export formats (e.g. Excel, STATA, SAS, SPSS, R)
- Interactive system
- Audit trail (history, log)
- User management

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# HRA-compliant CDMS used at CTU Bern

- **REDCap** - recommended for simple study designs
  - Simple visit plan (e.g. no/few unscheduled visits, no treatment arms)
  - Simple data monitoring functionalities

- **secuTrial** - recommended for more complex study designs
  - Minimization (e.g. adaptive randomization)
  - Complex visit plan (e.g. unscheduled visits, several treatment arms, etc.)
  - More complex data monitoring functionalities

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# HRA-compliant CDMS example

- **R**esearch **E**lectronic **D**ata **Cap**ture (http://project-redcap.org)
- Web-based Clinical Data Management System
- Developed by Vanderbilt University, Nashville, USA in 2004


REDCap™

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# REDCap - Advantages

- Easy to learn and easy to work with
- Offline CRF creation
- Patient-completed surveys (can be sent directly to patients)
- Data import (from Excel)
- Double data entry (inexperienced staff, poor pCRF quality)
- Online randomization (stratified; static randomization only)
- Data queries can be generated, handled and resolved online
- http://www.project-redcap.org/

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# CTU Bern offers two REDCap Service Models

- REDCap **Full** Service Project
  - CTU Bern builds up the REDCap database according to the specifications from the PI (paper CRFs, Study Protocol, etc.)
  - PI tests the database until she/he is satisfied with database setup

- REDCap **Light** Service Project
  - ONLY available for University of Bern and Inselspital Bern
  - IT infrastructure (daily back-up, secure system, frequent updates)
  - PI/database developer attends one of our monthly REDCap training sessions (2 hours)
  - Deployment of database
  - User creation and super user support after deployment

# REDCap Light*

* Available for Insel & UniBe

## Light Service Package

- IT infrastructure (daily back-up, secure system, frequent updates)
- Attendance of our monthly REDCap training sessions (2 hours)
- Deployment of database
- User creation and super user support after deployment

**Data management**
- Support
- Review of DB
- Data Import

**Monitoring**

**Statistics**
- Randomization list
- Analysis
- Review of DB

## Additional Service Options

(agreed in the costing)

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# Sponsor responsibilities regarding CDMS

- Ensure that CDMS is validated (conforms to the sponsor's requirements for completeness, accuracy, reliability, and consistent intended performance).
- Maintains SOPs for using these systems describing system setup, installation, updates and use (training of new users).
- Clarify responsibilities within the CDMS (among Sponsor, Investigator and other personnel).
- Ensure that the system permits documented data changes, and no deletion of data is possible.
- Regulates access to and maintains adequate backup of data.
- Ensures data integrity during updates or data migration.

*ICH GCP E6, §5.5.3*

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# Sponsor responsibilities regarding CDMS

**CTU Bern ensures that sponsor responsibilities can be fulfilled!**

- Validation and vendor assessments
- Maintaining of SOPs
- User management
- Performing and testing of updates
- Backup of data

*ICH GCP E6, §5.5.3*

# REDCap Light Service Project

**First Steps**

- Contact CTU Bern (e.g. when scope of study is defined)
- CTU Bern asks PI to provide study Sponsor contact's details as well as other study- and database-specific information
- CTU Bern creates a cost estimate and sends it to study Sponsor for approval/signature
- CTU Bern creates a new REDCap Project and provides study PI/Database developer with access rights

For more information, please consult our REDCap Light Service Project Checklist

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# Contact CTU Bern

- CTU Bern
  Mittelstrasse 43
  3012 Bern
  Switzerland

- CTU Bern Website
  www.ctu.unibe.ch

- Contact Form:
  www.ctu.unibe.ch/services/data_management/index_eng.html

- Data Management Support
  ctu-datamanagement.dcr@unibe.ch

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# REDCap: how it works…step by step

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https://redcap.ctu.unibe.ch

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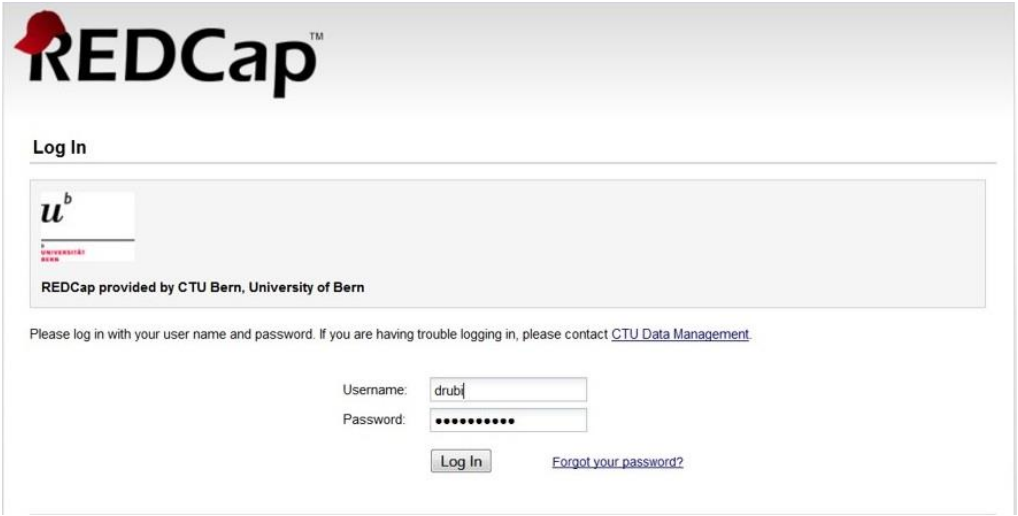
# Login

- https://redcap.ctu.unibe.ch
- Login = Username (created by CTU DM) + password



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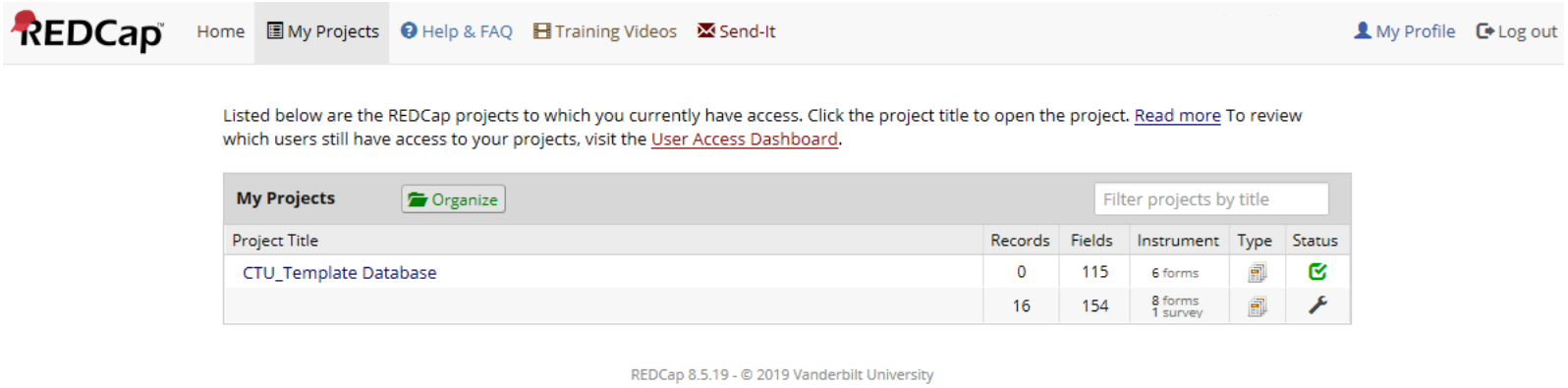
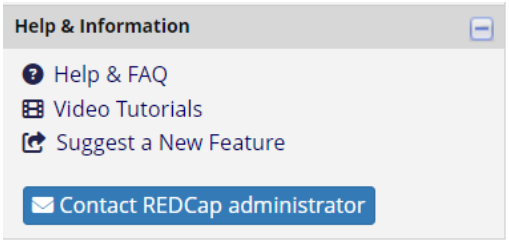
# Homepage

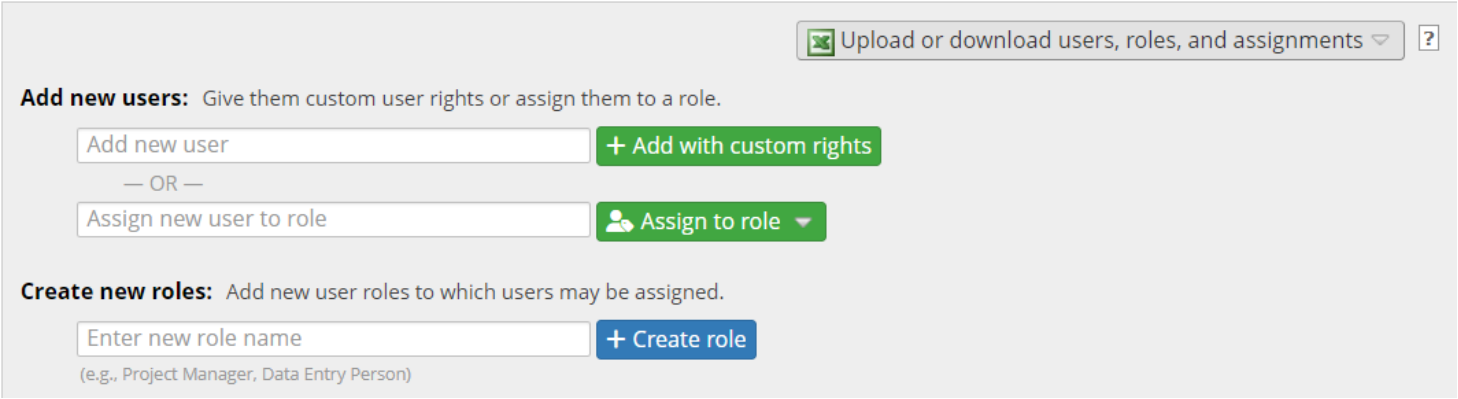
- Home
- My Projects
- Training Resources (Videos)
- Help & FAQ
- Send-It
  - Secure data transfer application
  - For large files and/or files that contain sensitive information






# User Management

- Adding New Users
  1. Creating a new REDCap User Account by **CTU Bern**
     - ➢ Requested by Super User (Email with database title, name, and email address)
  2. Optional: Create new role (standard roles available)
  3. Add user by assigning a role



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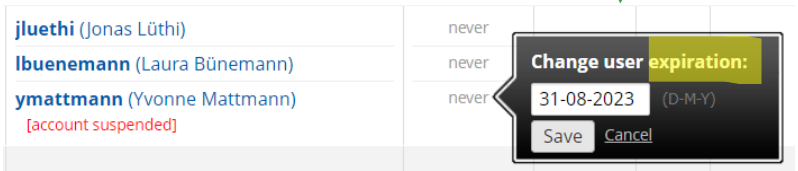
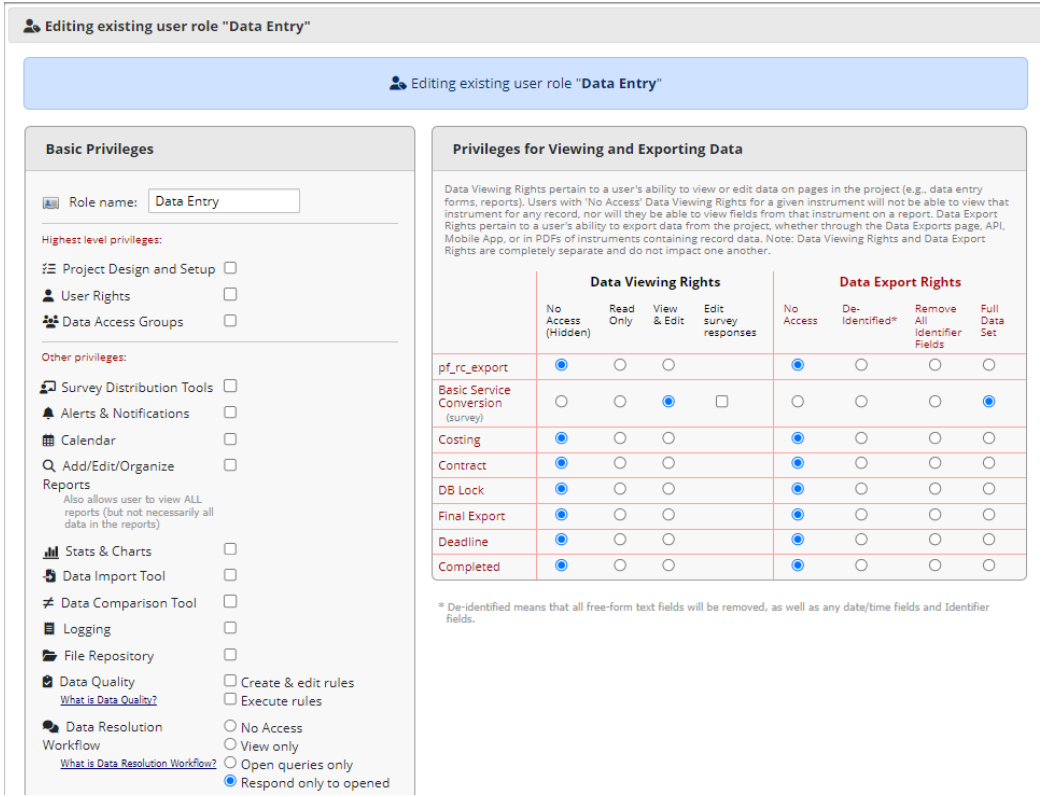
# User Management

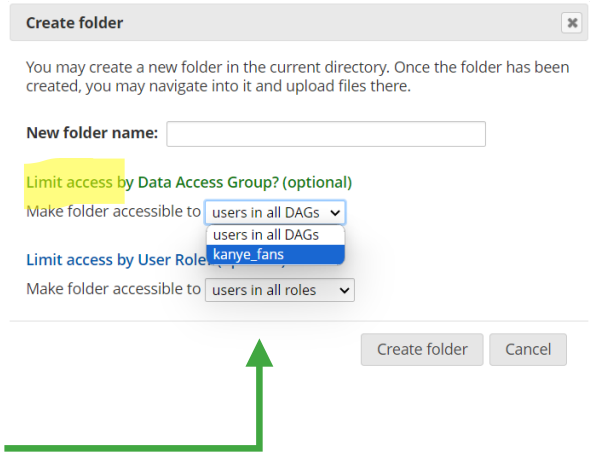
- Adding New Users
  4. Adjust role
  5. Once known: Set expiration date

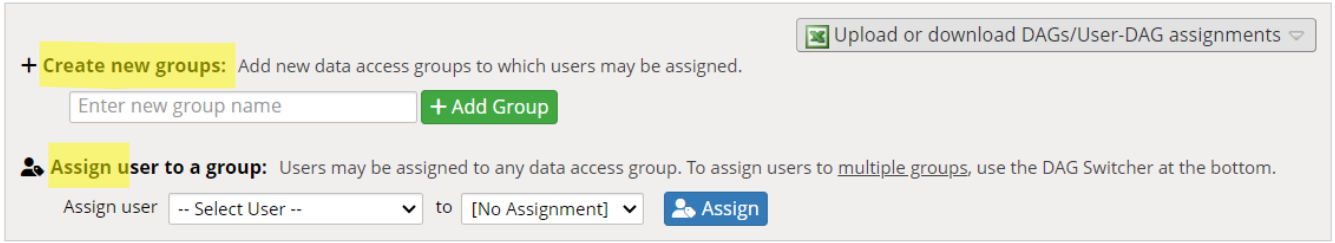


# DAGs

- Data Access Groups
  - Organisation der Daten nach Sites/Center
  - Verhindert, dass die User der einen Site die Daten der anderen sehen
  - Achtung: Exportierte Daten sind im «File Repository» für alle sichtbar, ausser sie werden in separate Ordner mit limitiertem Zugriff verschoben.




| Data Access Groups | Users in group | Number of records in group | Unique group name (auto-generated) | Group ID number | Delete group? |
|---|---|---|---|---|---|
| kanye_fans | lbuenemann (Laura Bünemann) | 1 | kanye_fans | 5731 | ✖ |
| [Not assigned to a group] | jluethi (Jonas Lüthi),<br>joensi_test (Jönsi Test),<br>jonas_test2 (Jonas Luethi)<br>* Can view ALL records | 11 | | | |

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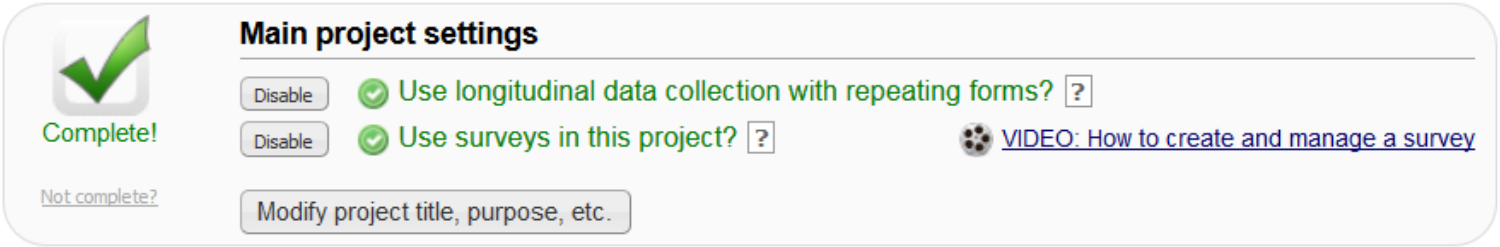
# Project setup – Main project settings

- **Main project settings**
  - Longitudinal data collection? *(Use longitudinal data collection with repeating forms?)*
  - Electronic survey(s)? *(Use of electronic surveys in this project?)*



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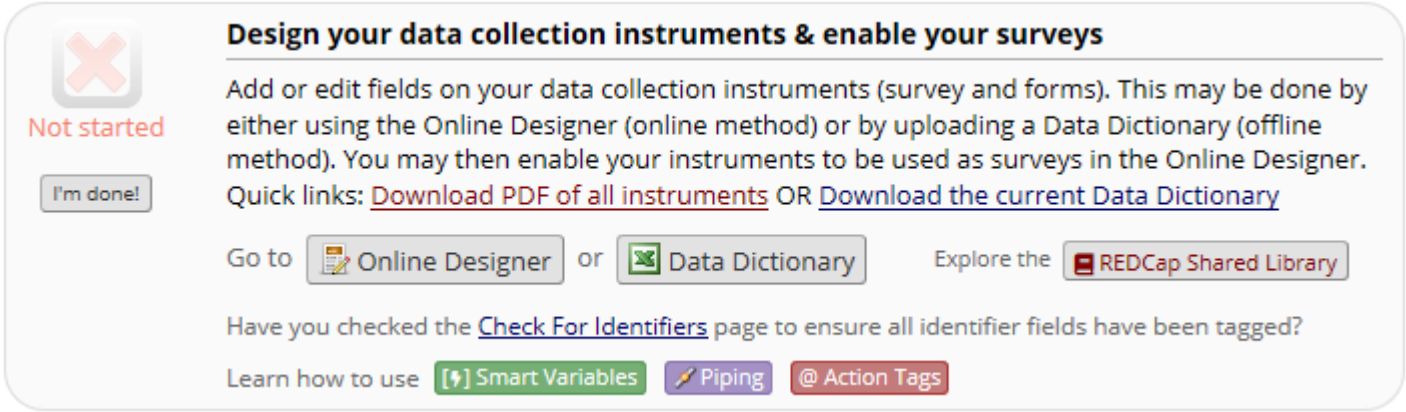
# Project setup – CRF creation

- **Design your data collection instruments**
  - Online Designer (online CRF creation => user-friendly)
  - Data Dictionary (offline CRF creation => experience required)



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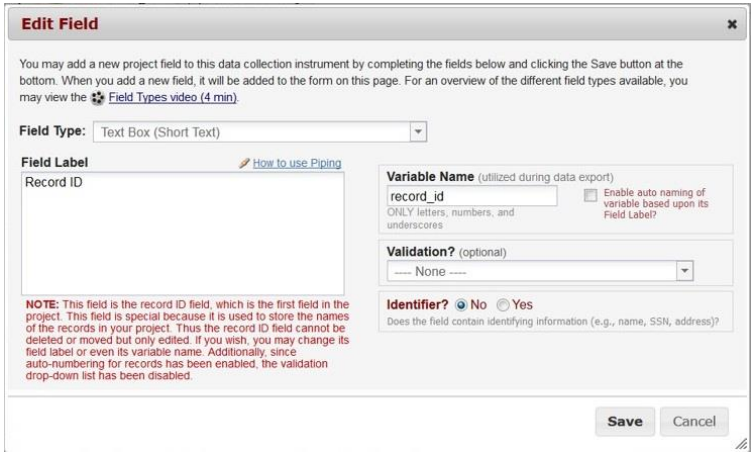
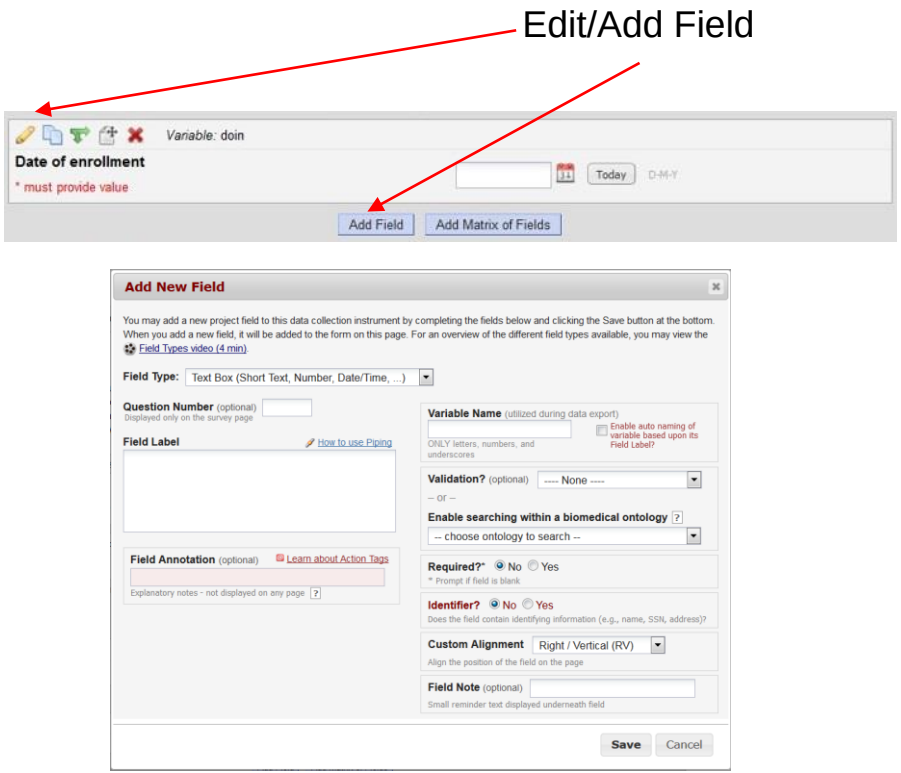
# Online Designer – Record ID

- The first field of the first form is the Record ID. DON'T CHANGE IT! This field allows REDCap to uniquely identify each record (patient).




- If you want to collect an additional identifier (e.g. patient ID), please create a new field (and set it as a secondary unique field).

# Online Designer – Field creation




- Field Type
- Field Label
- Choices
- Variable Name
- Validation
- Required?
- Identifier?
- Custom Alignment
- Field Note
- Field Annotation

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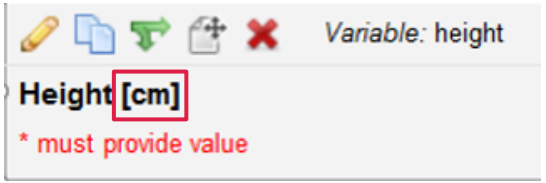
# Field creation – Pre-defined field types

- **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 choice, single answer
- **Checkboxes***: multiple answers possible
- **Calculated Fields***: perform calculations (numbers/dates only)
- **File Upload**: document upload, e.g. PDF file (small files only)
- **Slider / Visual Analogue Scale**: coded from 0 to 100

* avoid if possible

# Field creation – Field label

- The field label contains the **question text**
- If a number is to be recorded, indicate the **unit** in square brackets:

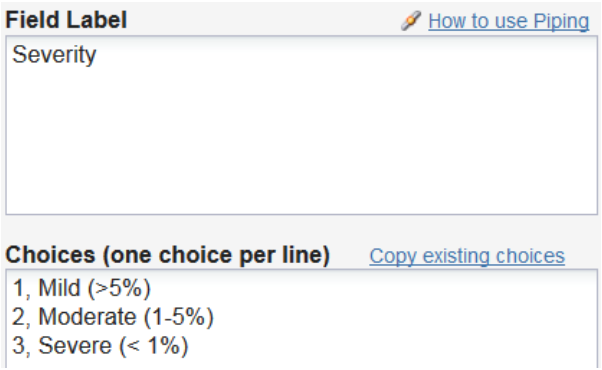


# Field creation – Answer choices

**CTU Standard Coding**

- **Multiple-choice fields**
  code first choice as 1, increment by 1 with every added choice

- **Special values / conventions**
  - 1, yes / true / positive / etc.
  - 0, no / none / false / negative / etc.
  - 77, not applicable
  - 88, other / etc.
  - 99, unknown / not available / not done / etc.




Use consistent coding within your project!

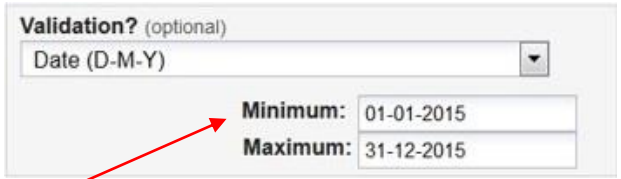
# Field creation – Variable name

- Must be unique within a project
- Should be short and meaningful (do NOT use auto-naming)
- Recommended length: < 26 characters
- Must start with a lowercase and can only contain letters, numbers and underscores. All letters must be lowercase.
- Add a suffix to indicate field type (e.g. blood_draw_date)

| | |
|---|---|
| date | Date |
| dt | Date and Time |
| yn | Yes/no |
| txt | Text |
| nr | Number |
| code | Coding of a variable |
| spec | Specify, when to specify a variable |
| other | Other, when to specify "other" of a variable |
| def | Define/definition |

# Field creation – Validation formats

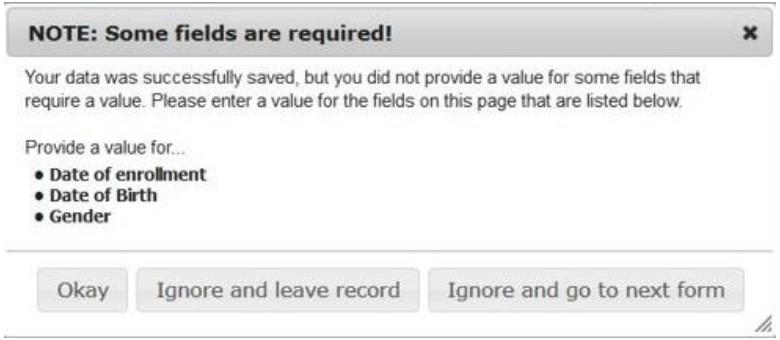
- **Main validation formats**
  - Numeric Fields
    - Integer (whole number)
    - Number (1, 2, 3 or 4 decimal place(s))
    - Number (any type of number is tolerated)
  - **Dates / Time**
    - DD-MM-YYYY
    - HH:MM
  - **Text**
    - Email
    - Letters only (whitespaces not allowed!)




- **Range values (for numeric and date fields only)**
  Add min. and max. range values to prevent entry of erroneous data

# Field creation – Required fields & Identifiers

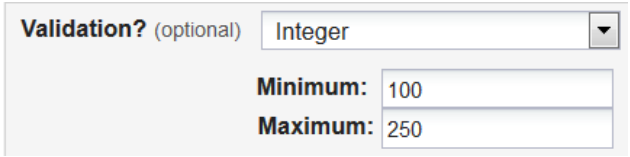
– **Required fields:** If one or several required fields have no value when you save your data entry form, REDCap will show a warning message but will not prevent you from saving your work (≠ survey).




– **Identifiers:** It is possible to export data without identifiers.

# Field creation – Field note

- **Field note:** Is used to give clear data entry instructions. Particularly useful for numeric and date fields (REDCap does not tolerate any error in validation type).
  - Validation format
  - Min. & max. range values

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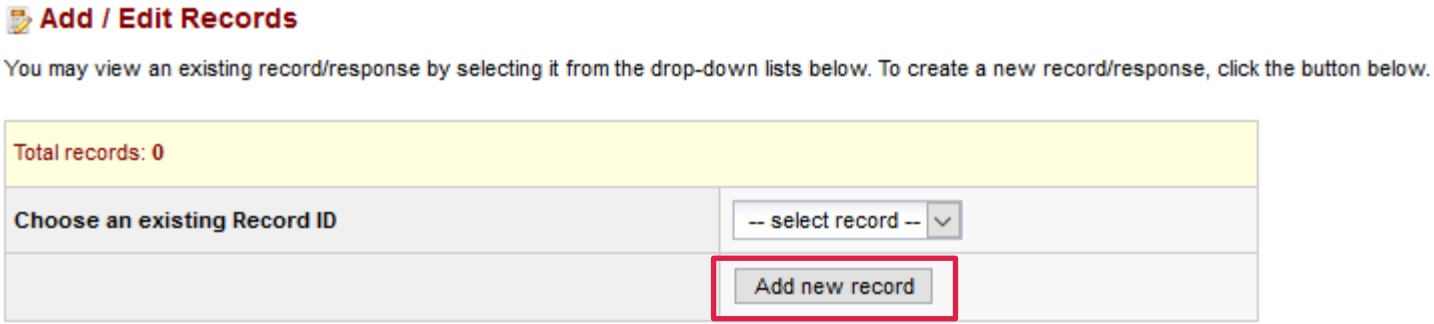
# Data Collection – Add / Edit Records

- **Add/Edit Records (i.e. patients, participants)**

# Data Collection – Record Status Dashboard

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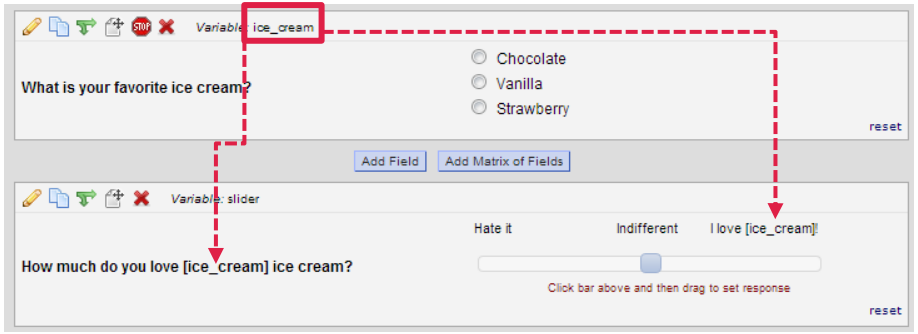
- **Record Status Dashboard**
  - Form status icon (colour coded; can be set manually at the bottom of each data entry form)
    - Red = Data entry incomplete
    - Yellow = Data entry complete, but form unverified (optional)
    - Green = Data entry complete, form checked (ready for locking)


| Record ID | Personal Information Patient Information | Diagnosis and Comorbidities Patient Information | Annual Form 2015 | Annual Form 2016 | Annual Form 2017 |
|---|---|---|---|---|---|
| 188-1 (Registry-specific patient ID AAR-A-001) | ● | ● | ○ | ○ | ○ |
| 189-1 (Registry-specific patient ID AAR-P-001) | ● | ● | ● | ○ | ○ |
| 189-2 (Registry-specific patient ID AAR-P-002) | ● | ● | ● | ○ | ○ |
| 189-3 (Registry-specific patient ID AAR-P-003) | ● | ● | ● | ○ | ○ |
| 189-4 (Registry-specific patient ID AAR-P-004) | ● | ● | ● | ○ | ○ |
| 189-5 (Registry-specific patient ID AAR-P-005) | ● | ● | ● | ○ | ○ |
| 189-6 (Registry-specific patient ID AAR-P-006) | ● | ● | ● | ○ | ○ |
| 189-7 (Registry-specific patient ID AAR-P-007) | ● | ● | ○ | ○ | ○ |
| 191-1 (Registry-specific patient ID) | ● | ● | ○ | ○ | ● |
| 191-2 (Registry-specific patient ID BAS-P-001) | ● | ● | ● | ● | ○ |
| 192-1 (Registry-specific patient ID BEL-P-001) | ● | ● | ● | ● | ○ |
| 193-1 (Registry-specific patient ID BER-A-001) | ● | ● | ● | ● | ○ |

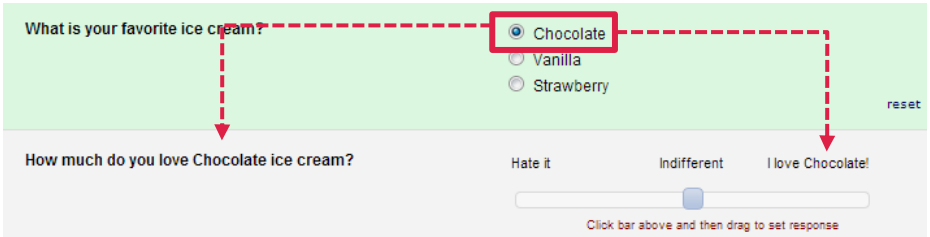
# Online Designer – Piping

- **Piping:** Allows inserting previously collected data into text on a data collection form. This is achieved by inserting the variable name inside square brackets into your text.

Setup:

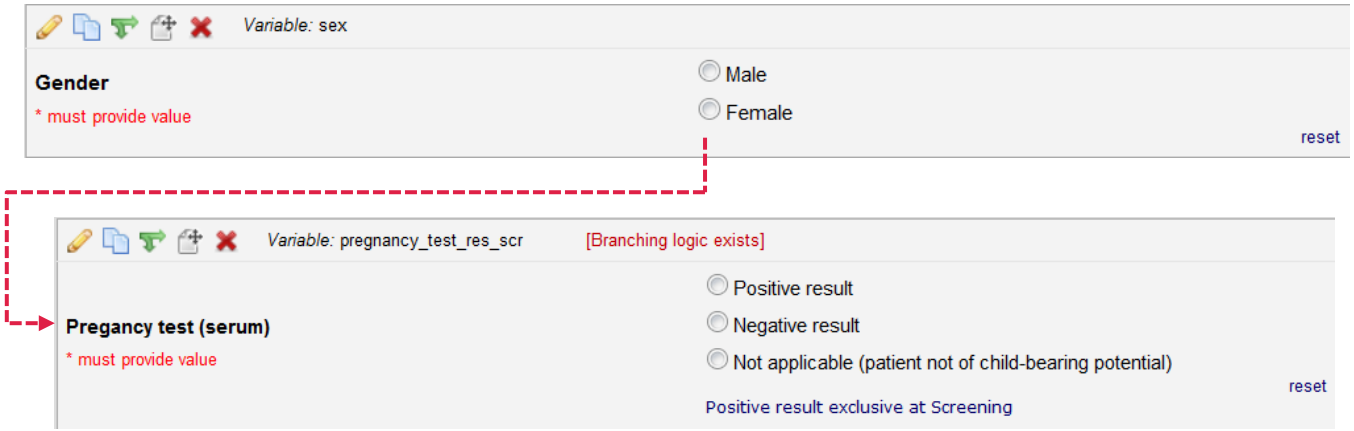



Data Entry:



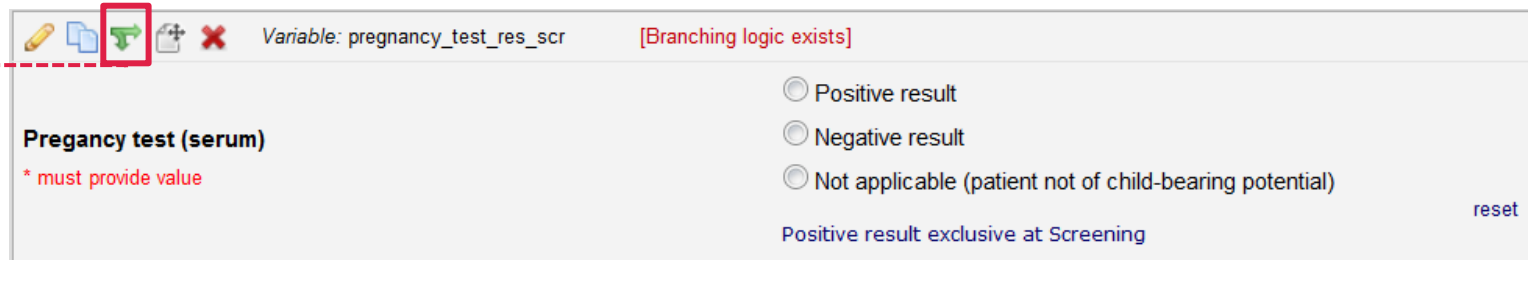
# Online Designer – Branching logic I

– **Branching logic:** Branching logic enables you to display a field only if a specific (set of) condition(s) is met.

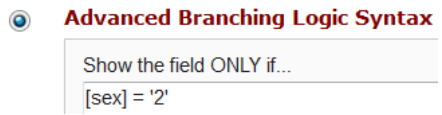



Pregnancy test result should only be displayed for female patients!

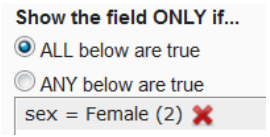
# Online Designer – Branching logic II




- **Branching logic** can be implemented by:
  - programming




  - “drag & drop”




- Branching logic can only be tested by entering test data (cannot be checked in the online designer or in preview)

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# Calculations

- Examples of available functions: mean, sum, date difference, round, if/then statement *if (CONDITION, value if CONDITION is TRUE, value if CONDITION is FALSE)*
- Allowed operations are the following:

| | |
|---|---|
| + Add | * Multiply |
| - Subtract | / Divide |

- A calculation can only output numbers
- Other important operators: **“”** (NULL), <> (UNEQUAL), = (EQUAL), …
- Tip: Visit REDCap’s MyCalc to get help with your calculations

Calculations can become highly complex. Therefore, it is important to validate / test them thoroughly before using them.
ATTENTION: If a calculation outputs a medical diagnosis, then it is considered a medical device.

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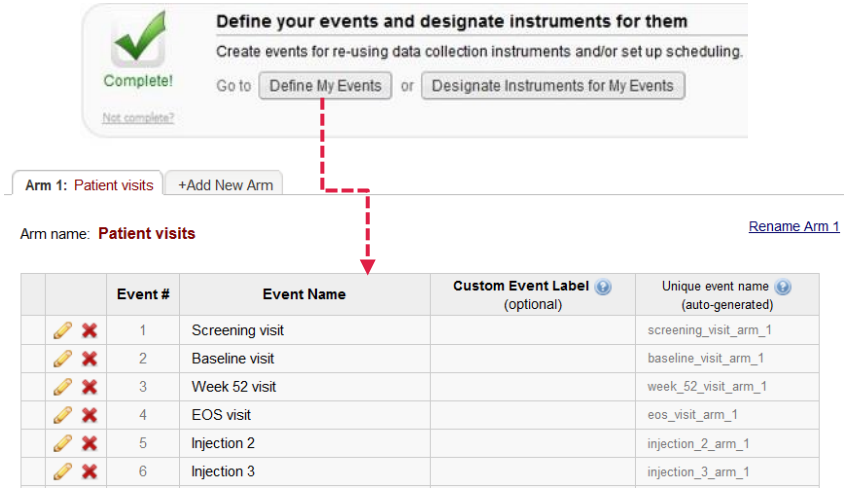
# Project setup – Define my events

- **For longitudinal data collection only**
  - Define your events by naming them
  - Possibility to define several arm(s), i.e. groups of events/visits (e.g. cases vs. controls)



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# Project Setup – Visit plan

- Allocate the created Instruments (CRFs) to the corresponding events (i.e. visits)


| Data Collection Instrument | Screening visit (1) | Baseline visit (2) | Week 52 visit (3) | EOS visit (4) | Injection 2 (5) | Injection 3 (6) |
|---|---|---|---|---|---|---|
| Demographics | ✔ | | | | | |
| General and Ophthalmic Data at Screening | ✔ | | | | | |
| Eligibility at Screening | ✔ | | | | | |
| General and Ophthalmic Data | | ✔ | ✔ | ✔ | ✔ | ✔ |
| Eligibility at Baseline | | ✔ | | | | |
| Randomization | | ✔ | | | | |
| Aflibercept Injection | | ✔ | | | ✔ | ✔ |
| BPRC - Disease Activity Form | | | | | ✔ | ✔ |
| End of Study Form | | | | ✔ | | |

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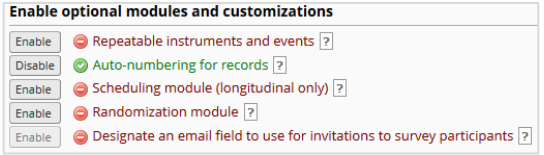
# Project Setup – Optional modules and customizations

- **Optional modules and customizations**
  - **Repeatable instruments and events**
    - Repeated instruments: for both classic and longitudinal projects
    - Repeated events: for longitudinal projects only
  - **Auto-numbering for records**
    - Please keep it enabled!
  - **Scheduling module (i.e. use of REDCap internal calendar)**
    - For longitudinal projects only
  - **Randomization module**
    - For randomized trials only
  - **E-mail field to use for invitations to survey participants**
    - Main project setting «Use surveys in this project» must first be enabled



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# Optional modules – Repeatable instruments and events

- **Specify the instruments/events (i.e. visits) that shall be repeatable**
  - Not repeating vs. Repeat Instruments vs. Repeat Entire Event
  - If desired, specify custom label for repeating instruments

| | Event Name | Repeat entire event or selected instruments? | Instrument name (select instruments to repeat) | Custom label for repeating instruments (optional) Example: [visit_date], [weight] kg |
|---|---|---|---|---|
| | Baseline Visit | -- not repeating -- | ☐ Demographics<br>☐ Clinical Data<br>☐ Laboratory Data | |
| ✓ | Follow-up Visit | Repeat Entire Event (repeat | ☑ Clinical Data<br>☑ Laboratory Data | |
| ✓ | Medication | Repeat Instruments (repeat | ☑ Medication | [med_name], [med_dose] [med_uni |
| ✓ | Adverse Events | Repeat Instruments (repeat | ☑ Adverse Event | [ae_description], [ae_date] |

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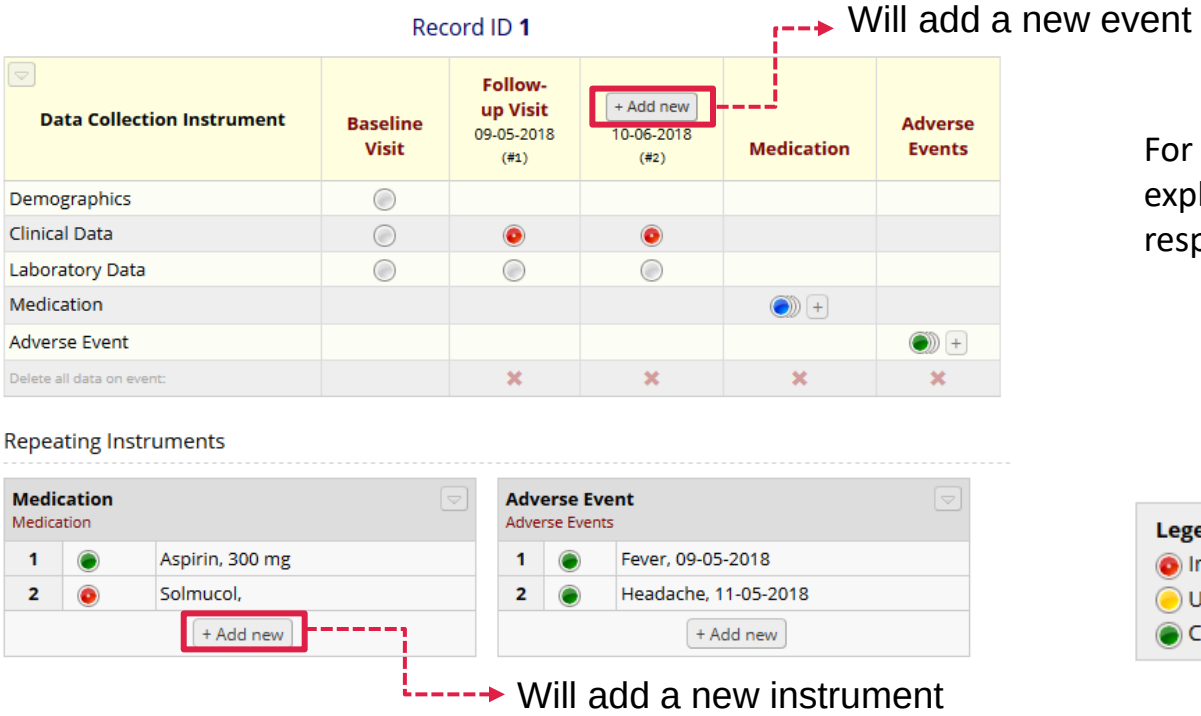
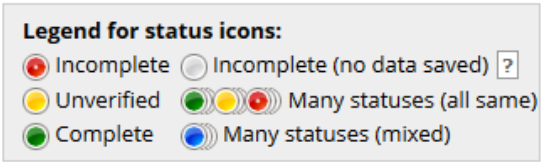
# Optional modules – Repeatable instruments and events




For more details or explanations, please watch the respective training video!



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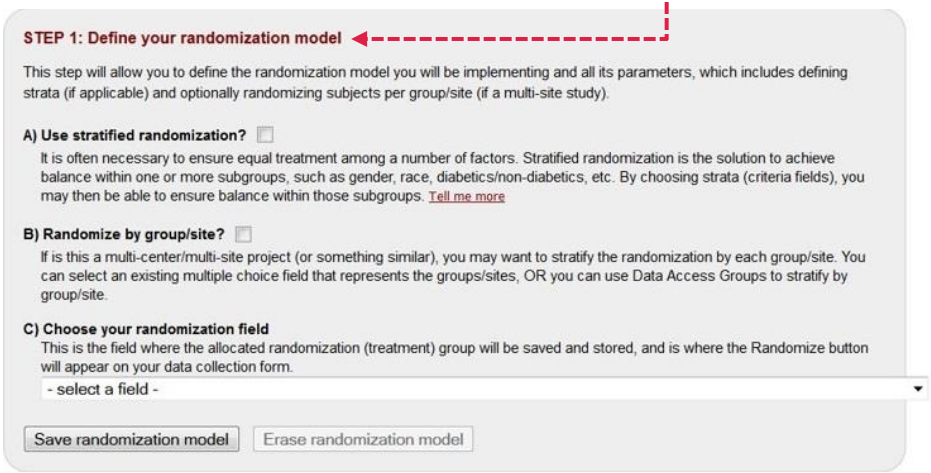
# Optional modules - Randomization module (I)

– **Defining the randomization module**
Configuration by CTU Bern, requires experience
  - Stratification (optional)
  - Group/Study site (optional)
  - Randomization field

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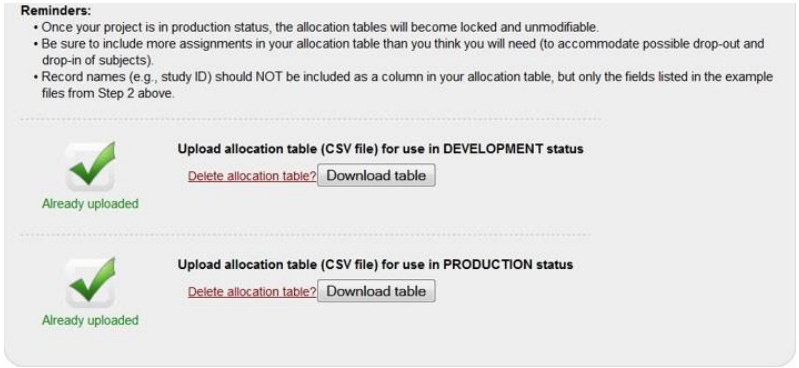
# Optional modules - Randomization module (II)

- **Two randomization lists are uploaded:**
  1 for development mode
  1 for production status

| | A | B |
|---|---|---|
| 1 | random_res | redcap_data_access_group |
| 2 | 2 | 19 |
| 3 | 2 | 19 |
| 4 | 3 | 19 |
| 5 | 3 | 19 |
| 6 | 1 | 19 |
| 7 | 2 | 19 |
| 8 | 1 | 19 |
| 9 | 3 | 19 |
| 10 | 3 | 19 |
| 11 | 2 | 19 |
| 12 | 2 | 19 |
| 13 | 3 | 19 |
| 14 | 1 | 19 |
| 15 | 1 | 19 |
| 16 | 3 | 19 |
| 17 | 1 | 19 |
| 18 | 2 | 19 |
| 19 | 3 | 19 |
| 20 | 1 | 19 |
| 21 | 3 | 20 |
| 22 | 2 | 20 |
| 23 | 1 | 20 |
| 24 | 3 | 20 |




Study sites: Bern (19), Aarau (20)
Stratification factors: 1, 2 or 3

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# Project Setup – Additional customizations

- **Additional Customizations**
  - *Secondary unique field* (e.g. patient ID)
  - Data error resolution systems (Monitoring)
    - Field Comment Log
    - Data Resolution Workflow (user/role-specific monitoring rights)

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# Applications

- **Data Quality and Resolve Issues (=> Monitoring)**
  - Predefined rules to identify missing or inconsistent data
  - Custom rules can be implemented
  - Rules can be executed at data entry (real-time check), separately or for the entire data set at the same time
  - Identified discrepancies are linked to the Data Resolution Workflow

- **Data Exports, Reports, and Stats (=> Analysis)**
  - Data can be exported to Excel and several commonly used statistical softwares (R, STATA, SAS, SPSS)
  - Possibility to build online Reports which can be exported.
  - See next slide: The person who will be analysing the data should be involved early on!

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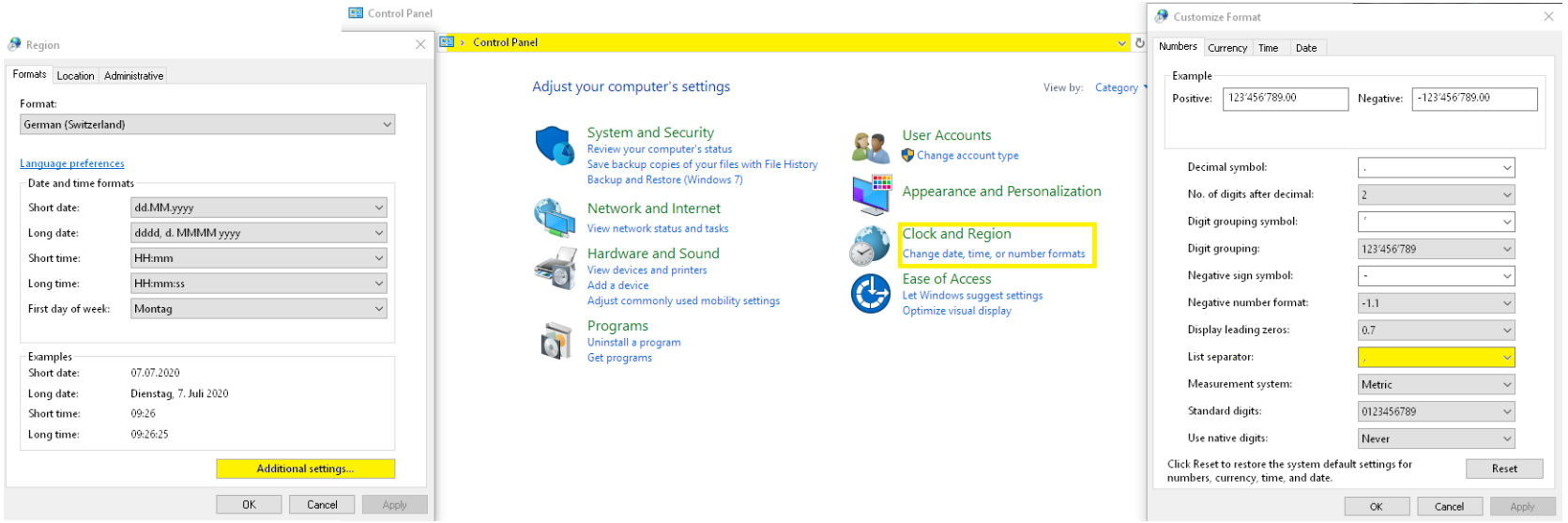
# Important when working with .CSV (Data Dictionary / Export)

Make sure your computer settings are set correctly to read the .csv

Go to control panel – change date, time, or number formats – Additional settings – List separtator needs to be «,» not «;»!



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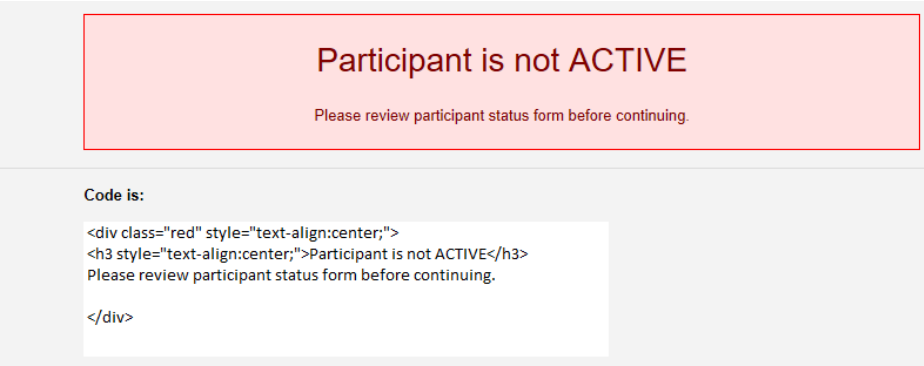
# DB Setup / Data Entry – General Considerations

- Before starting data collection, define when a certain “form status” (e.g. “complete”, “unverified”) should be set and what it should indicate / signal to whom
- Central Data Monitoring: Define early on who will be in charge of frequently checking the data quality during study conduct (i.e. who performs “data quality fules” and emits and closes queries; REDCap offers overviews of missing and erroneous data and you can create your own data quality rules)
- Statistics: Involve the person who will perform the final analysis at an early stage! (Database review regarding primary and secondary outcomes, definition of variable coding)

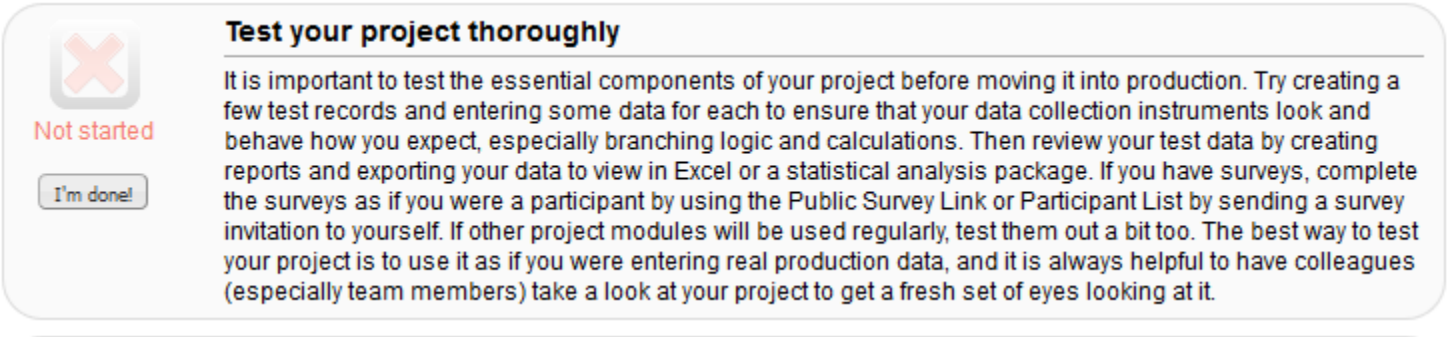
# General: Changing the format (color, text) of the form, field or text display using HTML

- **You can find good examples in “REDCap Help & FAQ”:**

  *https://redcap.vanderbilt.edu/surveys/?s=u7B74tUTsa*



# **Important**: Test the database thoroughly!



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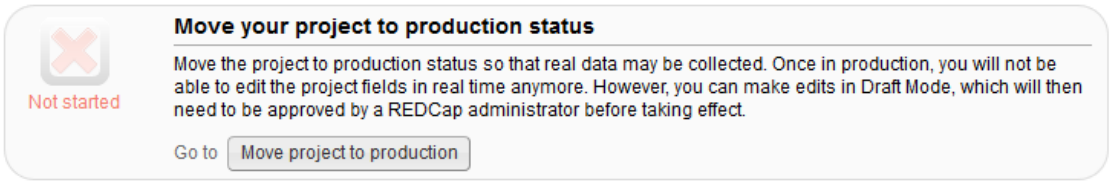
# Database deployment

Moving a project to production status

- A project should only be moved to production mode when it works the way you expect it to i.e. once thoroughly tested.
- **All test data will be deleted.** You are now ready to collect “real” data.
- Once in production mode, minor structural changes can be implemented in Draft Mode (collection of data is still possible while implementing changes in Draft Mode).
- Consider carefully if a change is risky before implementing it! (i.e. if it results in data damage or loss)
- Changes are not executed instantaneously anymore but must be approved by CTU Bern
- In REDCap Light, the CTU Bern does not check the changes!
- Upon request, CTU Bern can perform a technical review of the database for a fee.



# Content

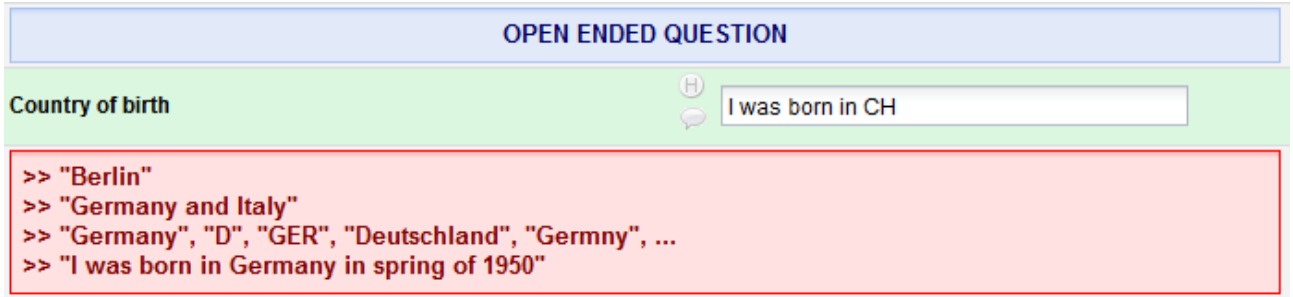
1. Human Research Act (HRA)
2. Clinical Data Management Systems (CDMS)
3. REDCap Services Models at CTU Bern
4. REDCap: how it works…step by step
5. **Principles of CRF Design**

# Principles of CRF Design

- Open-ended vs. closed-ended response format
- Validation and data entry instructions
- Multiple- vs. single-answer fields
- Complete, consistent and accurate datasets

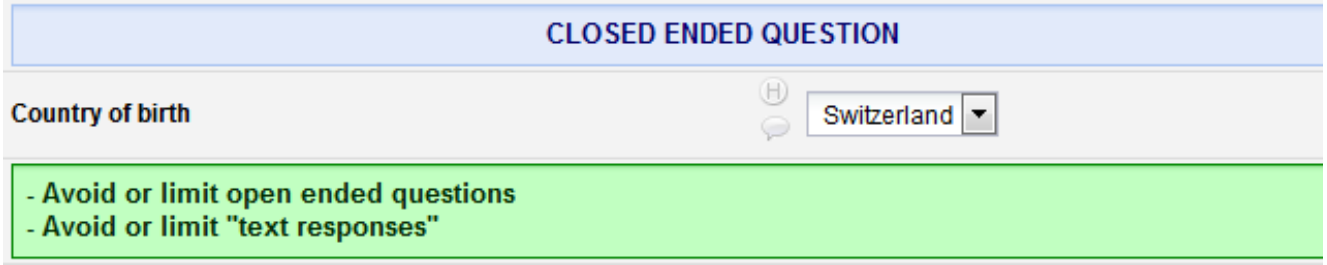
https://redcap.ctu.unibe.ch

# Open Ended Question Format




- Free text entry
- Recording of details
- Time-consuming for participants
- Answers must be prepared for analysis

# Closed Ended Questions

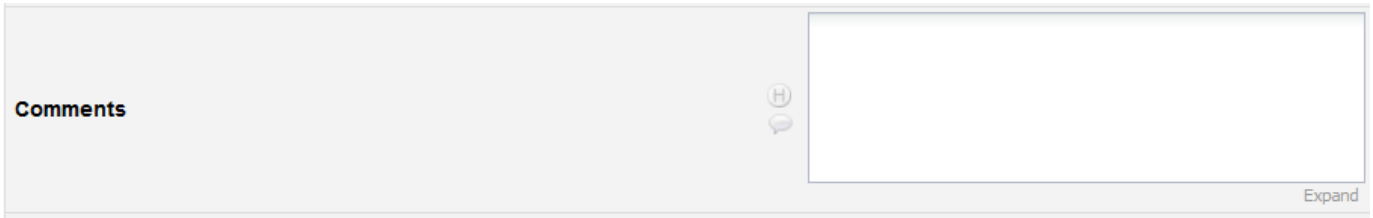



- Pre-defined answer options
- Fast and easy to complete
- Branching logic can be used
- Answers do not need to be prepared for analysis
- Consistency checks can be implemented
- Answer options might not be exhaustive *(=> use ‘other’, ‘none’, ‘unknown’)*

# Open vs. closed ended Questions

**Take Home Message**

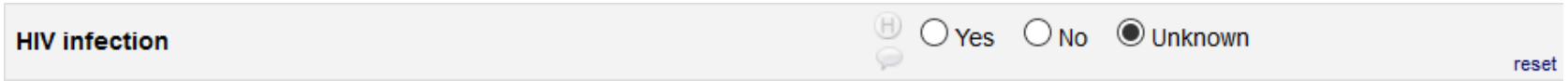
Only use open ended questions if it is not foreseeable how the answers will turn out (e.g., comments).



# Branching & Consistency Checks (completeness, consistency and correctness of dataset)


- What if the participant has never been tested for HIV?
- “No” would mean that the participant has been tested negative for HIV

# Branching & Consistency Checks (completeness, consistency and correctness of dataset)




**Take Home Message**

Always consider providing a response option
“unknown /  not available / not collected”.

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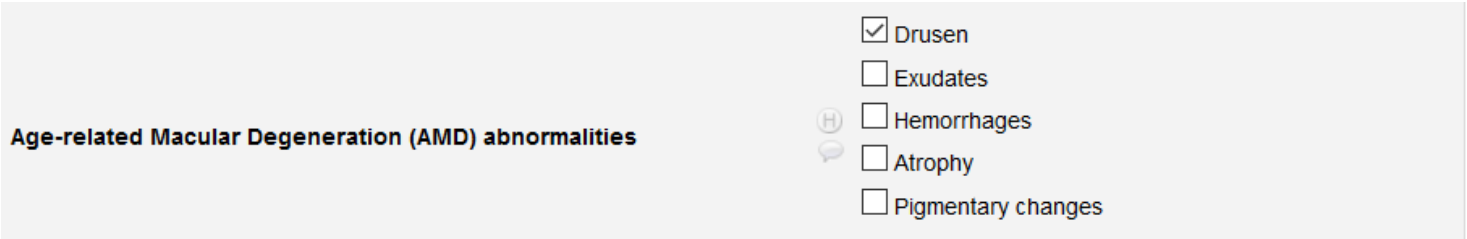
# Branching & Consistency Checks (completeness, consistency and correctness of dataset)




- What do you do if other AMD abnormalities were detected?

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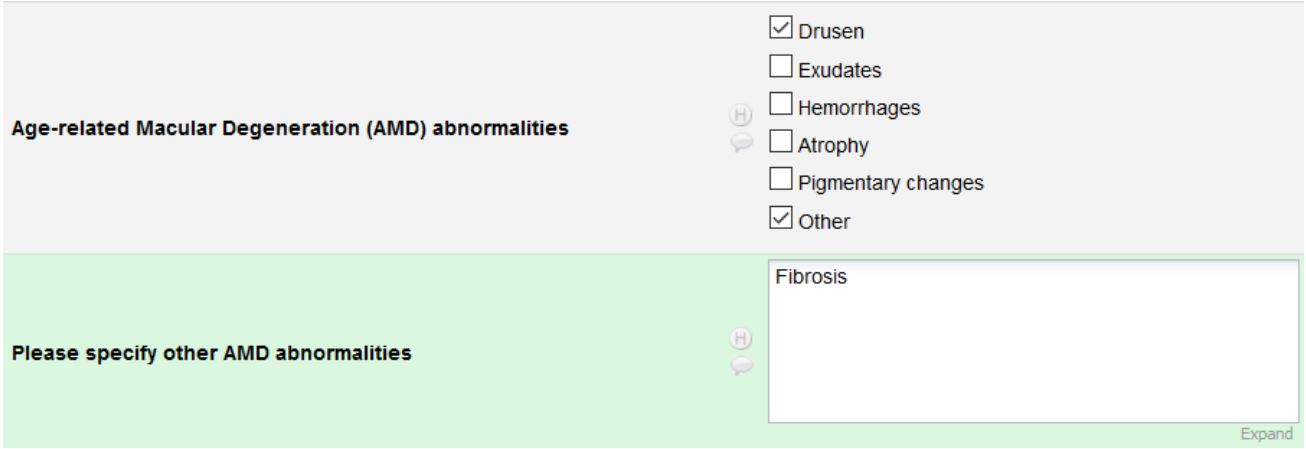
# Branching & Consistency Checks (completeness, consistency and correctness of dataset)




**Take Home Message**

Always consider providing a response option “other“ and link it to a comment field (notes box) using branching logic.

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# Branching & Consistency Checks (completeness, consistency and correctness of dataset)

| | |
|---|---|
| **Do you smoke?** | ○ Yes ○ No reset |
| **How many cigarettes do you smoke a day in average?** | ○ 1-3<br>○ 4-6<br>○ 7-10<br>○ 11-20<br>○ >20 reset |

- What if the participant is a non-smoker?
- The average number of cigarettes smoked per day should only be recorded for smokers.

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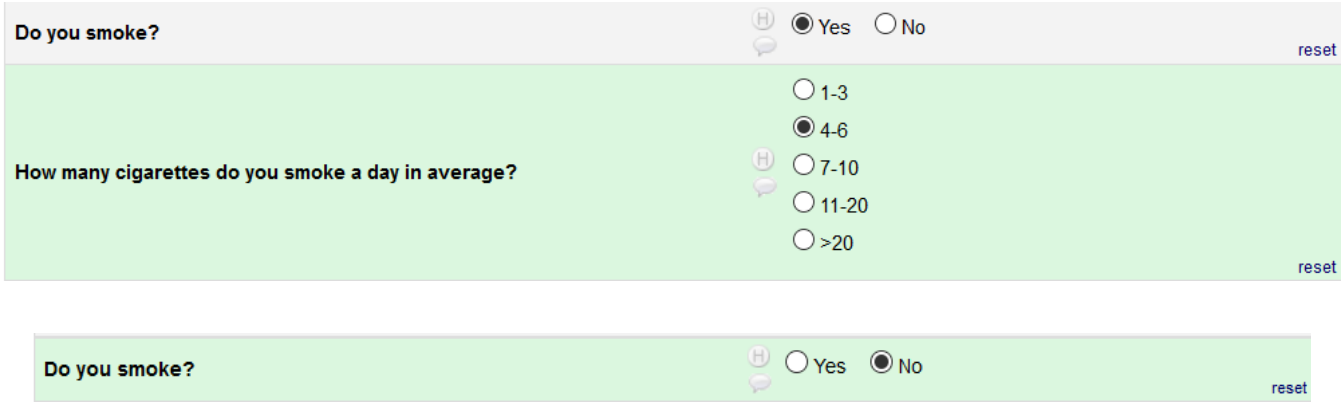
# Branching & Consistency Checks (completeness, consistency and correctness of dataset)




**Take Home Message**

Always consider using REDCap's branching logic to only show the relevant entry fields.

# Validation & Instructions for Data Entry

Numeric fields


**Take Home Message:**

- Add the unit to the field label (e.g. [mmHg]) if applicable
- Define a validation format for all numeric fields (e.g. integer)
- Define value ranges (e.g. min=50, max=250)
- Specify validation format and value range in the field note

# Validation & Instructions for Data Entry

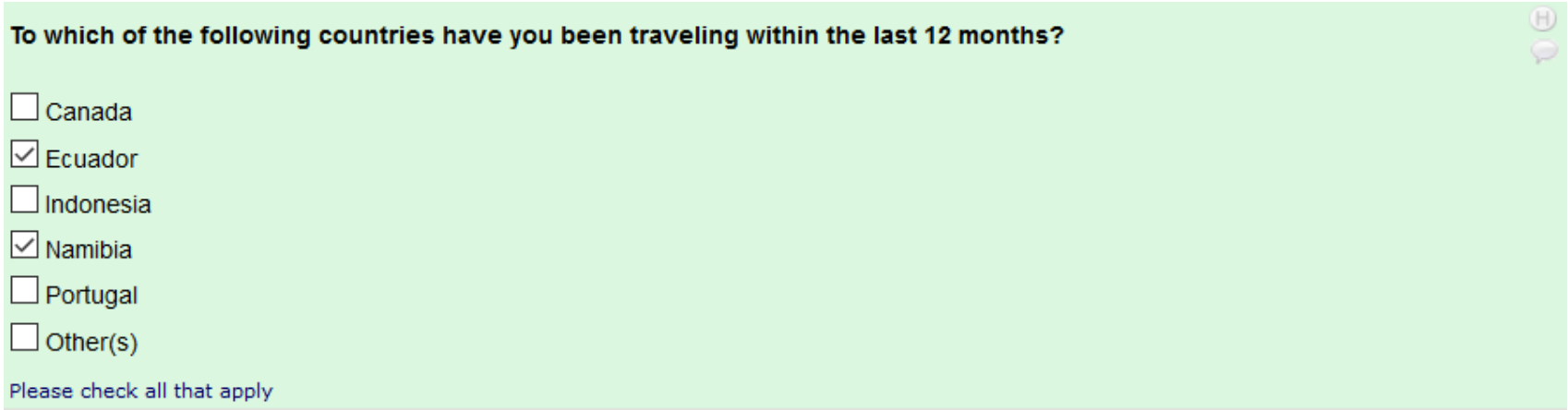
Date Fields:


Format and range in field note

**Take Home Message:**

- Define a validation format for each date field (e.g. D-M-Y)
- Define value ranges (e.g. min=01-01-2017, max=31-12-2019)
- Specify validation format and value range in the field note

# Multiple Choice Questions




- Rapid data collection
- BUT: Can you be sure that the participant has not travelled to Canada in the last 12 months?

# Multiple Choice Questions (single answer)

| To which of the following countries have you been traveling within the last 12 months? | | |
|---|---|---|
| | Yes | No |
| Canada | ○ | ◉ reset |
| Ecuador | ◉ | ○ reset |
| Indonesia | ○ | ◉ reset |
| Namibia | ◉ | ○ reset |
| Portugal | ○ | ◉ reset |
| Other(s) | ○ | ◉ reset |

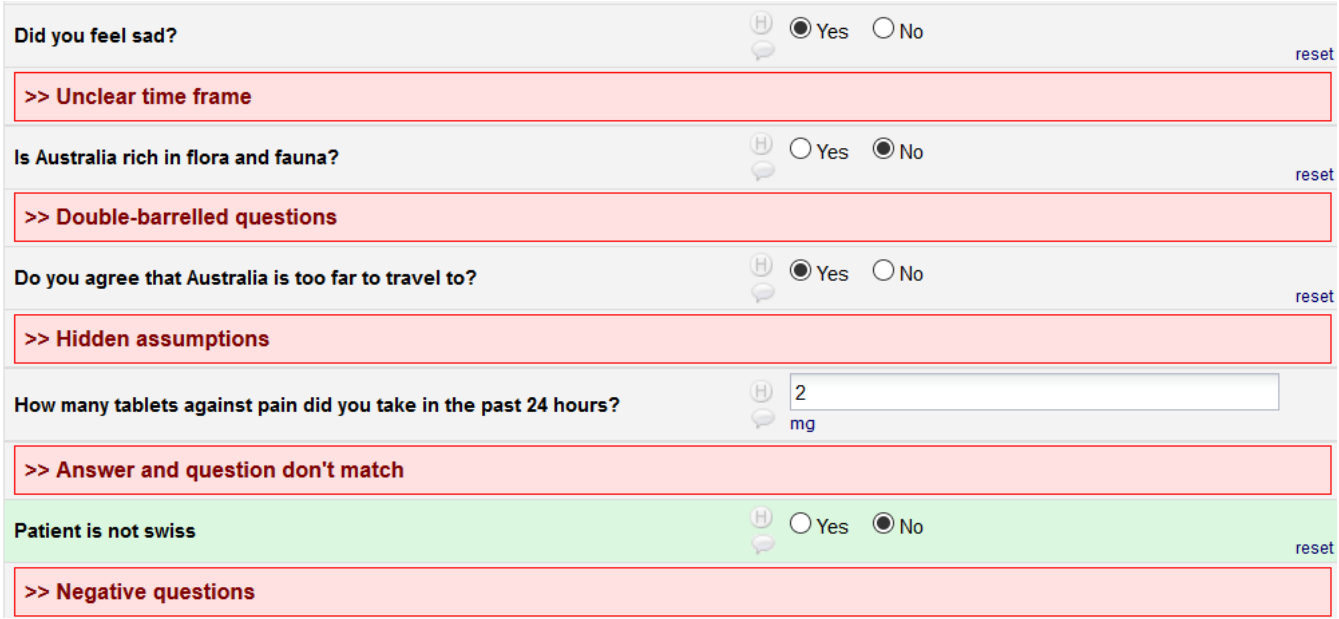
- Slow data entry
- But: Can you be sure that the participant did not travel to Canada in the last 12 months?

# Single vs. Multiple Choice

**Take Home Message**

For primary endpoints, always use (matrices of) single choice answers
(e.g., yes/no radio buttons) instead of multiple choice questions (e.g. check boxes).

# Validation & Instructions for Data Entry - some things to avoid



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# Literature


- Society for Clinical Data Management (SCDM), www.scdm.org
  (e.g. Good Clinical Data Management Practice, GCDMP)
- European Clinical Research Infrastructure Network (ECRIN), www.ecrin.org
  (e.g. Requirements for Certification of ECRIN Data Centers)
- Association for Clinical Data Management (ACDM), www.acdm.org.uk
- Swiss Clinical Trial Organization (SCTO), www.scto.ch
  (e.g. Data Management Guidelines)
- Prokscha, S: Practical Guide to Clinical Data Management, 2012.
  ISBN 978-1-439-84829-6
- McFadden, E: Management of Data in Clinical Trials, 2007. ISBN 978-0-470-04608-1

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# Thank you for your attention!