

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

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

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:

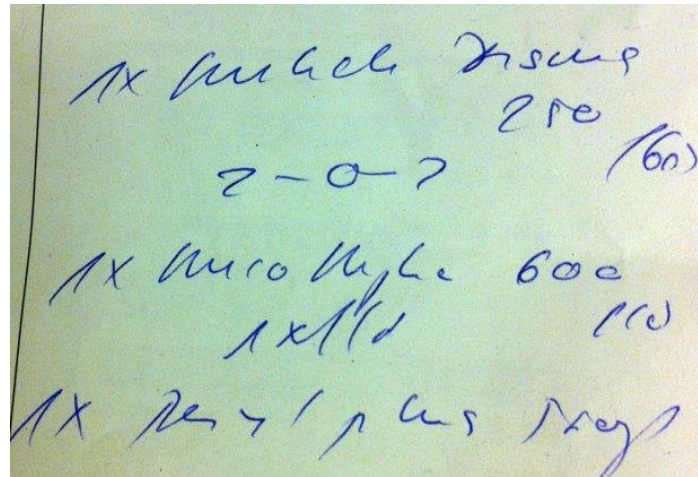
(not subject to Swiss Data Protection Law)

=> 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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5. Principles of CRF Design

- 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

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

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



HRA-compliant CDMS example

- **Research Electronic Data Capture** (<http://project-redcap.org>)
- Web-based Clinical Data Management System
- Developed by Vanderbilt University, Nashville, USA in 2004



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

Additional Service Options
(agreed in the costing)

Statistics

- Randomization list
 - Analysis
- Review of DB

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.

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

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](#)

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

Content

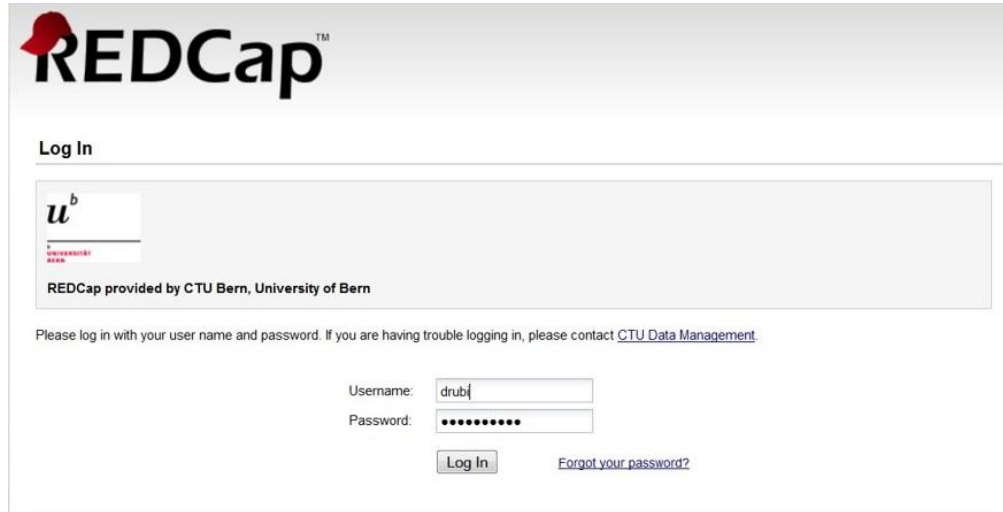
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<https://redcap.ctu.unibe.ch>

Login

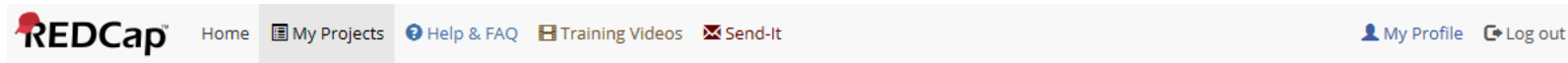
- <https://redcap.ctu.unibe.ch>
- Login = Username (created by CTU DM) + password






The screenshot shows the REDCap login interface. At the top left is the REDCap logo. Below it is a 'Log In' section. Inside this section, there is a box containing the University of Bern logo and the text 'REDCap provided by CTU Bern, University of Bern'. Below this box, there is a message: 'Please log in with your user name and password. If you are having trouble logging in, please contact [CTU Data Management](#).' Underneath the message are two input fields: 'Username:' with the text 'drubj' and 'Password:' with a masked password of ten dots. At the bottom of the form are two buttons: 'Log In' and '[Forgot your password?](#)'.

Homepage

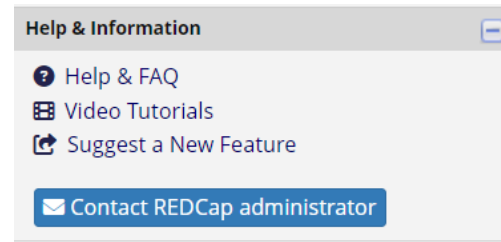
- Home
- My Projects
- Training Resources (Videos)
- Help & FAQ
- Send-It
 - Secure data transfer application
 - For large files and/or files that contain sensitive information



Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

My Projects Organize		Filter projects by title			
Project Title	Records	Fields	Instrument	Type	Status
CTU_Template Database	0	115	6 forms		
	16	154	8 forms 1 survey		

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

A screenshot of the REDCap user management interface. At the top right, there is a dropdown menu labeled 'Upload or download users, roles, and assignments' with a question mark icon. Below this, the section 'Add new users: Give them custom user rights or assign them to a role.' contains two options: 'Add new user' with a green '+ Add with custom rights' button, and 'Assign new user to role' with a green '+ Assign to role' button. The 'Create new roles: Add new user roles to which users may be assigned.' section contains 'Enter new role name' with a blue '+ Create role' button. Below the input field, there is a note: '(e.g., Project Manager, Data Entry Person)'. A green arrow from the text 'CTU Bern' in the list above points to the 'Contact REDCap administrator' button in the screenshot above.

User Management

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

jluethi (Jonas Lüthi)	never	
lbuemann (Laura Büemann)	never	
ymattmann (Yvonne Mattmann)	never	
[account suspended]		

Change user expiration:

31-08-2023 (D-M-Y)

Save Cancel

Editing existing user role "Data Entry"

Basic Privileges

Role name:

Highest level privileges:

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

Other privileges:

- Survey Distribution Tools
- Alerts & Notifications
- Calendar
- Add/Edit/Organize Reports
- Stats & Charts
- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository
- Data Quality
 - Create & edit rules
 - Execute rules
- Data Resolution Workflow
 - No Access
 - View only
 - Open queries only
 - Respond only to opened

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.

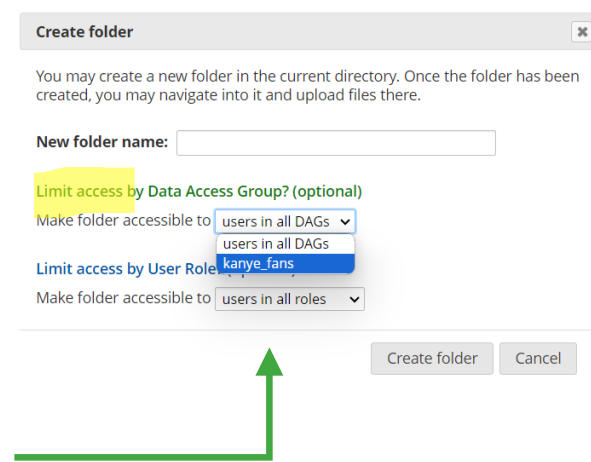
	Data Viewing Rights			Data Export Rights			
	No Access (Hidden)	Read Only	View & Edit	No Access	De-Identified*	Remove All Identifier Fields	Full Data Set
pf_rc_export	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Basic Service Conversion (survey)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Costing	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Contract	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
DB Lock	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Final Export	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Deadline	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Completed	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input 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.

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.



+ **Create new groups:** Add new data access groups to which users may be assigned. Upload or download DAGs/User-DAG assignments

+ Add Group

Assign user to a group: Users may be assigned to any data access group. To assign users to multiple groups, use the DAG Switcher at the bottom.


Assign user to Assign

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]	jlueithi (Jonas Lüthi), joensi_test (Jönsi Test), jonas_test2 (Jonas Luethi) * Can view ALL records	11			

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?*)




Complete!

[Not complete?](#)

Main project settings


Use longitudinal data collection with repeating forms? [?](#)

Use surveys in this project? [?](#)

 [VIDEO: How to create and manage a survey](#)

Project setup – CRF creation

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






Not started




I'm done!

Design your data collection instruments & enable your surveys

Add or edit fields on your data collection instruments (survey and forms). This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). You may then enable your instruments to be used as surveys in the Online Designer. 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

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).

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)

Field Label: Record ID [How to use Piping](#)

Variable Name (utilized during data export): record_id Enable auto naming of variable based upon its Field Label?
ONLY letters, numbers, and underscores

Validation? (optional): None

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

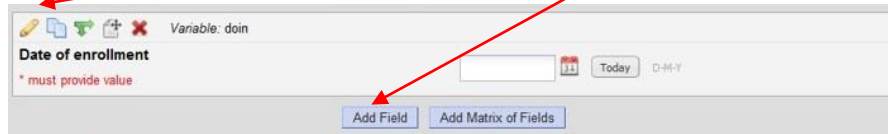
NOTE: This field is the record ID field, which is the first field in the project. This field is special because it is used to store the names of the records in your project. Thus the record ID field cannot be deleted or moved but only edited. If you wish, you may change its field label or even its variable name. Additionally, since auto-numbering for records has been enabled, the validation drop-down list has been disabled.

Save Cancel

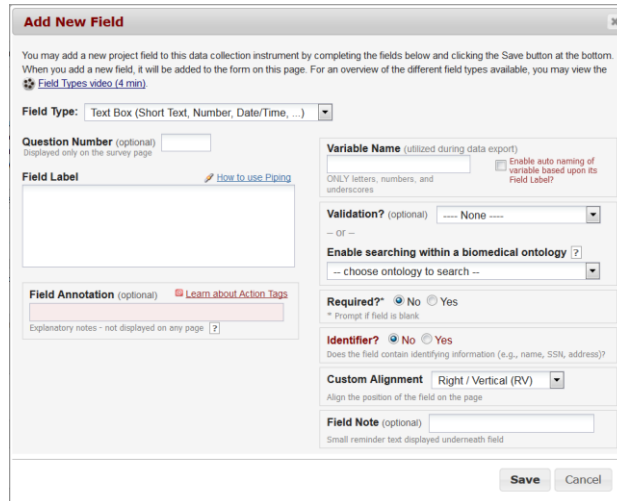
- If you want to collect an additional identifier (e.g. patient ID), please create a new field (and set it as a secondary unique field).

Online Designer – Field creation

Edit/Add Field



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



The 'Add New Field' dialog box contains the following fields and options:

- Field Type:** Text Box (Short Text, Number, Date/Time, ...)
- Question Number (optional):** []
- Field Label:** []
- Field Annotation (optional):** []
- Variable Name (utilized during data export):** []
- Validation? (optional):** --- None ---
- Enable searching within a biomedical ontology?** []
- Required?*** No Yes
- Identifier?** No Yes
- Custom Alignment:** Right / Vertical (RV)
- Field Note (optional):** []

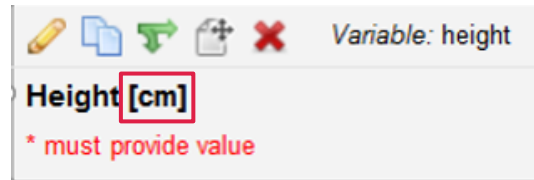
Field creation – Pre-defined field types

- **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.

Field Label	 How to use Piping
Severity	
Choices (one choice per line)	Copy existing choices
1, Mild (>5%)	
2, Moderate (1-5%)	
3, Severe (< 1%)	

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!)

Validation? (optional)

Date (D-M-Y)

Minimum: 01-01-2015

Maximum: 31-12-2015

– 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

Validation? (optional) Integer

Minimum: 100

Maximum: 250

    Variable: height

Height [cm]

* must provide value

Integer, min=100, max=250

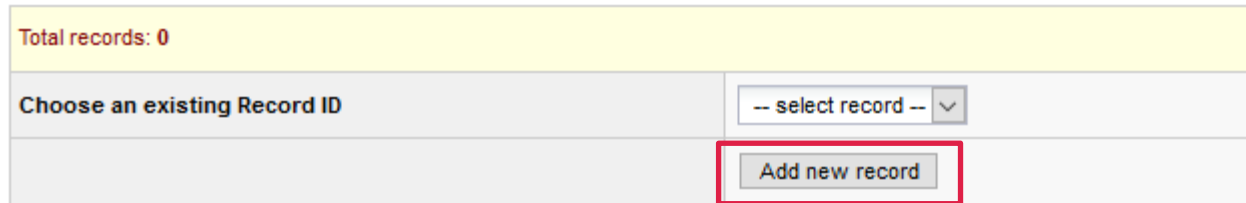
Data Collection – Add / Edit Records

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



Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.



A screenshot of the REDCap 'Add / Edit Records' form. The form has a yellow header bar that says 'Total records: 0'. Below this, there is a section titled 'Choose an existing Record ID' which contains a drop-down menu with the text '-- select record --' and a downward arrow. Below the drop-down menu is a button labeled 'Add new record', which is highlighted with a red rectangular box.

Data Collection – Record Status Dashboard

– 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:

The screenshot shows the 'Setup' phase in REDCap Online Designer. At the top, a variable named 'ice_cream' is defined with three radio button options: 'Chocolate', 'Vanilla', and 'Strawberry'. Below this, a question is created: 'How much do you love [ice_cream] ice cream?'. The response options are 'Hate it', 'Indifferent', and 'I love [ice_cream]!'. A slider control is shown below the text, with a blue bar and a slider knob. A red dashed line indicates the flow of data from the 'ice_cream' variable to the question text and the response options.

Data Entry:

The screenshot shows the 'Data Entry' phase. The question 'What is your favorite ice cream?' is now answered with 'Chocolate', which is highlighted with a red box. The question 'How much do you love Chocolate ice cream?' is shown below. The response options are 'Hate it', 'Indifferent', and 'I love Chocolate!'. A slider control is shown below the text, with a blue bar and a slider knob. A red dashed line indicates the flow of data from the 'Chocolate' selection to the question text and the response options.

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.

The screenshot displays two form fields in the REDCap Online Designer interface. The top field is for 'sex' with radio buttons for 'Male' and 'Female'. The bottom field is for 'pregnancy_test_res_scr' with radio buttons for 'Positive result', 'Negative result', and 'Not applicable (patient not of child-bearing potential)'. A red dashed line connects the 'Female' radio button to the 'Pregnancy test (serum)' field, indicating that the pregnancy test field is only displayed when the patient is female. The 'Pregnancy test (serum)' field also has a note: 'Positive result exclusive at Screening'.

Pregnancy test result should only be displayed for female patients!

Online Designer – Branching logic II

Variable: pregnancy_test_res_scr [Branching logic exists]

Pregnancy test (serum)
* must provide value

Positive result
 Negative result
 Not applicable (patient not of child-bearing potential)

reset

Positive result exclusive at Screening

– **Branching logic** can be implemented by:

- programming

Advanced Branching Logic Syntax

Show the field ONLY if...

[sex] = '2'

- “drag & drop”

Show the field ONLY if...

ALL below are true

ANY below are true

sex = Female (2) ❌

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

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.

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)

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

Complete! Not complete?

Arm 1: Patient visits +Add New Arm

Arm name: **Patient visits** [Rename Arm 1](#)

	Event #	Event Name	Custom Event Label (optional)	Unique event name (auto-generated)
	1	Screening visit		screening_visit_arm_1
	2	Baseline visit		baseline_visit_arm_1
	3	Week 52 visit		week_52_visit_arm_1
	4	EOS visit		eos_visit_arm_1
	5	Injection 2		injection_2_arm_1
	6	Injection 3		injection_3_arm_1

Project Setup – Visit plan

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

Define your events and designate instruments for them

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

Go to or

[Not complete?](#)

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				✓		

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)**

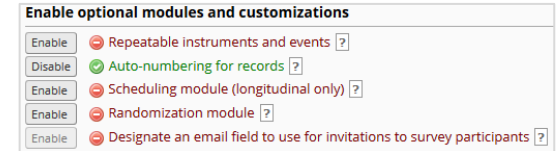
- For longitudinal projects only

- **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



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 --	<input type="checkbox"/> Demographics <input type="checkbox"/> Clinical Data <input type="checkbox"/> Laboratory Data	<input type="text"/> <input type="text"/> <input type="text"/>
✓ Follow-up Visit	Repeat Entire Event (repeat	<input checked="" type="checkbox"/> Clinical Data <input checked="" type="checkbox"/> Laboratory Data	<input type="text"/> <input type="text"/>
✓ Medication	Repeat Instruments (repeat	<input checked="" type="checkbox"/> Medication	[med_name], [med_dose] [med_uni]
✓ Adverse Events	Repeat Instruments (repeat	<input checked="" type="checkbox"/> Adverse Event	[ae_description], [ae_date]

Optional modules – Repeatable instruments and events

Record ID 1

Data Collection Instrument	Baseline Visit	Follow-up Visit 09-05-2018 (#1)	+ Add new 10-06-2018 (#2)	Medication	Adverse Events
Demographics	<input type="radio"/>				
Clinical Data	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>		
Laboratory Data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Medication				<input checked="" type="radio"/> +	
Adverse Event					<input checked="" type="radio"/> +
Delete all data on event:		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Will add a new event

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

Repeating Instruments

Medication		
Medication		
1	<input checked="" type="radio"/>	Aspirin, 300 mg
2	<input checked="" type="radio"/>	Solmucol,
+ Add new		

Adverse Event		
Adverse Events		
1	<input checked="" type="radio"/>	Fever, 09-05-2018
2	<input checked="" type="radio"/>	Headache, 11-05-2018
+ Add new		

Will add a new instrument

Legend for status icons:

- Incomplete Incomplete (no data saved) ?
- Unverified Many statuses (all same)
- Complete Many statuses (mixed)

Optional modules - Randomization module (I)

– Defining the randomization module

Configuration by CTU Bern, requires experience

- Stratification (optional)
- Group/Study site (optional)
- Randomization field



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

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 (criteria fields), you may then be able to ensure balance within those subgroups. [Tell me more](#)

B) Randomize by group/site?

If is this 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.

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 -

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

Reminders:

- Once your project is in production status, the allocation tables will become locked and unmodifiable.
- Be sure to include more assignments in your allocation table than you think you will need (to accommodate possible drop-out and drop-in of subjects).
- 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 from Step 2 above.

Upload allocation table (CSV file) for use in DEVELOPMENT status
[Delete allocation table?](#)

Upload allocation table (CSV file) for use in PRODUCTION status
[Delete allocation table?](#)

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

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)

Enable optional modules and customizations

Complete!

Not complete?

Disable	<input checked="" type="checkbox"/> Auto-numbering for records ?
Enable	<input type="checkbox"/> Scheduling module (longitudinal only) ?
Disable	<input checked="" type="checkbox"/> Randomization module ?
Enable	<input type="checkbox"/> Designate an email field to use for invitations to survey participants ?

Additional customizations

Applications

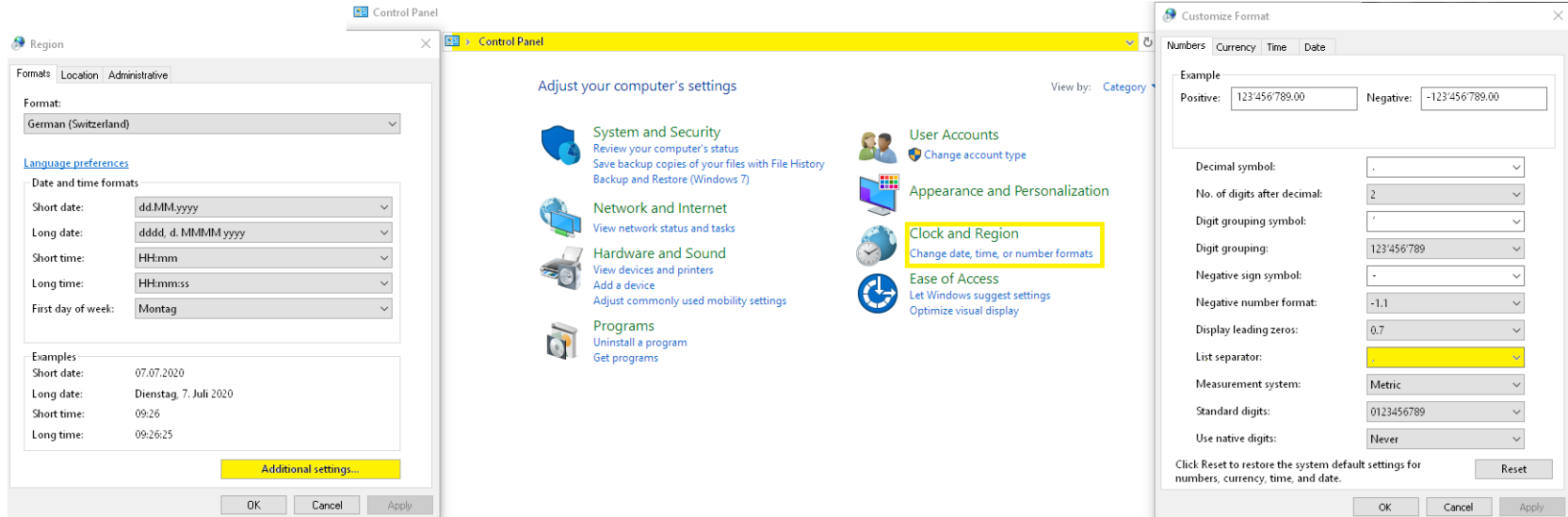
- **Data Quality and Resolve Issues (=> Monitoring)**
 - Predefined rules to identify missing or inconsistent data
 - Custom rules can be implemented
 - Rules can be executed at data entry (real-time check), separately or for the entire data set at the same time
 - Identified discrepancies are linked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

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 separator needs to be «,» not «;»!



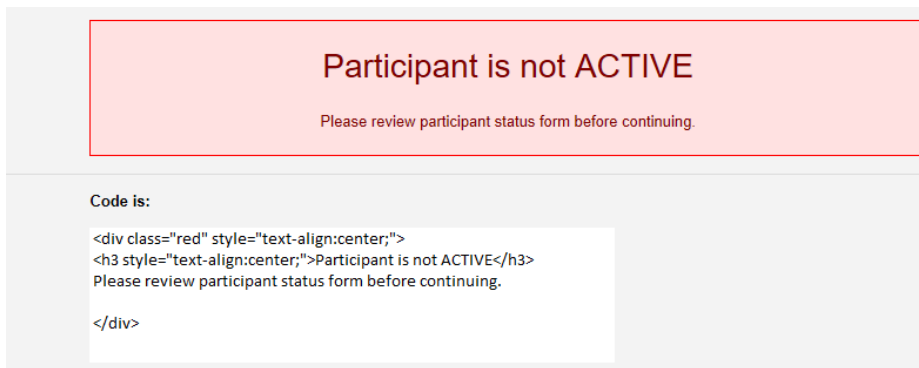
DB Setup / Data Entry – General Considerations

- 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 rules” 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>



The image shows a screenshot of a REDCap interface. At the top, there is a red-bordered box with a light red background. Inside this box, the text reads: "Participant is not ACTIVE" in a bold, dark red font, followed by "Please review participant status form before continuing." in a smaller, dark red font. Below this box, the text "Code is:" is displayed. Underneath, a white box contains the following HTML code:

```
<div class="red" style="text-align:center;">  
<h3 style="text-align:center;">Participant is not ACTIVE</h3>  
Please review participant status form before continuing.  
</div>
```

Important: Test the database thoroughly!



Not started

I'm done!


Test your project thoroughly

It is important to test the essential components of your project before moving it into production. Try creating a few test records and entering some data for each to ensure that your data collection instruments look and behave how you expect, especially branching logic and calculations. Then review your test data by creating reports and exporting your data to view in Excel or a statistical analysis package. If you have surveys, complete the surveys as if you were a participant by using the Public Survey Link or Participant List by sending a survey invitation to yourself. If other project modules will be used regularly, test them out a bit too. The best way to test your project is to use it as if you were entering real production data, and it is always helpful to have colleagues (especially team members) take a look at your project to get a fresh set of eyes looking at it.

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.



Not started

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 then need to be approved by a REDCap administrator before taking effect.

Go to [Move project to production](#)

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

OPEN ENDED QUESTION	
Country of birth	<input type="text" value="I was born in CH"/>
<p>>> "Berlin" >> "Germany and Italy" >> "Germany", "D", "GER", "Deutschland", "Germny", ... >> "I was born in Germany in spring of 1950"</p>	

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

Closed Ended Questions

CLOSED ENDED QUESTION

Country of birth 

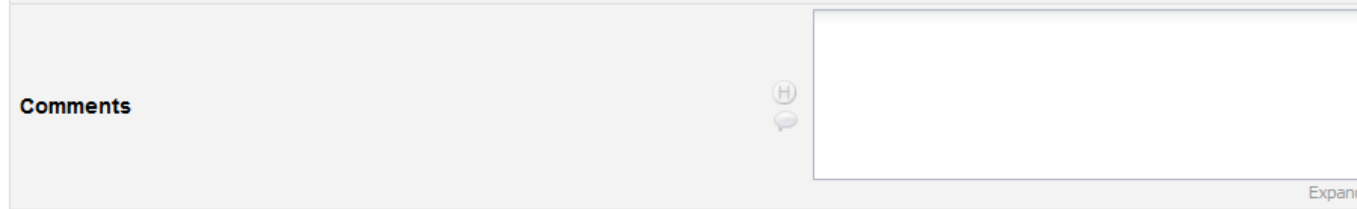
- Avoid or limit open ended questions
- Avoid or limit "text responses"

- 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).



The image shows a screenshot of a form element. On the left, the word "Comments" is written in a bold, black font. To its right, there are two small circular icons: one with a plus sign and one with a speech bubble. Further right is a large, empty rectangular text input box. At the bottom right corner of this input box, the word "Expand" is written in a small, grey font.

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

HIV infection  Yes No reset

- 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)

HIV infection Yes No Unknown [reset](#)

Take Home Message

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

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

Age-related Macular Degeneration (AMD) abnormalities

- Drusen
- Exudates
- Hemorrhages
- Atrophy
- Pigmentary changes

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

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

The screenshot shows a CRF form with two sections. The top section, titled "Age-related Macular Degeneration (AMD) abnormalities", has a light grey background and contains a list of checkboxes: "Drusen" (checked), "Exudates", "Hemorrhages", "Atrophy", "Pigmentary changes", and "Other" (checked). To the right of the list are two small icons: a speech bubble with an 'H' and a speech bubble. The bottom section, titled "Please specify other AMD abnormalities", has a light green background and contains a text input field with the word "Fibrosis" entered. To the right of the input field are the same two icons as in the top section. At the bottom right of the green section is an "Expand" button.

Take Home Message

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

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
 4-6
 7-10
 11-20
 >20 reset

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

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 4-6 7-10 11-20 >20 reset

Do you smoke? Yes No reset

Take Home Message

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

Validation & Instructions for Data Entry

Numeric fields

Systolic blood pressure	<input type="text" value="1200"/>
Systolic blood pressure [mmHg]	<input type="text" value="120"/> Integer, min=50, max=250

Unit in field label

Validation and range in field note

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:

Date of baseline visit 12-06-2117

Date of baseline visit 12-06-2017 Today D-M-Y
DD-MM-YYYY, min=01-01-2017, max=31-12-2018

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

To which of the following countries have you been traveling within the last 12 months?













- Canada
- Ecuador
- Indonesia
- Namibia
- Portugal
- Other(s)

Please check all that apply

- 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	 	<input type="radio"/>	<input checked="" type="radio"/>	reset
Ecuador	 	<input checked="" type="radio"/>	<input type="radio"/>	reset
Indonesia	 	<input type="radio"/>	<input checked="" type="radio"/>	reset
Namibia	 	<input checked="" type="radio"/>	<input type="radio"/>	reset
Portugal	 	<input type="radio"/>	<input checked="" type="radio"/>	reset
Other(s)	 	<input type="radio"/>	<input checked="" type="radio"/>	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

Did you feel sad?	<input type="radio"/> Yes <input type="radio"/> No	reset
>> Unclear time frame		
Is Australia rich in flora and fauna?	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
>> Double-barrelled questions		
Do you agree that Australia is too far to travel to?	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
>> Hidden assumptions		
How many tablets against pain did you take in the past 24 hours?	<input type="text" value="2"/> mg	
>> Answer and question don't match		
Patient is not swiss	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
>> Negative questions		

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.eclin.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

Thank you for your attention!