

# 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

# Handling of health-related personal data according to the Human Research Act

## The Human Research Act, HRA, 01.01.2014, ClinO, Art. 18 / HRO, Art. 5

- a) Restrict the handling of health-related personal data to those persons who require this data to fulfill their duties  
=> **Personalized Login**
- b) Prevent unauthorized or accidental disclosure, alteration, deletion and copying of the health-related personal data  
=> **Control of access levels**
- c) Document all processing operations which are essential to ensure traceability  
=> **Audit-Trail**

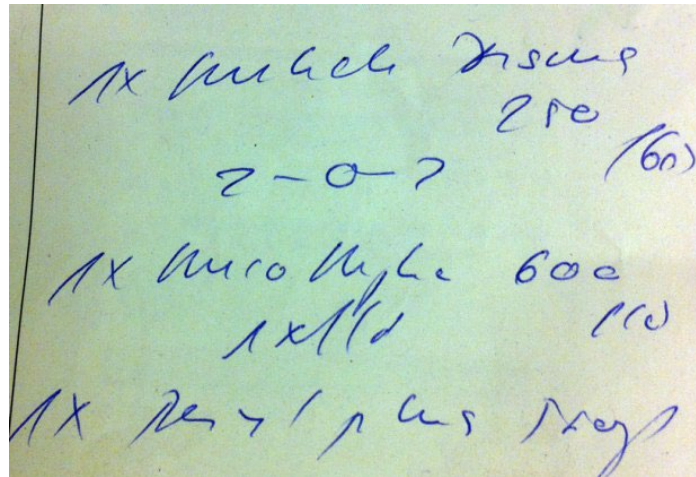
# Excel is not a HRA-compliant solution

- a) Handling of health-related personal data must be restricted to the individuals who need these data to fulfill their duties  
=> **Login** (password protection, no personalized access)
- b) Unauthorized or accidental disclosure, alteration, deletion and copying of the health-related personal data must be prevented  
=> **Control of access levels** (not possible)
- c) All processing operations which are essential to ensure traceability must be documented  
=> **Audit-Trail** (no audit trail available)

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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

# CDMS main characteristics

- Project setup interface
- Data entry interface
- Data entry status overview
- User management interface
- Audit trail
- Predefined data types ensuring controlled data entry
- Real time data validation
- Standard export formats (CSV/Excel, STATA, SAS, SPSS, R)

# HRA-compliant CDMS used at CTU Bern

- **REDCap** - recommended for simple study designs
  - Simple visit plan (i.e. no/few unscheduled visits, no treatment arms)
  - Simple data monitoring functionalities
- **secuTrial** - recommended for more complex study designs
  - Minimization (i.e. adaptive randomization)
  - Complex visit plan (i.e. unscheduled visits, treatment arms, etc.)
  - Complex data monitoring functionalities





# REDCap, a web-based CDMS

- **R**esearch **E**lectronic **D**ata **C**apture
- Developed by Vanderbilt University, Nashville, USA in 2004
- Compliant to GCP & HRA
- Free license for non-commercial purposes
- Very active developer and user community



# REDCap – Key facts

- Easy to learn and easy to work with
- Offline CRF creation
- Patient-completed surveys
- Data import (from Excel)
- Offline data entry (mobile App)
- Double data entry (inexperienced staff, poor eCRF quality)
- Online randomization (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
  - Costs: starting from 1500.- CHF
  - Annual costs: user management and support after deployment

# REDCap Light\*

\* Available for Bern

## Light Service Package

- IT infrastructure (daily back-up, secure system, frequent updates)
- Attendance of our monthly REDCap training sessions (2 hours)
  - Deployment of database
  - Costs: starting from 1500.- CHF
- Annual costs: user management 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.

# 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](http://www.ctu.unibe.ch)
- Data Management Support  
[ctu-datamanagement.dcr@unibe.ch](mailto:ctu-datamanagement.dcr@unibe.ch)



# CTU Bern: Data Management Division



Muriel  
Helmers



Miriam  
Wegmann



Eva  
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Dominik  
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Mario  
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Pelzer



Sheila  
Appadoo



Anna  
Glenck



Flurina  
Jenal



Laura  
Bünemann

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4. **REDCap: how it works...step by step**
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<https://redcap.ctu.unibe.ch>

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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>

# Literature

- Society for Clinical Data Management (SCDM), [www.scdm.org](http://www.scdm.org)  
(e.g. Good Clinical Data Management Practice, GCDMP)
- European Clinical Research Infrastructure Network (ECRIN), [www.ecriin.org](http://www.ecriin.org)  
(e.g. Requirements for Certification of ECRIN Data Centers)
- Association for Clinical Data Management (ACDM), [www.acdm.org.uk](http://www.acdm.org.uk)
- Swiss Clinical Trial Organization (SCTO), [www.scto.ch](http://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!**

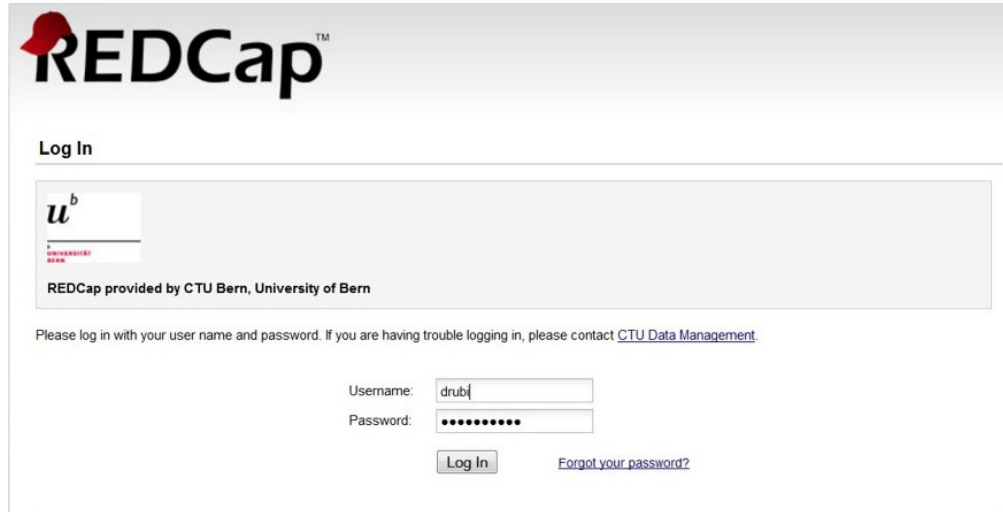
# Addendum I

## REDCap: How it works... Step by step



# Login

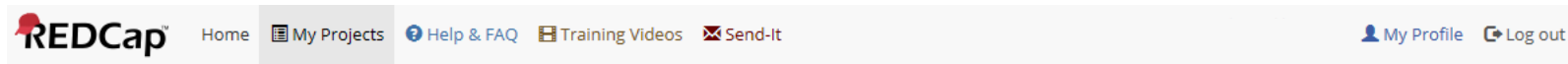
- <https://redcap.ctu.unibe.ch>
- Login = Username + password



The screenshot shows the REDCap login interface. At the top left is the REDCap logo. Below it is a 'Log In' section with a header. Inside this section is a box containing the University of Bern logo and the text 'REDCap provided by CTU Bern, University of Bern'. Below this box is a message: 'Please log in with your user name and password. If you are having trouble logging in, please contact [CTU Data Management](#).' There are two input fields: 'Username:' with the text 'drubj' and 'Password:' with masked characters. Below the fields 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 heavy files or/and 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 <span>Organize</span>		Filter projects by title			
Project Title	Records	Fields	Instrument	Type	Status
<a href="#">CTU_Template Database</a>	0	115	6 forms		
	16	154	8 forms 1 survey		

# 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

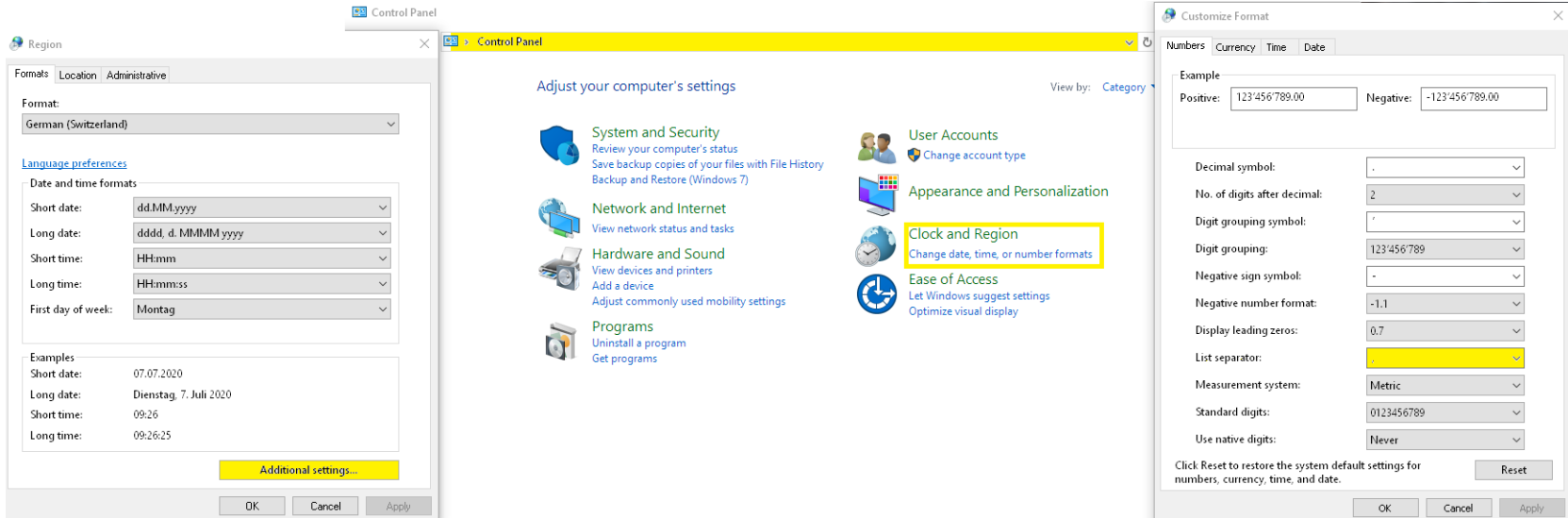
Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been tagged?

Learn how to use  Smart Variables  Piping  @ Action Tags

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

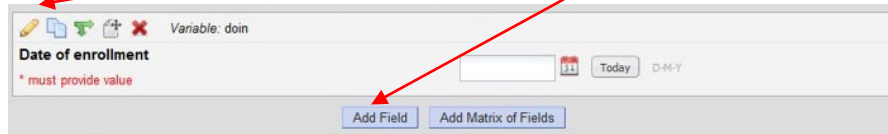
Make sure your computer settings are set correctly to read the .csv

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

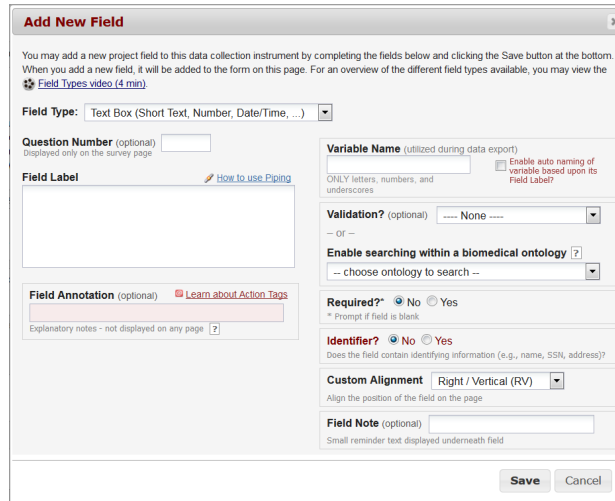


# Online Designer – Field creation

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):** [input field]
- Field Label:** [input field]
- Field Annotation (optional):** [input field]
- Variable Name (utilized during data export):** [input field]
- Validation? (optional):** [dropdown menu]
- Enable searching within a biomedical ontology?** [checkbox]
- Required?\*** [radio buttons: No, Yes]
- Identifier?** [radio buttons: No, Yes]
- Custom Alignment:** [dropdown menu]
- Field Note (optional):** [input field]

Buttons: Save, Cancel

# Field creation – Predefined field types

- **Text Box, validated**
  - Numeric fields (validation required)
  - Dates (validation required)
- **Text Box, unvalidated\***: single-line text box
- **Notes Box\***: large text box for longer text
- **Dropdown List / Radio Buttons**: multiple choices, single answer
- **Checkboxes\***: multiple answers possible
- **Calculated Fields\***: perform calculations (numbers/dates only)
- **File Upload**: document upload, e.g. PDF file (light 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 shall be recorded, indicate the **unit** in square brackets:






# Field creation – Choices

## CTU Standard Coding

- **Multiple-choices fields**  
code first choice as 1, increment by 1 with every added choice
- **Special values**
  - 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	 <a href="#">How to use Piping</a>
Severity	
<b>Choices (one choice per line)</b>	<a href="#">Copy existing choices</a>
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 autonaming)
- 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

## – Main validation formats

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

Validation? (optional)  
Date (D-M-Y) ▼

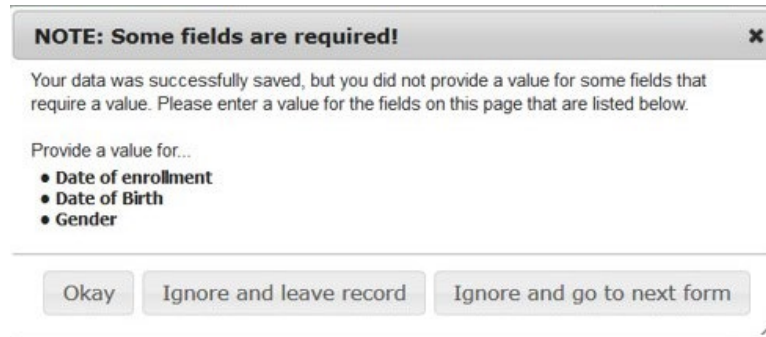
Minimum: 01-01-2015  
Maximum: 31-12-2015

## – Range values (for numeric and date fields only)

Add min. and max. range values to prevent erroneous data entry

# Field creation – Required fields & Identifiers

- **Required fields:** If one or several required fields have no value while saving your data entry form, REDCap will send you a warning 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)  ▼

Minimum:

Maximum:

     Variable: height

**Height [cm]**

\* must provide value Integer, min=100, max=250

# Online Designer – Piping

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

Setup:

The screenshot shows the 'Setup' phase in the REDCap Online Designer. It features two question fields. The first field is a radio button question: 'What is your favorite ice cream?' with options 'Chocolate', 'Vanilla', and 'Strawberry'. A red dashed box highlights the variable name 'ice\_cream' in the 'Variable:' field above the question. A red dashed arrow points from this box to the second field. The second field is a slider question: 'How much do you love [ice\_cream] ice cream?'. The slider has labels 'Hate it', 'Indifferent', and 'I love [ice\_cream]!'. A red dashed arrow points from the 'ice\_cream' variable in the first field to the '[ice\_cream]' placeholder in the second field's text and also to the 'I love [ice\_cream]!' label on the slider.

Data Entry:

The screenshot shows the 'Data Entry' phase. The first question is 'What is your favorite ice cream?' with radio buttons for 'Chocolate', 'Vanilla', and 'Strawberry'. The 'Chocolate' option is selected and highlighted with a red dashed box. A red dashed arrow points from this box to the second question. The second question is 'How much do you love Chocolate ice cream?'. The slider has labels 'Hate it', 'Indifferent', and 'I love Chocolate!'. A red dashed arrow points from the 'Chocolate' selection in the first question to the 'Chocolate' text in the second question's text and also to the 'I love Chocolate!' label on the slider.

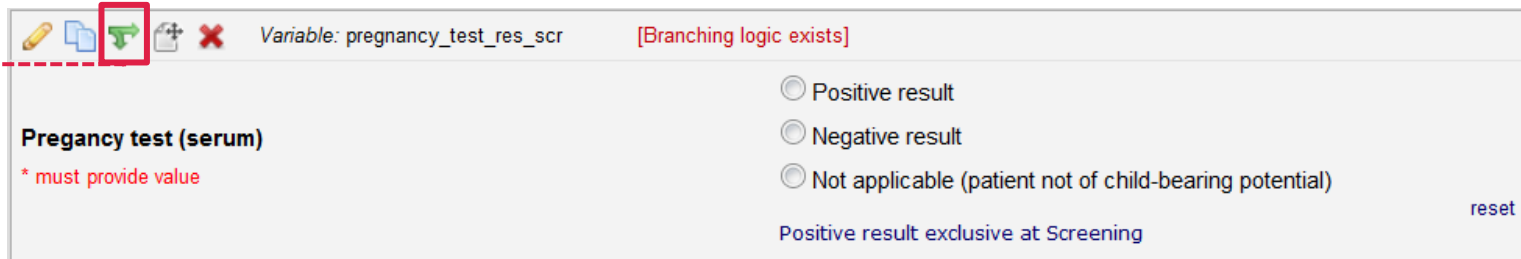
# Online Designer – Branching logic I

- **Branching logic:** Branching logic enables you to display a field only if a specific (set of) condition 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 in the top field to the 'Pregnancy test (serum)' field in the bottom field, indicating that the pregnancy test field is only displayed when the patient is female. The bottom field also includes a note '[Branching logic exists]' and a 'Positive result exclusive at Screening' label.

Pregnancy test result should only be displayed for female patients!

# Online Designer – Branching logic II



– **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 cannot be tested without entering test data (Rules can however now be tested within the Online Designer)



# 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 (i.e. patient ID), please create a new field (and, eventually, set it as secondary unique field).

# Project setup – Define my events

- For longitudinal data collection only
  - Define your events by entering their name
  - 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

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 – Event table

- Designate the created Instruments (CRF) 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		✓				
Afibrcept 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)**

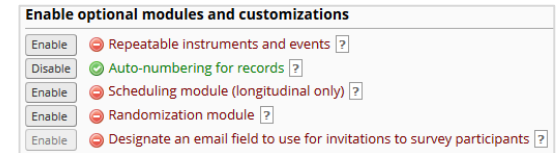
- For longitudinal projects only

- **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 that shall be repeatable**
  - Not repeating vs. Repeat Instruments vs. Repeat Entire Event
  - If wanted, 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:**

<input checked="" type="radio"/>	Incomplete	<input type="radio"/>	Incomplete (no data saved) ?
<input type="radio"/>	Unverified	<input checked="" type="radio"/>	Many statuses (all same)
<input checked="" type="radio"/>	Complete	<input checked="" type="radio"/>	Many statuses (mixed)

# Randomization module – Model definition

- Define your randomization model
- usually done by CTU Bern, experience required
  - Stratification factors (optional)
  - Group/Site (optional)
  - Randomization field

The screenshot displays the 'Set up a randomization model' interface. At the top right, there is a button labeled 'Set up a randomization model'. Below it, a text box explains: '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)'. A 'Go to' button labeled 'Set up randomization' is present. On the left, a 'Not started' indicator with a red 'X' icon and an 'I'm done!' button are visible. A red dashed arrow points from the 'Set up randomization' button to the 'STEP 1: Define your randomization model' section.

**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 -

Save randomization model Erase randomization model

# Randomization module – Allocation tables

## – Two allocation tables will be uploaded

1 for development mode


1 for production mode

	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)

Treatments: 1, 2 or 3



# Project Setup – Additional customizations

## – Additional Customizations

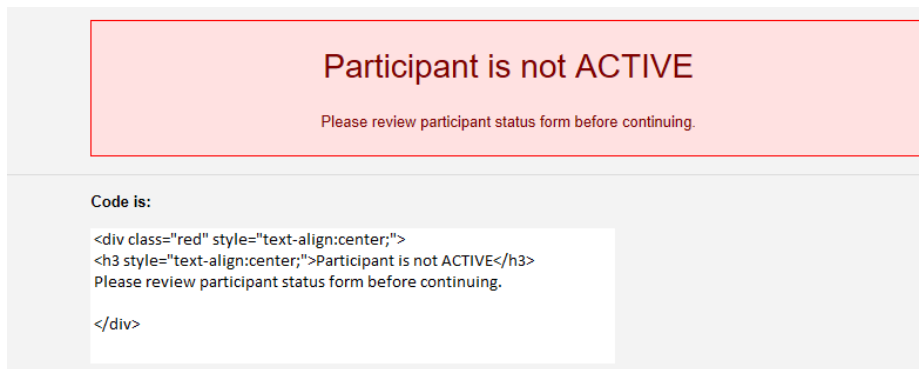
- *Secondary unique field* (e.g. patient ID)
- Data error resolution systems (Monitoring)
  - Field Comment Log
  - Data Resolution Workflow (user/role-specific monitoring rights)



# 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 followed by a code block containing the following HTML: 

```
<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>
```

# Database deployment

## Move your project to production status

- CTU Bern will move your project to production mode, after your database works the way you expect (i.e. once thoroughly tested).
- On request CTU Bern will review your database before deployment.
- **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).
- Changes are not executed instantaneously anymore but must be approved by CTU Bern
- **With REDCap Light: CTU Bern does not review your changes! Be careful if changes provoke data damage or loss.**
- **A Review by CTU Bern can be requested in the costing.**



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](#)

# 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.

Total records: 0	
Choose an existing Record ID	-- select record -- ▾
<b>Add new record</b>	

# Data Collection – Record Status Dashboard

## – Record Status Dashboard

- Form status icon (can be set manually at the bottom of each data entry form)
  - Red = Data entry incomplete
  - Yellow = Data entry complete, 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
<a href="#">188-1</a> (Registry-specific patient ID AAR-A-001)	🔴	🔴	⊖	⊖	⊖
<a href="#">189-1</a> (Registry-specific patient ID AAR-P-001)	🟢	🟢	🟢	⊖	⊖
<a href="#">189-2</a> (Registry-specific patient ID AAR-P-002)	🟢	🟢	🟢	⊖	⊖
<a href="#">189-3</a> (Registry-specific patient ID AAR-P-003)	🟢	🟢	🟢	⊖	⊖
<a href="#">189-4</a> (Registry-specific patient ID AAR-P-004)	🟢	🟢	🟢	⊖	⊖
<a href="#">189-5</a> (Registry-specific patient ID AAR-P-005)	🟢	🟢	🟢	⊖	⊖
<a href="#">189-6</a> (Registry-specific patient ID AAR-P-006)	🟢	🟢	🟢	⊖	⊖
<a href="#">189-7</a> (Registry-specific patient ID AAR-P-007)	🟢	🟢	⊖	⊖	⊖
<a href="#">191-1</a> (Registry-specific patient ID)	🔴	🔴	⊖	⊖	🔴
<a href="#">191-2</a> (Registry-specific patient ID BAS-P-001)	🟢	🟢	🟢	🟢	⊖
<a href="#">192-1</a> (Registry-specific patient ID BEL-P-001)	🟢	🟢	🟢	🟢	⊖
<a href="#">193-1</a> (Registry-specific patient ID BER-A-001)	🟢	🟢	🟢	🟡	⊖

# Applications

- **Data Exports, Reports, and Stats (Analysis)**
  - Data can be exported to Excel and several statistics softwares (R, STATA, SAS, SPSS)
  - Possibility to build up online Reports which can be exported.
- **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 all at the same time
  - Identified discrepancies are linked to the Data Resolution Workflow

# Addendum II

## Principles of CRF Designs

# Open-Ended Response Format

OPEN ENDED QUESTION

Country of birth

>> "Berlin"  
>> "Germany and Italy"  
>> "Germany", "D", "GER", "Deutschland", "Germny", ...  
>> "I was born in Germany in spring of 1950"

- Free text responses
- Details are captured
- Burden of participants might be increased
- Responses need to be coded for analysis



# Closed-ended Response Format

CLOSED ENDED QUESTION

Country of birth

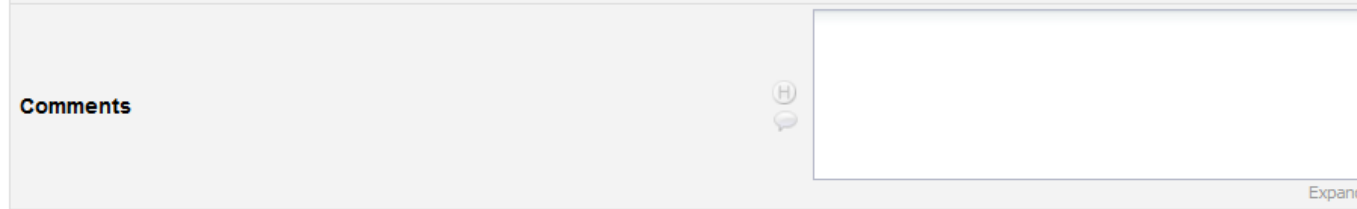
- Avoid or limit open ended questions  
- Avoid or limit "text responses"

- Pre-defined (limited) responses
- Easy to complete
- Branching possible
- Coding done in advance
- Edit checks can be defined

# Open- vs. Closed-Ended Response Format

## Take Home Message

Use open-ended response format only if you can not foresee how responses will look like (e.g. comments)



The image shows a screenshot of a form field in REDCap. On the left, the label "Comments" is displayed. To the right of the label is a large, empty text input area. Above the input area, there are two small circular icons: one with a plus sign and one with a minus sign. At the bottom right corner of the input area, the word "Expand" is written in a small font.

# Validation & Data Entry Instructions

## Numeric fields



Systolic blood pressure	1200
Systolic blood pressure [mmHg]	120

Integer, min=50, max=250

Field label

Field note

### Take Home Message:

- If applicable, indicate the units in the field label (e.g. mmHg)
- Validate every numeric field with a predefined validation format (e.g. integer)
- Set min. and max. range values (e.g. min=50, max=250)
- Indicate the field validation format as well as the range values in field note

# Validation & Data Entry Instructions

## Date fields

The image shows two examples of a date field in a REDCap form. The top example, highlighted with a red border, shows a text input field with the value '12-06-2117'. The bottom example, highlighted with a green border, shows a date picker interface with the value '12-06-2017', a 'Today' button, and a 'D-M-Y' format indicator. Below the date picker, a field note is displayed: 'DD-MM-YYYY, min=01-01-2017, max=31-12-2018'. An arrow points from the text 'Field note' to this note.

Field note

## Take Home Message:

- Validate every date field with a predefined validation format (e.g. D-M-Y)
- Set min. and max. range values (e.g. min=01-01-2017, max=31-12-2019)
- Indicate the field validation format as well as the range values in field note

# Multiple-answers fields







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

- Fast data entry
- Are you sure this participant has not been travelling to Canada within the past 12 months?

# Single answers

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

- Time consuming data entry

# Multiple vs. single answer fields

## **Take Home Message**

For primary endpoints, always use (matrices of) single-answer fields (e.g. yes/no fields) instead of multiple-answers fields (i.e. checkboxes)!

# Complete, consistent and accurate datasets

**HIV infection**  H Yes  No [reset](#)

- What if this patient was never tested for HIV?
- “No” would mean that this patient is not HIV-positive



# Complete, consistent and accurate datasets

HIV infection  Yes  No  Unknown [reset](#)

## Take Home Message

For every single-answer field where it is applicable, add a choice “Unknown/Not done/etc”.

# Complete, consistent and accurate datasets

**Age-related Macular Degeneration (AMD) abnormalities**

- Drusen
- Exudates
- Hemorrhages
- Atrophy
- Pigmentary changes

- What if other AMDs have been observed?

# Complete, consistent and accurate datasets

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

## Take Home Message

For every multiple-choice field, where it is applicable, add a choice “Other” and branch it with a text box/note box

# Complete, consistent and accurate datasets

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 this patient does not smoke?
- The average daily number of cigarettes smoked should only be collected for smokers.

# Complete, consistent and accurate datasets

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

Use branching logic to display only the fields that are necessary.

# Complete, consistent and accurate datasets

*Tricks to pay attention to:*

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		