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REDCap Database Setup: An Introduction

CTU Bern

Data Management

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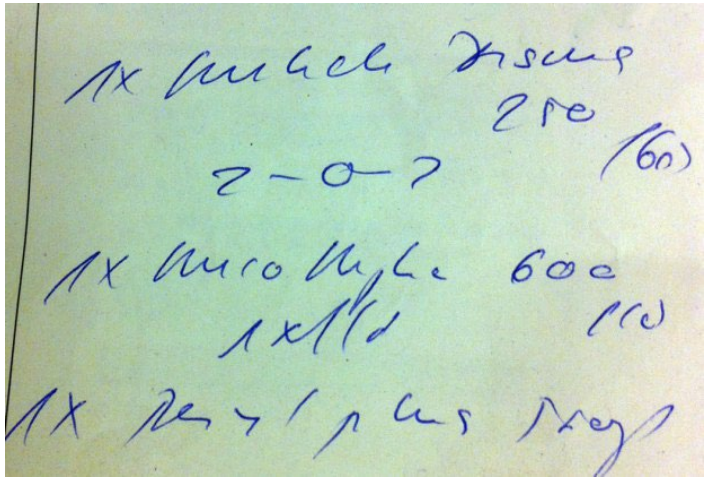
– Computerized system designed for the collection of clinical data (i.e. CRF data) in electronic format.



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

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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)

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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

REDCap
Research Electronic Data Capture

- **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

secuTrial®
web-based data capture in clinical trials

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REDCap, a web-based CDMS

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

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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

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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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

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

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CTU Bern: Data Management Division

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Content

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5. Principles of CRF Design

REDCap: how it works…step by step

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https://redcap.ctu.unibe.ch

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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

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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!

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Addendum I
REDCap: How it works… Step by step

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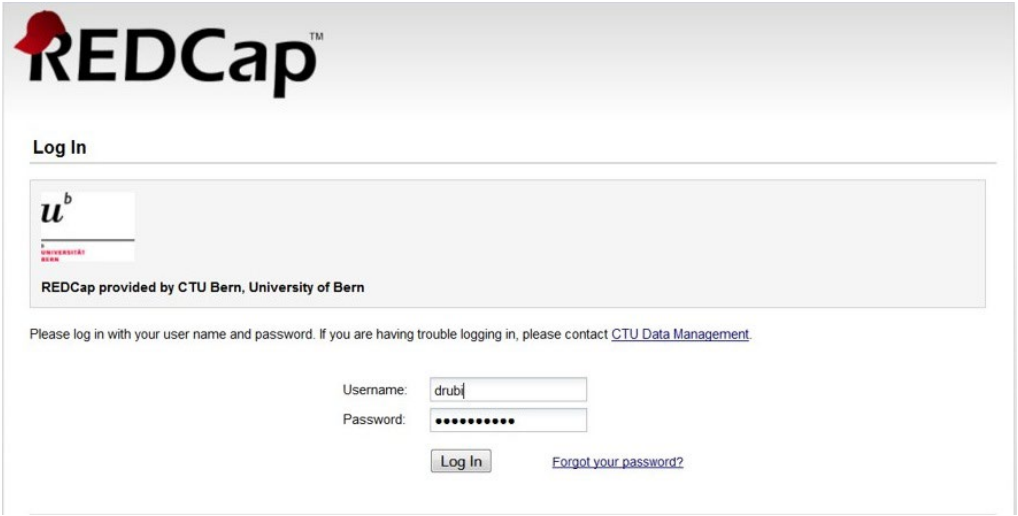
Login

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



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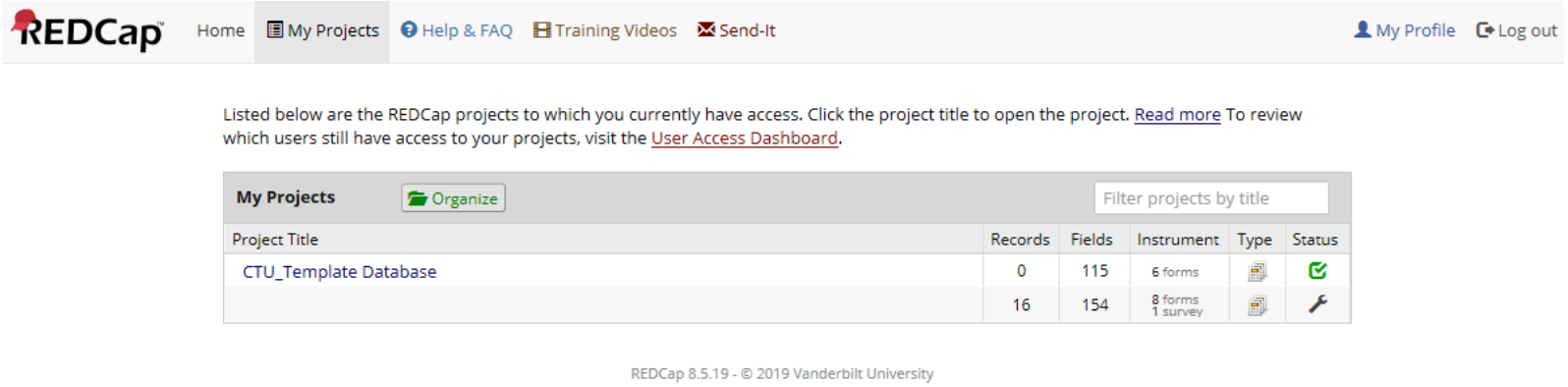
Homepage

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



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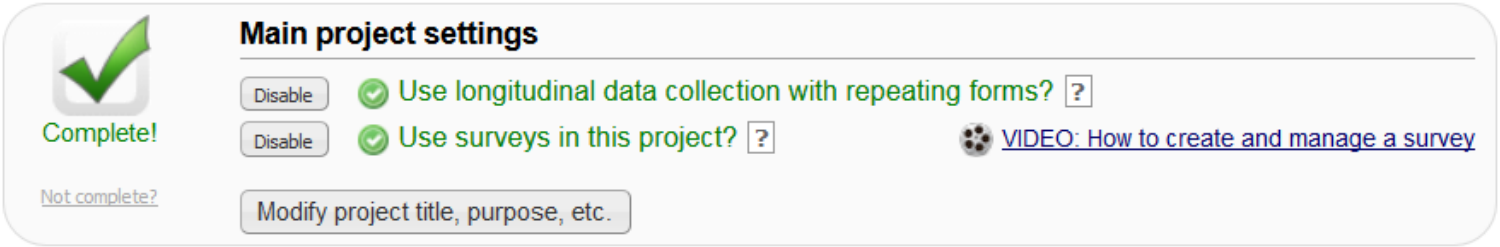
Project setup – Main project settings

- **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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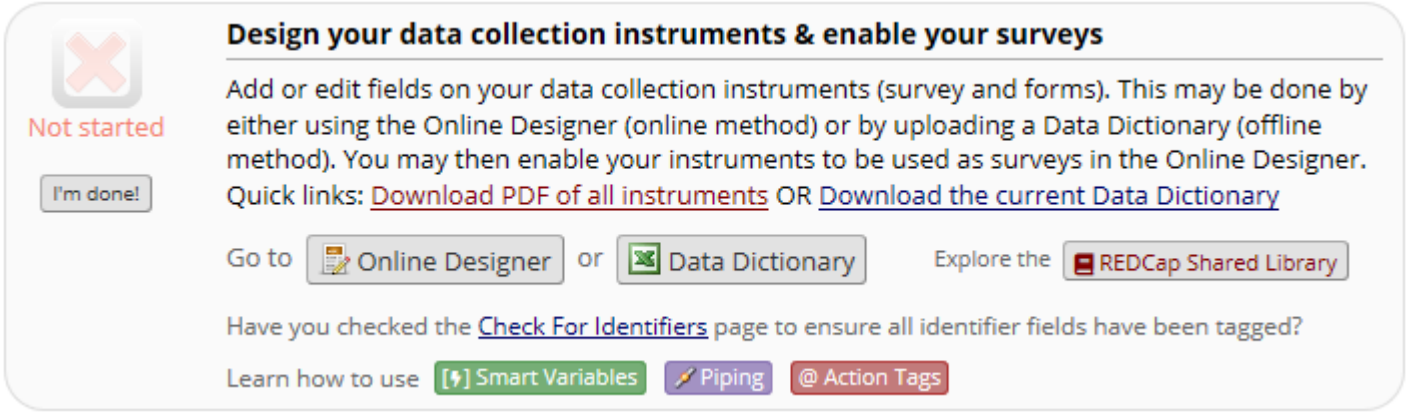
Project setup – CRF creation

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



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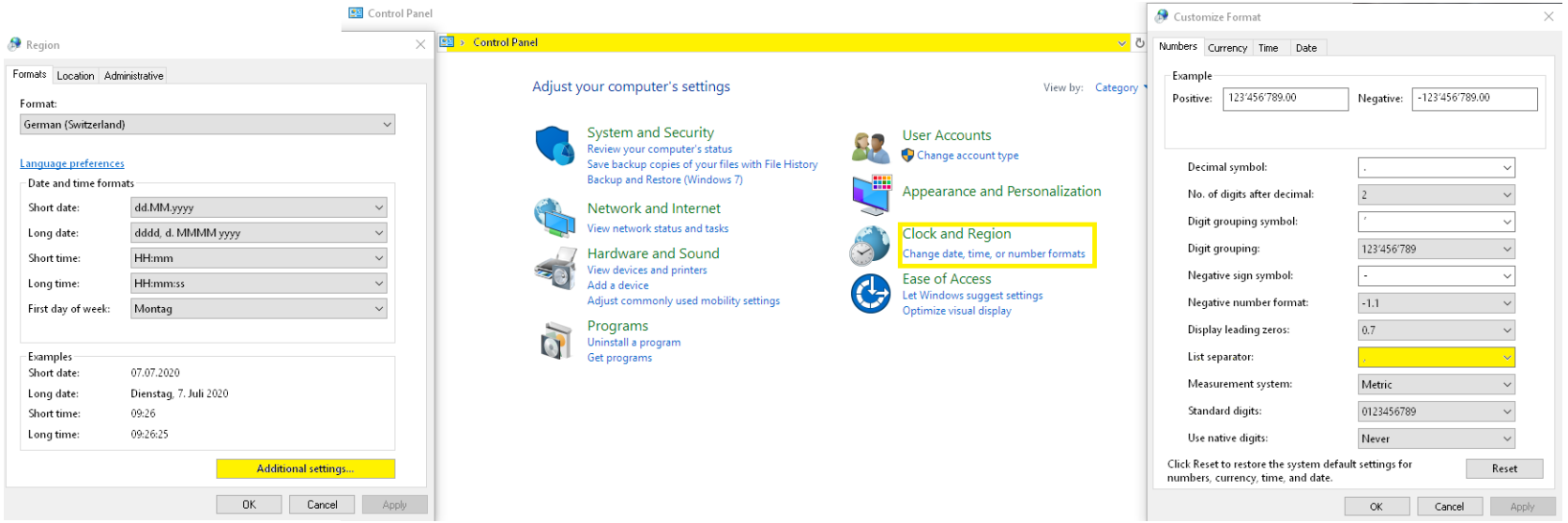
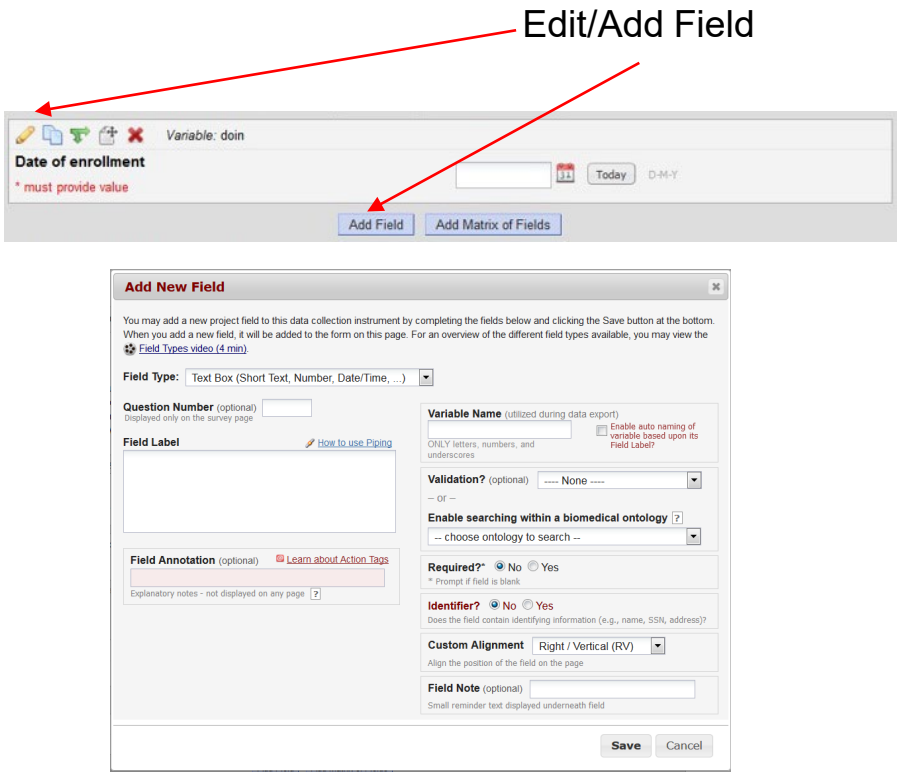
Important when working with .CSV (Data Dictionary / Export)

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 «;»!



Online Designer – Field creation



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

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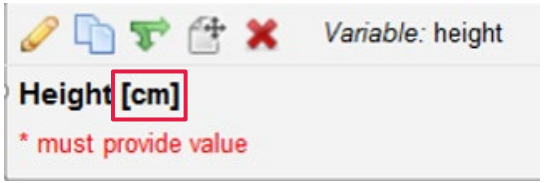
Field creation – Predefined field types

- **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 to100

* 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:

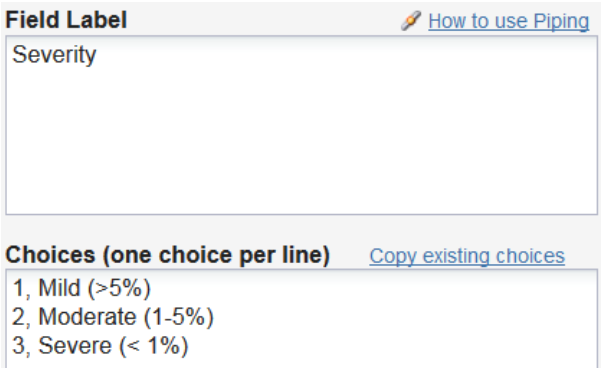


Field creation – Choices

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.



Use consistent coding within your project!

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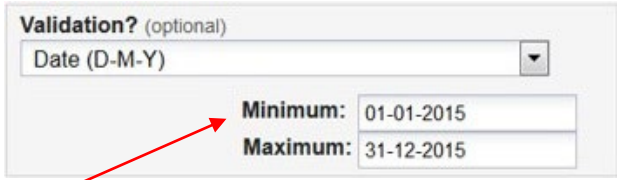
Field creation – Variable name

- 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

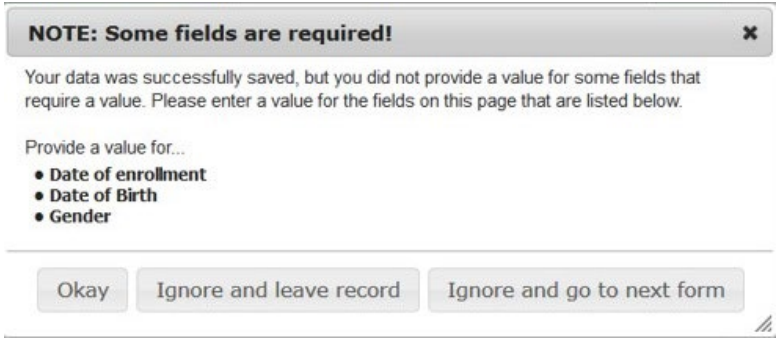
- **Main validation formats**
  - Numeric Fields
    - Integer (whole number)
    - Number (1, 2, 3 or 4 decimal place(s))
    - Number (every type of numbers is tolerated)
  - **Dates / Time**
    - DD-MM-YYYY
    - HH:MM
  - **Text**
    - Email
    - Letters only (whitespaces not tolerated!)



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

Field creation – Required fields & Identifiers

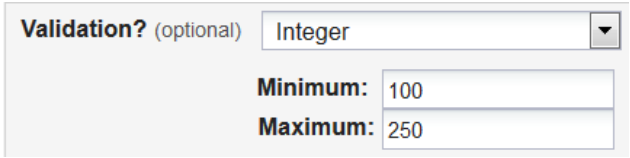
- **Required fields:** If one or several required fields have no value while saving your data entry form, REDCap will send you a warning but will not prevent you from saving your work (≠ survey).



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

Field creation – Field note

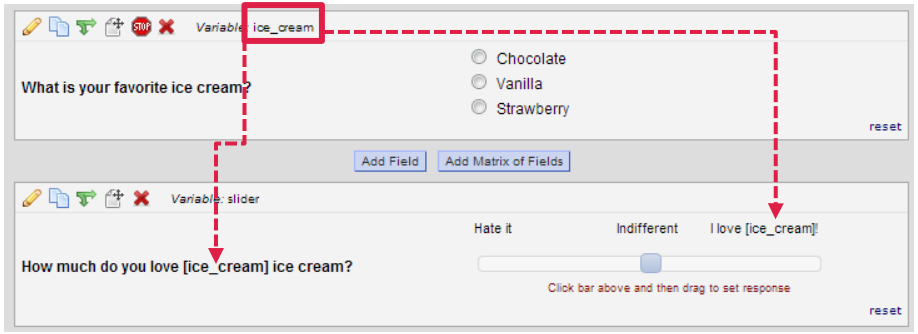
- **Field note:** Is used to give clear data entry instructions. Particularly useful for numeric and date fields (REDCap does not tolerate any error in validation type).
  - Validation format
  - Min. & max range values



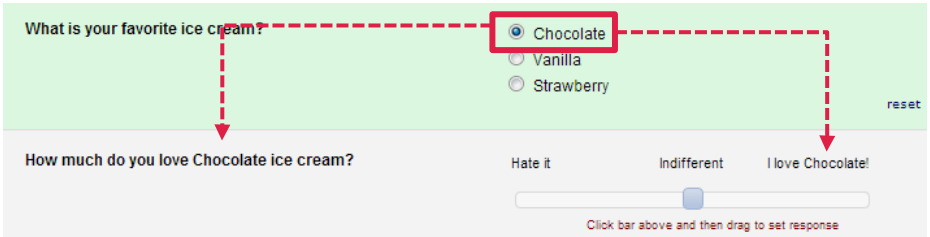
Online Designer – Piping

– **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:

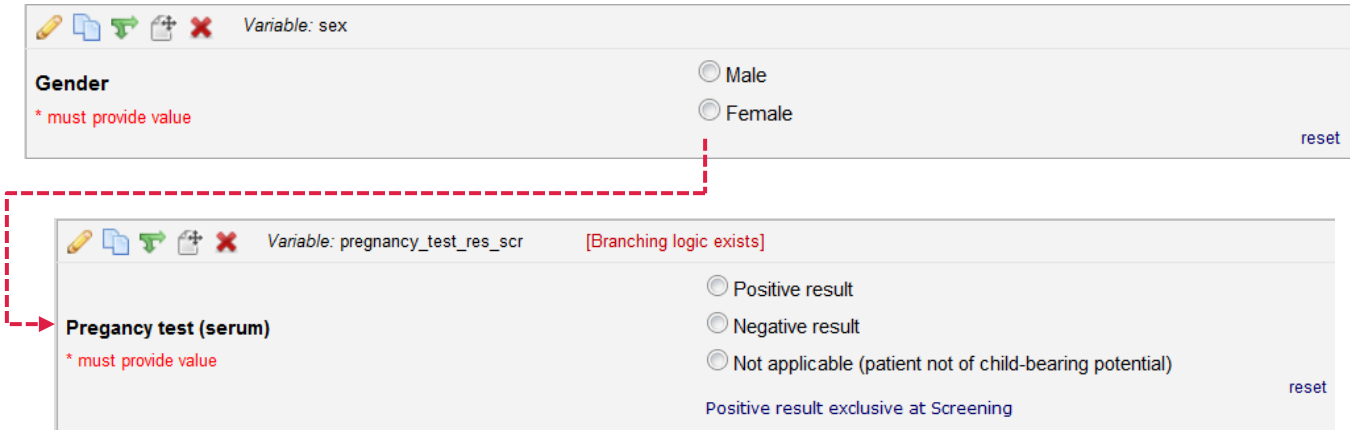


Data Entry:



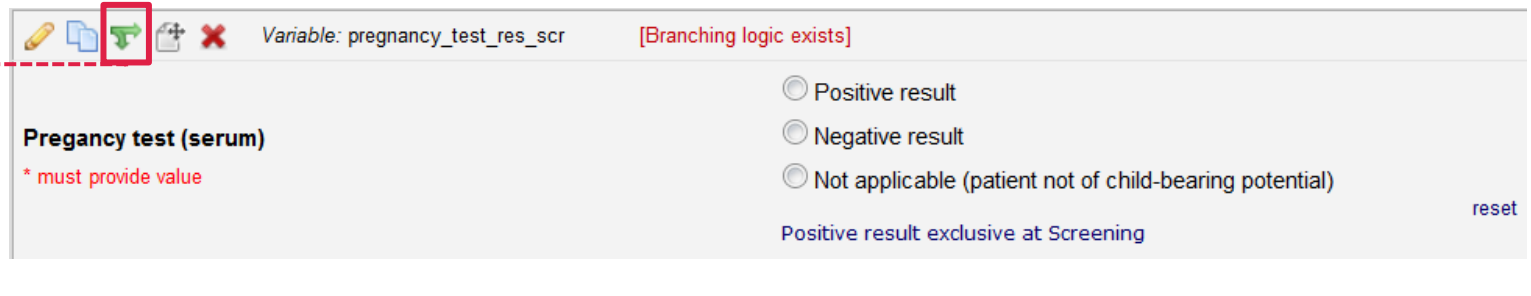
Online Designer – Branching logic I

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

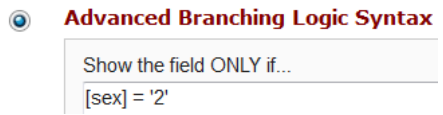


Pregnancy test result should only be displayed for female patients!

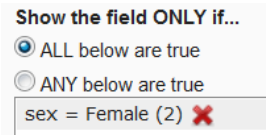
Online Designer – Branching logic II



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



  - “drag & drop”



- Branching logic cannot be tested without entering test data (Rules can however now be tested within the Online Designer)

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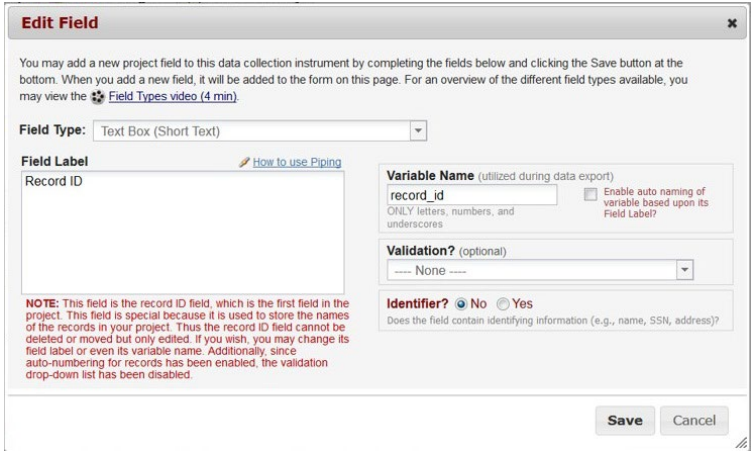
Online Designer – Record ID

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

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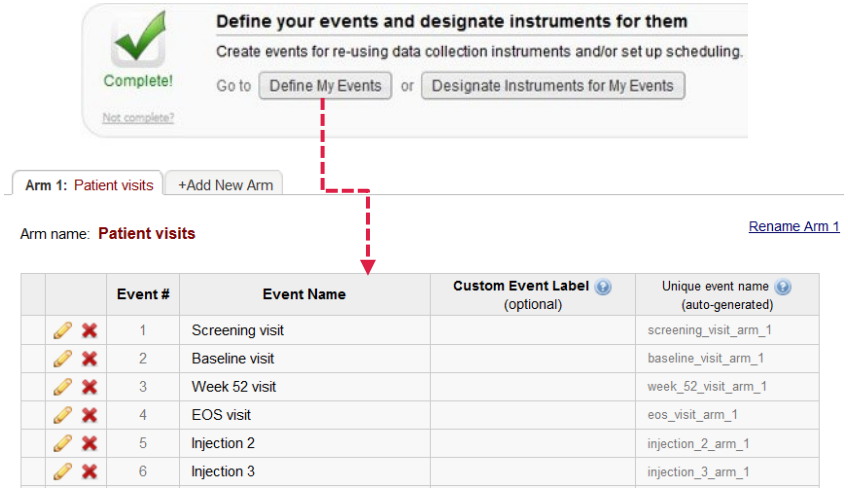
Project setup – Define my events

- **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)



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Project Setup – Event table

- Designate the created Instruments (CRF) 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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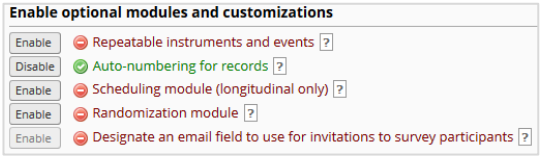
Project Setup – Optional modules and customizations

- **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



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 --	☐ Demographics ☐ Clinical Data ☐ Laboratory Data	
✓	Follow-up Visit	Repeat Entire Event (repeat	☑ Clinical Data ☑ 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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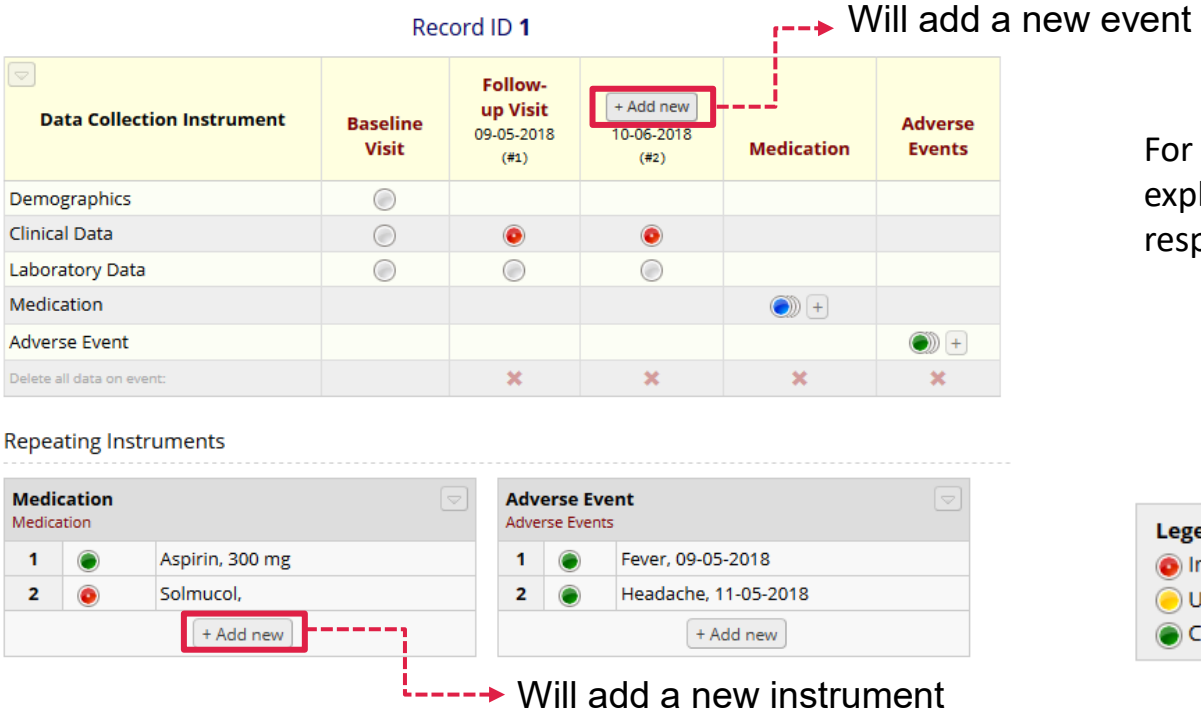
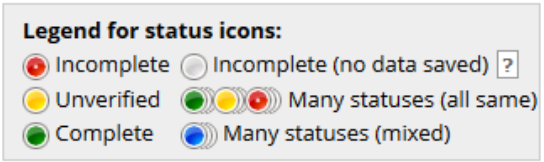
Optional modules – Repeatable instruments and events



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



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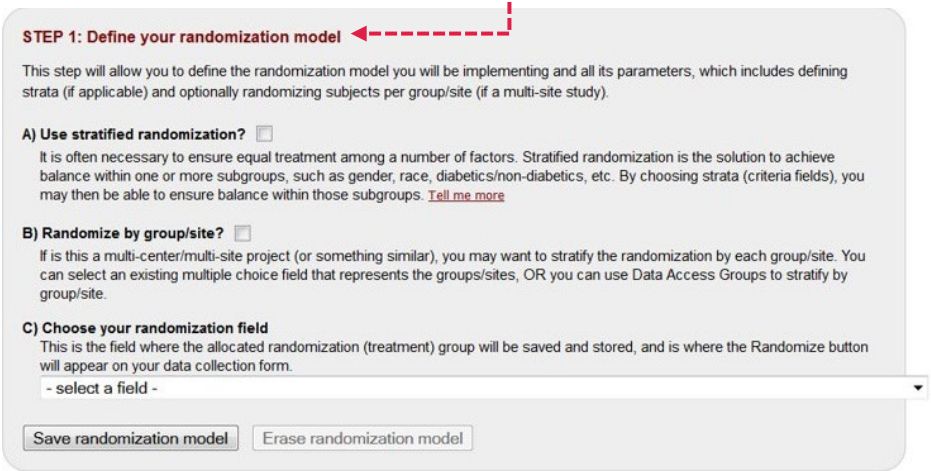
Randomization module – Model definition

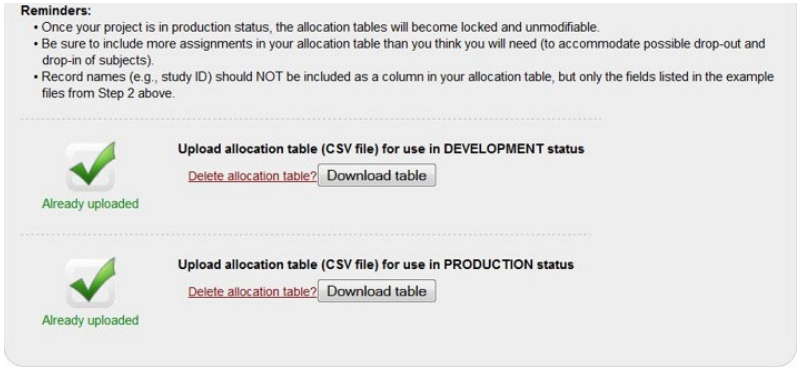
- **Define your randomization model**
- usually done by CTU Bern, experience required
  - Stratification factors (optional)
  - Group/Site (optional)
  - Randomization field



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



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

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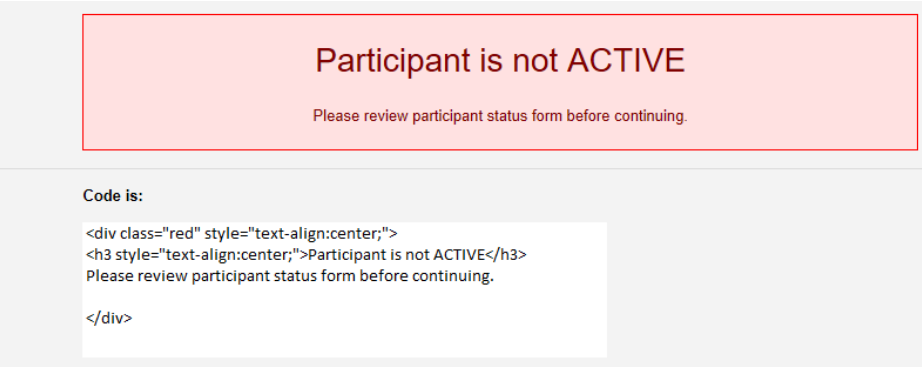
Project Setup – Additional customizations

- **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)

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



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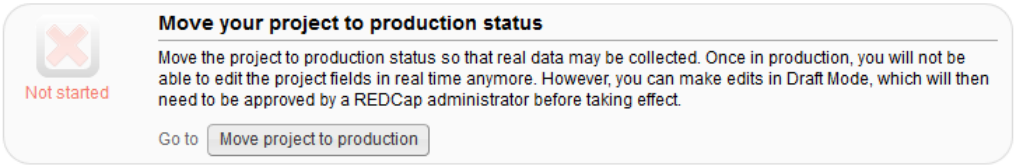
Database deployment

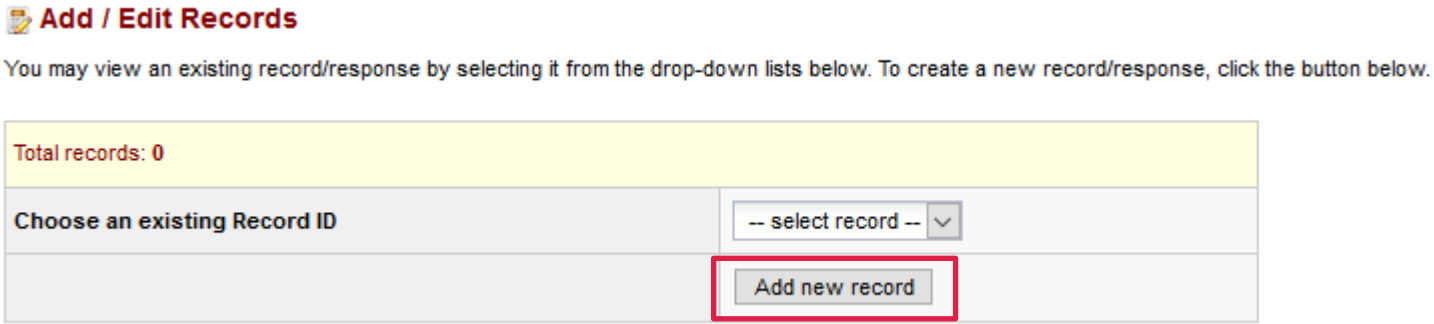
Move your project to production status

- 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 you 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.



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 (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
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)	●	●	●	●	○

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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

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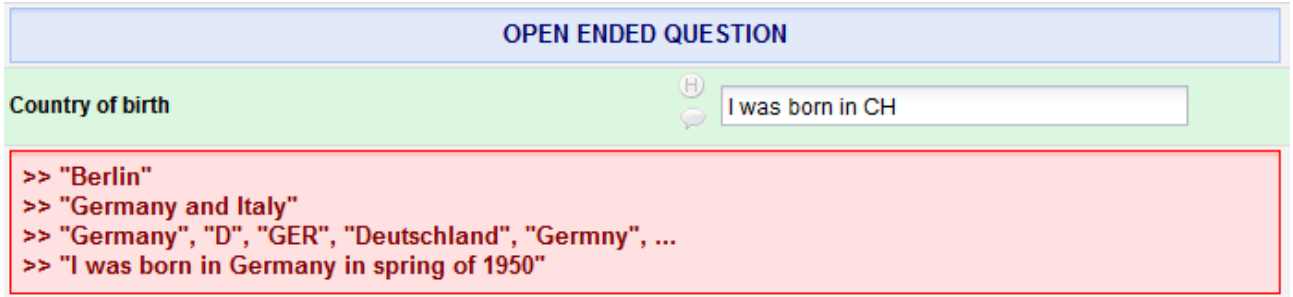
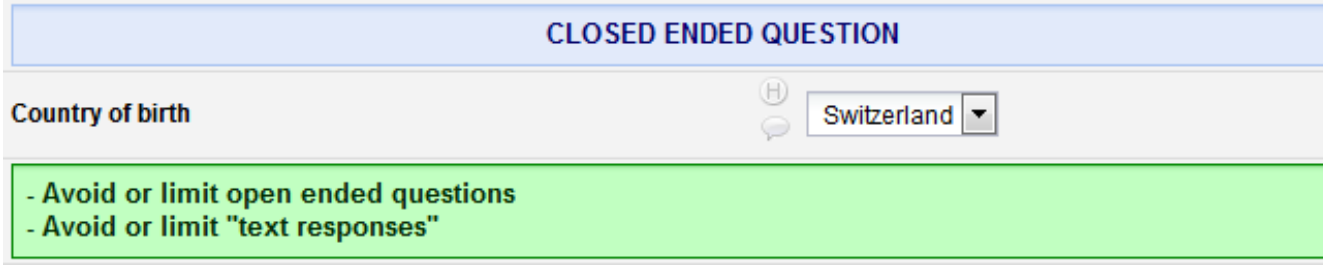
Addendum II
Principles of CRF Designs

Open-Ended Response Format



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

Closed-ended Response Format

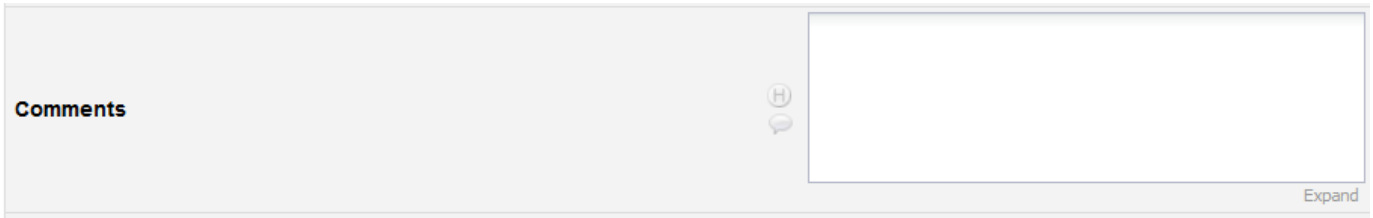


- Pre-defined (limited) responses
- Easy to complete
- Branching possible
- Coding done in advance
- Edit checks can be defined

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)



Validation & Data Entry Instructions

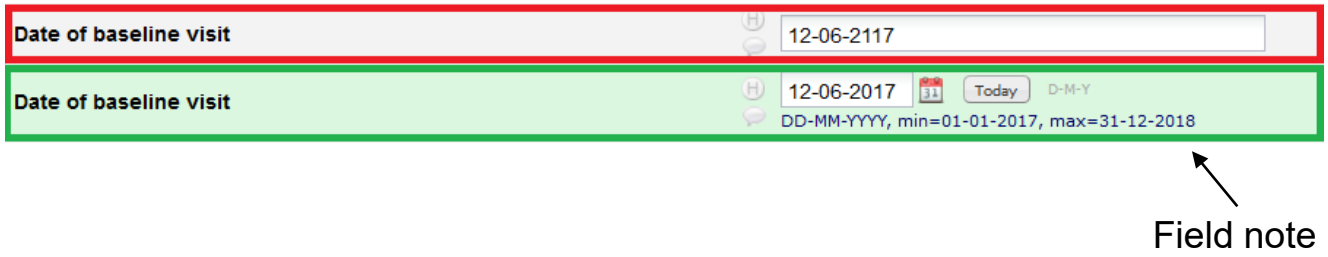
Numeric fields

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

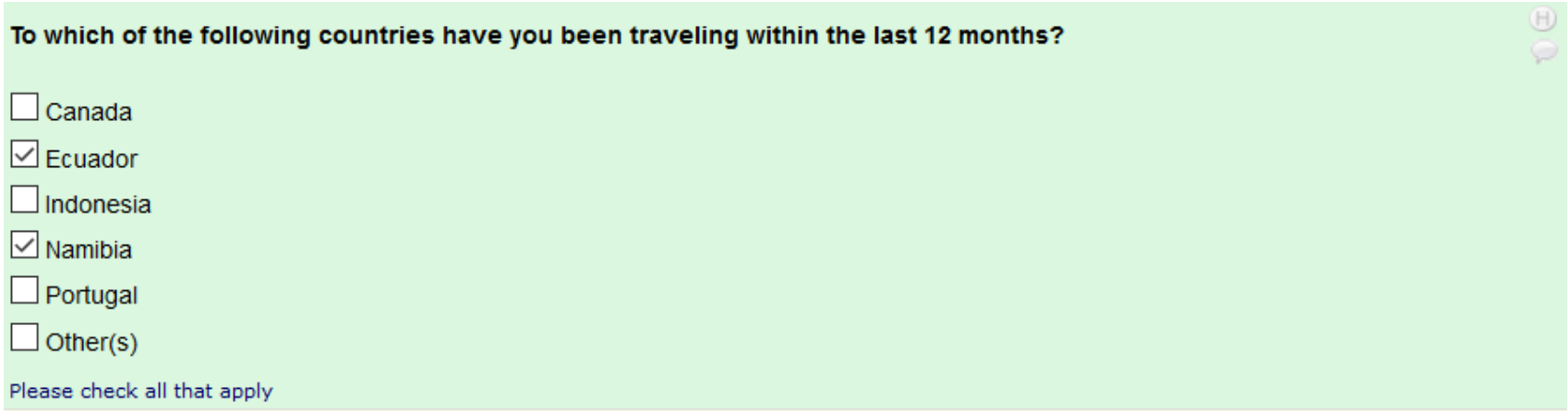
Date fields



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



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

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Single answers

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

- Time consuming data entry

Multiple vs. single answer fields

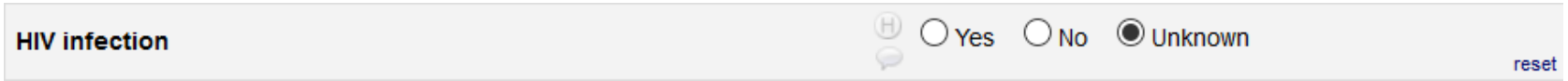
Take Home Message

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

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

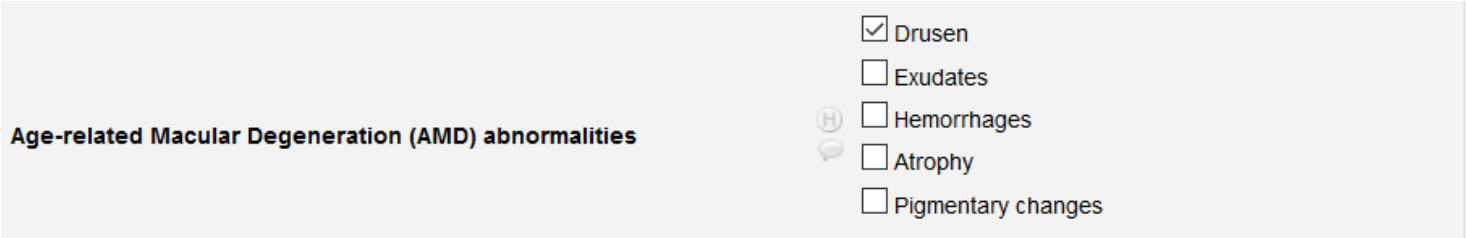
Complete, consistent and accurate datasets



Take Home Message

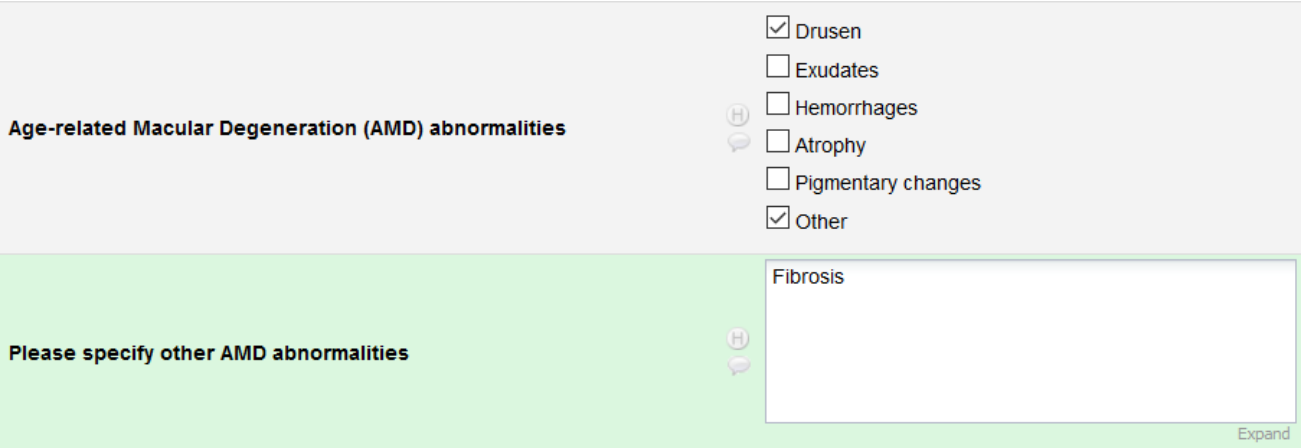
For every single-answer field where it is applicable,
add a choice “Unknown/Not done/etc”.

Complete, consistent and accurate datasets



- What if other AMDs have been observed?

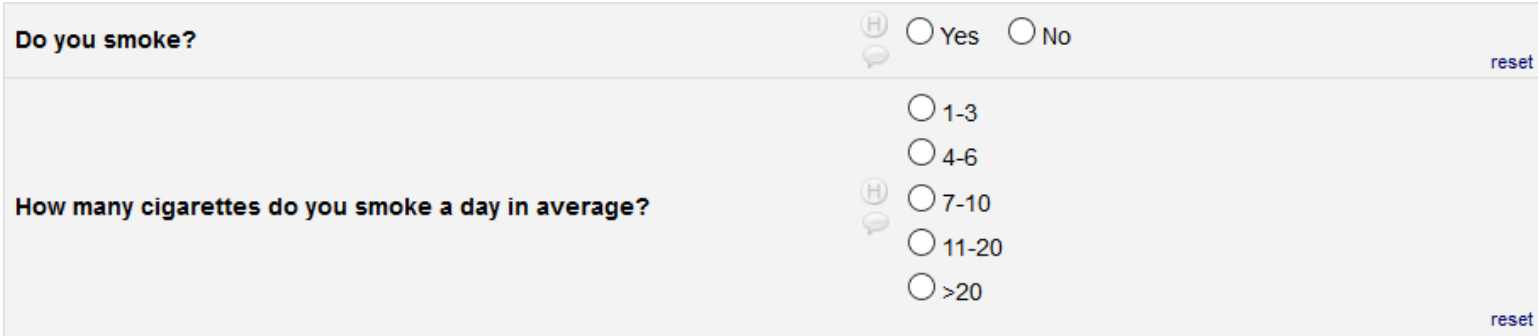
Complete, consistent and accurate datasets



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



- 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

Take Home Message

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

Complete, consistent and accurate datasets

Tricks to pay attention to: