

CRF design using REDCap

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Outline

- REDCap introduction
- Terminology and how to navigate the REDCap interface
- Basic study design
- Report building
- Data export and import
- Privacy and security features







"REDCap is a secure web application for building and managing online surveys and databases.

[....]

it is specifically geared to support online or offline data capture for research studies and operations."





Background on **REDCap**



- **2004:** Initially developed and deployed at Vanderbilt U. Medical Center by Paul Harris
- 2006: REDCap system was offered to other institutions and a consortium of domestic and international users was formed
- Today (9/2018):
 - >3000 active institutional partners in 127 countries
 - >580k projects with over >780k users

Beth Israel Deaconess Medical Center **Duke University** Kent State University Northwestern University Oregon Health & Science University Stanford Univ. School of Medicine University of Colorado-Denver University of Pennsylvania **UW Seattle**

Cornell University The Cleveland Clinic Columbia University Mayo Clinic Partners HealthCare (2009) Stony Brook University University of New Mexico University of Minnesota Vanderbilt University

Children's Hospital Boston Case Western Reserve University University of Cincinnati/Cincinnati Children's Hospital Medical University of South Carolina Singapore Clinical Research Institute The Methodist Hospital Research Institute The University of Kansas Medical Center University of Massachusetts Medical School Yale University





Background on REDCap™ (2)

- Free for not-for-profit partners (license agreement with Vanderbilt U)
- REDCap Cloud for commercial entities
- Web-based application
- Simplified methodology for building projects
- Feature rich





Technical Details

- For end-users, most web-browsers are compatible:
 - IE, Firefox, Safari, Chrome, Opera
- Server side:
 - 1. Web server with PHP (e.g. Apache or IIS) that has the PEAR package installed
 - 2. MySQL database server
 - 3. Email server





Home





Logged in as embo.user1



Welcome to REDCap!

REDCap is a mature, secure web application for building and managing online surveys and databases. Using REDCap's stream-lined process for rapidly developing projects, you may create and design projects using 1) the online method from your web browser using the Online Designer; and/or 2) the offline method by constructing a 'data dictionary' template file in Microsoft Excel, which can be later uploaded into REDCap. Both surveys and databases (or a mixture of the two) can be built using these methods.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

Learn more about REDCap by watching a 🗱 <u>brief summary video (4 min)</u>. If you would like to view other quick video tutorials of REDCap in action and an overview of its features, please see the Training Resources page.

NOTICE: If you are collecting data for the purposes of human subjects research, review and approval of the project is required by your Institutional Review Board.

If you require assistance or have any questions about REDCap, please contact REDCap Administrator (123-456-7890).

REDCap Features

Build online surveys and databases quickly and securely - Create and design your project rapidly using secure web authentication from your browser. No extra software is required.

Fast and flexible - Conception to productionlevel survey/database in less than one day.

Export data to common data analysis packages - Export your data to Microsoft Excel, PDF, SAS, Stata, R, or SPSS for analysis.

Ad Hoc Reporting - Create custom queries for generating reports to view or download.

Scheduling - Utilize a built-in project calendar and scheduling module for organizing your events and appointments.

Easily manage a contact list of survey respondents or create a simple survey link -

Build a list of email contacts, create custom email invitations, and track who responds, or you may also create a single survey link to email out or post on a website.

REDCap Mobile App - Collect data offline using an app on a mobile device when there is no WiFi or cellular connection, and then later sync data back to the server.

Password Recovery

Set Up Password Recovery Question

×

To help you easily and quickly recover your REDCap password (in case you forget it in the future), we need you to select a security question of your choice below and then provide an answer for it. Once you have filled out this information, if you forget your password, you can click the 'Forgot Your Password?' link on the REDCap login screen, and it will ask you to provide a correct answer to your security question (the one you will select below). In such a case, it will send a new temporary password to the email address associated with your REDCap account. Setting up your password recovery question below will prevent you from having to wait on a REDCap administrator to reset it manually if you ever forgot your password.

NOTICE: It is highly recommended that you set your password recovery question now, or else you might get accidentally locked out of your REDCap account.

Select a question: - select a	ecurity question -	
Provide answer to question:	(not case sensitive	2)
Please confirm your email add	ess: kroomp@gmail.com	

Save

Not now. Remind me again in 2 days.





My Projects



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.

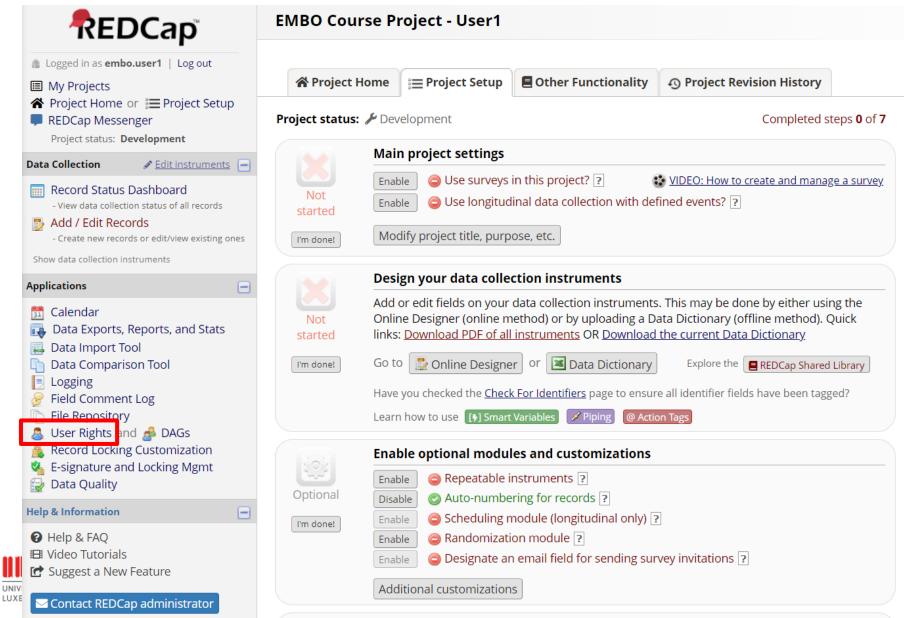


REDCap 8.7.0 - © 2018 Vanderbilt University





User Rights



User Rights (2)

EMBO Course Project - User1

A Pro	ject Home	≡ Project Setup	User Rights	📤 Data Access Groups

This page may be used for granting users access to this project and for managing the user privileges of those users. You may also create roles to which you may assign users (optional). User roles are useful when you will have several users with the same privileges because they allow you to easily add many users to a role in a much faster manner than setting their user privileges individually. Roles are also a nice way to categorize users within a project. In the box below you may add/assign users or create new roles, and the table at the bottom allows you to make modifications to any existing user or role in the project, as well as view a glimpse of their user privileges.

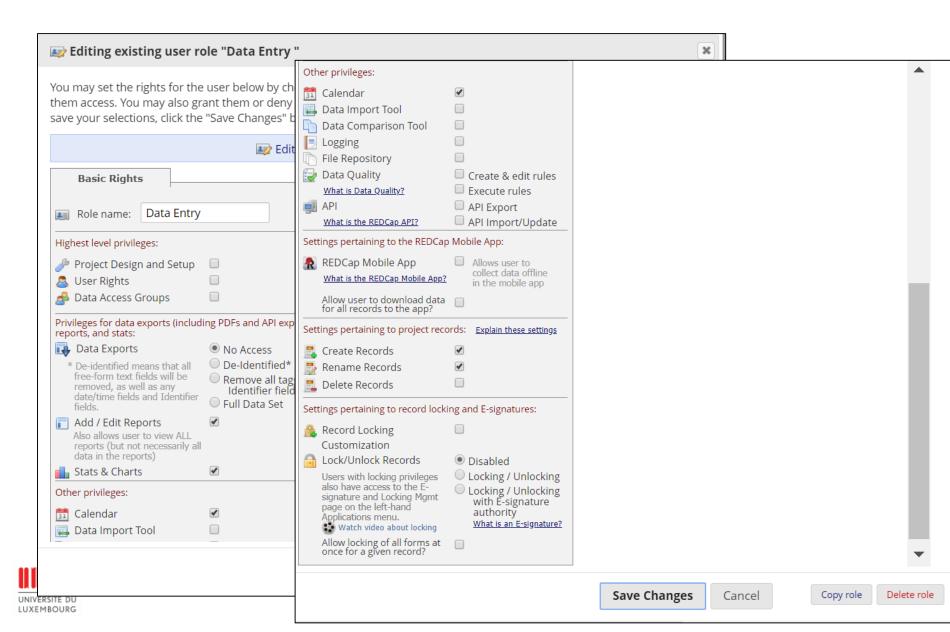


Role name (click role name to edit role)	Username or users assigned to a role (click username to edit or assign to role)	Expiration (click expiration to edit)	Project Design User and Rights Setup		Data Access Groups	Data Export Tool	Reports & Report Builder
Data Entry	embo.usertest1 (Usertest1 EMBO)	never	×	×	×	×	4
Project Management	embo.user1 (User1 EMBO)	never				Full Data Set	
Project Management	roomp_luxparktest (Kirsten Roomp)	never	~	•	•	Full Data Set	•

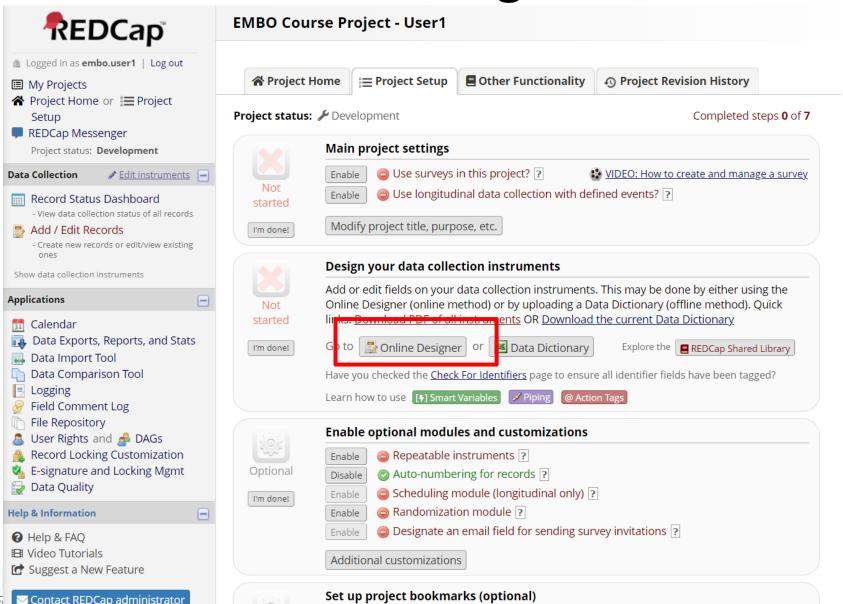




User Roles



Online Designer



Online Designer (2)



The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.







Online Designer (3)

Ready to add fields

You may now begin adding fields to your data collection instrument below using the Online Designer. Alternatively, you may build your fields in the Data Dictionary (offline method) by clicking its tab above.

This module will allow you to create new data collection instruments/surveys or edit existing ones. Changes may be made by either using the **Online Designer** or **Upload Data Dictionary** (see tabs above), in which you may use either method or both. The Online Designer may help you get some initial fields/forms built quickly or to make quick edits, but using the Data Dictionary file may be more helpful if you will be adding a large number of fields for this project.

This page allows you to build and customize your data collection instruments one field at a time. You may add new fields or edit existing ones. New fields may be added by clicking the Add Field buttons. You can begin editing an existing field by clicking on the **Edit** icon. If you decide that you do not want to keep a field, you can simply delete it by clicking on the **X Delete** icon. To reorder the fields, simply **drag and drop** a field to a different position within the form below. NOTE: While in development status, all field changes will take effect immediately in real time. Are you using Action Tags yet? If not, learn about Action Tags here.

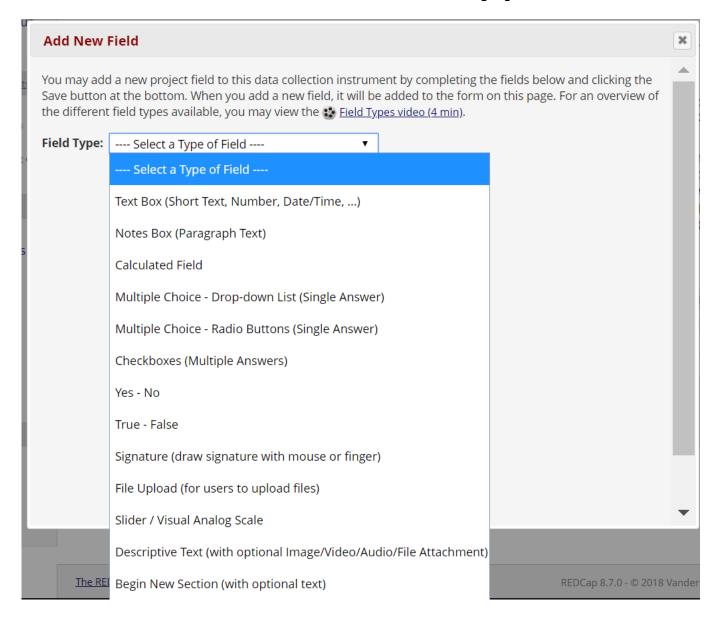
Return to list of instruments

Current instrument: My First Instrument Variable: record_id Record ID NOTE: The field above is the record ID field and thus cannot be deleted or moved. It can only be edited. Add Field Add Matrix of Fields





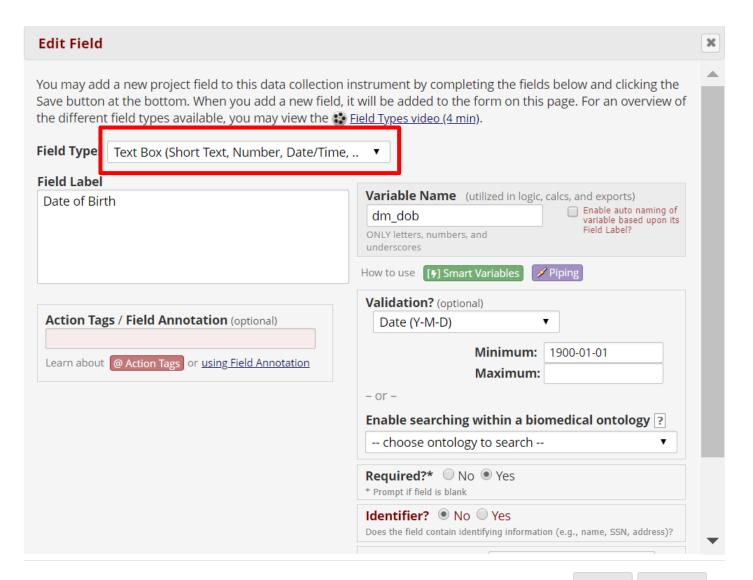
Variable/Field Types







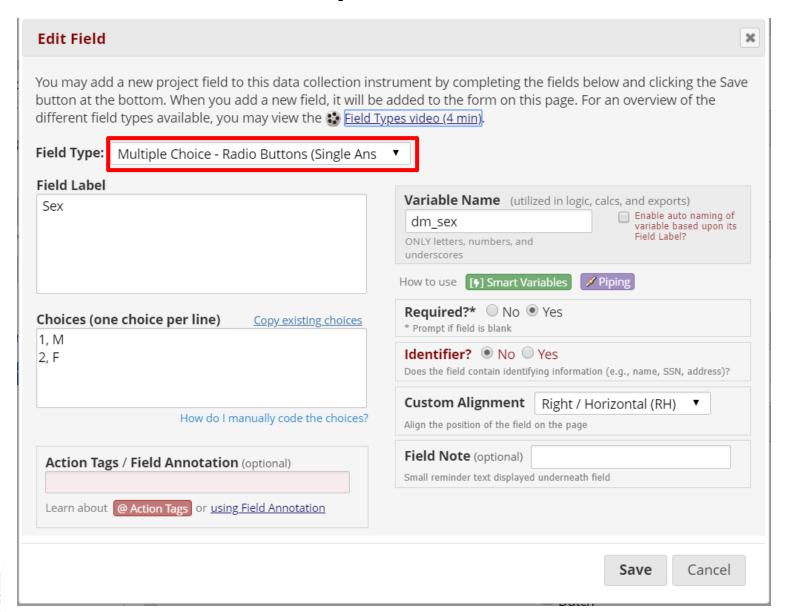
Text Box







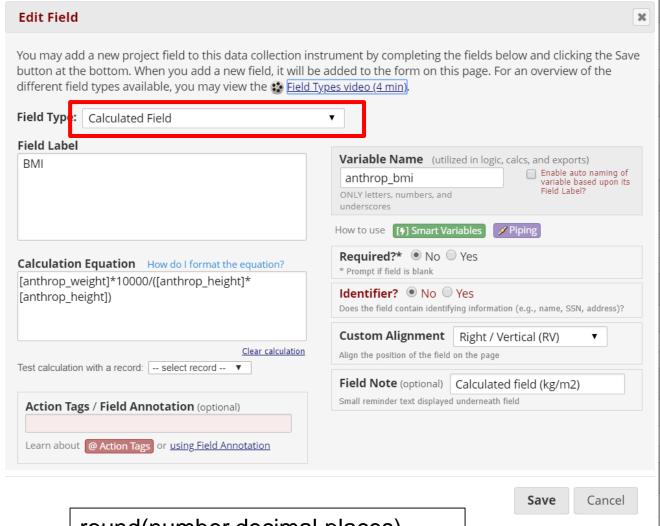
Multiple Choice







Calculation

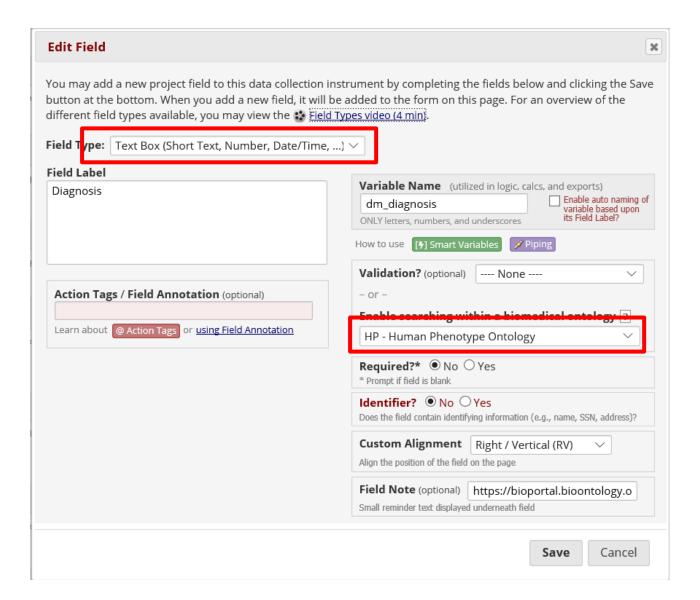




• L C S B

round(number,decimal places) round((calculation),decimal places)

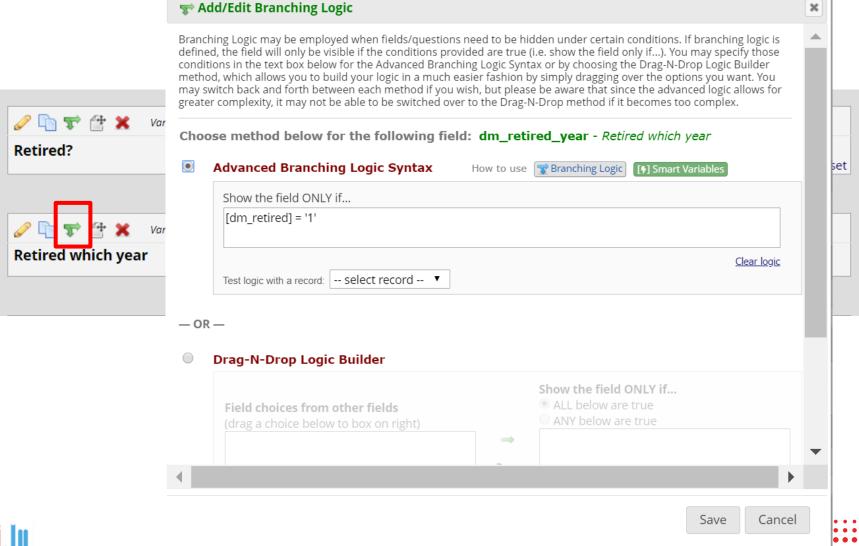
Ontology





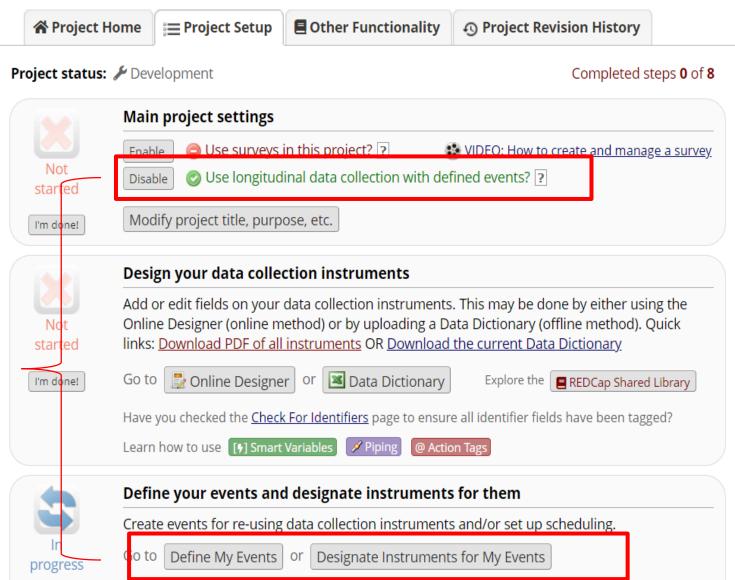


Branching Logic





Longitudinal

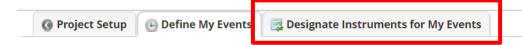




I'm done!



Events



This application allows you to define 'events' for your project that allow for the **utilization of data collection forms multiple times for any given project record** (often used when collecting longitudinal data). An 'event' may be a temporal event in the course of your project, such as a participant visit or a task to be performed. After events have been defined, you will need to designate the data collection instruments that you wish to utilize for any or all events, thus allowing you to use a form for multiple events for the same project record. You may **group your events into 'arms'**, in which you may have one or more arms/groups for your project. Each arm can have as many events as you wish. You may use the table below to create new events and/or arms, or modify existing ones. (One arm and one event will be initially defined as the default for all projects.)

STEP #1:

To add new events below, provide an **Event Name** for that event, and then click the *Add new event*. Once events have been added, you can easily change their order by dragging and dropping the event using the up-down arrow icon on the far left for a given row in the table.

STEP #2:

Once you have defined your events on this page, you may navigate to the <u>Designate Instruments for My Events</u> page, where you may select which data collection instruments that you wish to utilize for each event you defined.

① **NOTE:** To get you started, we have already added one event for you below. You may edit this event and also add as many events as you need.

		■ Upload or download a	ms/events
Arm 1 : Arm 1	+Add New Arm		

Arm name: Arm 1

	Event #	Event Name	Custom Event Label (optional)	Unique event name 😉 (auto-generated)
<i></i>	1	Event 1		event_1_arm_1
Add ne	w event	Descriptive name for this event	Custom Event Label (optional) Example: [visit_date], [weight] kg	





Scheduling



Design your data collection instruments

Add or edit fields on your data collection instruments. This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). Quick links: Download PDF of all instruments OR Download the current Data Dictionary

Online Designer or

Mata 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 [7] Smart Variables







Define your events and designate instruments for them

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

progress

Define My Events | or

Designate Instruments for My Events





I'm done!

Enable optional modules and customizations

Enable

Repeatable instruments ?

Disable

Auto-numbering for records ? Disable

🕝 Scheduling module (longitudinal only) ?

Enable

Randomization module ?

Enable

Designate an email field for sending survey invitations 💽

Additional customizations



I'm done!

Set up project bookmarks (optional)

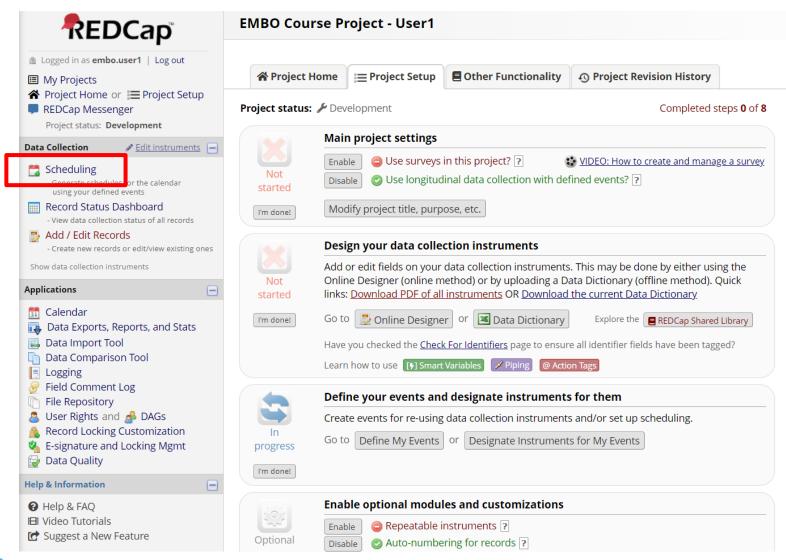
You may create custom bookmarks to webpages that exist inside or outside of REDCap. These bookmarks will be seen as links on the left-hand project menu and can be accessed at any time by users who are given privileges to do so. Every project bookmark has custom settings that allow one to control its appearance and behavior.

Add or edit bookmarks





Scheduling (2)







Scheduling (3)



View/Edit Existing Schedule for "Patient_1"

Below are the calendar events for Subject ID "Patient_1". Dates that fall on weekends will be listed in red. You may edit any calendar event by clicking the 🌽 Edit icon, remove an event by clicking the 🧩 Delete icon, or view the full details of the event by clicking the Q View icon. You may also add a new unscheduled event at the bottom of the table by selecting a date and clicking the Add button.

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	Time	Date / Day of Week Y.M.D	Event Name	Status	Notes
<i>⊘</i> × ⊆	08:00	2018.09.12 Wednesday Range: 2018.09.03 - 2018.09.23	Visit 1	☆ Due Date	
⊘ × ⊆	09:00	2019.03.15 Friday Range: 2019.03.05 - 2019.03.25	Visit 2	☆ Due Date	
<i>⊘</i> × ⊆	08:30	2019.09.13 Friday Range: 2019.09.03 - 2019.09.23	Visit 3	☆ Due Date	

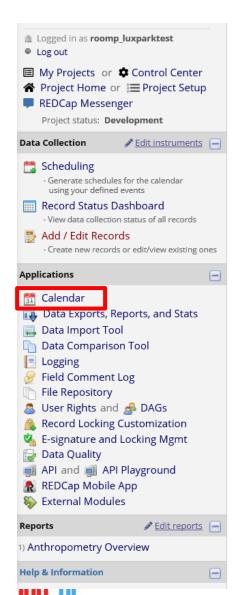
Add new Ad Hoc calendar event on 2018,09.18

Add



🖳 Print Schedule

Calendar



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VIDEO: How to use the calendar (7 min)

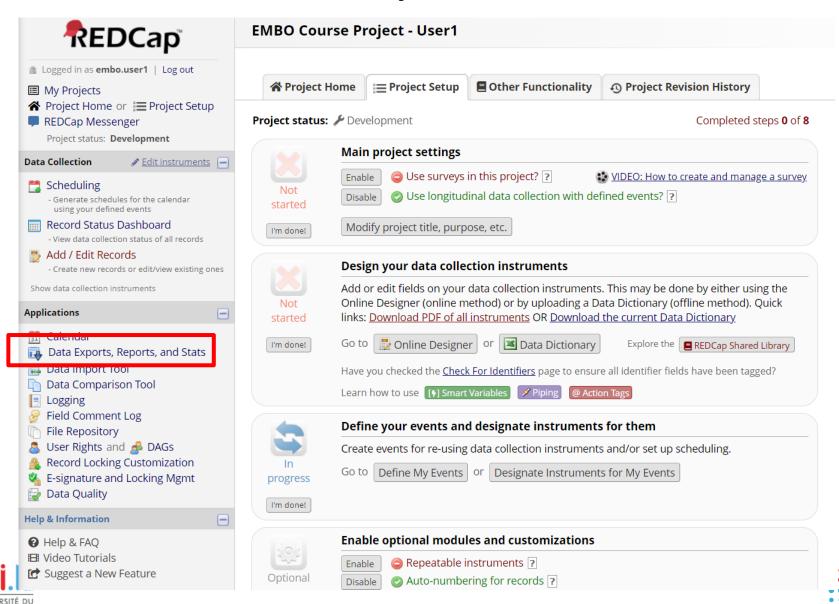
The Calendar application can be used as a project calendar within this project to help organize your schedule and keep track of any upcoming events. It will allow you to add or modify calendar events and then view them either in a daily, weekly, or monthly format below. To add a new note or calendar event to any day, click **+New** at the top of that day's box to begin entering the information. Since you have already defined multiple events for this project, you may additionally generate a schedule using your pre-defined Events, which will then be added to the calendar.



			ay	Wednesda	ıy	Thursday		Frida	у	Saturo	Jay
										+ New	1
2 + New	3	+ New	4	+ New	5	+ New	6	+ New	7	+ New	8
- 1404	,	11401	-	. 14044	,	. 14074	·	114044	,	. 1404	Ü
9 + New	10	+ New	11	+ New	12	+ New	13	+ New	14	+ New	15
				□ 08:00 Patient_	1 (Vi	10:00 Patient_	2 (Vi				
6 + New	17	+ New	18	+ New	19	+ New	20	+ New	21	+ New	22
3 + New	24	+ New	25	+ New	26	+ New	27	+ New	28	+ New	29
	2 + New 9 + New 16 + New	9 + New 10	9 + New 10 + New 16 + New 17 + New	9 + New 10 + New 11 16 + New 17 + New 18	9 + New 10 + New 11 + New \$\phi\$ 08:00 Patient_ 16 + New 17 + New 18 + New	9 + New 10 + New 11 + New 12 \$\pm\$ 08:00 Patient_1 (Vi) 16 + New 17 + New 18 + New 19	9 + New 10 + New 11 + New 12 + New	9 + New 10 + New 11 + New 12 + New 13 \$\frac{1}{10000000000000000000000000000000000	9 + New 10 + New 11 + New 12 + New 13 + New	9 + New 10 + New 11 + New 12 + New 13 + New 14 \$\phi\$ 08:00 Patient_1 (Vi \$\phi\$ 10:00 Patient_2 (Vi 16 + New 17 + New 18 + New 19 + New 20 + New 21	9 + New 10 + New 11 + New 12 + New 13 + New 14 + New 10:00 Patient_2 (Vi 10:00 Patient_2



Reports



LUXEMBOURG

Reports (2)

Data Exports, Reports, and Stats

VIDEO: How to use Data Exports, Reports, and Stats

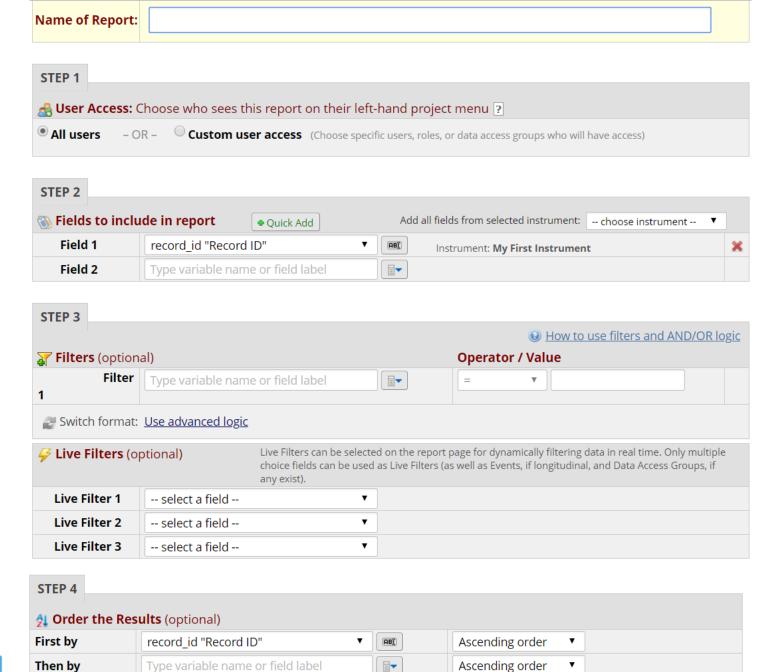


This module allows you to easily view reports of your data, inspect plots and descriptive statistics of your data, as well as export your data to Microsoft Excel, SAS, Stata, R, or SPSS for analysis (if you have such privileges). If you wish to export your *entire* data set or view it as a report, then Report A is the best and quickest way. However, if you want to view or export data from only specific instruments (or events) on the fly, then Report B is the best choice. You may also create your own custom reports below (if you have such privileges) in which you can filter the report to specific fields, records, or events using a vast array of filtering tools to make sure you get the exact data you want. Once you have created a report, you may view it as a webpage, export it out of REDCap in a specified format (Excel, SAS, Stata, SPSS, R), or view the plots and descriptive statistics for that report.

Му	My Reports & Exports								
		Report name	View/Export Options	Management Options	Report ID (auto-generated				
	Α	All data (all records and fields)	I View Report ♣ Export Data I View Report ♣ Export Data						
	В	Selected instruments (all records)	Make custom selections						
		+ Create New Report							







Ascending order

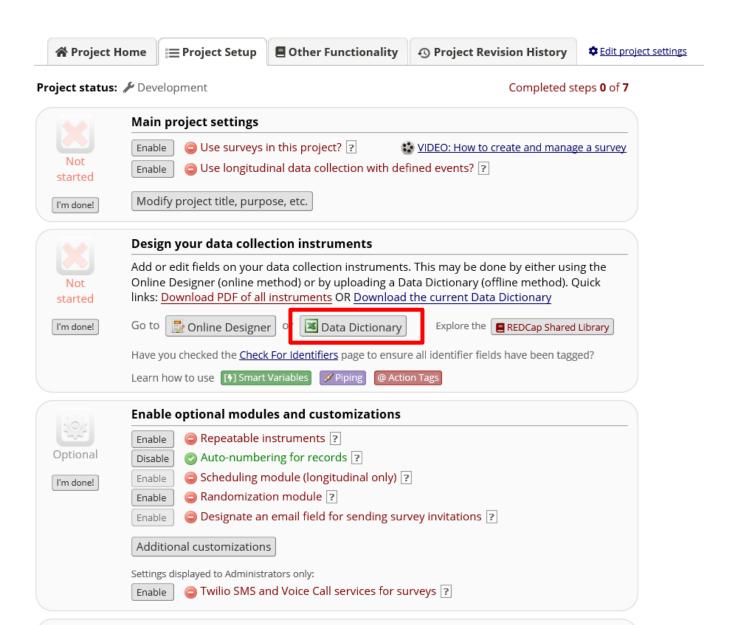


Then by

Type variable name or field label



Data Dictionary







Data Dictionary (2)

☆ Project Home	tup 👺 Online Designer	i □ Data Dictionary
----------------	-----------------------	----------------------------

VIDEO: How to use this page

This module will allow you to create new data collection instruments/surveys or edit existing ones. Changes may be made by either using the **Online Designer** or **Upload Data Dictionary** (see tabs above), in which you may use either method or both. The Online Designer may help you get some initial fields/forms built quickly or to make quick edits, but using the Data Dictionary file may be more helpful if you will be adding a large number of fields for this project.

This module may be used for making changes to the project, such as adding new fields or modifying existing fields, by using an offline method called the Data Dictionary. The Data Dictionary is a specifically formatted CSV (comma delimited) file within which you may construct your project fields and afterward upload the file here to commit the changes to your project.

Click the 'Browse' or 'Choose File' button below to select the file on your computer, and upload it by clicking the 'Upload File' button. Once your file has been uploaded, changes will NOT immediately be made but will be displayed and checked for errors to ensure that all the formatting in your Data Dictionary is correct before official changes are made to the project. **Snapshot note:** A snapshot of your project's current Data Dictionary will be created automatically during the Data Dictionary upload process before committing the new Data Dictionary. The snapshot can later be accessed and downloaded from the Project Revision History page.

Need some help?

If you wish to view an example of how your Data Dictionary may be formatted, you may download the <u>Data Dictionary demonstration file</u>, or you may view the <u>Data Dictionary Tutorial Video (10 min)</u>. For help setting up your Data Dictionary, you may also see the instructions listed on the <u>Help & FAQ</u>.

Steps for making project changes:

- 1.) Download the current Data Dictionary
- 2.) Edit the Data Dictionary (see the Help & FAQ for help)
- 3.) Upload the Data Dictionary using the form below
- 4.) The changes will be made to the project after the Data Dictionary has been checked for errors

Upload your Data Dictionary file (CSV file format only)							
Format for min/max validation values for date and datetime fields: MM/DD/YYYY or YYYY-MM-DD \vee							
	Brow	se					
Upload File							





Data Dictionary (3)

Variable / Field Name		Section Header	Field Type		Choices, Calculations, OR Slider Labels	Field Note
dm_subjectid	demographics		text	Subject ID		
dm_dob	demographics		text	Date of Birth		
dm_sex	demographics		radio	Sex	1, M 2, F	

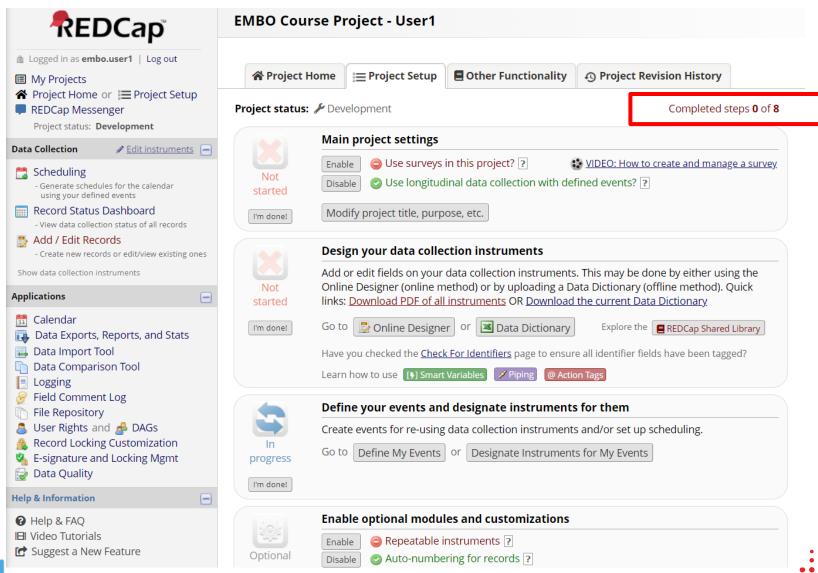
Text Validation Type OR	Text	Text
Show Slider Number	Validation	Validation
	Min	Max
date_ymd	01-01-00	

Identifier?	Branching Logic (Show field only if)	Required Field?	Custom Alignment	Question Number (surveys only)		Matrix Ranking?	Field Annotation
	neid Only II,			(Surveys Offiy)	Ivaille		
		У	RH				





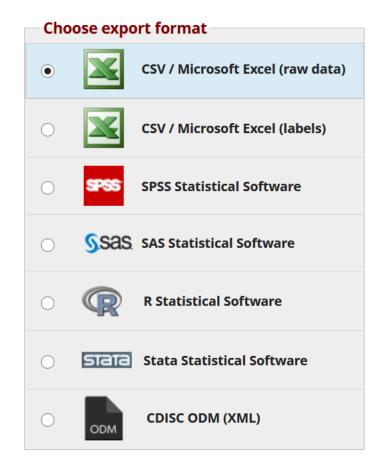
Production Mode





Data Export

- Data can be exported to statistical packages (SPSS, SAS, R or Excel)
- Data access can be granted or restricted when exporting for analysis
- Exports can include identified or deidentified data only on a per user basis







Data Import Tool

- Tool used for importing data into project from a CSV (comma delimited) file
- Import template available for each project
- 'dropdown' or 'radio' fields use the numerical value (rather than the text value) or it cannot be processed
- Any empty rows or columns can be deleted before importing the file
 - reduces the upload processing time, especially for large projects

	A	В	С	D	Е	F	G	Н	
1	cdisc_dm_usubjd	redcap_event_name	redcap_data_access_group	dm_mpowerid	cdisc_dm_subjid_2	cdisc_dm_brthdtc	cdisc_dm_sex	cdisc_sc_sctestcd_maritstat	cdisc
2									
3									
4									





Data Import Tool (2)

- CDISC ODM (Operational Data Model) is a specific XML data format
- ODM is a vendor neutral, platform independent format for interchange and archival of data
- Data can be imported/exported using CDISC ODM format
- Data from ODM-compatible system outside of REDCap can be used
 - The XML must be ODM version 1.3.X.

```
<?xml version="1.0" encoding="UTF-8" ?>
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" xmlns:ds="http://www.w3.org/2000/09/xmldsig#" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance
<ClinicalData StudyOID="Project.LuxPARK" MetaDataVersionOID="Metadata.LuxPARK 2017-07-05 1926">
        <SubjectData SubjectKey="ND0001">
                <StudyEventData StudyEventOID="Event.visit 1 arm 1" StudyEventRepeatKey="1" redcap:UniqueEventName="visit 1 arm 1">
                        <FormData FormOID="Form.demographics" FormRepeatKey="1">
                                <ItemGroupData ItemGroupOID="demographics.cdisc dm usubjd" ItemGroupRepeatKey="1">
                                         <ItemData ItemOID="cdisc dm usubjd" Value="ND0001"/>
                                </ItemGroupData>
                        </FormData>
                        <FormData FormOID="Form.psp mdtpd munich dysphagia test parkinsons disease" FormRepeatKey="1">
                                <ItemGroupData ItemGroupOID="psp mdtpd munich dysphaqia test parkinsons disease.psp mdtpd munich dysphaqia test parkinsons</pre>
                                         <ItemData ItemOID="psp mdtpd munich dysphagia test parkinsons disease complete" Value="2"/>
                                </ItemGroupData>
                        </FormData>
                        <FormData FormOID="Form.visit dates" FormRepeatKey="1">
                                <ItemGroupData ItemGroupOID="visit_dates.sv_age" ItemGroupRepeatKey="1">
                                        <ItemData ItemOID="sv age" Value="83.36099760205"/>
                                </ItemGroupData>
                        </FormData>
```

REDCap API

- 'API' = 'Application Programming Interface'
- The REDCap API is an interface that allows external applications to connect to REDCap remotely
 - used for programmatically retrieving or modifying data or settings within REDCap
 - e.g. performing automated data imports/exports for a specified REDCap project
 - Formats: CSV, JSON, XML





Security, Privacy Features

- Identifying data can be flagged in the interface
- Data protection can be applied to those that have restricted access to identifiers
- All transactions are fully encrypted
- Logins use secure authentication
- 2 factor authentication possible

