Computational Tools for the Clinical Researcher

REDCap 101

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Scientific Computing, Research Data Services

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Icahn School of Medicine at Mount Sinai

Introduction – Team Members



Patricia Kovatch

Professor and Dean for Scientific Computing and Data Div.





Senior Director





Eric Rosenberg System Administrator



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Sheersha Kandwal **REDCap Technical Support** Analyst



Mark Green Executive Director Scientific Computing and Data Div



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Savas Sevil REDCap Product Owner



Cate Bauer-Martinez Senior REDCap Analyst



Priscilla Acquaye **REDCap Analyst**



Jing Yang, PhD Applications Support Analyst

Scientific Computing and Data Science Mission

To enable and accelerate biomedical discovery through collaborative research using high performance computing, biomedical informatics and data science.

- ► Scientific Computing
 - High Performance Computing
 - Mount Sinai Data Warehouse
 - Research Data Services
- Unlike other computing resources, Scientific Computing stakeholders are also actively engaged in research projects
- We work with investigators to create a robust research environment at Mount Sinai, expand our profile in national research efforts, and partner for grant funding success

REDCap at Mount Sinai

- <u>Research Electronic Data Capture a platform developed by Vanderbilt University as a proper replacement for pen and paper data collection</u>
- We are working towards 21 CFR Part 11 compliance joint effort by Scientific Computing, IT Security, IRB and Privacy Offices
- > Data resources and integration between many existing systems with more to come
 - > Import clinical data into REDCap from Epic
 - –Basic Demographics
 - Condition/Problem list
 - Medications
 - –Vital signs
 - –Laboratory
- > We host more than 11,000 databases with over 20,000 active users
- > Services for project building, data protection, support, and training

REDCap at Mount Sinai

- Useful as a tool for different stages of research and operations
 - Industry sponsored studies
 - Private and Government grant funded research projects and programs
 - Hospital Quality Improvement initiatives
 - Flexible platform that is finding uses in new contexts
- ► Easily accessible and well-rounded open-source learning materials
 - Training and Presentation Materials Repository
 - Language Center translation sharing
 - Plugin and Hook Libraries
 - External Modules
 - Survey Library
- Collaborative platform that reduces barriers for research

Digital Concierge Service

- ▶ Virtual REDCap Office Hours: Wednesdays at 3:30pm to 4:30pm
 - Open to all users
 - Get help with specific project questions

https://zoom.us/my/digitalconcierge

Overview

Project Setup -Templates -Project page -Online Designer -Surveys -Variables -Obtaining Data -Longitudinal Studies Managing Users **Project Life Cycle** Data Management

REDCap Access for Mount Sinai Users

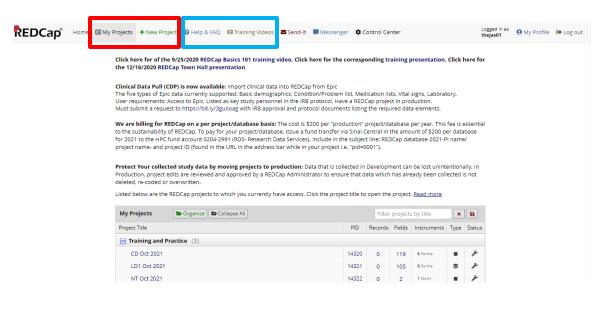
Ensure that you're able to log into REDCap

- Mount Sinai faculty, students and staff can log into REDCap using their regular Mount Sinai username and password here: https://redcap.mountsinai.org
- Users new to Mount Sinai's REDCap instance will need to verify their email. After email verification, and 2FA authentication you can log in to create new projects or be added to existing ones.

REDCap Homepage

Mount Sinai REDCap: https://redcap.mountsinai.org

- Users can find the projects they have access to under My Projects at the top of the page. These are projects they've been added to or have created.
- To create a project, click on the adjacent New Project button.
- Along the top bar, users will also find great resources under Help & FAQ as well as Training Videos for learning to use REDCap.



Creating a New Project Cont'd

- When creating a new project, users can fill out project details and the type of research that will be conducted
- On the same page are **templates** for getting started on a new project

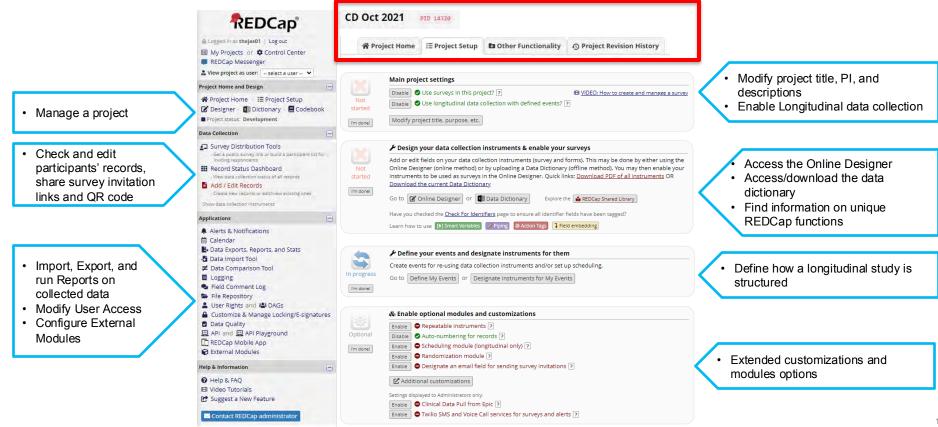
+ Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the Create Project button at the bottom

	6		
Project title:	New Proj	ject	
	Title to be d	lisplayed on project web	bpage
Purpose of this project: How will it be used?	Research	ı •	
	Name of	P.I. (if applicable):	Principal Investigator
			First name MI Last name
	Email of I	P.I. (if applicable)	pi_username@mssm.edu
	Name of	P.I. as cited in publ	lications (if applicable): (e.g., Harris PA)
	IRB numb	ber (if applicable):	
	✓ Clinical ☐ Transla ☐ Transla comm ☐ Behavio ☐ Epidem	r bench research i research study or tri itional research 1 (ap itional research 2 (er nunity) oral or psychosocial niology	pplying discoveries to the development of trials and studies in humans) inhancing adoption of research findings and best practices into the
Assign project to a Project	:t		
Folder?			
Project notes (optional): Comments describing the project or purpose that are displayed on My Projects page.			
Start project from scratc or begin with a template		an empty project (bl l a REDCap project X	blank slate) KML file (CDISC ODM format) 2
🚖 Choose a project temp	olate (comes pre	-filled with fields, form	ms/surveys, and other settings) + Add templates (Administrators only)
select template Template title (sorted by title)	Template descripti	cion
O Basic Demograph	ıy	Contains a single da	ata collection instrument to capture basic demographic information.
O Classic Database			ntry forms, including forms for demography and baseline data, three s, and concludes with a completion data form.
O Longitudinal Data	abase (1 arm)		entry forms (beginning with a demography form) for collecting data eight different events.
O Longitudinal Data	abase (2 arms)		entry forms (beginning with a demography form) for collecting data on (Drug A and Drug B) with each arm containing eight different events.
	Creat	e Proiect Ca	ancel

Create Project

Getting Familiar with the Project Page



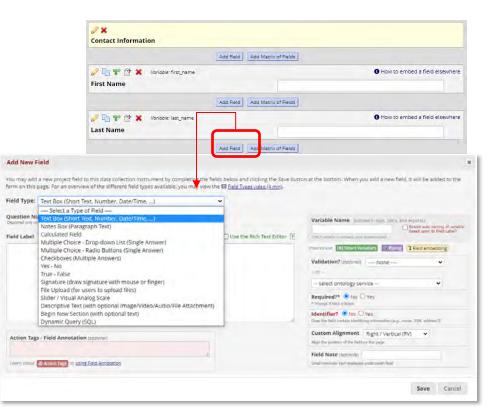
Online Designer – Instruments/Surveys

- Create, Import, and Manage data collection forms
- Enable instruments as surveys
- Edit data collection instruments and variables
- Define how participants can get automated invitations by email

	Survey options:			Add ne	w instrumen	t:		
Data Collection	E Survey Queue	🕆 Survey Login		• Crea	te a new ins	trument from scratch		
Instruments	Survey Notificatio				_	strument from the offi ent ZIP file from anoth		
Instrument name			Fields	View PDF	Enabled as survey	Instrument actions		
Demographics			25	D	3	Choose action 🗢	Survey settings	+ Automated Invitations
Baseline Data			18	Ø		Choose action 🗢	Survey settings	+ Automated Invitations
Month 1 Data			19	Ø	Enable	Choose action 👓		
Completion Data			5	D	Enable	Choose action 😒		

Online Designer – Variables

- Variables allow users to define discrete data points for collection
- Short, simple, and identifiable names for variables are preferred
- Choose the field type that best fits the data point



Obtaining Data

- Invite participants to take a survey by sharing Public Survey URLs or QR codes
- Monitor follow-up surveys and previously sent invitations, manage the survey's participants list

Survey Distribution Tools Public Survey Link 28 Participant List Survey Invitation Log Using a public survey link is the simplest and fastest way to collect responses for your survey. You may obtain the survey link below to email it to your participants. Responses will be collected anonymously (unless the survey contains questions asking for identifying data from the participant). NOTE: Since this method uses a single survey link for all participants, it allows for the possibility of participants taking the survey multiple times, which may be necessary in some cases. To obtain the survey link, copy the URL below and paste it into the body of an email message in your own email client. Your email recipient(s) can then click the link to begin taking your survey. Public Survey URL: https://redcap.mountsinai.org/redcap/surveys/?s=CPKFMHNF8R OR Short Public Survey URL: https://j.mp/3jrz1wM Link Actions Link Customizations Open public survey Get Short Survey Link 🚜 Create Custom Survey Link Send me URL via email </>> Get Embed Code 🚕 Survey Access Code or 🎇 QR Code

Obtaining Data – Data Entry Form

- For data points that are not collected during the surveys, they can be entered in the Record Home Page
- Can enter new data, overwrite data, or make notes on data for the record

 My Projects or Control Center REDCap Messenger 	Demographics		
🏖 View project as user: 🧠 select a user 💙	Adding new Study ID 1		
Project Home and Design	Study ID	đ	
 ☆ Project Home - ≅ Project Setup ☑ Designer - ☑ Dictionary - ☑ Codebook 	Date subject signed consent	UVVV-MM	-DD
Project status: Development Data Collection	Upload the patient's consent form	8	1 Upload file
Survey Distribution Tools	Contact Information		
 Get a public survey link or build a participant list for invibing respondents 	First Name	2	
We Record Status Dashboard	Last Name	P.	
Add / Edit Records Orease new records or edit/view axisting anes States new records or edit/view axisting anes Select other record Data Collection instruments Cemographics	Street, City, State, ZIP		
Baseline Data			Expand
Month 1 Data Completion Data	Phone number	Include A	Irea Code
Applications	E-mail		
Alerts & Notifications	Date of birth		Today YHHO
Data Exports. Reports. and Stats Data Import Tool	Age (years)	100	View equation

Data Collection Instrument	Event 1	Event 2	Event 3
Demographics (survey)	0		
Baseline Data (survey)	۲		
Month 1 Data		0	
Completion Data			0
Delete all data on event	×	×	

Longitudinal Studies

- With longitudinal studies, additional options are available
- Define each of the study Arms and Events for those Arms
- Designate Instruments for each Arm and Event

	m 1: Ari	Arm 1	New Arm						Rename Arm 1
		Event #		Eve	ent Name	9		Event Label 😡	Unique event name () (auto-generated)
۲	0 ×	1.1	Event 1						event_1_arm_1
	0 ×	2	Event 2						event_2_arm_1
	0 ×	3	Event 3						event_3_arm_1
	Add n	ew event	1				1		
			Descriptive	name for t	his event			Label (optional) _date], [weight] kg	
0	Project S	etup 🗂 🛱 D	efine My E	vents	🗄 Designat	te Instruments	s for My Events)	
nce y utiliz oject ick th	ou have o re for eac record. A e <i>Begin E</i> shed mal	defined multip h event by usi my and all dat diting button t	ble events of ing the tabl ta collection to change t	on the <u>Defi</u> e below. T n instrume he relatior	ine <u>My Ever</u> his allows y ents can thu nships below	nts page, you m you to enter dat us be used for a w by designatin your changes.	ay now select wh a on any data co ny event defined g which forms yo	llection form multi l.	ple times for any given
nce y utiliz roject ick th re fini Begin	ou have e e for eac record. A e Begin E shed mal	defined multip h event by usi ny and all dar diting button t cing changes,	ble events of ing the tabl ta collection to change ti click the Sa	on the <u>Defi</u> e below. T n instrume he relatior <i>ve</i> button	ine <u>My Ever</u> his allows y ents can thu nships below to finalize y	nts page, you m you to enter dat us be used for a w by designatin your changes.	ay now select wh a on any data co ny event defined g which forms yo	llection form multi I. ou wish to utilize fo	r which events. When you
nce y utiliz roject ick th e fini Begin	ou have e e for eac record. A e Begin E shed mal	defined multin h event by usi my and all dat diting button t cing changes, Save	ble events of ing the table ta collection to change ti click the Sa	on the <u>Defi</u> e below. T n instrume he relation we button	ine My Even his allows y ents can thu nships below to finalize y Event 3	nts page, you m you to enter dat us be used for a w by designatin your changes.	ay now select wh a on any data co ny event defined g which forms yo	llection form multi I. ou wish to utilize fo	ple times for any given
nce y utiliz oject ick th e fini Begin Data	ou have o record. A e <i>Begin E</i> shed mal Editing	defined multig h event by usion y and all dat diting button to cing changes, Save	ble events c ing the tabl ta collection to change ti click the <i>Sa</i>	on the <u>Defi</u> e below. T n instrume he relation we button	ine My Even his allows y ents can thu nships below to finalize y Event 3	nts page, you m you to enter dat us be used for a w by designatin your changes.	ay now select wh a on any data co ny event defined g which forms yo	llection form multi I. ou wish to utilize fo	ple times for any given
nce y utiliz oject ick th e fini Begin Data pemo	ou have o e for eac record. A e <i>Begin E</i> shed mal Editing Collectio graphics	defined multig h event by usion y and all dat diting button to cing changes, Save	ble events c ing the tabl ta collection to change t click the <i>Sa</i>	on the <u>Defi</u> e below. T n instrume he relation we button	ine My Even his allows y ents can thu nships below to finalize y Event 3	nts page, you m you to enter dat us be used for a w by designatin your changes.	ay now select wh a on any data co ny event defined g which forms yo	llection form multi I. ou wish to utilize fo	ple times for any given

Managing Project Users



Identifier fields

Create & edit rules

Execute rules

Allows Loss to

API Export API Import/Update

Identifier fields and Identifier field Q. Add/Edit/Organize Reports 🗹

1

45% allows upper to year ALL apports (but not precised) data in the superird

M Stats & Charts

Z Data Comparison Tool

What is Data Quality?

White is the REDCER APIZ Settings pertaining to the REDCap Mobile App: REDCap Mobile App

Créate Récords

Rename Records Delete Records

What is the REDCap Hobile App? Allow user to download data for all records to the appl

Seturing containing to project records. Exclaim treas setting

12

Other privileges Distribution Tools E Calendar - Data Import Tool

E Logging E File Repository Data Guality

API

olei				edit)	Setup	
Role nam	ie name to edit		or users assigned to a role me to edit or assign to role)	Expiration (click expiration to	Project Design and	User Rights
(e.g., Project Man	ager, Data Entry P	erson)			
24	Enter new role	e name	Create role			
Create n	ew roles: Add	new user roles	to which users may be assig	ned.		
	Assign new us	er	Assign to role 🤝			
	- OR -					
20	Add new user		Add with custom rig	hts		

- Users with accounts can be added to a project in the **User Rights** section of your project
 - When adding or modifying existing users, a long checkbox section will appear to manage their access
 - It is important to properly manage user rights to protect data and PHI, control project design and life cycle, and maintain accountability

Project Life Cycle

- Development phase of the project is best for creating and testing a project. Avoid entering real data if changes still need to be made.
- Production phase protects collected data by flagging project changes for data loss review. The bulk of data collection should be performed in this phase if feasible.
- ► Analysis/Cleanup phase for finalizing analysis and ending a study.



Data Management

- Data Exports, Reports, and Stats contain methods to export collected data in various formats
- Custom selections can be made to isolate data of interest from larger project databases



Exporting "All data (all records and fields)"

Select your export settings, which includes the export format (Excel/CSV, SAS, SPS5, R, Stata) and if you wish to perform de-identification on the data set.

Cho	oose expo	rt format	De-identification options (optional)	Additional export options
۲	×	CSV / Microsoft Excel (raw data)	The options below allow you to limit the amount of sensitive information that you are exporting out of the project. Check all that	Export survey identifier field and survey timestamp field(s)?
0		CSV / Microsoft Excel (labels)	apply. Known identifiers:	Advanced data formatting options
0	SPSS	SPSS Statistical Software	Remove all tagged Identifier fields (tagged in Data Dictionary) Hash the Record ID field (converts record name to an unrecognizable value)	Set the delimiter used to separate values in the CSV data (only valid for CSV Raw Data and CSV Labels export form, , (comma) - default 👻
0	sas sas	SAS Statistical Software	Free-form text: Aremove unvalidated Text fields (i.e. Reit fields other than dates, northers, etc.) Remove Notes/Essay box fields	Force all numbers into a specified decimal forma You may choose to force all data values containing a deci to have a specified decimal character (comma or period/ stop). This will be applied to all calculations and number-
0	R	R Statistical Software	Date and datetime fields:	validated text values in the export file. Use fields' native decimal format (default)
0	Siele	Stata Statistical Software	— OR — Shift all dates by value between 0 and 364 days (shifted amount determined by algorithm for each -record) What is date shifting?	NOTE: Your data formatting selections above will be remembered in the future and will be pre-selected upon next export.
0	ODM	CDISC ODM (XML)	Also shift all survey completion timestamps by Value between 0 and 364 days (shifted amount determined by algorithm for each record)	
			Deselect all options	Export Data Car
_				Export Data Car
		1967	soft Excel (raw data) ad the survey results in CSV (comma-separated) format, which toxes! You have the choice of downloading the cara either with	Chicol Branchis to damamania

201202

invisions the date will only be read to 255 columns when upened.

Part A: To be able to create a web-based survey form with a link that can be emailed to the subjects.

- Modified BDI questions
- ► Field label & Variable name: Q1
 - Choices:
 - 0, I do not feel sad.
 - 1, I feel sad
 - 2, I am sad all the time and I can't snap out of it.
 - 3, I am so sad and unhappy that I can't stand it.
- ▶ Q2
 - 0, I am not particularly discouraged about the future.
 - 1, I feel discouraged about the future.
 - 2, I feel I have nothing to look forward to.
 - 3, I feel the future is hopeless and that things cannot improve. cannot improve.

- ▶ Q3
 - 0, I do not feel like a failure.
 - 1, I feel I have failed more than the average person.
 - 2, As I look back on my life, all I can see is a lot of failures.
 - 3, I feel I am a complete failure as a person.
- ▶ Q4
 - 0, I get as much satisfaction out of things as I used to.
 - 1, I don't enjoy things the way I used to.
 - 2, I don't get real satisfaction out of anything anymore.
 - 3, I am dissatisfied or bored with everything.

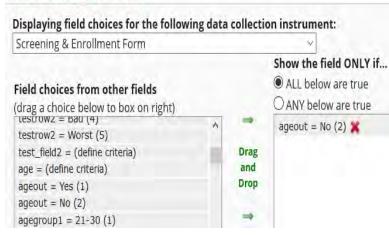
Database vs Longitudinal

- 1. Classic Database Each form can only be completed once. One record per subject.
- 2. Longitudinal
 - Data collected multiple times per subject
 - Fixed number of collection points that correspond to pre-defined events (e.g. initial evaluation, 3mo. follow-up, 6mo. follow-up, 1yr follow-up)
 - Optional scheduling via a project calendar
 - Can have multiple study arms

Building Forms: Branching Logic

- You can use a Drag-N-Drop Logic Builder or Advanced Branching Logic Syntax ►
- You can use fields on the current data entry form OR other forms
- If fields from different events are used in branching logic, the field name needs to be preceded by ► an event name, e.g. [screening arm 1][field1]
 - Event names can be found in 'Define My Events' page

Drag-N-Drop Logic Builder



Advanced Branching Logic Syntax

Show the field ONLY if...

[ageout] = '2'

-- select record --Test logic with a record:

Building Forms: Piping

Without Piping:

What kind of ice cream do you like?	Chocolate Strawberry Vanilla	reset
How often do you eat ice cream?	Once a week Twice a week Three times a week	reset

With Piping:

 Chocolate Strawberry Vanilla 	reset
 Once a week Twice a week Three times a week 	reset
	 Strawberry Vanilla Once a week Twice a week

Building Forms: Piping



How to use piping:

Add Field	Add Marm of Fields		
J 🕼 🐨 😤 🎟 🗙 Variable ice_cream	Edit Fi	eld	ډ
What kind of ice cream do you like?	Vanilla the bottom available,		
Non often do you eat (jce_cream) ice cream?	Question	Number (optional)	Variable Name (utilized during data export) icecream_often
		en do you eat <mark>[ice_cream]</mark> ice cream?	Required?* No Yes Prompt if field is blank
Add Feld	Add Mann of Fields		Identifier? No Ves Does the field contain identifying information (e.g., name, SSN, address)?
			Custom Alignment Right / Vertical (RV) Align the postion of the field on the page
	1, Once 2, Twice		Field Note (optional)
			Looking for Branching Logic? Try clicking the 🐨 icon for this field after clicking the Save or Cancel button below.
		How do I manually code the	e choices?
			Save Cancel

Building Forms: Field Embedding

No field embedding:

Field Embedding

Test Date 1	Today M-D-Y
Test Result 1A	
Test Result 1B	
Test Date 2	Today M-D-Y
Test Result 2A	
Test Result 2B	

With field embedding:

Date		Test Result A	Test Result B	
	Today M-D-Y			
	Today M-D-Y			

Defining Events Longitudinal Projects



- Defining Events allows you to:
 - Use data collection forms multiple times for any given project record.
 - Generate new schedules to display on the Calendar.



How to Define Events

					Upload or downloa	d arms/events	
Arm 1:	U19 Arm	2: IMAGIN	+Add New	/ Arm			Unique event
Arm nan	ne: U19				Renan	ne Arm 1 Delete Arm 1	name is auto- generated.
	Event #	Days Offset	Offset Range Min / Max	Event Name	Custom Event Label 🐠 (optional)	Unique event name 👔 (auto-generated)	
0 ×	1	0	-0/+0	Flu Clinic		flu_clinic_arm_1	
0 ×	2	2	-0/+2	Day 2-4 Blood Draw		day_24_blood_draw_arm_1	This is where yo
0 ×	3	7	-0/+0	Day 7 Blood Draw		day_7_blood_draw_arm_1	will find the
0 ×	4	28	-0/+0	Day 28 Blood Draw		day_28_blood_draw_arm_1	event names fo
2 ×	5	70	-0/+0	Day 70 Blood Draw		day_70_blood_draw_arm_1	use in branchin
ø ×	6	100	-0/+0	Non-Flu Blood Draw		nonflu_blood_draw_arm_1	logic.
Add ne	w event	Days	- 0 + 0				
		Convert from other units		Descriptive name for this event.	Custom Event Label (optional) Example: [Vist_date], [Vist_date],		

How to Designate Instruments to Events

Upload or download instrument mappings						
Arm 1: U19 Arm 2: IMAGIN						
Arm name: U19 Begin Editing Save Sel	ect All Dese	lect All				
Data Collection Instrument	Flu Clinic	Day 2-4 Blood Draw	Day 7 Blood Draw (3)	Day 28 Blood Draw (4)	Day 70 Blood Draw (5)	Non-Flu Blood Draw (6)
Screening & Enrollment Form						
Phone Interview						
Blood Draw Form						
Frailty Assessment						
Study Withdrawal						
Genetic Data Repository Consent						
Additional Blood Draw Form (Non-Flu)						

The event list and instrument mappings can be downloaded from one project and uploaded to another project.

How to Set Up your Project

1	Main project settings						
1	Disable 🖉 Use surveys in this project? 🔋 😵 VIDEO: How to create and manage a survey						
tel	Disable 👩 Use longitudinal data collection with defined events? ?						
ete?	Modify project title, purpose, etc.						
1	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: <u>Download PDF of all instruments</u> OR <u>Download the current Data Dictionary</u>						
	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 [1] Smart Variables Profile @ Action Tags						
	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						
	Enable optional modules and customizations						
	Modify Sepeatable instruments and events 2						
	Modify Repeatable instruments and events ?						
1							
	Enable Suto-numbering for records ?						
J	Enable Auto-numbering for records ? Disable Scheduling module (longitudinal only) ?						
[Enable Auto-numbering for records ? Disable Scheduling module (longitudinal only) ? Disable Randomization module ?						

Optional Modules: Repeatable Instruments

REDCap can repeat a data collection instrument or a entire event an unlimited number of time without having to pre-specify the frequency.

	Event Name	Repeat entire event or selected instruments?		Custom label for epeating instruments (optional) 🥥 xample: [visit_date]; [iveight] kg
in es	Baseline (Arm 1: Intervention)	Repeat Instruments (repeat	Screening Tracking Visits Goal Facilitation Visit PCP Visit Cardiology Visit OPACIC Collaborate V5.0 MoCA Recall Introduction TBQ Global Health Promis Scale V1.2 MoCA Recall Demographics Interviewer Observation Discontinuation Eligibility Waiver Medication Chronic Condition Chronic Condition Category	[gfdate] [pcpdate] [carddate] [ca
	FU (Arm 1: Intervention)	not repeating	Collaboration VAID	

Optional Modules: Repeatable Instruments



▶ Repeatable instruments shown on record home page:

Repeating Instruments





