

Clinical Database Management using REDCap: Tips and Tricks for Efficient Data Capture



I have no conflicts of interest to disclose.



The views expressed in this presentation are that of my own, and they do not serve as a representation of Northwestern University nor that of the statistical community at large.



Outline for today

- Data management and electronic data capture (EDC)
- Getting started with REDCap
- Designing case report forms (CRFs)
- Customization in REDCap
- Special features
- Resources / Limitations



Keep the goals in mind

Collect all the data you need in the right format so that they can be analyzed appropriately later

- 1. Collecting analyzable data
- 2. Ensuring protocol compliance
- 3. Ensuring data quality (few anomalies, inconsistencies, etc.)



Why do we care about Database Management?

- General statistics tends to focus on the methods of analyzing the data and/or study design methods
- (Study design) → study conduct → analysis methods
- But study conduct (including capturing and managing data) can also have large impact on analysis methods appropriate
 - Bias
 - Variability
 - Poor data quality
 - Missing data
 - Etc.
- My job as the statistician = tell a story
 - ...but it's hard to tell a story if I only know the beginning and end
 - The middle is also important



Why do we care about Database Management?

- General statistics tends to focus on the methods of analyzing the data and/or study design methods
- (Study design) → study conduct → analysis methods
- Interim reporting may be important depending on the needs of the study
 - Reports to funder
 - Reports to FDA
 - Reports to Data Monitoring Committees (DMCs)
 - Reports to external advisory boards or Steering Committees
- To prevent difficulties and streamline generation of these reports, it is imperative to understand
 - Study workflow
 - Structure of database
 - Fields that we need





Electronic Data Capture

Electronic Data Capture (EDC)

Note: much of the material I cover will come from the clinical trials perspective, but much of the material can and should be extended to other study types.

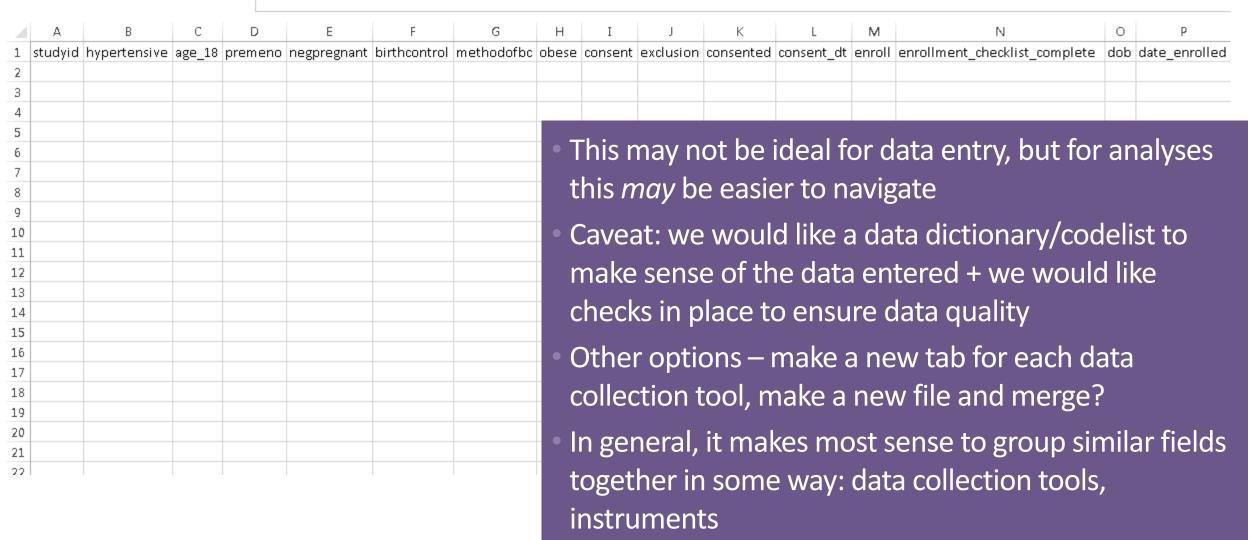
- Study data are usually captured in a series of instruments or forms →
 - These are groupings of similar data fields
 - Although not required, this helps orient the data enterer

Instrument name
Enrollment Checklist
Demographics
Medical History
Treatment Allocation
Vitals
Laboratory Assessment
IP Tracking
Termination
Departures
Adverse Events



Electronic Data Capture

An alternative to data collection tools or instruments...a simple (long) Spreadsheet





Electronic Data Capture (EDC)

- These instruments are given the term Case Report Forms (CRFs)
- Historically, CRFs were paper-based and then converted to electronic format
- Recently, CRFs → electronic CRFs (eCRFs)
 - These terms are often used interchangeably
 - eCRFs have substantial advantages over paper CRFs
 - But there are special considerations regarding EDC-only
- Example CRF →

Demographics

Height in centimeters

BMI

Study ID

Date of Birth

Date of enrollment

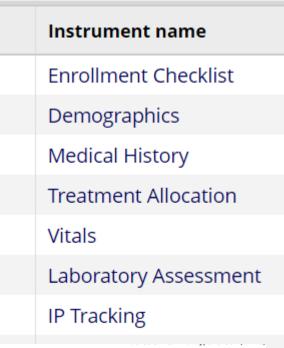
Age

Gender

Race

Ethnicity

Weight in kg



Page 1 of 1

_	
	Female Male
0000	White Black or African American American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islande Other
	Not Hispanic/Latino Hispanic/Latino



Electronic Data Capture

Whether we like it or not, we are moving toward EDC-only studies

- Paper CRFs are becoming outdated
- There are countless ways of maintaining an electronic database
 - Excel single sheet, multiple tabs, multiple files THIS IS NOT RECOMMENDED IN GENERAL
 - Access
 - Oracle
 - SurveyMonkey
 - SPSS
 - OpenClinica
 - StudyTrax
 - ...
- Most Contract Research Organizations (CROs) or Academic Research Organizations (AROs) have homegrown platforms (e.g., EMMES: "Web Form Builder" and "AdvantageEDC")



EDC at Northwestern

What are investigators at NU using for EDC?

- Sadly, Excel = most popular
- Study Tracker/eNOTIS
- SPSS
- REDCap!





- Research Electronic Data Capture
- Used for building and managing surveys and study databases efficiently, on a fixed budget, and securely
 - This includes protected health information (PHI)
- Developed at Vanderbilt University in 2004
- Over 3200 institutions in about 130 countries





- FREE
- Secure
- Easy to learn
- Easily accessible, becoming more universal (>3200 institutions, 130 countries)
- Features that allow for efficient and flexible data capture/management
- •
- •





Getting Started...

NOTE: Institutions may vary



REDCap at Northwestern

- redcap@northwestern.edu
- Online session for New Project Owners (email REDCap support for link)
- All users must complete: REDCap User Agreement
 (https://redcap.nubic.northwestern.edu/redcap/surveys/?s=WK39RMR44F)
- https://redcap.nubic.northwestern.edu/redcap/ (must be on campus network for VPN)
- https://nucats.northwestern.edu/

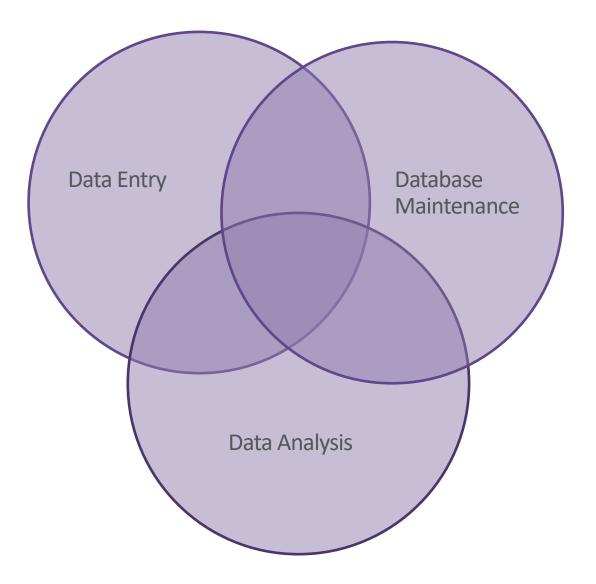


Something to keep in mind...the key players

Who is involved?

- Those that will enter the data
- Those that will build/maintain the database
- Those that will **analyze** the data

- This is extremely important in development of AND ensuring adherence to any data management plan
- All the key players must be on the same page and understand study workflow for this to work





Keep the goals in mind

Collect all the data you need in the right format so that they can be analyzed appropriately later

- 1. Collecting analyzable data
- 2. Ensuring protocol compliance
- 3. Ensuring data quality (few anomalies, inconsistencies, etc.)



Some Basic Terminology

- Development mode → Production mode
- Development
 - Design the database/data collection tools
 - Customize
 - Test!!!!
- Production
 - Live data capture
 - Post-production modifications must be made with caution and may require administrator approval



Getting Started







SCHEDULED MAINTENANCE ANNOUNCEMENT:

Do you have Spanish characters in your project? The recent update may have affected your Spanish characters if you just cut & paste them into your project. Revisit your project and consider hardcoding Spanish characters so that the insertion of these characters can withstand further upgrades. Click for more details.

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 👪 brief summary video (4 min). 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 PEDCan, please contact

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.

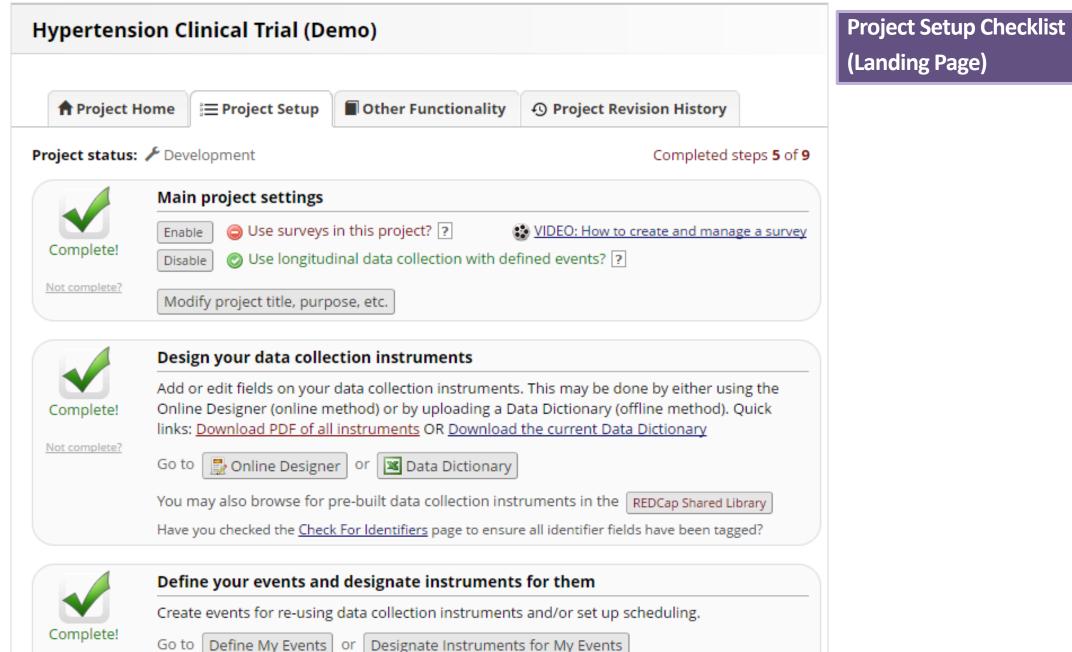
Export data to common data analysis packages - Export your data to Microsoft Excel, PDF, SAS, Stata, R, or SPSS for analysis.

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

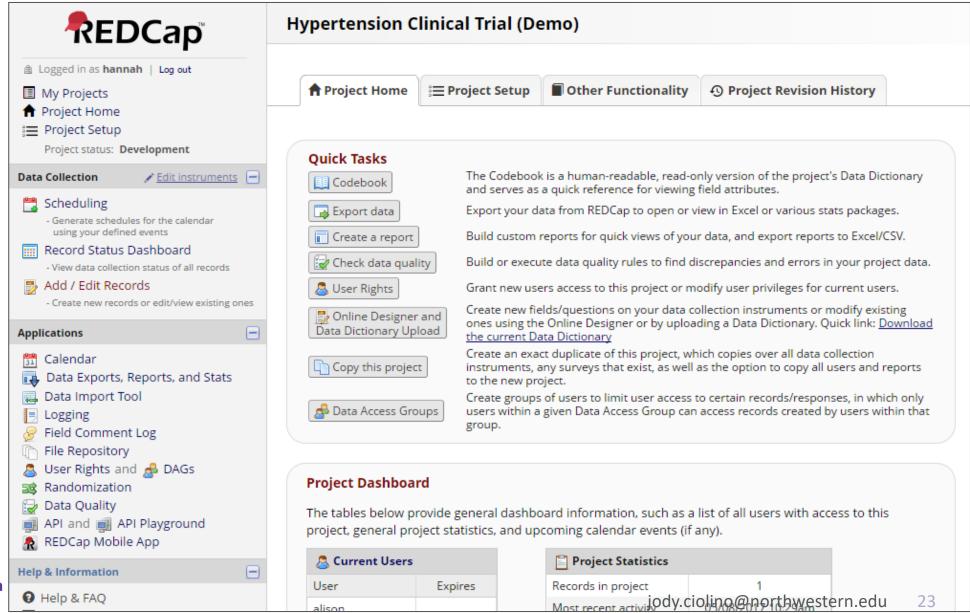






Not complete?

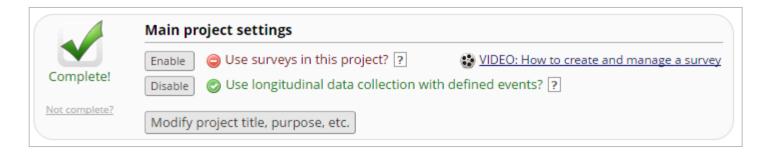
Project Home Tab





Getting Started

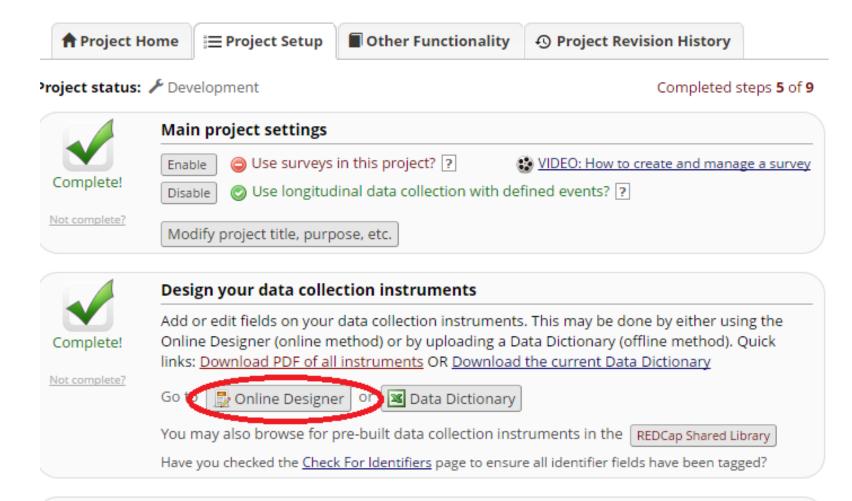
• If designing a prospective study database, almost always will use the longitudinal setting



- Two options in developing data collection tools (case report forms [CRFs])
 - Online designer
 - Data dictionary
- Designing data collection tools will inevitably take the most time



Project Setup: Online Designer





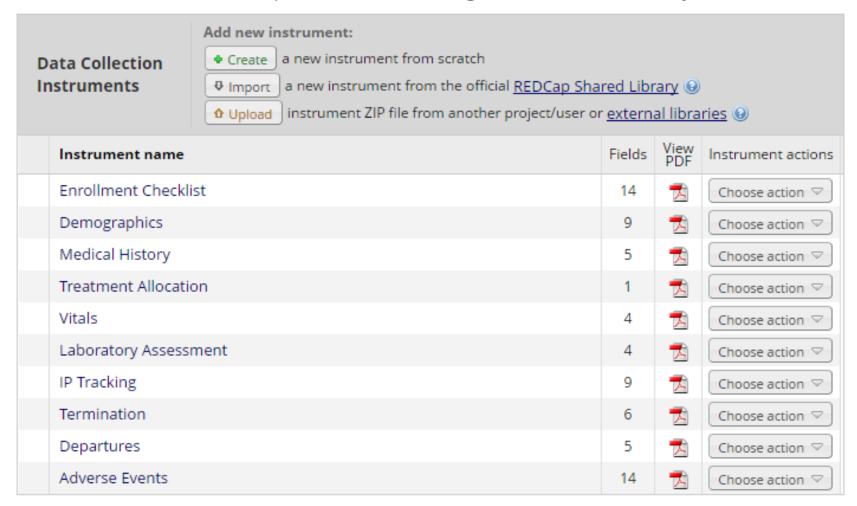
Complete!

Define your events and designate instruments for them

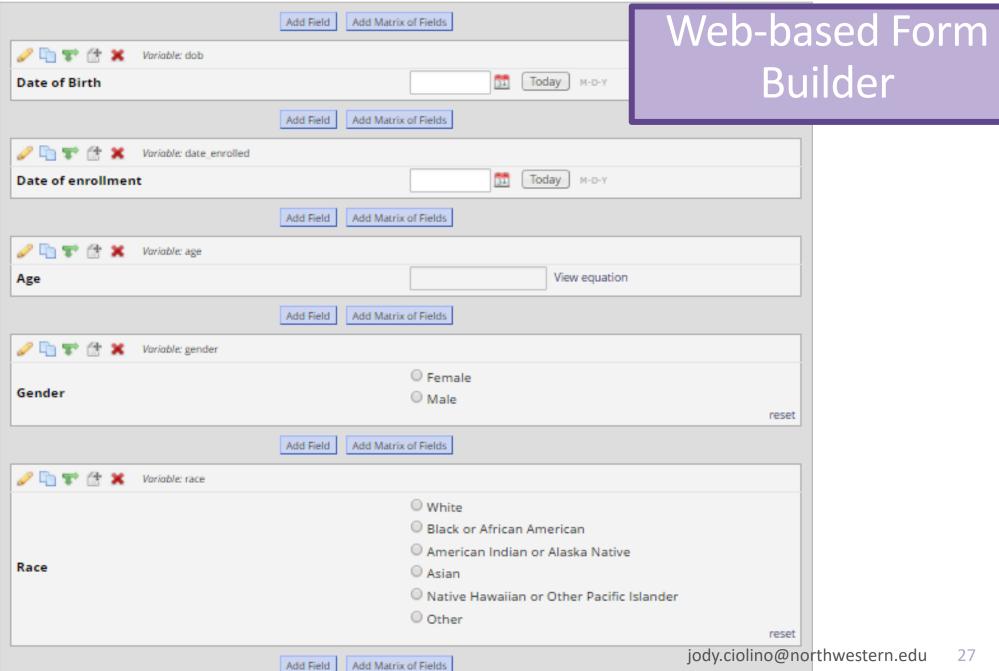
Create events for re-using data collection instruments and/or set up scheduling.

Go to Define My Events or Designate Instruments for My Events

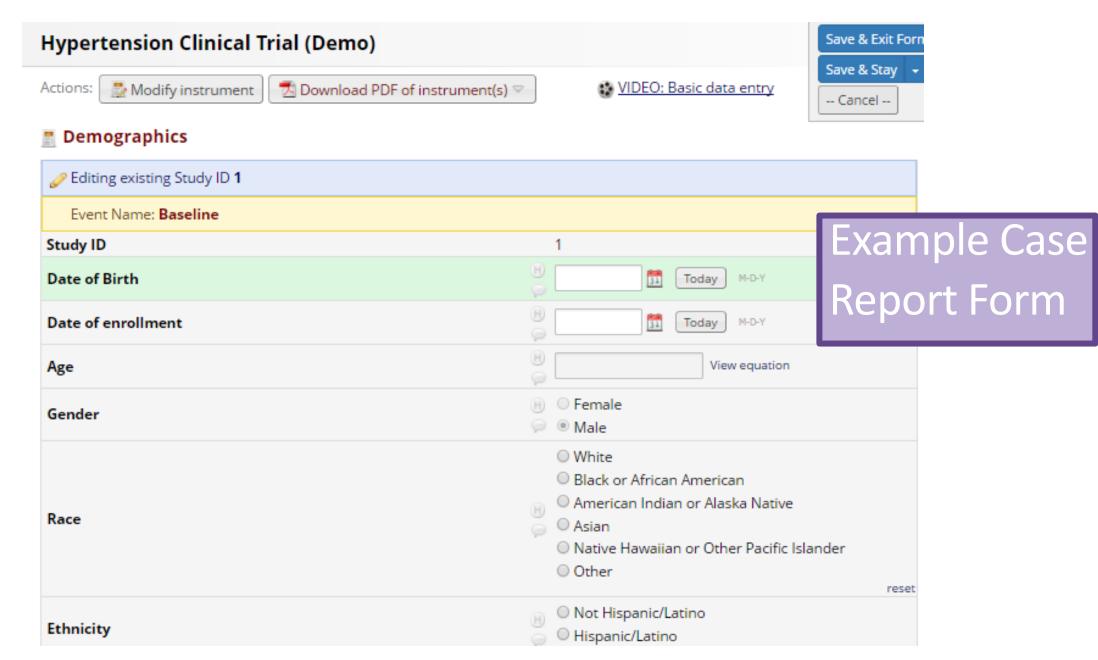
The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.





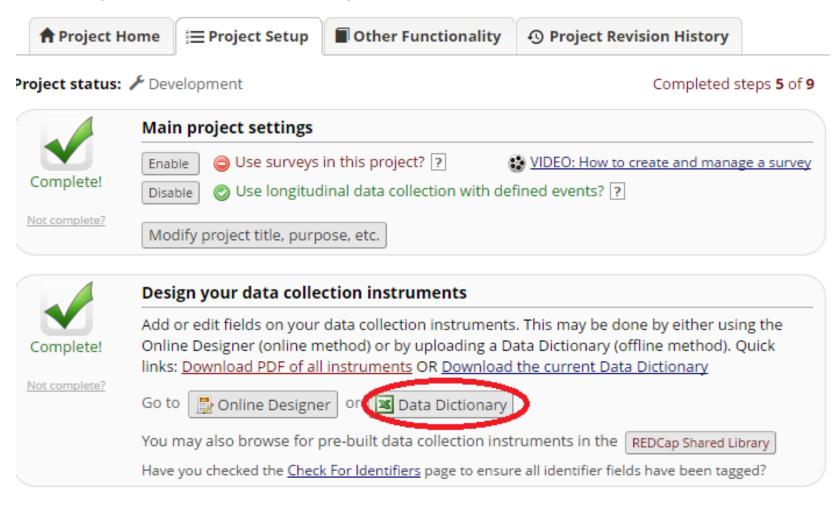








Project Setup: Data Dictionary



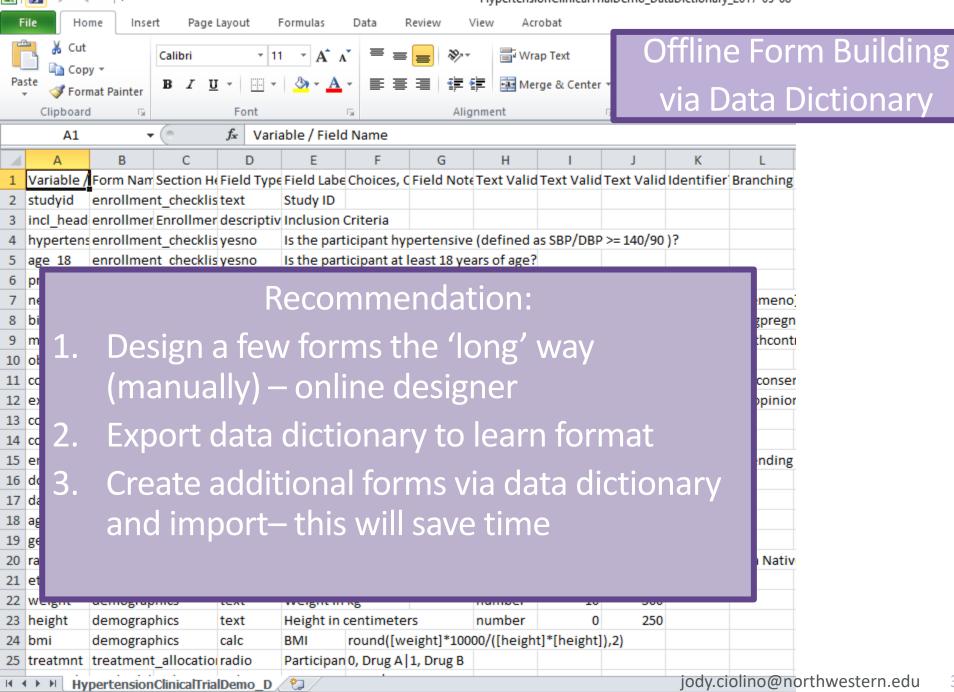


Complete!

Define your events and designate instruments for them

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

o to Define My Events or Designate Instruments for My Events



Ready 2



On designing forms...



Designing Data Collection Tools

- NOTE: REDCap platform distinguishes between data entry forms (Case Report Forms [CRFs]) and surveys (may also serve as CRF for clinical study purposes)
- "Regular" CRFs
 - Data entry must occur by authorized REDCap user (study team member with access to the database)
 - NOT participant facing



Designing Data Collection Tools

Surveys:

- Can be participant facing (participants do not need to access REDCap database to complete electronically)
- Can also be completed by a study team member directly in REDCap
- Have additional settings that allow for greater flexibility ('save and return later', 'survey queue', etc.)



Designing forms: most protocols should have...

...a study schedule (aka a visit matrix, a procedure matrix, etc.)

Procedure	Baseline	Week 4	Week 8	Week 12
Consent	X			
Survey Administration	X			X
Physical Examination	X	X	X	X
Laboratory Assessments	X	X	X	X
Dosing	X	X		
Adverse Events	X	X	X	X

- These matrices will vary in detail and complexity, depending upon study, IRB requirements, and the clinical teams who write them
- NOTE: "Clinical teams who write the protocols do not always provide the level of specificity that data management requires...go back to the study team and completely identify the appropriate fields" (Clinical Database Management, p. 11)



In building the set of CRFs, your job is to take...

...a study schedule (aka a visit matrix, a procedure matrix, etc.)

Procedure

Consent

Survey Administration

Physical Examination

Laboratory Assessments

Dosing

Adverse Events

Convert this to

CRF

Enrollment Checklist

Consent

Demographics

PROMIS-Anxiety

PROMIS-Global Health

PROMIS-Depression

Medical History

Vital Signs

Urinalysis

Hematology

PK Sampling

Intervention Dosing

Adverse Events

Concomitant Medications

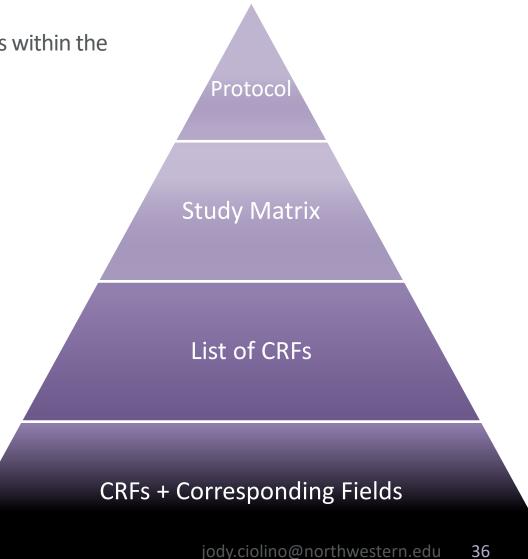
Study Termination jody.ciolino@northwestern.edu



Designing CRFs

• Protocol → Study Matrix → List of corresponding CRFs → Fields within the **CRFs**

Start general and move toward specifics gradually





Some "typical" CRFs

Standard across studies; often not explicitly stated in the protocol

- Screening (enrollment checklist, may want to capture ineligibility reasons)
- Demographics (you will inevitably need to describe your participants)
 - Sex, age, race/ethnicity
 - Marital status, insurance status, income, residence, etc.
- Medical history
 - General comorbidities
 - Often ensures eligibility
 - Again, allows for description of sample
- Concomitant medications
- Adverse events/SAEs
- Participant status or study termination
- Dosing/investigational product tracking (pill counts, etc.)



Some words of caution

Things to avoid

- Duplicate data (across forms, within forms)
 - Within: DOB and age
 - Across: visit date, drug type, etc.
- Calculations within the database
 - Either by study personnel (subject to error)
 - OR automatic calculations (may or may not be a problem)
- Collecting "just in case it proves interesting"
 - There is a cost to every data point
 - Programming
 - Cleaning
 - Verification in source documents
 - Follow-up on discrepancies



Specifying fields within CRFs

Now that you have your list of CRFs

- Move through them form-by-form
- Suggest: start with the most vital data
 - Enrollment/eligibility
 - Primary outcomes
- May want to divide up the forms
- May want to have a single/few person(s) develop and others review

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Enrollment Checklist

Demographics

Medical History

Treatment Allocation

Vitals

Laboratory Assessment

IP Tracking

Termination

Departures

Adverse Events



Field types vs. Data types

Distinguishing between field types vs. data types

- Statistically, data types are most relevant
 - Numeric/quantitative
 - Categorical/qualitative
- This will drive how we can analyze the data



Field types vs. Data types

Distinguishing between field types vs. data types

- From the database perspective, field types:
 - Categorical data-relevant fields:
 - Radio buttons
 - Dropdowns
 - Checkboxes
 - Quantitative data-relevant fields:
 - Numeric fields (integers, numbers, etc.)
 - Date fields
 - Calculated fields
 - Visual analog scales
- Field types that are often "not usable" statistically, but relevant for any database: free text, notes/comments, etc.



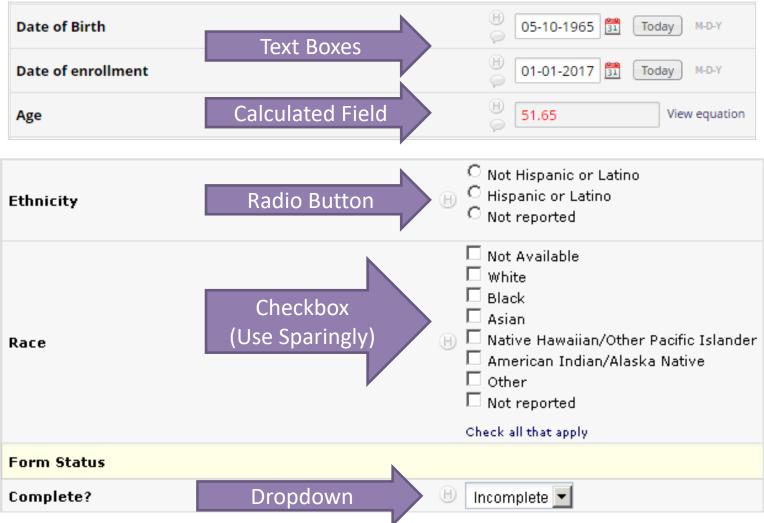
Common field types in REDCap

- Text single-line text box (text and numbers)
- **Dropdown** dropdown menu with multiple choice options
- Radio radio button with multiple choice options
- Calculated perform real-time calculations (e.g., age)

- Notes larger text box
- Checkbox allow selection of > 1 option
- File upload a document
- Descriptive text displayed with no data entry and optional image/file attachment
- Slider visual analog scale (0 100)

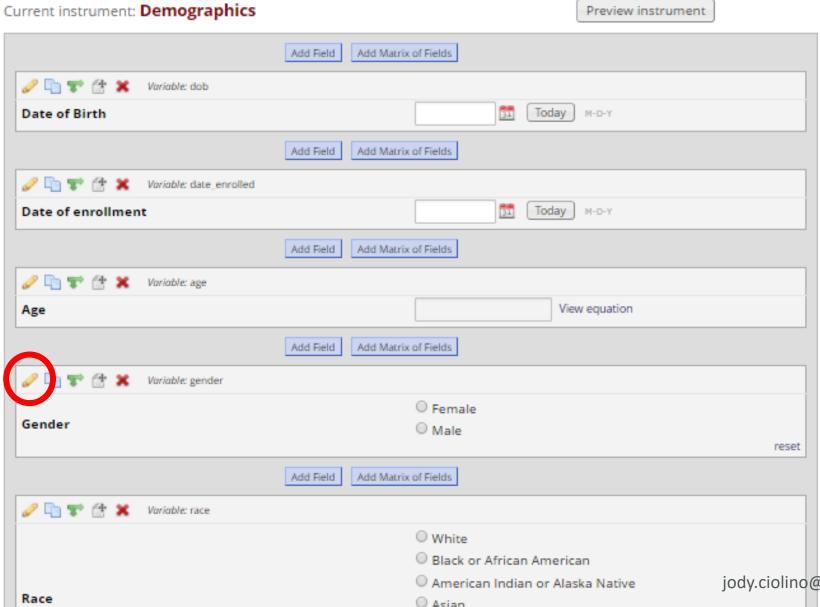


Field Types: Examples





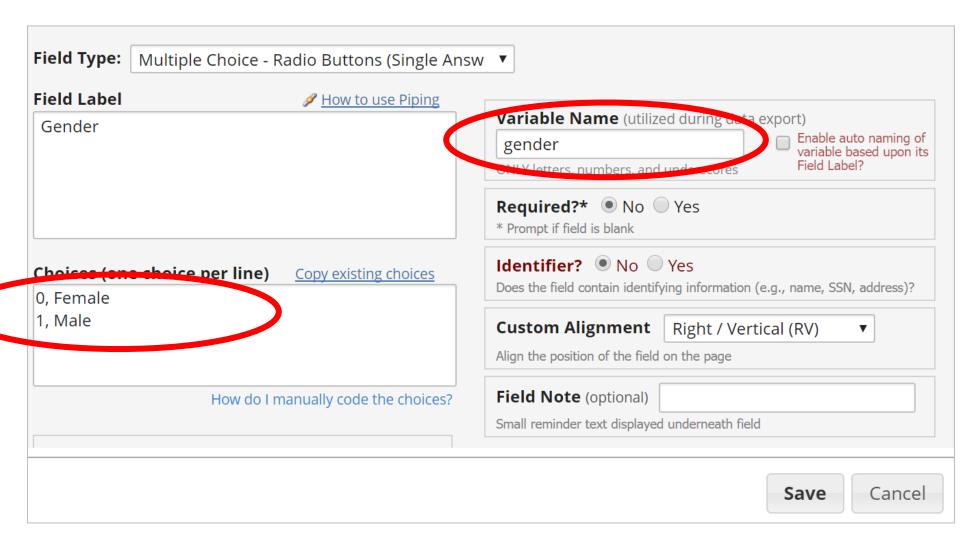
Manual Creation of Radio Button Field





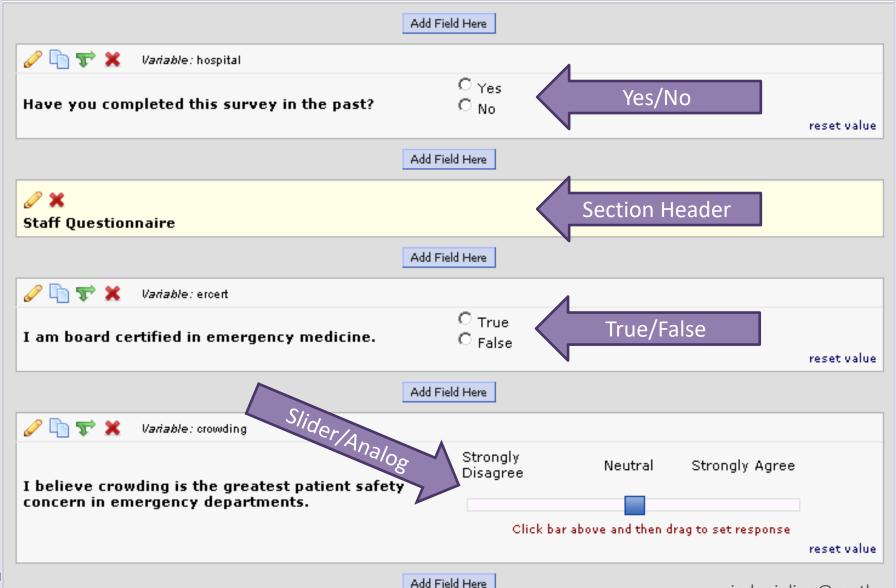
Manual Creation of Radio Button Field

Statistically speaking...



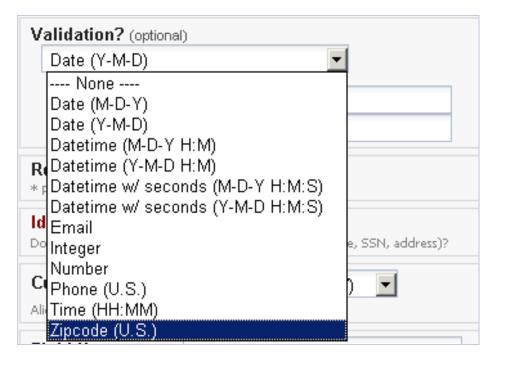


Field Types: Examples



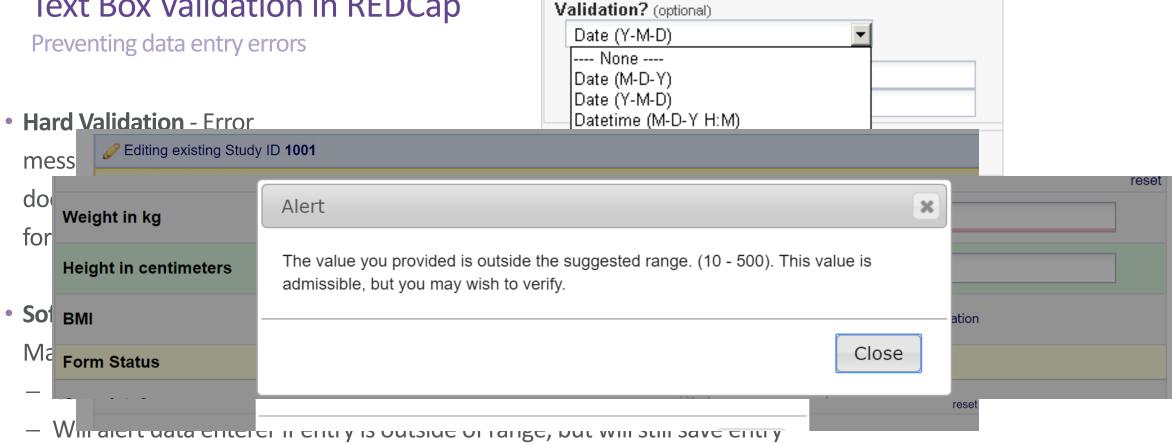
Text Boxes in REDCap

- REDCap **default** for a **text box** field = character
- In order to indicate that this field will be numeric in nature, you must add validation





Text Box Validation in REDCap





Statistically Speaking...

• Validation feature is invaluable in ensuring high-quality data for analyses

Edit Fiold

- Prevents many headaches later...
- Example:

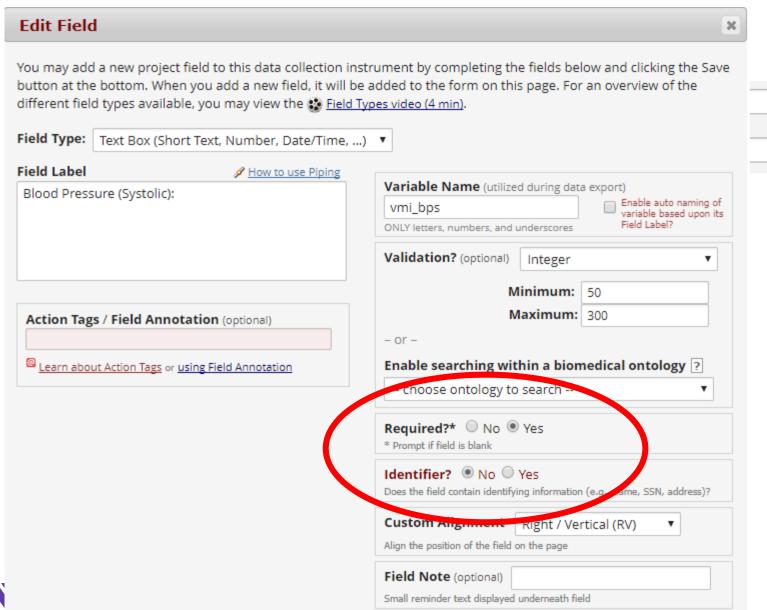
Excelvs.REDCap

1	Α	В
1	pat_id	bp
2	1001	124/76
3	1002	132/90
4	1003	140/85
5	1004	nd
6	1005	not done
7		
0		

ONLY letters, numbers, and Field underscores	
Blood Pressure (Systolic): Variable Name (utilized during data export) vmi_bps ONLY letters, numbers, and underscores	
Vmi_bps ONLY letters, numbers, and underscores	
ONLY letters, numbers, and Field underscores	le auto naming o ble based upon it
	Label?
Validation? (optional)	
Integer ▼	
Action Tags / Field Annotation (optional) jody.ciolino@northwestern.edu	



Required and Identifier Fields (REDCap)



Required and Identifier Fields (REDCap)

- Required Will alert data enterer if "required" field is left blank, but will allow you to opt to leave blank*
- Identifier Tags variables with PHI for removal option during export

intake_12	Full name:	text, Identifier
intake_105	Baby's Name(s):	text, Identifier
intake_101	Participant date of birth:	text (date_mdy, Max: 2003-12-01)
intake_150	Participant age: MUST BE >16	calc Calculation: datediff([intake_101],[intake_100],"y", "mdy")
intake_5	Primary language:	radio 1 English 2 Spanish
intake_2	Participant Email:	text (email), jkdម្ហាប់ថ្នាំទាំ០@northwestern.edu 51

Matrix of Fields

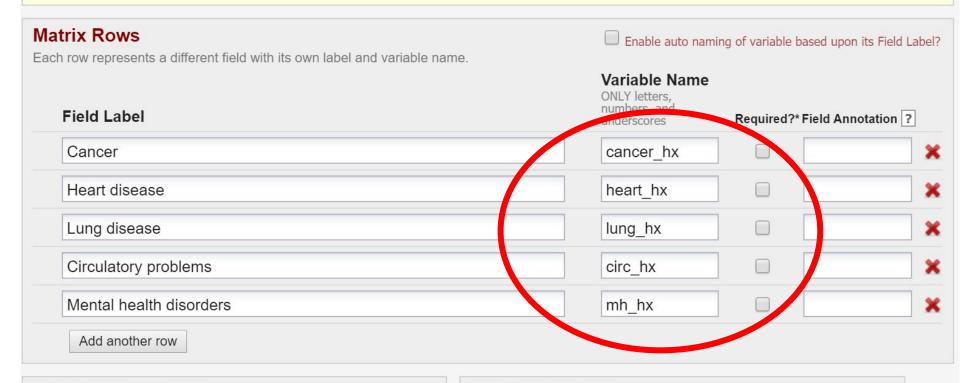
- Ideal for grouping of questions that share same response options (i.e., Likert scale questions)
- "Answer Format" can be specified as radio buttons or checkboxes
- May use "ranking" to allow only one selection per column across all fields in the matrix (radio buttons only)



Matrix Header Text (optional)

Indicate whether the participant has a history of any of the following conditions:

Field Matrix Setup



Matrix Column Choices

Choices (one shoice per line)

0, No 1, Yes

Other Matrix Info

Answer Format:

Single Answer (Radio Buttons) ▼

Ranking: What is a ranked matrix of fields?

Allow only 1 choice to be selected per column (radio buttons only)

Matrix group name: ONLY letters, numbers, and underscores

med hx

What is a matrix group name? jody.ciolino@northwestern.edu

Matrix of Fields: Example

Indicate whether the participant has a history of	of any of the following conditions:	
	No	Yes
Cancer		
		reset
Heart disease		reset
Lung disease		
		reset
Circulatory problems		reset
Mental health disorders		
merical fiedial aloof acto		reset



Codebook in REDCap (slight digression)

Oftentimes this is called the "codelist" (especially by other platforms)

- Easy-to-read version of project's Data Dictionary
- Quick reference for viewing field attributes
- Updated in real-time

	#	Variable / Field Name	Field Label Field Note	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Ins	trume	nt: Enrollment Checklist	(enrollment_checklist)	
<i></i>	1	studyid	Study ID	text
₽	2	incl_header	Section Header: Enrollment Checklist Inclusion Criteria	descriptive
₽	3	hypertensive	Is the participant hypertensive (defined as SBP/DBP >= 140/90)?	yesno 1 Yes 0 No
₩	4	age_18	Is the participant at least 18 years of age?	yesno 1 Yes 0 No



Branching (aka "skip") Logic



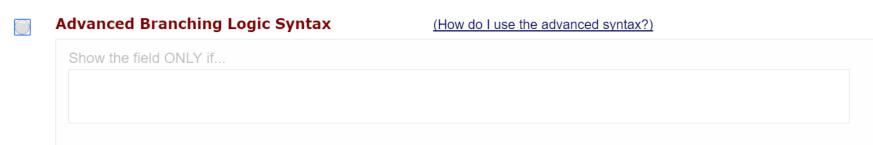
Branching Logic

- Information from other fields determines whether a particular field will be displayed (e.g., males should not have a pregnancy test, so we should not have any data on pregnancy in this population)
- Statistically speaking...this is yet another invaluable data quality tool that will make data cleaning prior to analyses much easier

Is the participant a female of childbearing a	ge? O Yes	
Add	Field Add Matrix of Fields	reset
	nching logic exists]	
Is there a negative pregnancy test?	○ Yes ○ No	reset
Add	Field Add Matrix of Fields	
	ching logic exists]	
Is the participant on birth control?	○ Yes ○ No jody.ciolino@no	orthwestern.edu

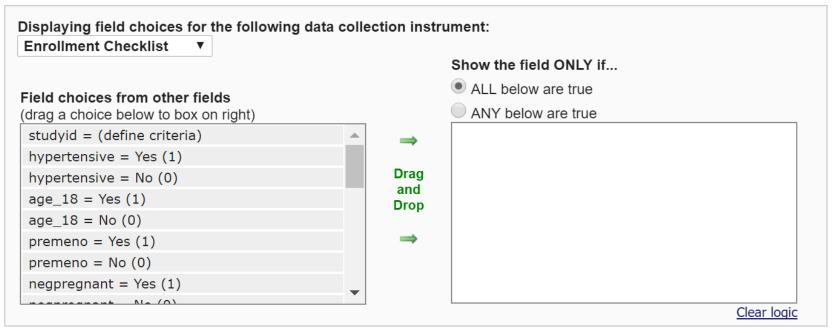


Choose method below for the following field: enroll - Enrollment Status:



- OR -

Drag-N-Drop Logic Builder





Best Practices: Developing Standards

Some tips to help streamline and prevent issues later

- Example: Date format will always be: YYYY-MM-DD
- Example: if "not detectable" value, enter: 8888
- Example: use <first three letters of form name>_<field #> to indicate variable name...



Best Practices: Developing Standards

Some tips to help streamline and prevent issues later

Ins	trument:	Demographics (demographics)		
₽	286	dem	Demographics	descriptive
<i>⊘</i>	287	dem_1	1. What is your date of birth?	text (date_mdy, Max: 2003-12-01), Required
₽	288	dem_2	2. What is your current marital status?	radio 1 Single 2 Engaged 3 Married 4 Separated 5 Widowed 6 Living with Partner
₩	289	dem_3	3. What is the highest level of education you have completed?	radio 1 1st to 8th grade 2 9th to 12th grade (no diploma) 3 High school diploma or GED 4 Some college, no degree 5 College degree or beyond
₽	290	dem_4	4. Was your current pregnancy planned?	yesno 1 Yes 0 No



Best Practices: Developing Standards

Some tips to help streamline and prevent issues later

- Develop study-wide codes for:
 - Yes/no = 1/0
 - "Not Detectable" (example: 8888)
 - "Could not obtain" (example: 9999)
 - "Other" (example: 7777)
- Use consistent units (cm vs. inches, lbs. vs kg, temperature)
- Time variables may be tricky...try to always use 24-hour clock (military time)
- Other example regarding labeling corresponding Spanish assessment items ("sp_")
- Avoid checkboxes
- Decide ahead of time regarding which fields are "required"
- Etc.
- Etc.





Customizations in REDCap

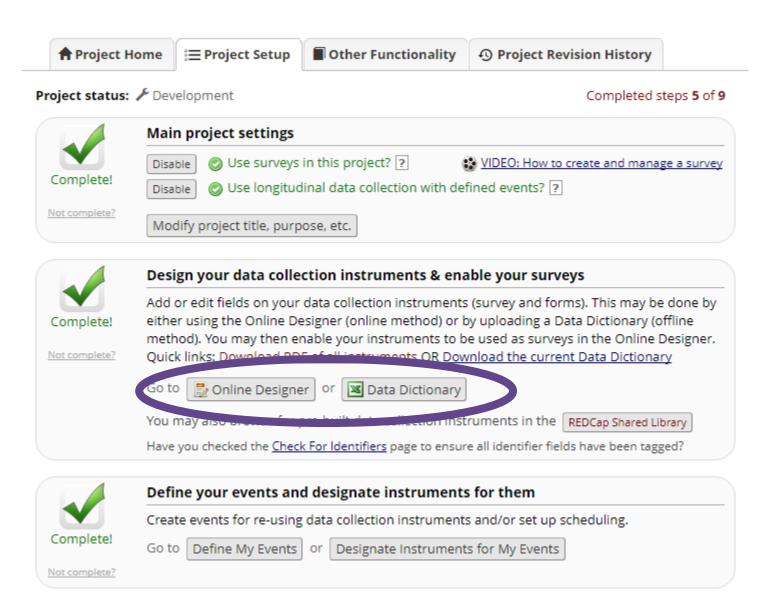




Longitudinal Designs

Recall...

- We previously discussed:
 - Field types (e.g., text, radio button, etc.)
 - Grouping fields in instruments or CRFs
 - These instruments are specified via the online designer or you may use the data dictionary option in REDCap



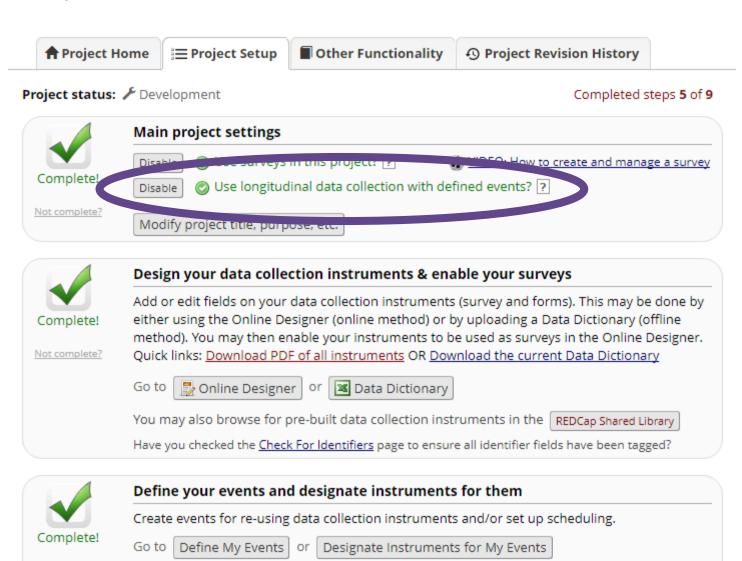


Longitudinal Designs in REDCap

Most likely the most common

- This will ensure that your data end up in "long" or "vertical" format
- Use this when:
 - Instruments/sets of fields are repeated across multiple instances
 - There are a set, finite number of "visits" or instances
- Recall, that most protocols should have...

Not complete?





Most protocols *should* have...

...a study schedule (aka a visit matrix, a procedure matrix, etc.)

Procedure	Baseline	Week 4	Week 8	Week 12
Consent	X			
Survey Administration	X			X
Physical Examination	X	X	X	X
Laboratory Assessments	X	X	X	X
Dosing	X	X		
Adverse Events	X	X	X	X

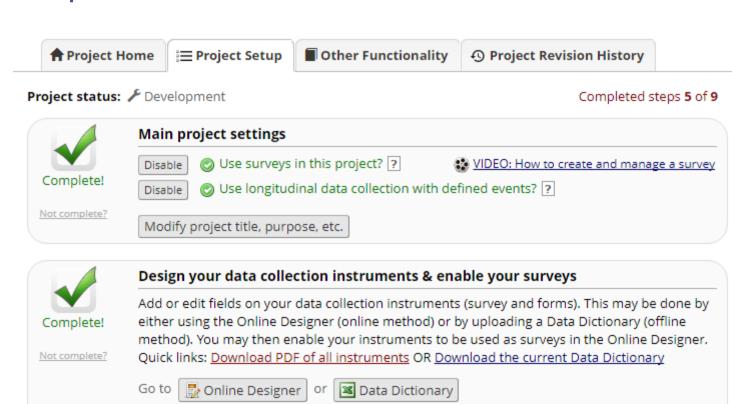
• These matrices will vary in detail and complexity, depending upon study, IRB requirements, and the clinical teams who write them



Longitudinal Designs in REDCap

Most likely the most common

- To specify the events: "Define My Events"
- To specify CRFs for each event:
 "Designate Instruments for My Events"
- Terminology:
 - Events = groupings of (repeated)forms at specific study time points
 - "Arms" = groupings of events
 (schedule for participants may vary according to study arm or study progress)





Not complete?

Define your events and designate instruments for them

Create events for scheduling.

You may also browse for pre-built data collection instruments in the REDCap Shared Library
Have you checked the Check For Identifiers page to ensure all identifier fields have been tagged?

50 to Define My Events or Designate Instruments for My Events



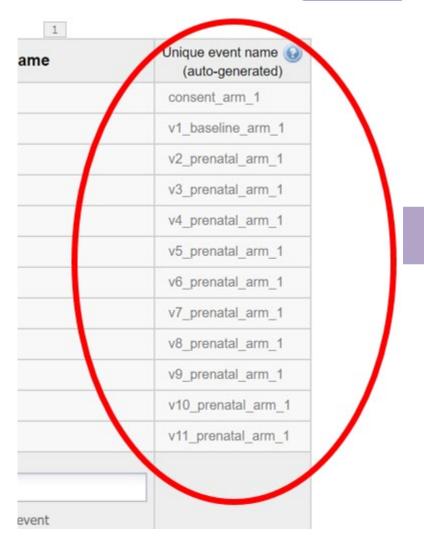
Arm name: Prenatal Rename Arm 1

	Event #	Days Offset	Offset Range Min / Max	Event Name	Unique event name (auto-generated)
Ø	1	0	-0/+0	Consent	consent_arm_1
0	2	0	-0/+0	V1 Baseline	v1_baseline_arm_1
Ø.	3	28	-14/+14	V2 Prenatal	v2_prenatal_arm_1
0	4	56	-14/+14	V3 Prenatal	v3_prenatal_arm_1
0	5	84	-14/+14	V4 Prenatal	v4_prenatal_arm_1
Ø	6	112	-14/+14	V5 Prenatal	v5_prenatal_arm_1
Ø	7	140	-14/+14	V6 Prenatal	v6_prenatal_arm_1
Ø	8	168	-14/+14	V7 Prenatal	v7_prenatal_arm_1
Ø	9	196	-14/+14	V8 Prenatal	v8_prenatal_arm_1
Ø	10	224	-14/+14	V9 Prenatal	v9_prenatal_arm_1
0	11	252	-14/+14	V10 Prenatal	v10_prenatal_arm_1
Ø	12	280	-14/+14	V11 Prenatal	v11_prenatal_arm_1
Add ne	w event	Days <u>Convert from other units</u>	-0 +0	Descriptive name for this event	



Upon Export...

Rename Arm 1



record_id	redcap_event_name	scr_date	scr_age	scr_care	scr_ssri
HT05-5001	consent_arm_1	2016-10-04	1	1	1
HT05-5001	v1_baseline_arm_1				
HT05-5001	v2_prenatal_arm_1				
HT05-5001	v3_prenatal_arm_1				
HT05-5001	v4_prenatal_arm_1				
HT05-5001	v5_prenatal_arm_1				
HT05-5001	v6_prenatal_arm_1				
HT05-5001	v7_prenatal_arm_1				
HT05-5001	v8_prenatal_arm_1				
HT05-5001	v9_prenatal_arm_1				
HT05-5001	delivery_arm_2				
HT05-5001	v1_pp_arm_2				
HT05-5001	v2_pp_arm_2				
HT05-5001	change_1_arm_3				
HT05-5001	baby_weights_arm_4				
HT05-5001	2_week_ifq_arm_4				
HT05-5001	6_week_ifq_arm_4				
HT05-5001	14_week_ifq_arm_4				



Designate Instruments for Events

Data Collection Instrument	Consent (1)	V1 Baseline	V2 Prenatal	V3 Prenatal	V4 Prenatal	V5 Prenatal (6)	V6 Prenatal	V7 Prenatal	V8 Prenatal	V9 Prenatal	V10 Prenatal	V11 Prenata (12)
Screen Consent Eligibility	✓											
Consent Change		~	~	~	V	~	~	~	~	~	~	V
Participant Status	4											
Visit Compliance		~										
SSRI Dose Trajectory	4											
Concomitant Medications	~											
Diagnosis Trajectory	~											
Concentration		~	~	~	4	~	✓	✓	~	~	~	4
Blood Draw		~	~	~	V	~	~	~	~	~	~	4
Vitals		~	~	~	V	~	~	~	~	~	~	4
Visit Medical Information		~	V	V	4	V	4	V	V	✓	~	4
Alcohol Cigarette And Other Drug Use		~	V	V	V	V	V	V	V	4	~	✓
Abbreviated Asberg Side Effect (ASE)		~	~	~	~	~	~	~	~	V	V	V





Cross-sectional designs

Cross-sectional designs in REDCap

- Less common, but can be useful
- Common uses:
 - Cross-sectional studies ("snapshot in time") single instance of assessment(s)
 - Simple pre-post designs few instruments, few time points
 - When desired output = "flat" or "horizontal" data file



Cross-sectional designs in REDCap

- These are simpler to design in REDCap, but still require careful considerations (I have an anecdote about this as well)
- Caution: for pre-post designs, ensure consistency in naming conventions of fields
 - anxiety_pre vs. anxiety_post versus anxiety_1 vs. anxiety_2
 - If multiple anxiety questions?
 - anx1_1, anx1_2 or anx2_1, anx2_2 what may be the best way to program these?
 - Whatever you choose, ensure consistency!





Repeatable Events

Repeatable Events

This is a newer feature!

- Recall this OPTI-MOM study example
 - We had to pre-program 11 prenatal events
 - Reason: we didn't know how many visits an individual woman would have

Arm 1: Prenatal Arm 2: Postpartum Arm 3: Rx Drug Change Log Arm 4: Baby Pilot +Add New Arm

Arm name: Prenatal Rename Arm 1

	Event #	Days Offset	Offset Range Min / Max	Event Name	Unique event name (auto-generated)
0	1	0	-0/+0	Consent	consent_arm_1
0	2	0	-0/+0	V1 Baseline	v1_baseline_arm_1
0	3	28	-14/+14	V2 Prenatal	v2_prenatal_arm_1
0	4	56	-14/+14	V3 Prenatal	v3_prenatal_arm_1
0	5	84	-14/+14	V4 Prenatal	v4_prenatal_arm_1
0	6	112	-14/+14	V5 Prenatal	v5_prenatal_arm_1
0	7	140	-14/+14	V6 Prenatal	v6_prenatal_arm_1
0	8	168	-14/+14	V7 Prenatal	v7_prenatal_arm_1
0	9	196	-14/+14	V8 Prenatal	v8_prenatal_arm_1
0	10	224	-14/+14	V9 Prenatal	v9_prenatal_arm_1
0	11	252	-14/+14	V10 Prenatal	v10_prenatal_arm_1
0	12	280	-14/+14	V11 Prenatal	v11_prenatal_arm_1
Add ne	w event	Days	-0 +0		
		Convert from other units		Descriptive name for this event	



Repeatable Events

- Additionally, we want to capture information around a dose change – each of these changes should be an "Event"...
- A woman may have 0 to many dose changes
- An alternative to having pre-defined/preprogrammed events = Repeatable Events

Arm name: Rx Drug Change Log

	Event #	Days Offset	Offset Range Min / Max	Event Name	Custom Event Label (a) (optional)	Unique event name (auto-generated)
Ø.	1	1	-0/+0	Change 1		change_1_arm_3
Ø.	2	2	-0/+0	Change 2		change_2_arm_3
Ø.	3	3	-0/+0	Change 3		change_3_arm_3
Ø	4	4	-0/+0	Change 4		change_4_arm_3
Ø	5	5	-0/+0	Change 5		change_5_arm_3
Ø	6	6	-0/+0	Change 6		change_6_arm_3
<i></i>	7	7	-0/+0	Change 7		change_7_arm_3
<i></i>	8	8	-0/+0	Change 8		change_8_arm_3
Ø.	9	9	-0/+0	Change 9		change_9_arm_3
<i></i>	10	10	-0/+0	Change 10		change_10_arm_3
Add ne	w event	Days Convert from other units	-0+0	Descriptive name for this event	Custom Event Label (optional) Example: [visit_date], [weight] kg	



Rename Arm 3

Example: Repeatable Events

The Retinoid Protocol (PI: Katherine Wisner [subcontract with UIC])

- Hypothesis: decreased levels of retinoic acid during pregnancy = responsible for some metabolic changes (CYP) observed during pregnancy
- Design: prospective, observational cohort study
 - Healthy, pregnant women (prior to 13 weeks gestation at entry)
 - Measure plasma levels of retinoid every four weeks during pregnancy + two visits postpartum
 - Ideally, at the same time of day (8am-noon) throughout
- Data collection tools (CRFs) →
- Since there will be varied numbers of visits per woman, we chose to use repeatable events feature

Instrument name	Fields
Enrollment	32
Participant Status	26
Visit Compliance	50
Demographics	15
Visit Medical Information	15
Alcohol Cigarette	5
Blood Draw	10
Blood Draw Results	8
Concomitant Medications	12
Adverse Event Protocol Departure	46



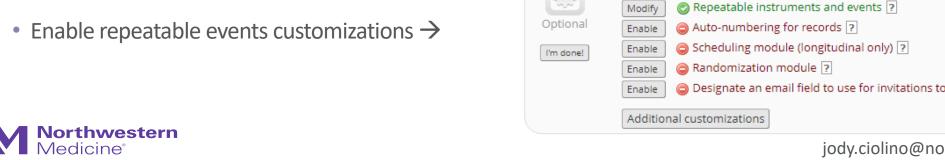
Example: Repeatable Events

The Retinoid protocol

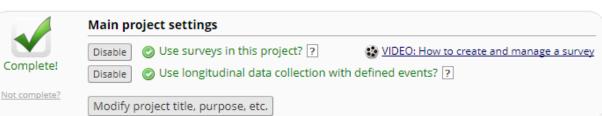
Set up as a longitudinal study →

• Create instruments →

Designate instruments for events →



Project status: 🔑 Development





Not complete?

Complete!

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



You may also browse for pre-built data collection instruments in the REDCap Shared Library

Have you checked the Check For Identifiers page to ensure all identifier fields have been tagged?



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

Designate an email field to use for invitations to survey participants ?

Completed steps 3 of 8

Retinoid Example, Continued

Designating instruments for events

- Just two "events": intake (consent, eligibility) + Follow-up
- All follow-up visits are identical
 - Visit medical information
 - Alcohol/cigarette use
 - Blood draw
- This current setup, only assumes two events, but adding the repeatable events will allow for unlimited number of followup visits

 Side note: ConMeds and AEs/protocol departures are repeatable instruments within a single event – will discuss later

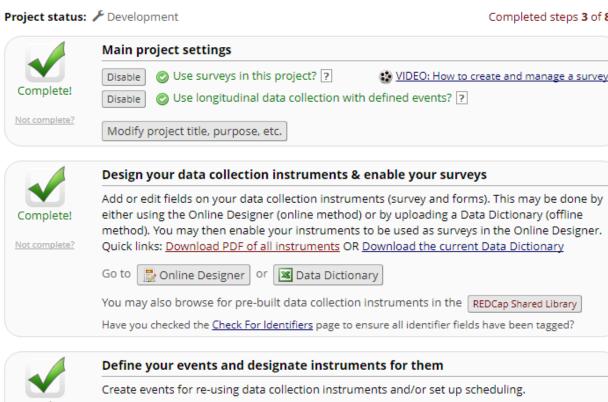
Data Collection Instrument	Intake	Follow- up
Enrollment	V	
Participant Status	V	
Visit Compliance	V	
Demographics (survey)	V	
Visit Medical Information		V
Alcohol Cigarette		V
Blood Draw		V
Blood Draw Results		4
Concomitant Medications	V	
Adverse Event Protocol Departure	V	

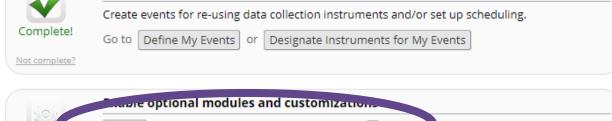


• Create instruments →

Designate instruments for events →

Enable repeatable events customizations →







Completed steps 3 of 8

Specifying the repeating event...

Repeatable instruments and events × An excellent way to collect repeating data in REDCap is to use repeatable instruments and/or repeatable events. This is sometimes called one-to-many data collection. Some examples may include but are not limited to the following: data from multiple visits or observations, concomitant medications, adverse events, or repetitive surveys (daily, weekly, etc.). Below you can specify a data collection instrument or a whole event of instruments to be infinitely repeatable, in which each repeating instrument or event can be repeated a different number of times for each record. You may set any event in the project to be repeatable *or* alternatively set selected instruments to be repeatable within an event. The 'Repeat Entire Event' option means that all the event's instruments will repeat together and stay connected, whereas the 'Repeat Instruments' option implies that the instruments will repeat separately and independently from each other on that event. Once an instrument or event is set to repeat, you will see options on the Record Home Page to add another instance of the instrument/event for the currently selected record. Custom label for Repeat entire event or selected repeating instruments (optional) (a) Instrument name Event Name instruments? (select instruments to repeat) Example: [visit_date], [weight] kg Enrollment Participant Status Visit Compliance Intake Repeat Instruments (repeat ▼ Demographics Concomitant Medications Advarea Event Protocol Depar... ✓ Visit Medical Information Follow-up ✓ Alcohol Cigarette Repeat Entire Event (repeat ▼ ✓ Blood Draw Cancel



Data entry + data export

Repeatable Events (Retinoid Example)

- This is what the record will look like →
- We have three follow-up visits logged for this participant

Corresponding export looks like this:

Record ID RET-0004

Data Collection Instrument	Intake	Follow- up	(#2)	+ Add new (#3)
Enrollment	•			
Participant Status	<u>-</u>			
Visit Compliance	<u>-</u>			
Demographics (survey)	Ø			
Visit Medical Information				
Alcohol Cigarette				
Blood Draw				

record_id	redcap_event_name	redcap_repeat_instance	scr_age	scr_preg13	scr_sgle_gest	scr_bd_time
RET-0004	intake_arm_1		25	1	1	1
RET-0004	followup_arm_1	1				
RET-0004	followup_arm_1	2				
RET-0004	followup_arm_1	3				



Which is better?

Pre-defined events vs. Repeatable Events

- This will depend on the situation: study design, the study team, etc.
- Again, will require input from all key players (enterers, builders, analyzers)
- Compare "Record Status Dashboards":



Pre-defined events

- Dashboard is essentially useless and unmanageable
- BUT Individual record log is clean and easy to follow (next page)

Record ID	Screen Consent Eligibility Consent (Arm 1: Prenatal)		SSRI Dose Trajectory Consent (Arm 1: Prenatal)	Concomitant Medications Consent (Arm 1: Prenatal)	Diagnosis Trajectory Consent (Arm 1: Prenatal)	_	Visit Compliance V1 Baseline (Arm 1: Prenatal)	Concentration V1 Baseline (Arm 1: Prenatal)	Blood Draw V1 Baseline (Arm 1: Prenatal)	Vitals V1 Baseline (Arm 1: Prenatal)	Visit Medical Information V1 Baseline (Arm 1: Prenatal)	Alcohol Cigarette And Other Drug Use V1 Baseline (Arm 1: Prenatal)	Abbreviated Asberg Side Effect (ASE) V1 Baseline (Arm 1: Prenatal)	Edinburgh Postnatal Depression Scale (EPDS) V1 Baseline (Arm 1: Prenatal)	Generalized Anxiety Disorder (GAD-7) V1 Baseline (Arm 1: Prenatal)	Quick Inventory Depressive Symptomatology (QIDS) V1 Baseline (Arm 1: Prenatal)	Global Health V1 Baseline (Arm 1: Prenatal)	Demographics V1 Baseline (Arm 1: Prenatal)	Adverse Childhood Experience (ACE) V1 Baseline (Arm 1: Prenatal)	Chronic Medical Conditions (CMC) V1 Baseline (Arm 1: Prenatal)	Mood Disorder Questionnaire (MDQ) V1 Baseline (Arm 1: Prenatal)
HT05- 5001								<u></u>						②	②	②	②	②	②	②	②
HT05- 5002	0		0		0	0			0		0	0									
HT05- 5003	0	•	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0		0
HT05- 5004	0	•	0	0	0	0			0		0	0		0		0	0	0			0
HT05- 5005	0	•	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0



Data Collection Instrument	Consent	V1 Baseline	V2 Prenatal	V3 Prenatal	V4 Prenatal	V5 Prenatal	V6 Prenatal	V7 Prenatal	V8 Prenatal	V9 Prenatal	V10 Prenatal	V11 Prenatal
Screen Consent Eligibility	•											
Consent Change												
Participant Status												
Visit Compliance												
SSRI Dose Trajectory	•											
Concomitant Medications	•											
Diagnosis Trajectory	•											
Concentration		<u></u>	<u>-</u>	<u></u>	<u>-</u>	<u></u>	<u>-</u>	<u>-</u>	<u>-</u>			
Blood Draw												
Vitals												
Visit Medical Information												
Alcohol Cigarette And Other Drug Use												
Abbreviated Asberg Side Effect (ASE)												
Edinburgh Postnatal Depression Scale (EPDS) (survey)		Ø										
Generalized Anxiety Disorder (GAD-7) (survey)		Ø										
Quick Inventory Depressive Symptomatology (QIDS) (survey)		Ø										
Global Health (survey)		Ø										
Demographics (survey)		Ø										
Adverse Childhood Experience (ACE) (survey)		Ø										
Chronic Medical Conditions (CMC) (survey)		Ø										
Mood Disorder Questionnaire (MDQ) (survey)		Ø										
Mini International Neuropsychiatric Interview v6 (MINI)		•										
Antidepressant Treatment History Form (ATHF)										northwe		lu 85

Retinoid

Note: this protocol is less complex in general BUT uses repeatable events

• Record Status Dashboard looks "better" →

Displaying: Instrument status only | Lock status only | All status types

Record ID	Enrollment Intake	Participant Status Intake	Visit Compliance Intake	Demographics Intake	Concomitant Medications Intake	Adverse Event Protocol Departure Intake	Visit Medical Information Follow-up	Alcohol Cigarette Follow-up	Blood Draw Follow- up
1									
RET-0001	•	•	•		+				
RET-0002		•	•	<u></u>	() (+	+	<u>-</u>		<u>-</u>
RET-0003	•	•	•	•	• +	+	•		()
RET-0004		<u></u>	<u></u>	Ø	+	+	()		

Record ID RET-0004

Data Collection Instrument	Intake	Follow- up (#1)	(#2)	+ Add new (#3)
Enrollment	•			
Participant Status	0			
Visit Compliance	0			
Demographics (survey)	Ø			
Visit Medical Information				
Alcohol Cigarette				
Blood Draw	lv.ciolina	enorth	• nwes	etern.edu

• Individual record is also relatively straightforward

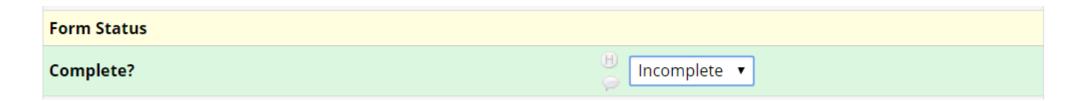




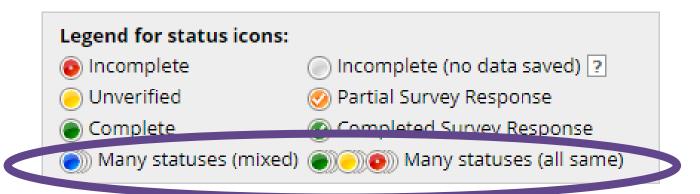
Minor digression on data entry

We can see that the complexity of form statuses increases with repeatable instruments/events

• EVERY form in REDCap (by default) has this field at the bottom:



• These icons illustrate the status of the individual form (or groups of forms for repeating events/instruments)



These only apply when we have repeating events/instruments!





Repeatable Instruments

Repeatable Instruments

Retinoid Study is also making use of this feature

- Recall: ConMeds and AEs/protocol departures are repeatable instruments within a single event
- Repeatable instruments are instruments that will vary in number per individual at any one event
- Example: a woman may have no concomitant medications (ConMeds) OR she may have *many*
- Similarly, she may have multiple or no AEs

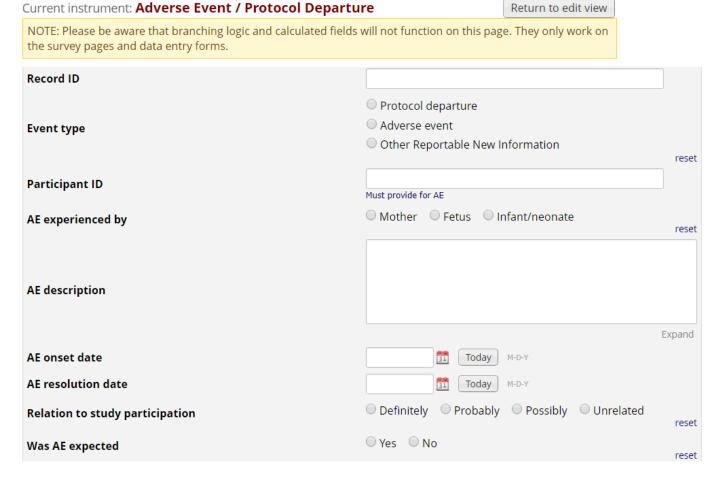
 Note: for this study, we chose to keep the repeatable instruments at just one event (noting that they may occur at any visit or in between visits)

Data Collection Instrument	Intake	Follow- up
Enrollment	/	
Participant Status	V	
Visit Compliance	V	
Demographics (survey)	V	
Visit Medical Information		V
Alcohol Cigarette		V
Blood Draw		V
Blood Draw Posults		V
Concomitant Medications	4	
Adverse Event Protocol Departure	✓	



Before repeatable instruments

- We have a separate database (OPTI-MOM Safety)
- Each record is an individual AE or departure →
- Several drawbacks:
 - Require merging of databases later (after export)
 - Require double data entry of participant IDs (opportunity for error)





Before repeatable instruments

Concomitant Medications

196

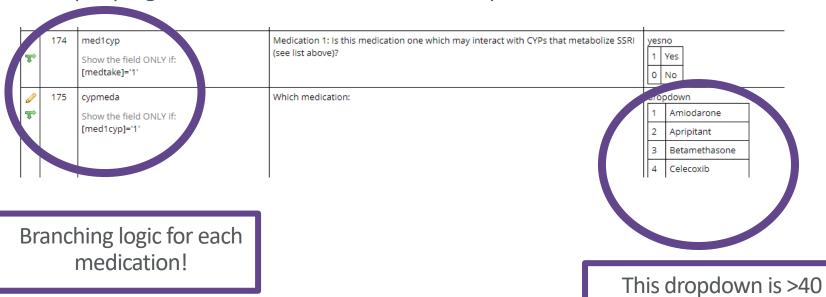






options!

- We have a ConMeds form within the main database
- It has 196 (-!) fields tied to it
- We pre-programmed the same set of fields for up to 15 medications...





Before repeatable instruments

- We would like to collect data around each medication
- Multiple fields:
 - Name
 - Dose
 - Route of administration
 - Frequency
 - Start/end dates
 - Etc.
- X 15 !!!
- The codebook is now large simply due to the ConMeds

0	176	cypmeda_o	Please specify 'other':	text
T		Show the field ONLY if: [cypmeda]='0'	Enter the medication name in ALL CAPS. When possible, use the generic name.	
⊘	177	med1 Show the field ONLY if: [med1cyp]='0'	Medication Name: Enter the medication name in ALL CAPS. When possible, use the generic name.	text
⊘	178	med1dose Show the field ONLY if: [med1cyp]='0' or [med1cyp]='1'	Dose:	text (number, Min: 0,
	179	med1unit Show the field ONLY if: [med1cyp]='0' or [med1cyp]='1'	Unit:	radio 1 mg 2 mcg 3 mL 0 Other
₽	180	med1unito Show the field ONLY if: [med1unit]='0'	If other unit, please specify:	text
⊘	181	med1rte Show the field ONLY if: [med1cyp]='0' or [med1cyp]='1'	Route:	radio 1 Drops 2 Intramuscular 3 Inhalation 4 Intravenous 5 Oral 6 Subcutaneous 7 Topical 0 Other
	182	med1rteo Show the field ONLY if: [med1rte]='0'	If other route of administration, please specify:	text
	183	med1freq Show the field ONLY if: [med1cyp]='0' or [med1cyp]='1'	Frequency: jody.ciolino@no	radio 1 Once daily 2 Twice daily



Repeatable Instruments in Retinoid

- No need for separate database for safety
- No need for such a large ConMeds form just program one set of fields and have as many/few completions of this form as needed

• Note: for this study, we chose to keep the repeatable instruments at just one event (noting that they may occur at any visit or in between visits)

Data Collection Instrument	Intake	Follow- up (2)
Enrollment	V	
Participant Status	V	
Visit Compliance	V	
Demographics (survey)	V	
Visit Medical Information		V
Alcohol Cigarette		✓
Blood Draw		✓
Blood Draw Results		✓
Concomitant Medications	4	
Adverse Event Protocol Departure	4	



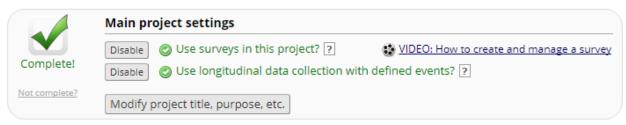
• Create instruments →

Designate instruments for events →

• Enable repeatable events + instruments customizations





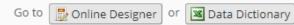




Not complete?

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



You may also browse for pre-built data collection instruments in the REDCap Shared Library

Have you checked the Check For Identifiers page to ensure all identifier fields have been tagged?

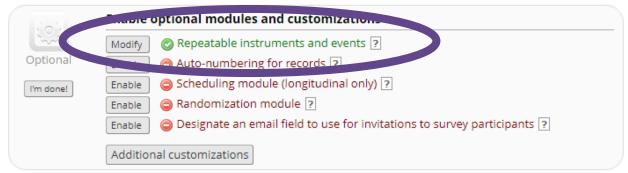


Define your events and designate instruments for them

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?



Completed steps 3 of 8

Specifying the repeating instruments...

Repeatable instruments and events × An excellent way to collect repeating data in REDCap is to use repeatable instruments and/or repeatable events. This is sometimes called one-to-many data collection. Some examples may include but are not limited to the following: data from multiple visits or observations, concomitant medications, adverse events, or repetitive surveys (daily, weekly, etc.). Below you can specify a data collection instrument or a whole event of instruments to be infinitely repeatable, in which each repeating instrument or event can be repeated a different number of times for each record. You may set any event in the project to be repeatable *or* alternatively set selected instruments to be repeatable within an event. The 'Repeat Entire Event' option means that all the event's instruments will repeat together and stay connected, whereas the 'Repeat Instruments' option implies that the instruments will repeat separately and independently from each other on that event. Once an instrument or event is set to repeat, you will see options on the Record Home Page to add another instance of the instrument/event for the currently selected record. Custom label for Repeat entire event or selected Instrument name repeating instruments (optional) (a) Event Name instruments? (select instruments to repeat) Example: [visit_date], [weight] kg Participant Status Visit Compliance Intake Repeat Instruments (repeat ▼ Demographics Concomitant Medications Adverse Event Protocol Depar... ✓ Alcohol Cigarette Follow-up Repeat Entire Event (repeat ▼ ✓ Blood Draw Cancel



Data entry + data export

Repeatable Events + Instruments (Retinoid Example)

- This is what the record will look like →
- We have three follow-up visits logged for this participant
- We have also entered two ConMeds and two safety events for this participant

• Corresponding export...

Record ID RET-0004

Data Collection Instrument	Intake	Follow- up	(#2)	+ Add new (#3)
Enrollment				
Participant Status	<u>-</u>			
Visit Compliance	<u>-</u>			
Demographics (survey)	Ø			
Visit Medical Information				
Alcohol Cigarette				
Blood Draw				
Concomitant Medications	(-)) (+)			
Adverse Event Protocol Departure	+			
Delete all data on event:	×	×	×	×

Repeating Instruments







Data export

Repeatable events + instruments (Retinoid Example)

This is what the corresponding export will look like

record_id	redcap_event_name	redcap_repeat_instrument	redcap_repeat_instance	scr_age	scr_preg13
RET-0004	intake_arm_1			25	1
RET-0004	intake_arm_1	concomitant_medications	1		
RET-0004	intake_arm_1	concomitant_medications	2		
RET-0004	intake_arm_1	adverse_event_protocol_departure	1		
RET-0004	intake_arm_1	adverse_event_protocol_departure	2		
RET-0004	followup_arm_1		1		
RET-0004	followup_arm_1		2		
RET-0004	followup_arm_1		3		

- The fields: redcap_event_name, redcap_repeat_instrument, + redcap_repeat_instance are all default fields
- Each instance is labeled with a number to help identify individual records per person
- "...instrument" will be blank if the data do not correspond to a repeat instrument
- "...instance" will be blank for non-repeating events



Which is better?

Pre-defined events/fields vs. Repeatable Events/Instruments

- This will depend on the situation: study design, the study team, etc.
- Again, will require input from all key players (enterers, builders, analyzers)
- Compare "Record Status Dashboards" once again
- Also think about study workflow (multiple databases vs. just one, etc.)

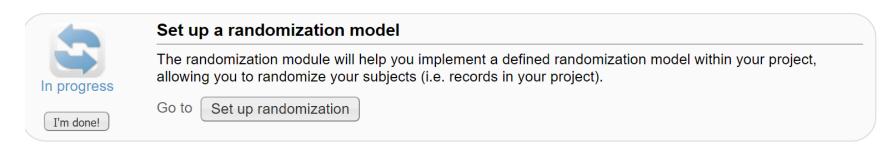




Randomization in REDCap

Randomization in REDCap

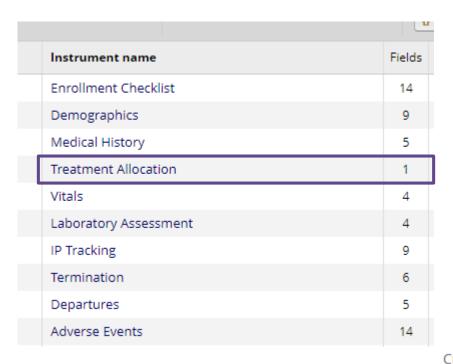
- Allows for custom **pre-generated** (i.e., not adaptive) randomization list
- Must be tied to a single event in a single "Arm"
- Differing rights:
 - Setup (programmer/analyst/statistician)
 - Dashboard (unblinded personnel)
 - Randomize (unblinded personnel performing randomization)
- To set up: select this option on the Project Setup checklist tab

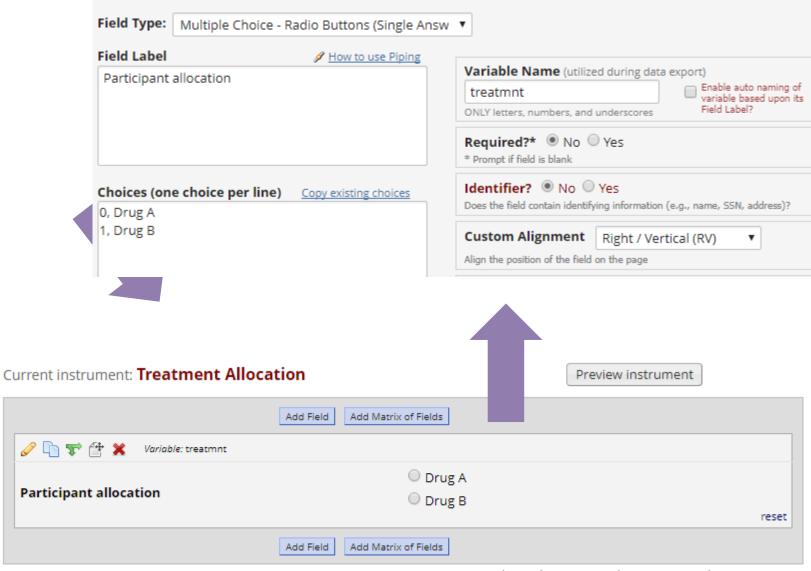




Example: Hypothetical Clinical Trial

Hypertension

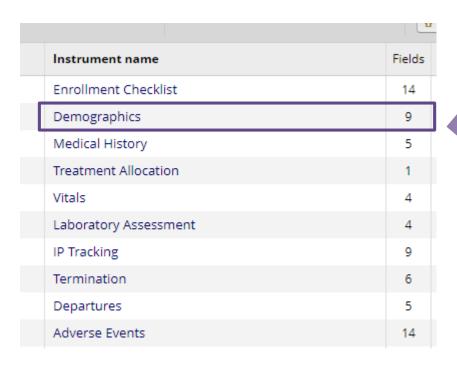


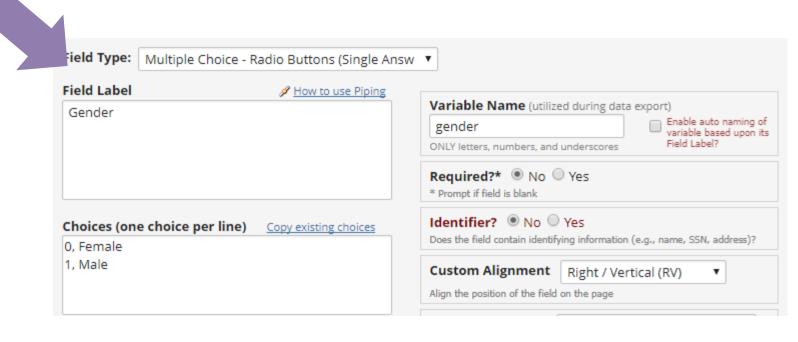




Example: Hypothetical Clinical Trial

Stratify on Sex (or gender in this case)







Setting up Randomization in REDCap

• To set up: select this option on the Project Setup checklist tab

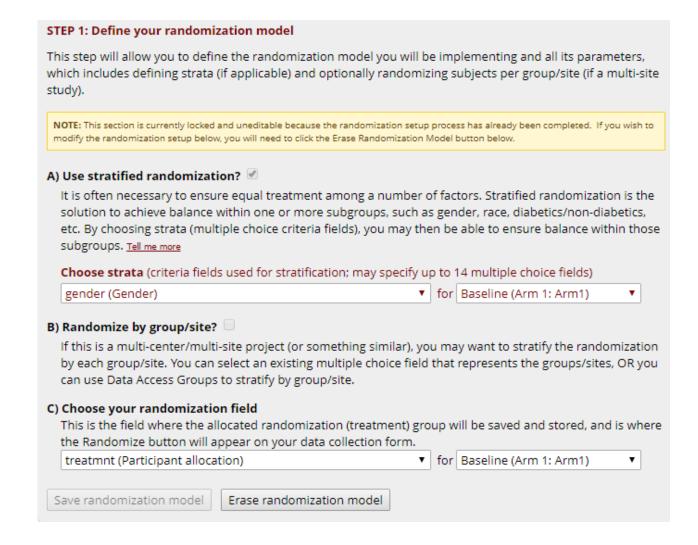




Setting up Randomization in REDCap

Stratified on "gender" →

"treatmnt" field from Arm 1 is the field for randomization





STEP 2: Download template allocation tables (as Excel/CSV files)

Below are some example files that you may download to get a general idea for how you may structure your own randomization table. You do not have to use any of these. In fact, we recommend that you NOT use these exact templates but instead recommend that you merely use them as an example or baseline to start from in order to create your own custom allocation file. After uploading your allocation table in Step 3 below, it will then be used as a lookup table to perform assignments when subjects are being randomized. NOTE: 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 below. More details

Example #1 (basic)

Example #2 (all possible combos)

Example #3 (5x all possible combos)

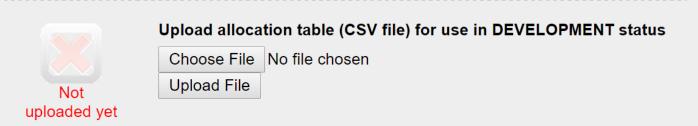
reatmnt gend													
0	0	NOTES											
1	0	NOTES:	1.5 .1	·			1.5				5-1		
0	1		- Do NOT modify the first row, although you may modify, add, or delete any other row in this file.										
1	1		- Remember that this file is ONLY a template and should NOT be used as-is as your allocation table.										
0	0		- You do not have to delete this 'notes' column when uploading your allocation table (it will be ignored).										
1	0	- Below i	s a list of all	raw coded	values a	nd their co	rrespondi	ng option I	abels for e	ach strata f	ield and/o	r Data Acce	ess Grou
0	1												
1	1	Values/la	bels for "tre	atmnt" (Pai	rticipant	allocation):						
0	0	C	Drug A										
1	0	1	Drug B										
0	1												
1	1	Values/la	bels for "ge	nder" (Gend	der):								
0	0	C	Female										
1	0	1	Male										
0	1												
1	1												
0	0												
1	0												
0	1												
1	1												
_													
								:.	ماير من مان	no@nort	avvosto ::	a adu 1	105

STEP 3: Upload your allocation table (CSV file)

Once you have created your custom allocation table as a CSV file and made sure that you kept the format prescribed in the template files from Step 2 above, you may now upload the file below. It will be checked for any possible errors first before it is accepted and stored in REDCap. Please note that you will need to create two different allocation tables: one to be used for testing while your project is in development status and the other for use when in production status. Below are some important reminders before you begin uploading your allocation tables.

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 dropout 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 PRODUCTION status

Choose File No file chosen
Upload File

Randomization Caution

- Always add a "cushion"
- Always test thoroughly with study team involved
- Tables will be "locked" once in production
- Development randomization table CANNOT be the same as the production table
- Blinded studies are rather difficult to work out logistically (possible, but may need to be creative with this restrict access and/or use code for randomization field)





Surveys in REDCap

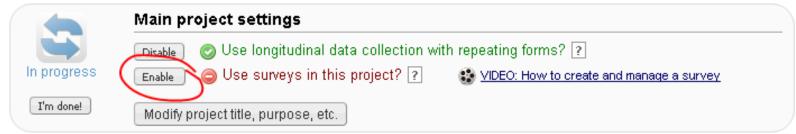
Survey Administration Overview

- Public survey link/URL can give access to CRF, regardless if REDCap user
- Data entry performed by the respondent
- Responses are defaulted to read-only after submission, though can be edited with appropriate user privileges to do so
- Multiple modes to administer surveys:
 - Public link (anonymous data collection)
 - Email invitation
 - Automated survey invitation



Survey Administration: Getting Started

• 1. Enable survey functionality under "Main project settings" in the Project Setup Checklist



• 2. Enable CRF as survey in the Online Designer





Survey Administration: Settings & Customization

- Instructions
- Logo
- Survey aesthetics (font, font size, survey theme)
- Question numbering and display, such as single or multiple page display
- View aggregate survey results
- Text-to-Speech functionality
- Survey expiration
- Option to "Save & Return Later"
- Survey completion, such as completion text or confirmation email



Survey Administration: Additional Options

- Survey Queue
 - Displays a "to-do" list of surveys to a respondent all on a single page
- Survey Login
 - Forces respondents to authenticate (log in) survey before they are allowed to view and complete the survey
- Notifications
 - Allows users to be notified via email every time a participant completes a specified survey
- Automated Survey Invitations
 - Allows invitations to be sent to respondents based upon specific conditions rather than manually sending an invitation



Survey Examples

- Evaluation Form for workshop
- Survey(s) and queues in OPTI-MOM
- Survey safety trigger for QUARTET USA



User Rights and Permissions

- Grant role-specific access privileges to study team personnel
- User rights include:
 - Project design and setup
 - Data entry
 - Data import and export
 - Form-specific access
 - Other custom/specific rights (e.g., randomization, logging, data import, etc.)



Role name

(click role name to edit role)

Coordinator

Custom

Data Entry Person

Database Management

Project Owner

READ Only

Statistician



Editing existing user role "Statistician"

	Basic Rights					
¥.	Role name: Statistician					
Hig	hest level privileges:					
B	Project Design and Setup	•				
8	User Rights	✓				
å	Data Access Groups	•				
	rileges for data exports (includi orts, and stats:	ng PDFs and API exports),				
	Data Exports	O No Access				
3	De-identified means that all free-form text fields will be	De-Identified*				
	removed, as well as any date/time fields and Identifier fields.	 Remove all tagged Identifier fields 				
		Full Data Set				
	Add / Edit Reports Also allows user to view ALL reports (but not necessarily all	•				
	data in the reports)					
<u>ı</u>		€				
_	data in the reports)	•				
Oth	data in the reports) Stats & Charts					
Oth	data in the reports) Stats & Charts er privileges: Manage Survey					
Oth	data in the reports) Stats & Charts er privileges: Manage Survey Participants					
Oth	data in the reports) Stats & Charts er privileges: Manage Survey Participants Calendar					
Oth	data in the reports) Stats & Charts er privileges: Manage Survey Participants Calendar Data Import Tool					
Oth	data in the reports) Stats & Charts er privileges: Manage Survey Participants Calendar Data Import Tool Data Comparison Tool					
	data in the reports) Stats & Charts er privileges: Manage Survey Participants Calendar Data Import Tool Data Comparison Tool Logging					
	data in the reports) Stats & Charts er privileges: Manage Survey Participants Calendar Data Import Tool Data Comparison Tool Logging File Repository					

Data Entry Rights										
NOTE: The data entry rights *only* pertain to a user's ability to view or edit data on a web page in REDCap (e.g., data entry forms, reports). It has no effect on daimports or data exports.										
	No Access	Read Only	View & Edit	Edit survey responses						
Screen Consent Eligibility	0	•	0							
Consent Change	0	•	0							
Participant Status	0	•								
Visit Compliance	0	•	0							
SSRI Dose Trajectory	0	•	0							
Concomitant Medications	0	•	0							
Diagnosis Trajectory	0	•	0							
Concentration	0	•	0							
Blood Draw	0	•	0							
Vitals	0	•	0							
Visit Medical Information	0	•	0							
Alcohol Cigarette And Other Drug Use	0	•	0							
Abbreviated Asberg Sid Effect (ASE)	le 🔾	•	0							
Rx Drug Change Intake	0	0	•							
Edinburgh Postnatal Depression Scale (EPDS) (survey)	0	•	0							
Generalized jQQlytÇiOl	lino@nc	rthw	esteri	n.edu 11						

Disorder (GAD-7)

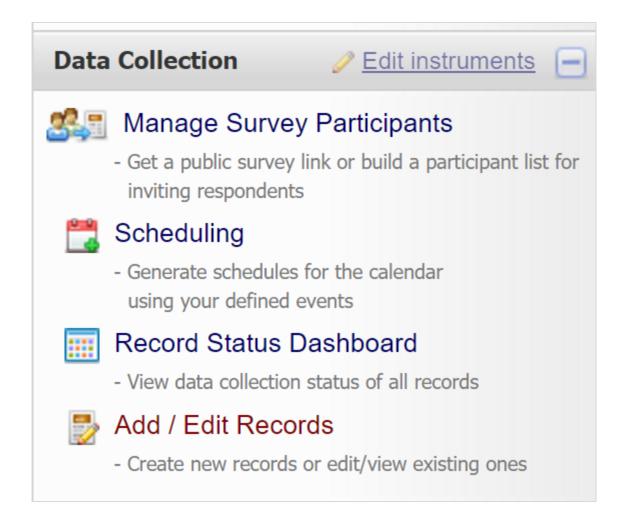


Post Database Development...

...Data Entry, Quality Control, and Reporting



Data Entry

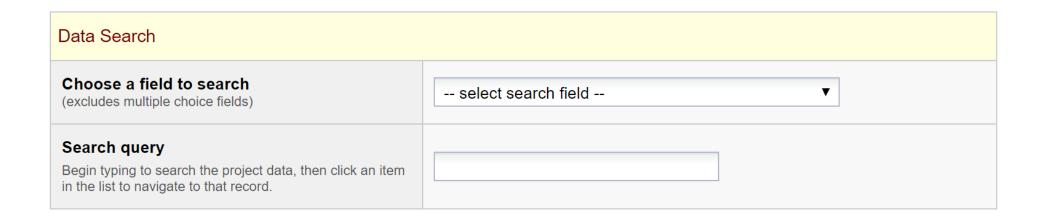




Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record begin to type in it, allowing you to select it.

Total records: 8		
Choose an existing Study ID	Arm 1: Arm1 ▼	select record ▼
Enter a new or existing Study ID	Arm 1: Arm1 ▼	9999





■ Record Home Page

② Record "9999" is a new Study ID. To create the record and begin entering data for it, click any gray status icon below.

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the <u>Define My Events</u> page.

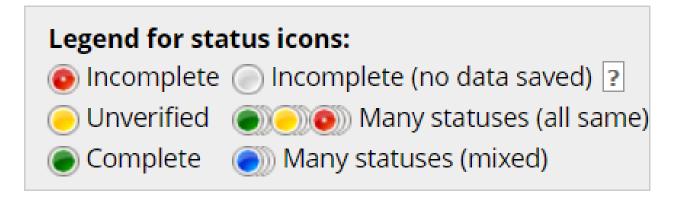
NEW Study ID **9999**

Data Collection Instrument	Baseline	Week2	Week4	Week6	Week8	Week10	Week12	Ad Hoc
Enrollment Checklist								
Demographics								
Medical History								
Treatment Allocation								
Vitals								
Laboratory Assessment								
IP Tracking								
Termination								
Departures								
Adverse Events								



Data Entry/Status Icons







Data Collection Instrument	Consent	V1 Baseline	V2 Prenatal	V3 Prenatal	V4 Prenatal	V5 Prenatal	V6 Prenatal	V7 Prenatal	V8 Prenatal	V9 Prenatal	V10 Prenatal	V11 Prenatal
Screen Consent Eligibility												
Consent Change												
Participant Status	<u>-</u>											
Visit Compliance												
SSRI Dose Trajectory	<u>-</u>											
Concomitant Medications	<u>-</u>											
Diagnosis Trajectory	<u>-</u>											
Concentration		<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u></u>						
Blood Draw												
Vitals												
Visit Medical Information												
Alcohol Cigarette And Other Drug Use	3											
Abbreviated Asberg Side Effect (ASE)												
Edinburgh Postnatal Depression Scale (EPDS) (survey)		Ø	Ø	②	②	②						
Generalized Anxiety Disorder (GAD-7) (survey)		Ø	Ø	Ø	②	②						
Quick Inventory Depressive Symptomatology (QIDS) (survey)		Ø	Ø	Ø	②	②						
Global Health (survey)		Ø	Ø	Ø	Ø	Ø						
Demographics (survey)		Ø										
Adverse Childhood Experience (ACE) (survey)		Ø										
Chronic Medical Conditions (CMC) (survey)		Ø										
Mood Disorder Questionnaire (MDQ) (survey)		Ø										
Mini International Neuropsychiatric Interview (MINI)											
Antidepressant Treatment History Form (ATHF)	/									jody	ciolino,	@north

Data Resolution Workflow



Da

VIDEO: Data Resolution Workflow

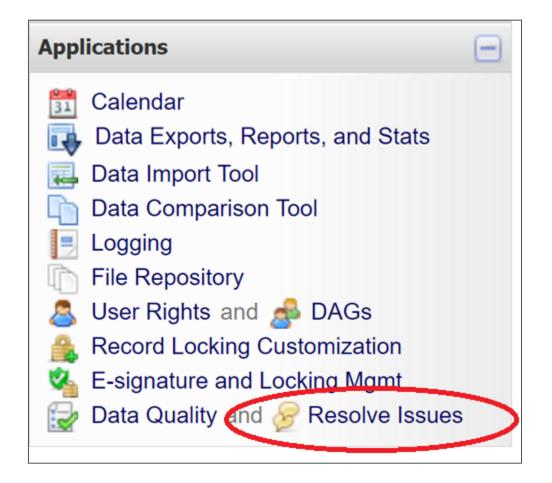
This pop-up displays the Data Resolution Workflow for the specified record for a given field and/or Data Quality rule. Users with appropriate user privileges may open data queries to begin a documented process of resolving an issue with the data. Opened data queries may thus be responded to by users with appropriate privileges, and then they may be closed once the issue has been resolved. All data queries can also be viewed on the Resolve Issues page in this project.

Date/Time	User	Comments and Details
02/11/2015 9:19pm	hal536	Action: Opened query Assigned to user: hal536 (Hannah Louks) Comment: "Added no response (previously discussed)"
02/11/2015 9:22pm	hal536	Data Changes Made: random_clear = 'No (0)'
02/16/2015 8:26am	jdc800	Action: Closed query Comment: "agree"
03/03/2017 2:15pm	jdc800	Reopen the closed query Comment:
		Comment (optional):



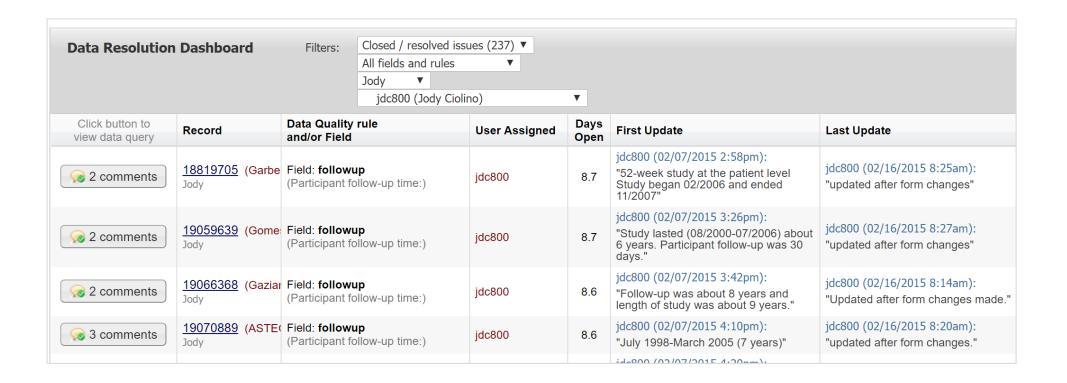
Data Resolution Workflow

- Use the resolution dashboard to see all queries
- You may organize/filter so that you can only view closed, open, etc. queries
- You may also filter by assigned REDCap user





Data Resolution Workflow





This module lists all changes made to this database, including data exports, data changes, and the creation or deletion of users.

Filter by events	All event types (excluding page views)	
	71 7 7 7	Audit Trail
Filter by user name:	All users	Addit ITali
Filter by record:	All records 🕶	
Displaying events (by most recent):	1 - 100	

Time / Date	User name	Action	List of Data Changes OR Fields Exported
4:09pm 12/22/2010	redcap3	Created User testuser	user = 'testuser'
4:09pm 12/22/2010	redcap3	Manage/Design	Create database field
4:08pm 12/22/2010	redcap3	Updated Record 1032	family_id = '1032', first_name = 'Brigitte', last_name = 'Raumann', dob = '2003-12-09', age = '7', sex = '2'
4:08pm 12/22/2010	redcap3	Created Record 1032	<pre>proband_relation = '0', subject_info_complete = '0', study_id = '1032'</pre>
4:07pm 12/22/2010	redcap3	Updated Record 1001	off_site_clinics(10) = checked
3:42pm 12/22/2010	redcap3	Data Export	study_id, proband_relation, proband_relation_other, family_id, first_name, last_name, dob, age, sex, birth, ethnic_ori, ethinic_ori_other, off_site_clinics, off_site_notes, comments, height, weight, subject_info_complete, indy_cioling@northwestern



Reports, Graphs, and Descriptive Stats

Reports, Graphs, and Descriptive Stats

• Reporting feature may be useful for quick summarizations and tracking/coordination

Screen Failures

Record ID (record_id)	Event Name (redcap_event_name)	Participant Status: (ps_status)	Comments: (ps_comments)
HT05-5002	Consent (Arm 1: Prenatal)	Ineligible (never enrolled) (8)	Not interested, work schedule is demanding
HT05-5003	Consent (Arm 1: Prenatal)	Ineligible (never enrolled) (8)	Not interested, did not return phone calls
HT05-5004	Consent (Arm 1: Prenatal)	Ineligible (never enrolled) (8)	Interested, but lacks time
HT05-5005	Consent (Arm 1: Prenatal)	Ineligible (never enrolled) (8)	Not interested
HT05-5006	Consent (Arm 1: Prenatal)	Ineligible (never enrolled) (8)	Not interested
HT05-5007	Consent (Arm 1: Prenatal)	Ineligible (never enrolled) (8)	Not interested
HT05-5008	Consent (Arm 1: Prenatal)	Ineligible (never enrolled) (8)	Out of window



Ncenters

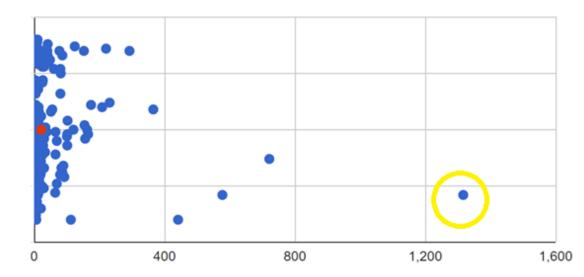
DISPLAY OPTIONS								
Optional: Select a re	ecord to overlay onto the		select record ▼					
Viewing options:	Show plots & stats							

How many centers? Refresh Plot

Total								Percentile							
Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95	
133	18 (11.9%)	69	2.00	1,315.00	65.48	148.92	8,709.00	2.00	3.00	7.00	20.00	68.00	152.60	223.40	

Lowest values: 2, 2, 2, 2, 2

Highest values: 364, 440, 576, 720, 1315



- REDCap can also generate simple descriptive statistics and summaries
- You can select an individual data point to navigate to that record

Data Export



♦ Exporting "All data (all records and fields)"



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

Choose export format			
	CSV / Microsoft Excel (raw data)		
	CSV / Microsoft Excel (labels)		
0	SPSS Statistical Software		
	SSAS SAS Statistical Software		
0	R Statistical Software		
0	Stata Statistical Software		
0	ODM CDISC ODM (XML)		

De-identification options (optional)				
The options below allow you to limit the amount of sensitive information that you are exporting out of the project. Check all that apply.				
Known Identifiers:				
Remove all tagged Identifier fields (tagged in Data Dictionary)				
Hash the Record ID field (converts record name to an unrecognizable value)				
Free-form text:				
Remove unvalidated Text fields (i.e. Text fields other than dates, numbers, etc.)				
Remove Notes/Essay box fields				
Date and datetime fields:				
Remove all date and datetime fields				
— OR —				
Shift all dates by value between 0 and 364 days (shifted amount determined by algorithm for each record) What is date shifting?				
Deselect all options				

Export Data

Cancel



REDCap API...

REDCap API

- API=Application Programming Interface
- Allows external applications (e.g., SAS, R) to connect to REDCap and retrieve and/or modify data
- Useful for performing automated data exports and transferring data between REDCap projects



API Token

- To use the REDCap API, users must be granted 'tokens' by a REDCap administrator that is specific to each username and project
- Each user running any code using the API must request their own API token, which should be treated like a password
- Token must be included in all API requests
- REDCap API Documentation



API: An Example

Crosstalk between two projects in OPTI-MOM Study at Northwestern University

Complex specimen labeling

Core Database:

How maternal plasma is labeled:

HT05-5001-PRG1-PL-S
For example, HT05-5001-PRG1-PL-S

- At each visit, we have multiple specimens labeled this way
- Need to 'track' specimens somehow (external database)
 - Each individual specimen should be a new record in this database
 - LOTS of room for data entry error/failure to enter
- API functionality will allow us to pre-populate records in a new database

Specimen

Record ID	Specimen Tracking
HT05-5001-PRG1-MDNA-S	
HT05-5001-PRG1-PL-S	
HT05-5001-PRG2-PL-S	
HT05-5001-PRG3-PL-S	
HT05-5001-PRG4-PL-S	
HT05-5001-PRG5-PL-S	



API: An Example

Crosstalk between two projects in OPTI-MOM

- Coordinator(s) now only need to update records in Specimen Tracking Database (will not need to enter manually)
- Example CRF completion in separate database

Ø Editing existing Record ID HT05-5001-PRG1-PL-S		
Record ID	HT05-5001-PRG1-PL-S (To rename this record, modify the value immediately below.)	
Record ID	HT05-5001-PRG1-PL-S	
Date Last Updated:	H 12-06-2016	
Aliquot 1 Status:	Not Collected Missing CRU Core Lab NUgene Avram Lab UTMB University of Pittsburgh In Transit Analyzed (Sample No Longer Available) Other	

API: Example R Script

```
###################
# User needs to replace the [API token] and [Import token] with the his/her assigned OPTI-MOM and
# OPTI-MOM specimen project tokens before running the program
########################
#install redcapAPI package if not already installed
*********
if(!require(redcapAPI)){
       install.packages("redcapAPI")
       library(redcapAPI)
############################
# Set up connection to NU REDCap
# The token_ex is the token for the main OPTI-MOM project
# Token is user specific
# Replace [API token] below with your assigned OPTI-MOM project token which can be found
 # inside orli-MOM project-->API
redcap_url <- "https://redcap.nubic.northwestern.edu/redcap/api/"
# rcon is the connect for
rcon <- redcapConnection(url=redcap_url, token=token_ex)
# Export all the records' blood draw form data into bd
bd <- exportRecords(rcon, forms="blood_draw")
# Data cleaning--extract relevant sample label fields into bd1
bd1=bd(,c("mdnalbl","pllbl","plmolbl","plmo_1lbl","plmo_25lbl","plmo_5lbl",

"plmo_75lbl","plm1lbl","plm2lbl","plm2_5lbl","plm3lbl","plplbl","plm4lbl",

"pl4lbl","plm5lbl","plm6lbl","pl24lbl","pltlbl","planeslbl","csflbl","pldellbl",

"cvlbl","calbl","fdnalbl","blood_draw_complete")]
# Data cleaning--filter out those without complete blood draw information
# Data cleaning--remove all the label fields that are NA
d_import=bd2[!is.na(bd2)]
# Create a data frame of the sample labels and name it as "record_id"
d_import=data.frame(d_import)
names(d_import)="record_id"
# Replace [Import token] with your assigned OPTI-MOM Specimen Tracking token below
# Create a connection to import our d_import dataframe into the specimen database
rconim=redcapConnection(url=redcap_url,token=token_im)
# The function below will upload the d_import dataframe we created into the "record_id"
# field of the specimen database
importRecords(rconim,data=d_import,overwriteBehavior = c("normal", "overwrite"),
              returnContent = c("count", "ids", "nothing"), returnData = FALSE,
              logfile = "")
# If import successfully you will see a message similar to this
#REDCap Data Import Log: 2016-09-09 13:31:36
#The following (if any) conditions were noted about the data.
```





Limitations and Resources



Limitations

- REDCap is intuitive, but there is a learning curve
- Differing institutions may host different versions and enable/disable different features for end users
- REDCap alone is 21 CFR Part 11 "ready" (not necessarily compliant) as a mode of direct data entry; may be suitable for FDA-governed studies, but this is project / study team specific



Caution / Pitfalls

- Less is more
 - Just because technology and features are available, does not mean you need to or should use it: "Don't use a hammer to swat a fly"
 - Consider how each feature and application will fit into your data management procedures
- Education, training, communication = key
- Like many things, REDCap's flexibility and ease of use may also open the door for error/disaster without proper education, due diligence, training, and communication
 - Test, test, and test again! (Checklist on DigitalHub: http://dx.doi.org/10.18131/G39311)
- It is essential that project owners take ownership and assume all responsibility for that project



Resources/References

- http://projectredcap.org
 - REDCap Shared Library a repository for REDCap data collection instruments
 and forms that can be downloaded and used (for free) by consortium partners
 - Video Resources Webinars and tutorials
 - Community Website
- Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap) A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. April 2009;42(2): 377-381.



REDCap at Northwestern

- redcap@northwestern.edu
- Online session for New Project Owners (email REDCap support for link)
- All users must complete: REDCap User Agreement (https://redcap.nubic.northwestern.edu/redcap/surveys/?s=WK39RMR44F)
- https://redcap.nubic.northwestern.edu/redcap/ (must be on campus network for VPN)
- https://nucats.northwestern.edu/





Thank you!

Questions:

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