Statistically Speaking Lecture Series

Sponsored by the Biostatistics Collaboration Center

Using REDCap for Data Capture in Clinical Studies: Database Management on a Budget

Jody D. Ciolino, PhD

Assistant Professor

Department of Preventive Medicine

BCC: Biostatistics Collaboration Center

Who We Are

Leah J. Welty, PhD
Assoc. Professor
BCC Director

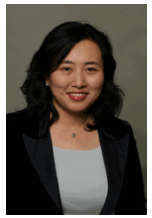
Lauren Balmert, PhD
Asst. Professor

Jody D. Ciolino, PhD
Asst. Professor

Kwang-Youn A. Kim, PhD
Assoc. Professor

Masha Kocherginsky, PhD
Assoc. Professor

Mary J. Kwasny, ScD
Assoc. Professor



Julia Lee, PhD, MPH
Assoc. Professor

David Aaby, MS
Senior Stat. Analyst

Elizabeth Gray, MS
Stat. Analyst

Kimberly Koloms, MS
Stat. Analyst

Amy Yang, MS
Senior Stat. Analyst

Tameka L. Brannon
Financial | Research
Administrator

Biostatistics Collaboration Center (BCC)

Mission: to support investigators in the conduct of high-quality, innovative health-related research by providing expertise in biostatistics, statistical programming, and data management.

How do we accomplish this?

1. Every investigator is provided a **FREE** initial consultation of 1-2 hours, subsidized by **FSM Office for Research**. Thereafter:
   a) Grants
   b) Subscription
   c) Re-charge (Hourly) Rates

2. Grant writing (e.g. developing analysis plans, power/sample size calculations) is also supported by FSM at **no cost to the investigator**, with the goal of establishing successful collaborations.

BCC: Biostatistics Collaboration Center

What We Do

- Many areas of expertise, including:
  - Bayesian Methods
  - Big Data
  - Bioinformatics
  - Causal Inference
  - **Clinical Trials**
  - **Database Design**
  - Genomics
  - Longitudinal Data
  - Missing Data
  - Reproducibility
  - Survival Analysis

Many types of software, including:

BCC: Biostatistics Collaboration Center

Shared Statistical Resources

Northwestern Medicine | NUCATS Clinical and Translational Sciences Institute

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

Stanley Manne Children's Research Institute | Ann & Robert H. Lurie Children's Hospital of Chicago

Biostatistics Collaboration Center (BCC)

- Supports **non-cancer** research at NU
- Provides investigators an initial 1-2 hour consultation subsidized by the FSM Office of Research
- Grant, Hourly, Subscription

Shirley Ryan AbilityLab

Quantitative Data Sciences Core (QDSC)

- Supports all **cancer-related** research at NU
- Provides free support to all Cancer Center members subsidized by RHLCCC
- Grant

Biostatistics Research Core (BRC)

- Supports **Lurie Children's Hospital affiliates**
- Provides investigators statistical support subsidized by the **Stanley Manne Research Institute at Lurie Children's**
- Hourly

BCC: Biostatistics Collaboration Center

Shared Resources Contact Info

- Biostatistics Collaboration Center (BCC)
  - Website: http://www.feinberg.northwestern.edu/sites/bcc/index.html
  - Email: bcc@northwestern.edu
  - Phone: 312.503.2288

- Quantitative Data Sciences Core (QDSC)
  - Website: http://cancer.northwestern.edu/research/shared_resources/quantitative_data_sciences/index.cfm
  - Email: qdsc_rhlccc@northwestern.edu
  - Phone: 312.503.2288

- Biostatistics Research Core (BRC)
  - Website: https://www.luriechildrens.org/en-us/research/facilities/Pages/biostatistics.aspx
  - Email: mereed@luriechildrens.org
  - Phone: 773.755.6328

Northwestern Medicine®
Feinberg School of Medicine

Using REDCap for Data Capture in Clinical Studies: Database Management on a Budget

Jody D. Ciolino, PhD
Assistant Professor
Department of Preventive Medicine

What is REDCap ?

Research Electronic Data Capture

- 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 2500 institutions in over 100 countries

Why use REDCap?

Research Electronic Data Capture

- FREE
- Secure
- Easy to learn
- Easily accessible, becoming more universal (>2500 institutions, >100 countries)
- Features that allow for efficient and flexible data capture/management
- …
- ….

Today's Goals

1. Brief introduction and overview of REDCap
2. Provide tips to ensure data quality: design features and data entry workflow
3. Illustrate advanced features for making the most out of REDCap

Statistically Speaking…

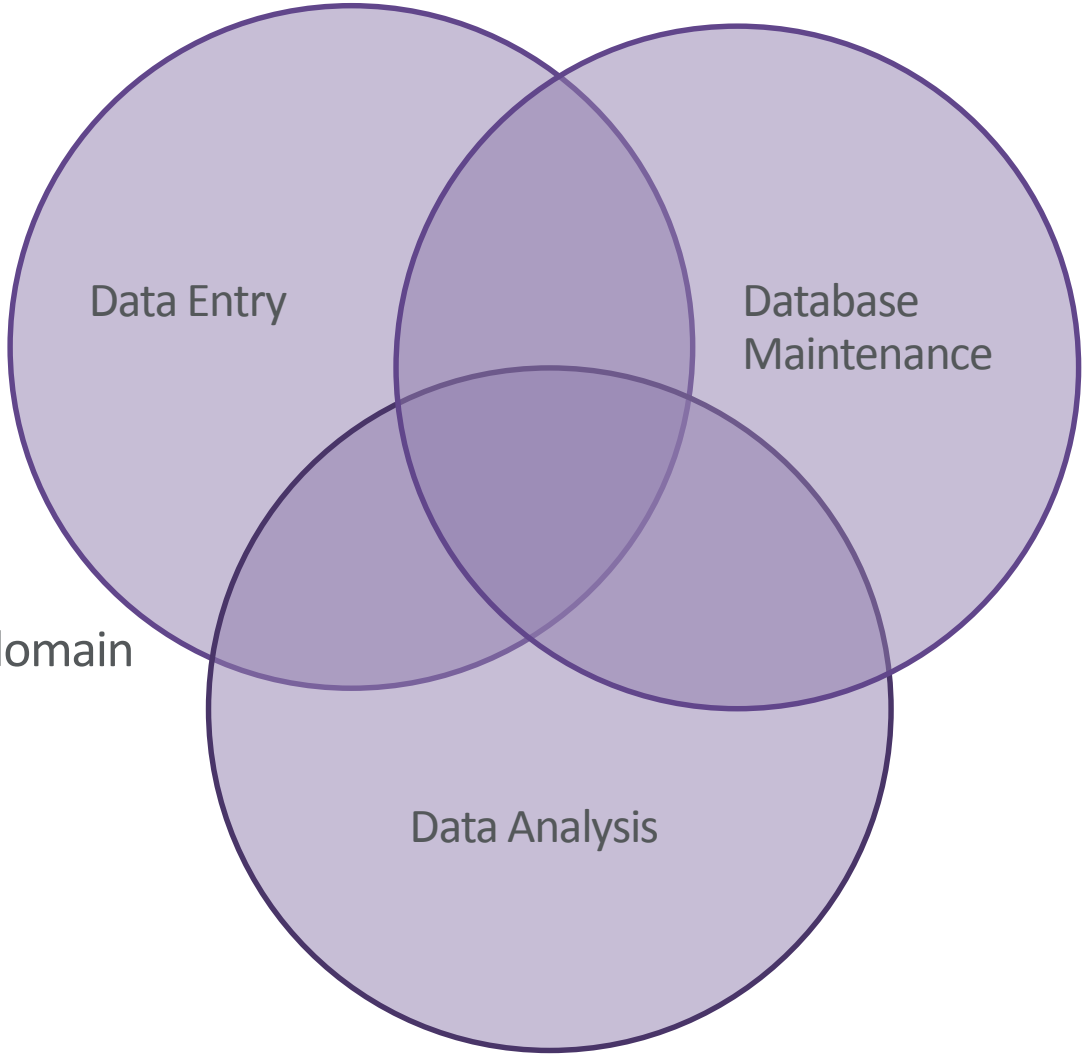
1. **Brief introduction and overview of REDCap (REDCap > Excel)**
   - REDCap = easy to use, but also easy to abuse
   - Sometimes users have a false sense of security that REDCap will solve all problems
2. **Provide tips to ensure data quality: design features and data entry workflow**
3. **Illustrate advanced features for making the most out of REDCap**
   - Purpose = ensure high-quality, analyzable data
   - Must be able to answer research question via statistical analyses

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

- Depending on study, these three roles may involve:
  - One person, taking on all responsibility
  - Many individuals, with specialized roles within each domain



Northwestern Medicine®

Getting Started...

NOTE: Institutions may vary

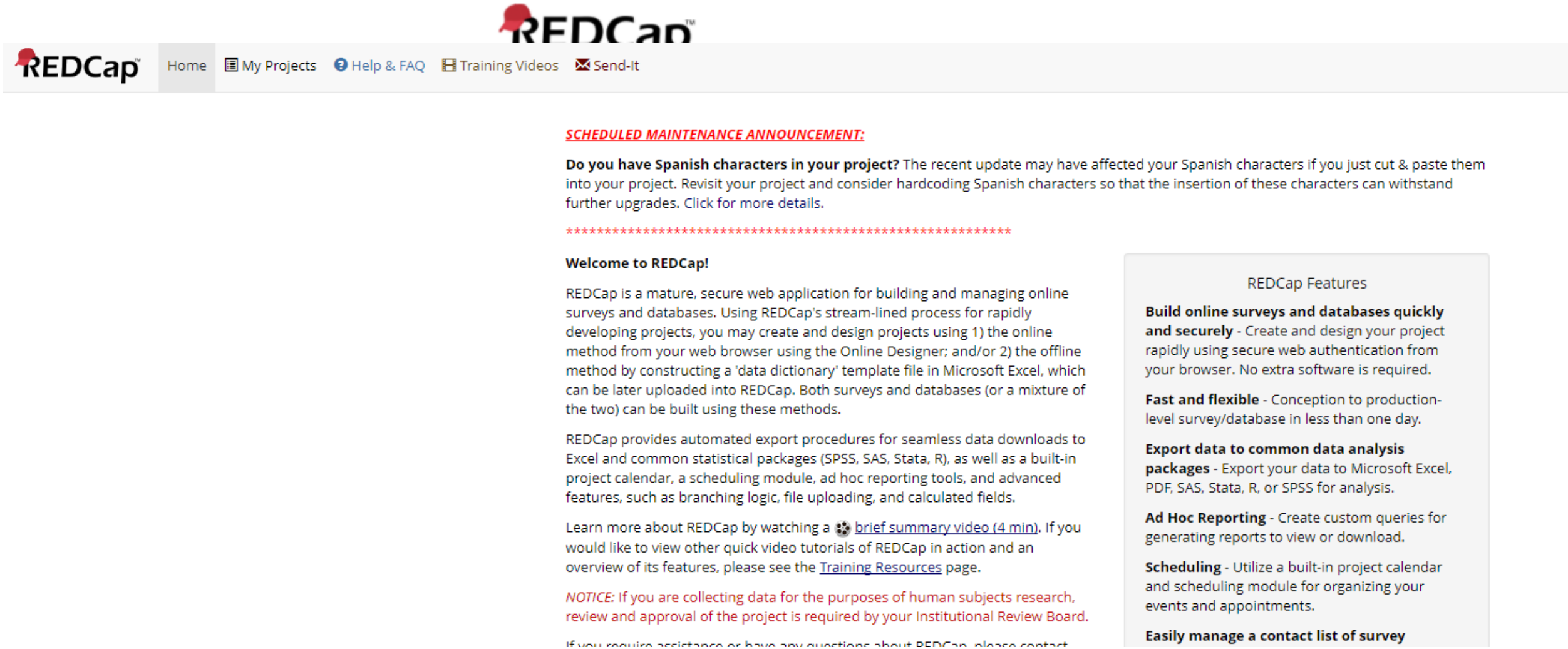
REDCap at Northwestern

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

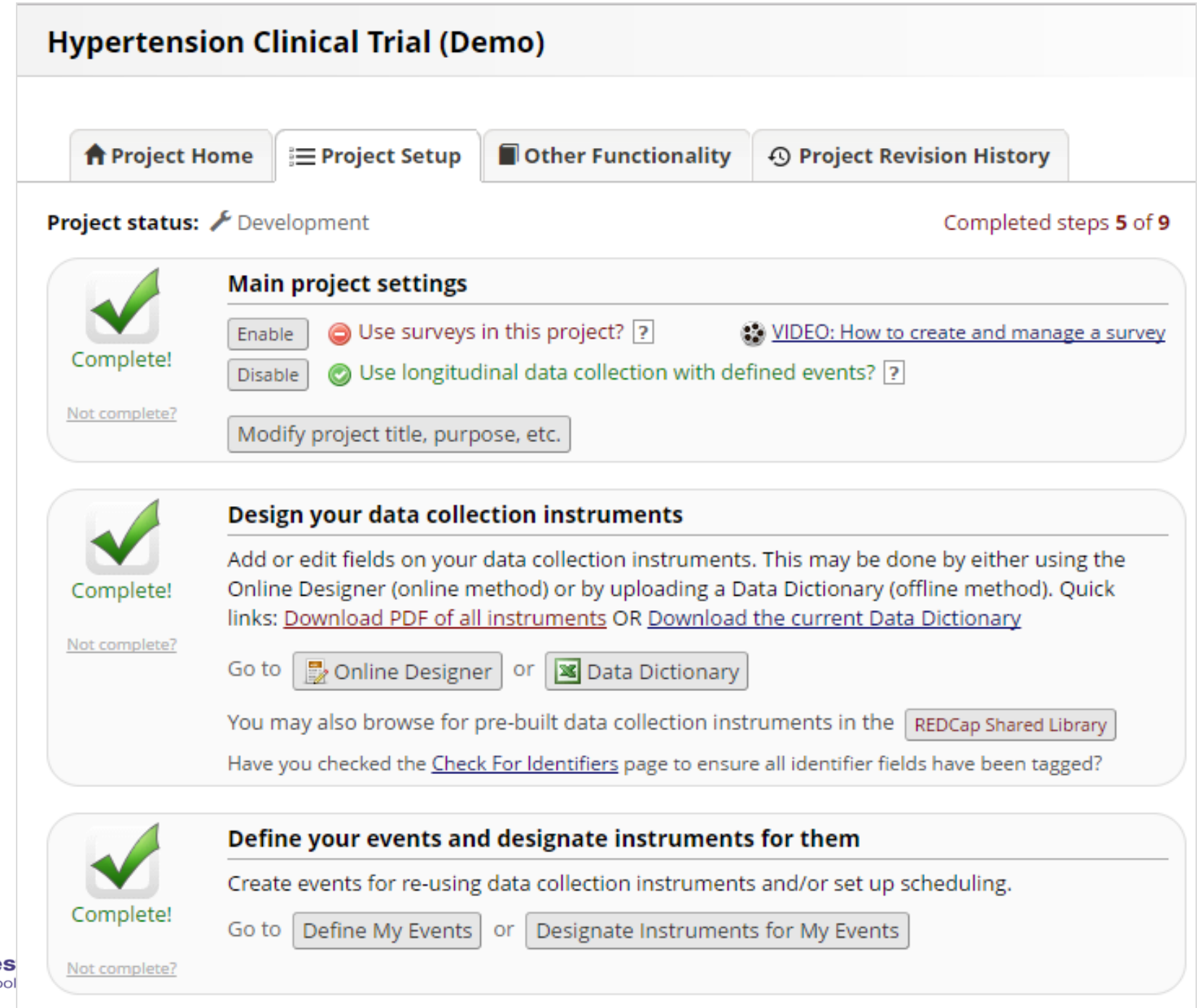
Some Basic Terminology

- 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

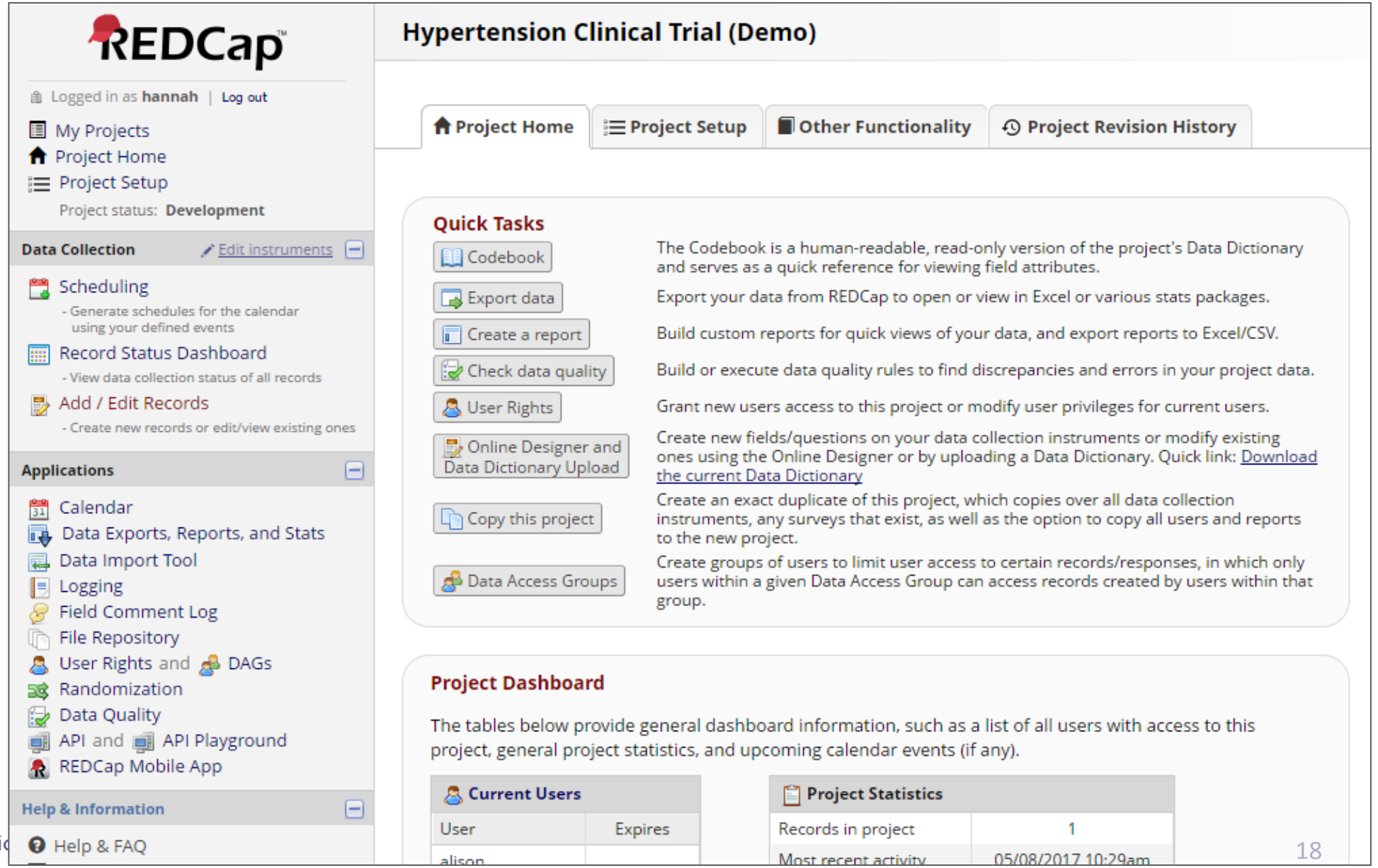
Getting Started



Project Setup Checklist (Landing Page)

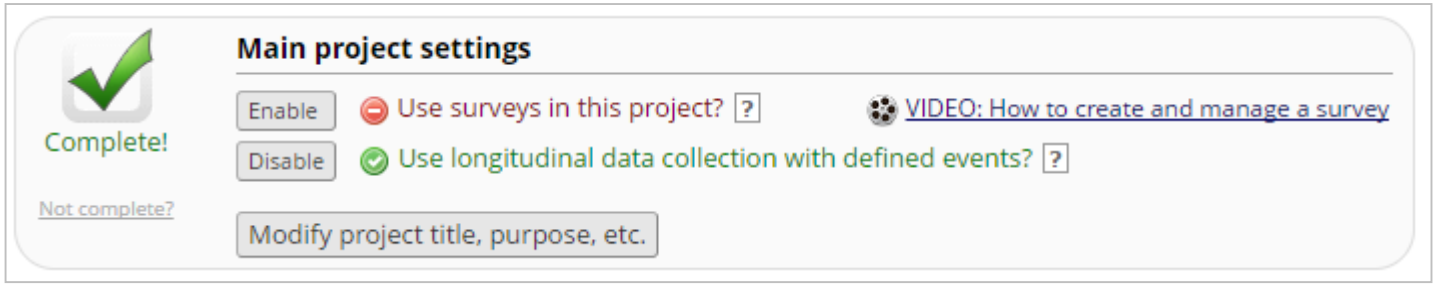


Project Home Tab



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

Designing Data Collection Tools

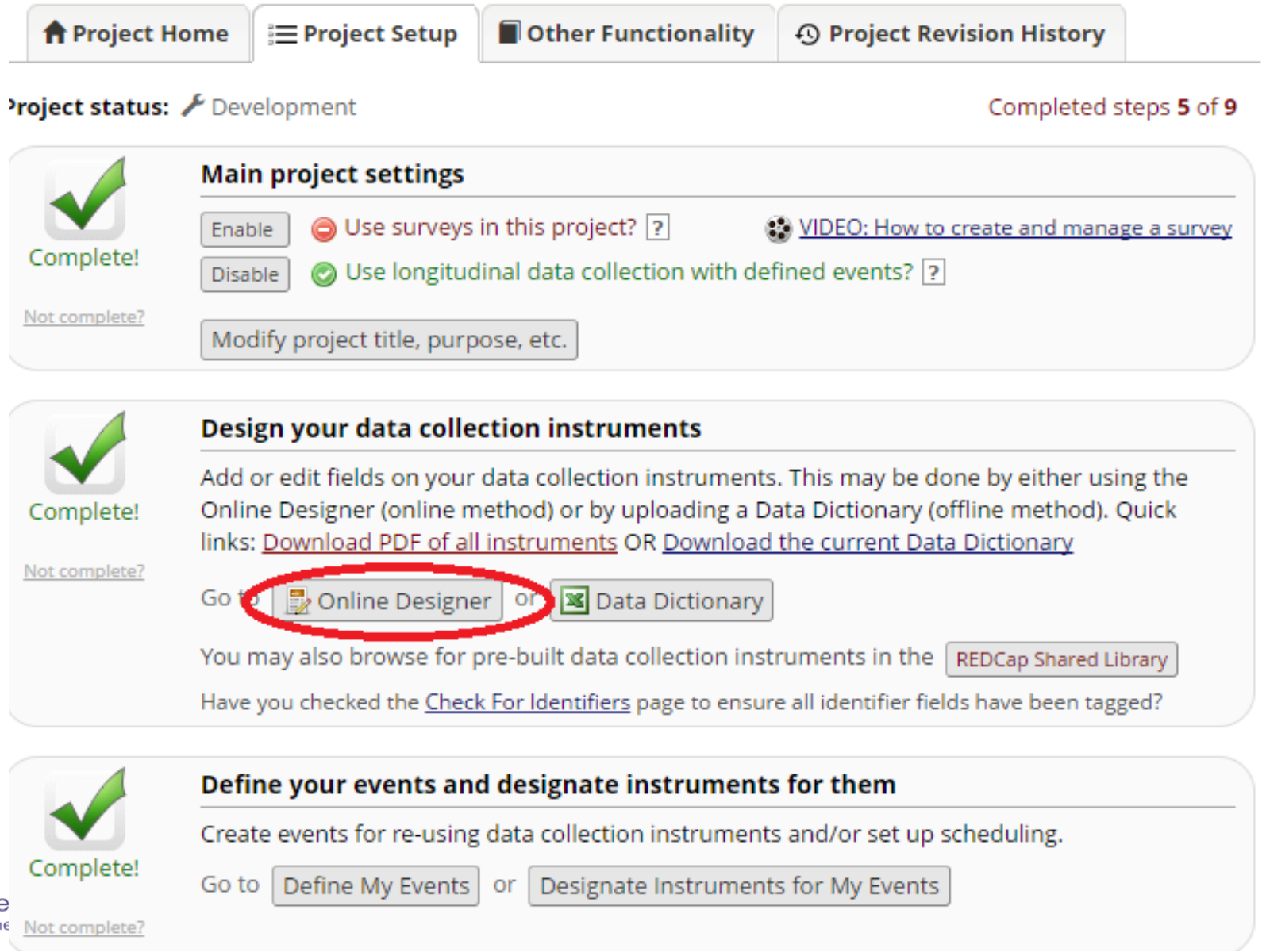
- NOTE: REDCap platform distinguishes between data entry forms (Case Report Forms [CRFs]) and surveys (may also serve as CRF for clinical study purposes)

- '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.)

Project Setup: Online Designer



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.

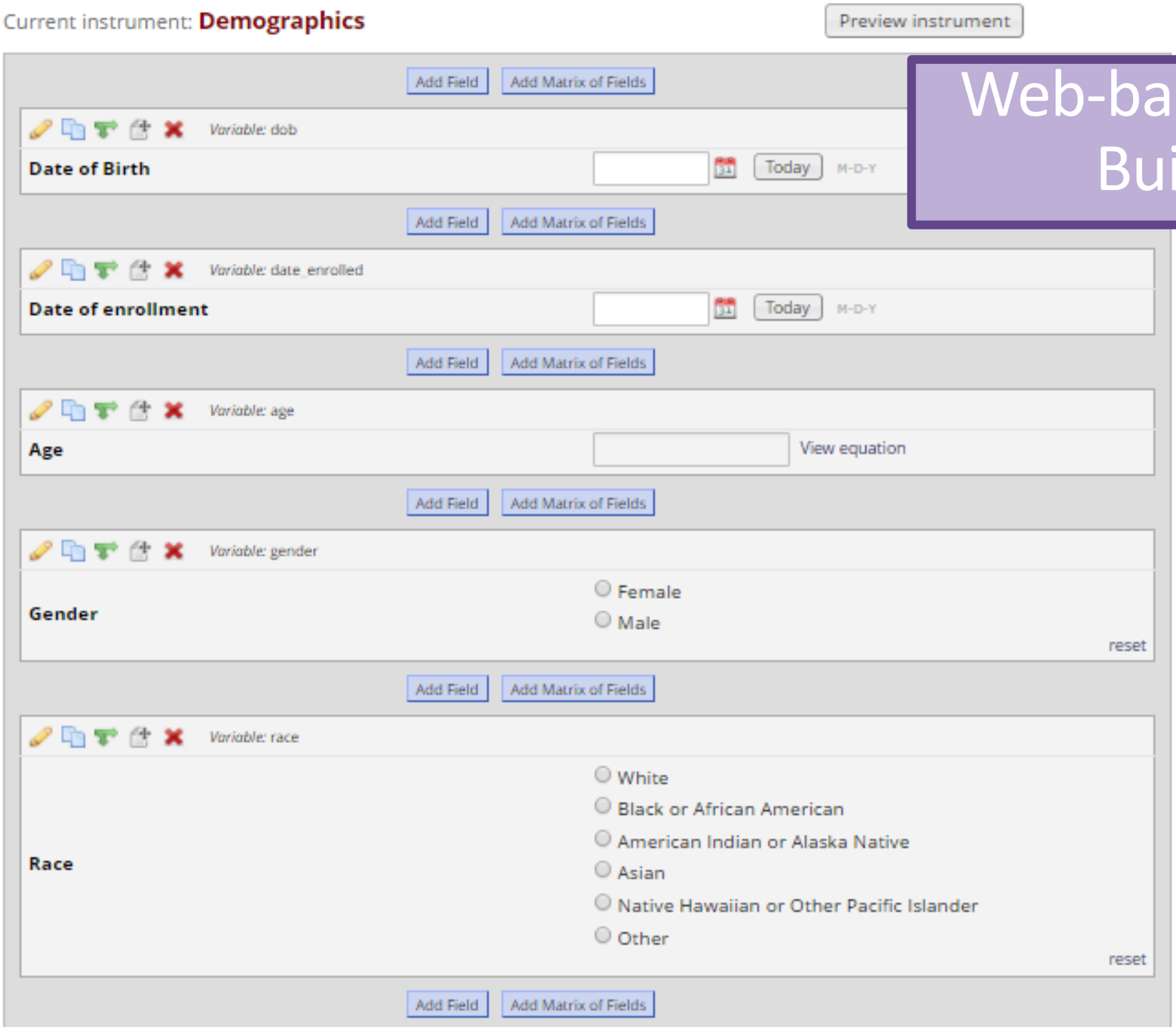
Data Collection Instruments

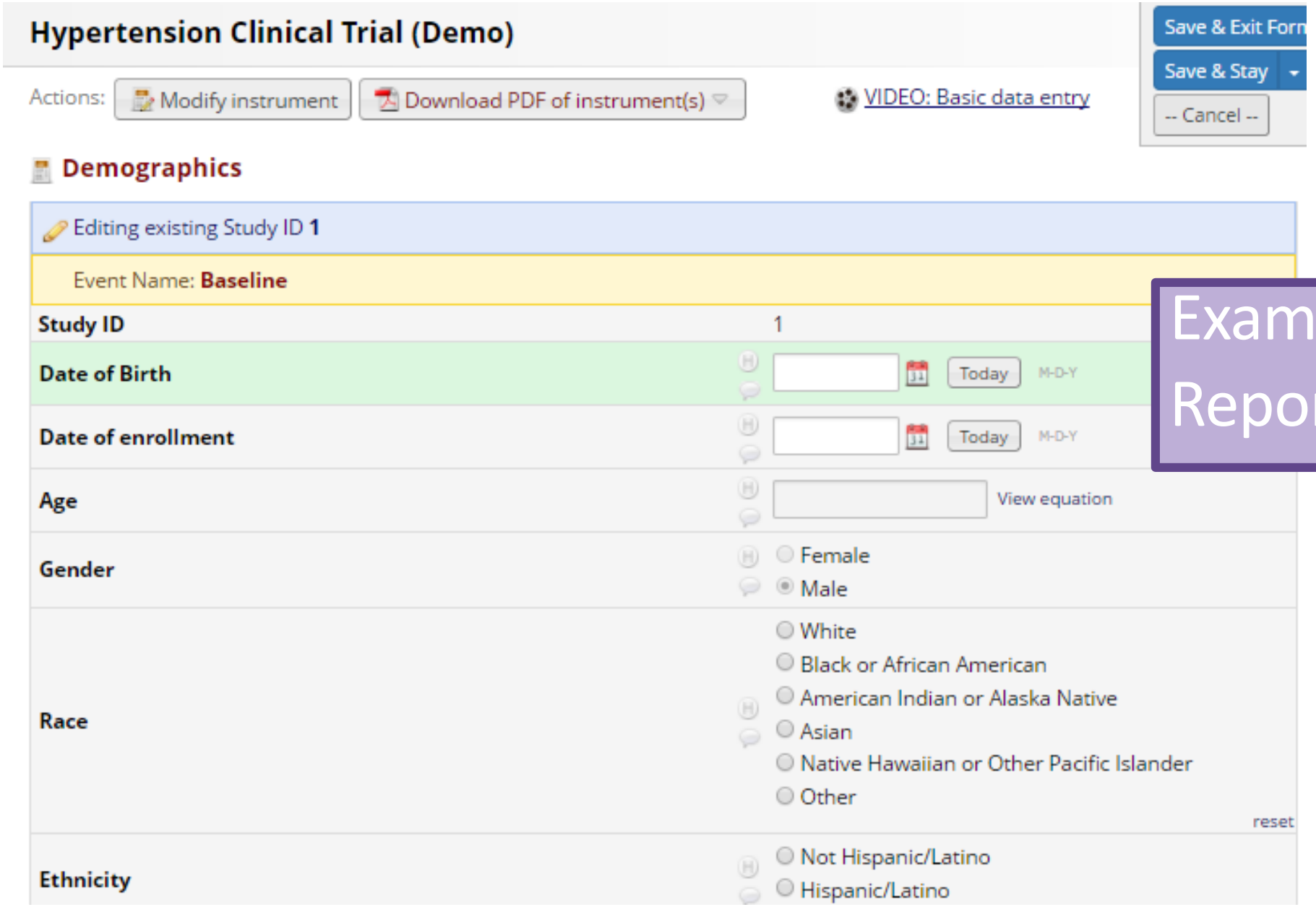
Add new instrument:

- Create a new instrument from scratch
- Import a new instrument from the official REDCap Shared Library
- Upload instrument ZIP file from another project/user or external libraries

Instrument name	Fields	View PDF	Instrument actions
Enrollment Checklist	14		Choose action
Demographics	9		Choose action
Medical History	5		Choose action
Treatment Allocation	1		Choose action
Vitals	4		Choose action
Laboratory Assessment	4		Choose action
IP Tracking	9		Choose action
Termination	6		Choose action
Departures	5		Choose action
Adverse Events	14		Choose action

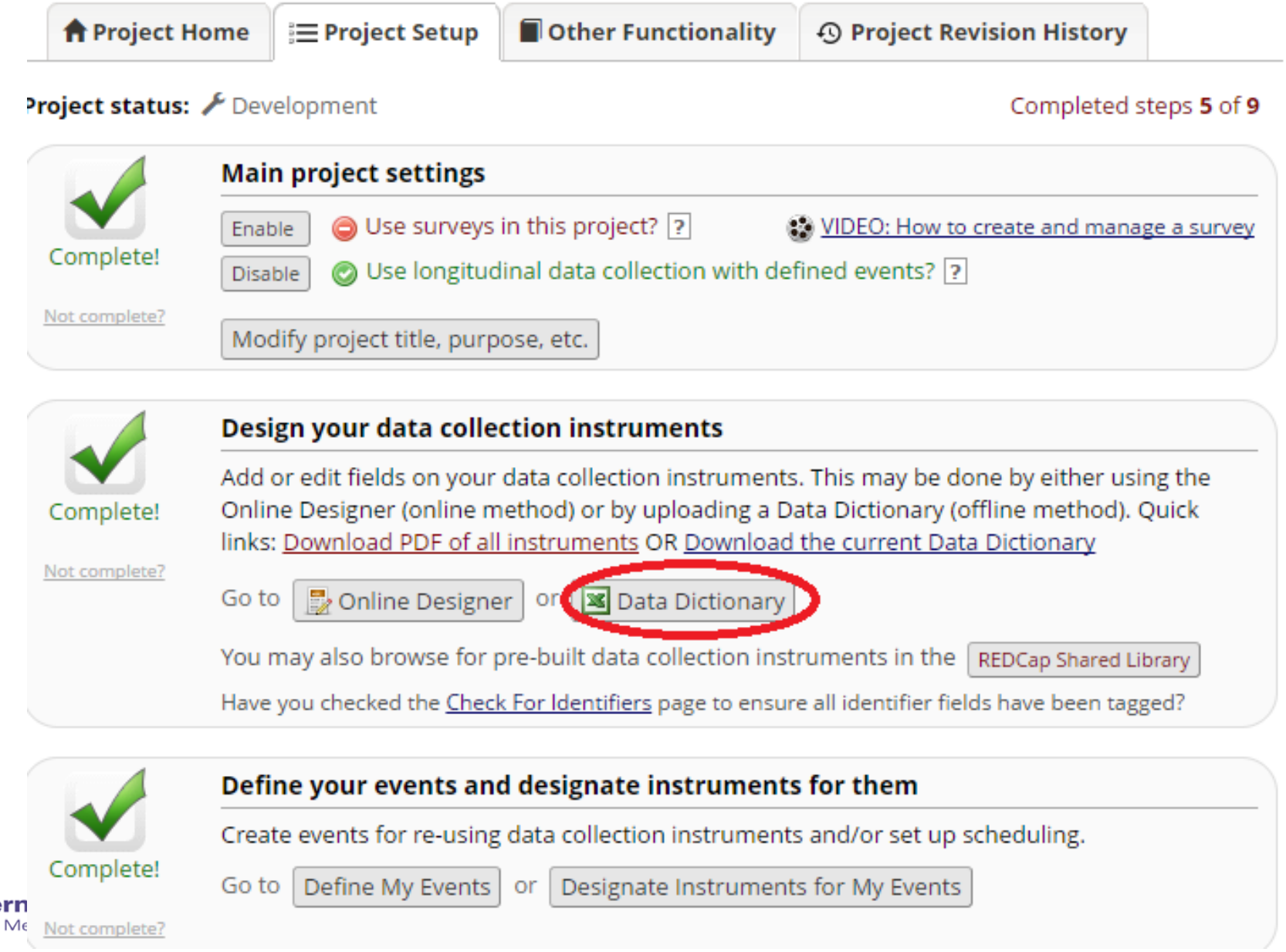
Web-based Form Builder



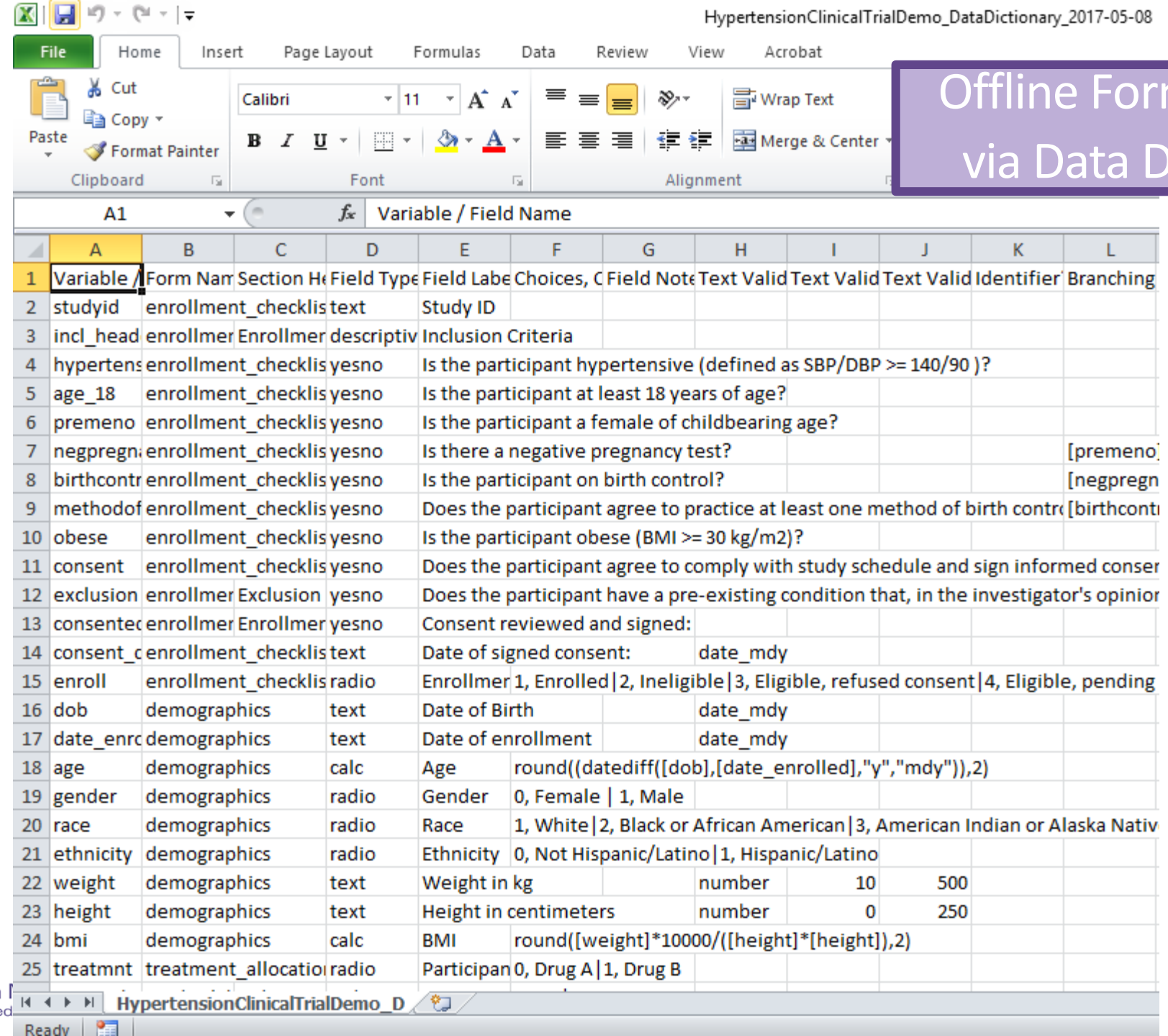


Example Case Report Form

Project Setup: Data Dictionary



Offline Form Building via Data Dictionary



HypertensionClinicalTrialDemo_DataDictionary_2017-05-08

File | Home | Insert | Page Layout | Formulas | Data | Review | View | Acrobat

Cut, Copy, Format Painter, Paste — Clipboard

Calibri 11 — Font

Wrap Text, Merge & Center — Alignment

A1: Variable / Field Name

	A	B	C	D	E	F	G	H	I	J	K	L
1	Variable /	Form Nam	Section He	Field Type	Field Labe	Choices, C	Field Note	Text Valid	Text Valid	Text Valid	Identifier	Branching
2	studyid	enrollment_checklis		text	Study ID							
3	incl_head	enrollmer	Enrollmer	descriptiv	Inclusion Criteria							
4	hypertens	enrollment_checklis		yesno	Is the participant hypertensive (defined as SBP/DBP >= 140/90)?							
5	age_18	enrollment_checklis		yesno	Is the participant at least 18 years of age?							
6	premeno	enrollment_checklis		yesno	Is the participant a female of childbearing age?							
7	negpregn	enrollment_checklis		yesno	Is there a negative pregnancy test?							[premeno]
8	birthcontr	enrollment_checklis		yesno	Is the participant on birth control?							[negpregn
9	methodof	enrollment_checklis		yesno	Does the participant agree to practice at least one method of birth contr							[birthcont
10	obese	enrollment_checklis		yesno	Is the participant obese (BMI >= 30 kg/m2)?							
11	consent	enrollment_checklis		yesno	Does the participant agree to comply with study schedule and sign informed conser							
12	exclusion	enrollmer	Exclusion	yesno	Does the participant have a pre-existing condition that, in the investigator's opinior							
13	consentec	enrollmer	Enrollmer	yesno	Consent reviewed and signed:							
14	consent_c	enrollment_checklis		text	Date of signed consent:			date_mdy				
15	enroll	enrollment_checklis		radio	Enrollmer	1, Enrolled|2, Ineligible|3, Eligible, refused consent|4, Eligible, pending						
16	dob	demographics		text	Date of Birth			date_mdy				
17	date_enrc	demographics		text	Date of enrollment			date_mdy				
18	age	demographics		calc	Age	round((datediff([dob],[date_enrolled],"y","mdy")),2)						
19	gender	demographics		radio	Gender	0, Female | 1, Male						
20	race	demographics		radio	Race	1, White|2, Black or African American|3, American Indian or Alaska Nativ						
21	ethnicity	demographics		radio	Ethnicity	0, Not Hispanic/Latino|1, Hispanic/Latino						
22	weight	demographics		text	Weight in kg			number	10	500		
23	height	demographics		text	Height in centimeters			number	0	250		
24	bmi	demographics		calc	BMI	round([weight]*10000/([height]*[height]),2)						
25	treatmnt	treatment_allocatio		radio	Participan	0, Drug A|1, Drug B						

HypertensionClinicalTrialDemo_D

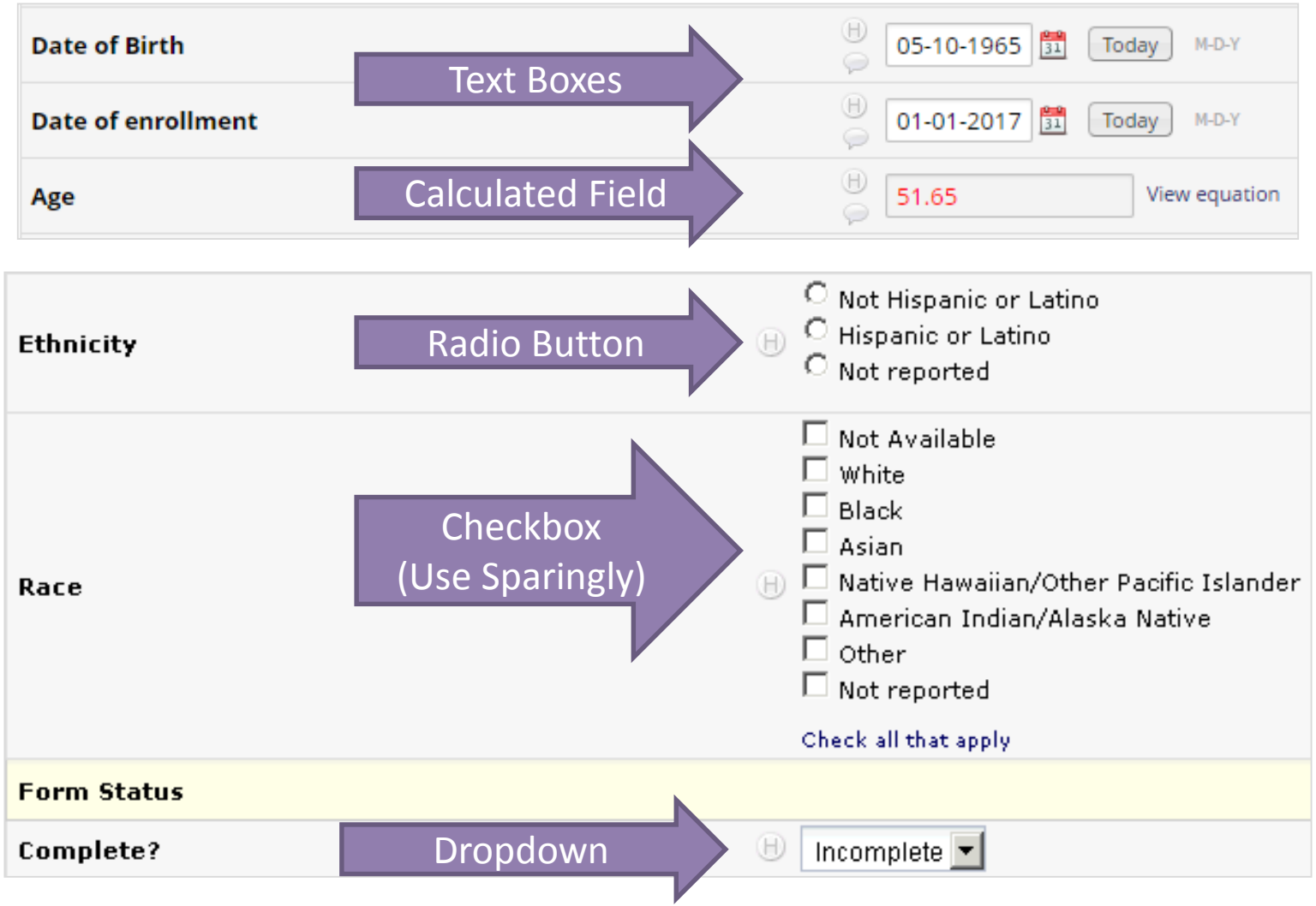
Ready

Common Field Types

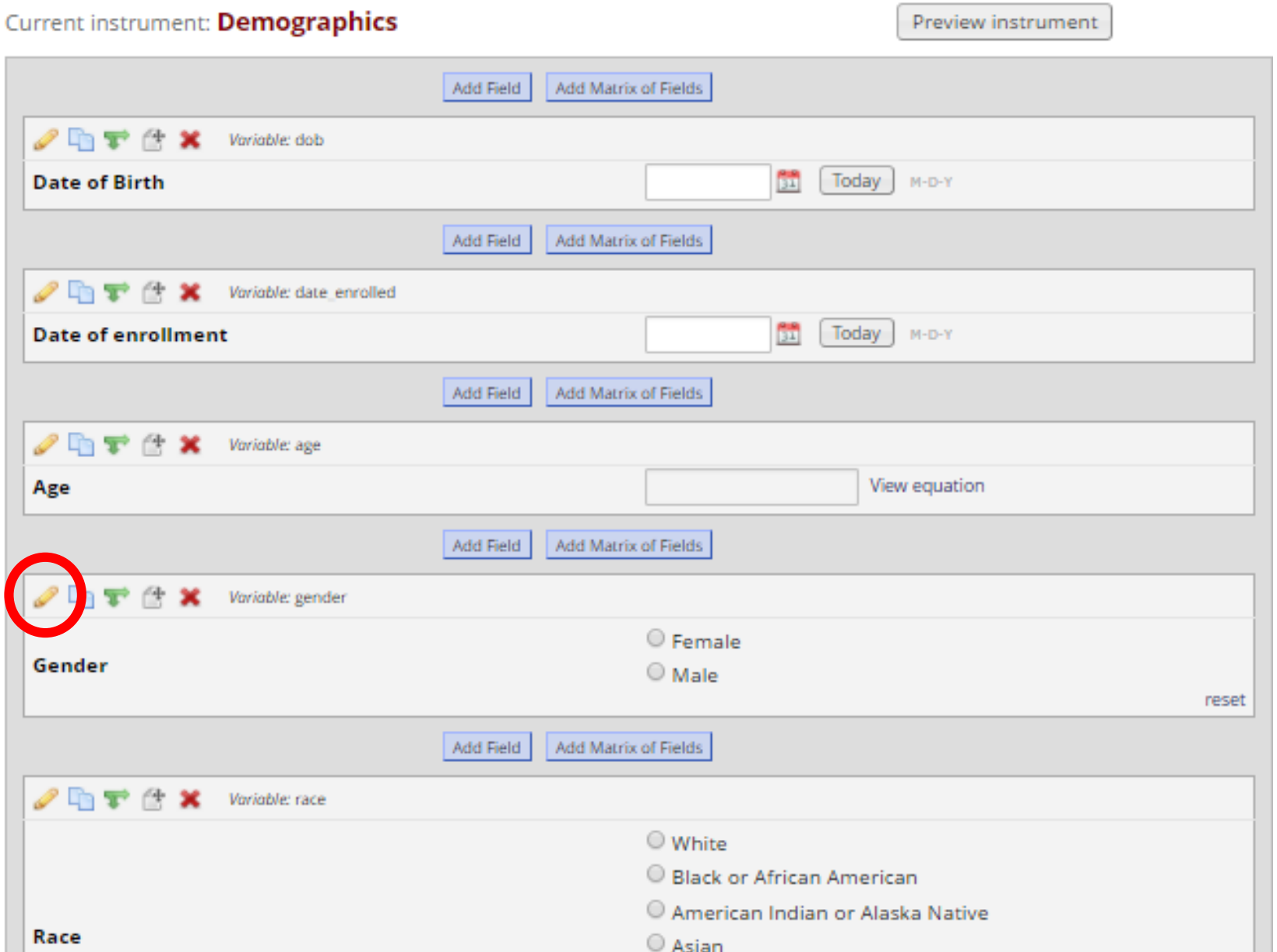
- **Text** – single-line text box (text and numbers)
- **Dropdown** – dropdown menu with multiple choice options
- **Radio** – radio button with multiple choice options
- **Calculated** – perform real-time calculations (e.g., age)

- *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

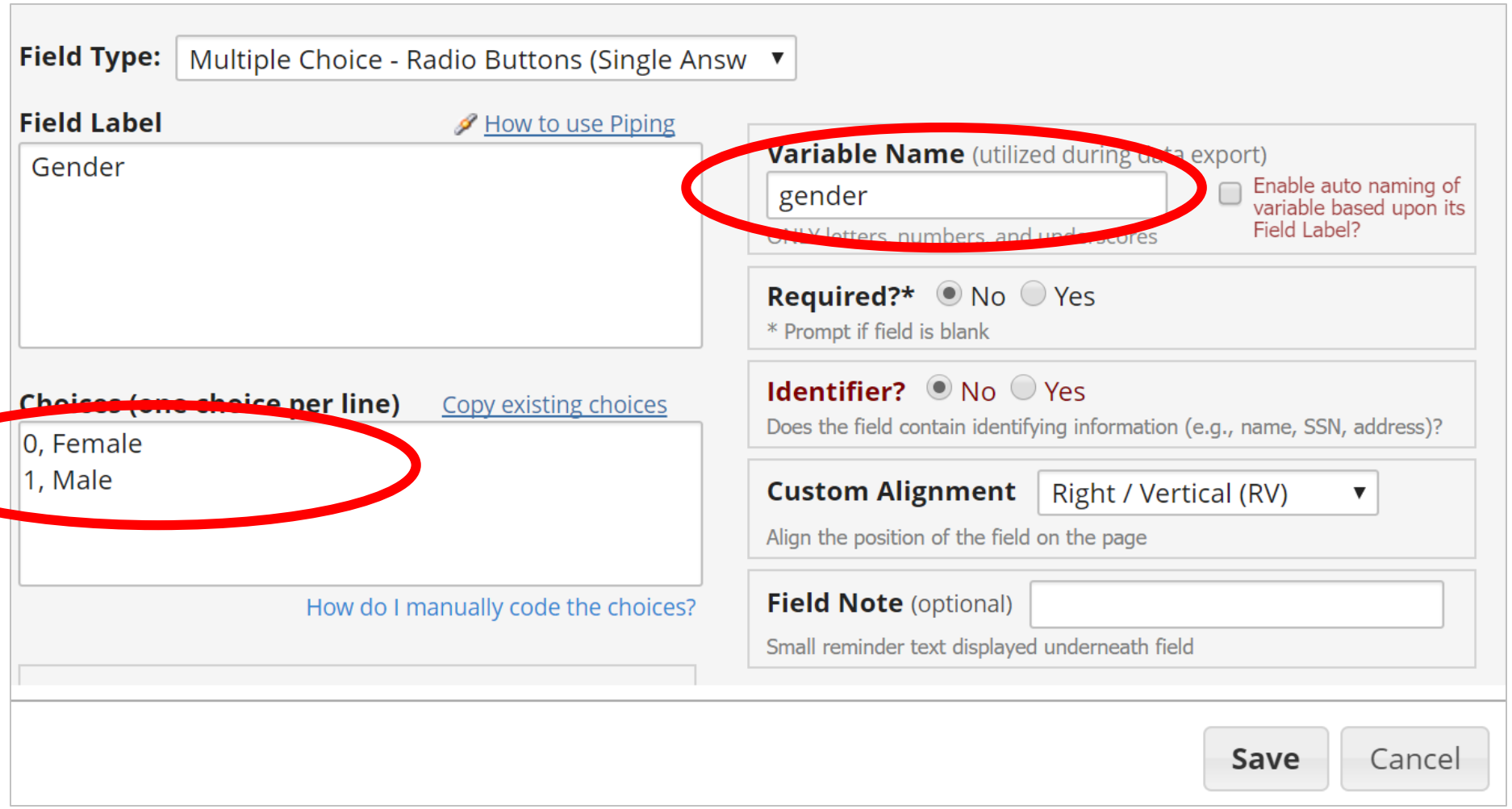


Manual Creation of Radio Button Field



Manual Creation of Radio Button Field

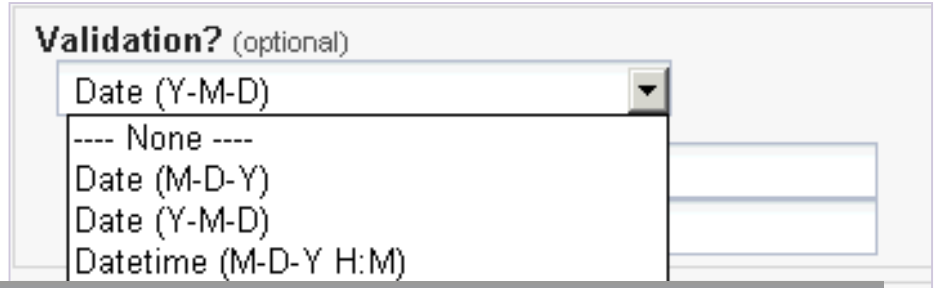
Statistically speaking…

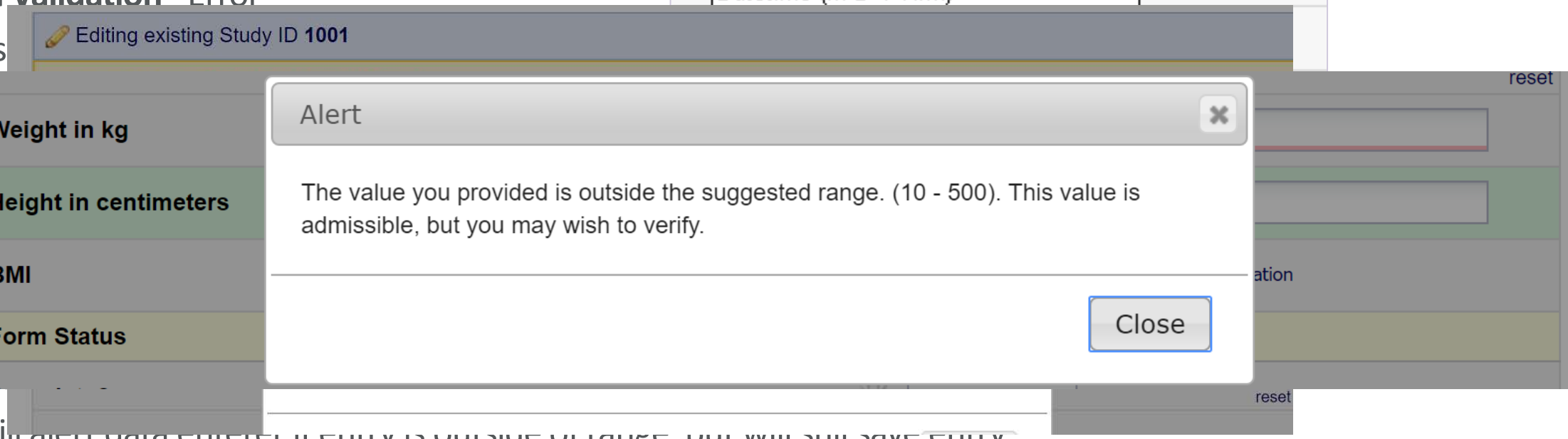


Text Box Validation

Preventing data entry errors

- **Hard Validation** - Error
  mess
  do
  for
- **Sof**
  Ma
  - (
  - Wil

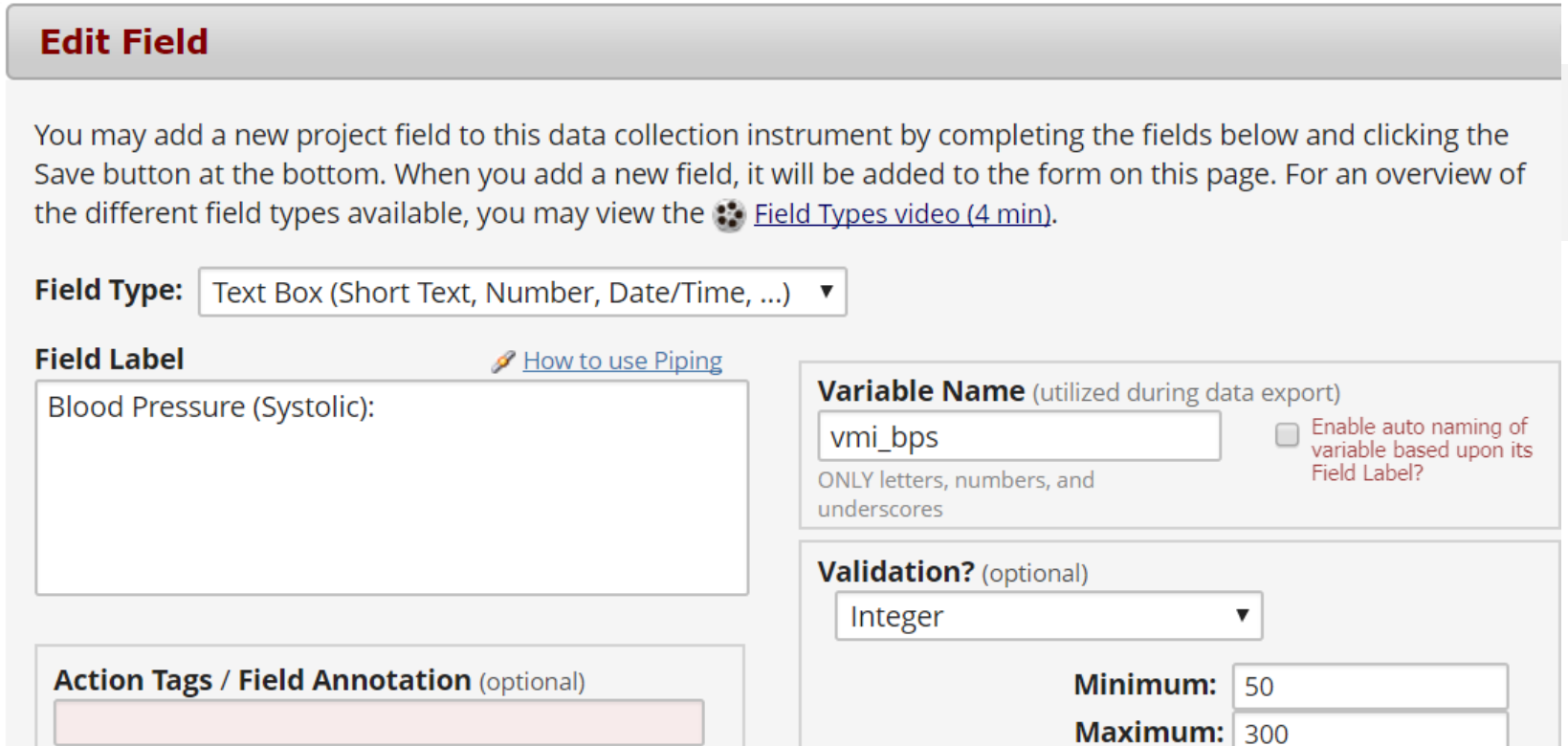




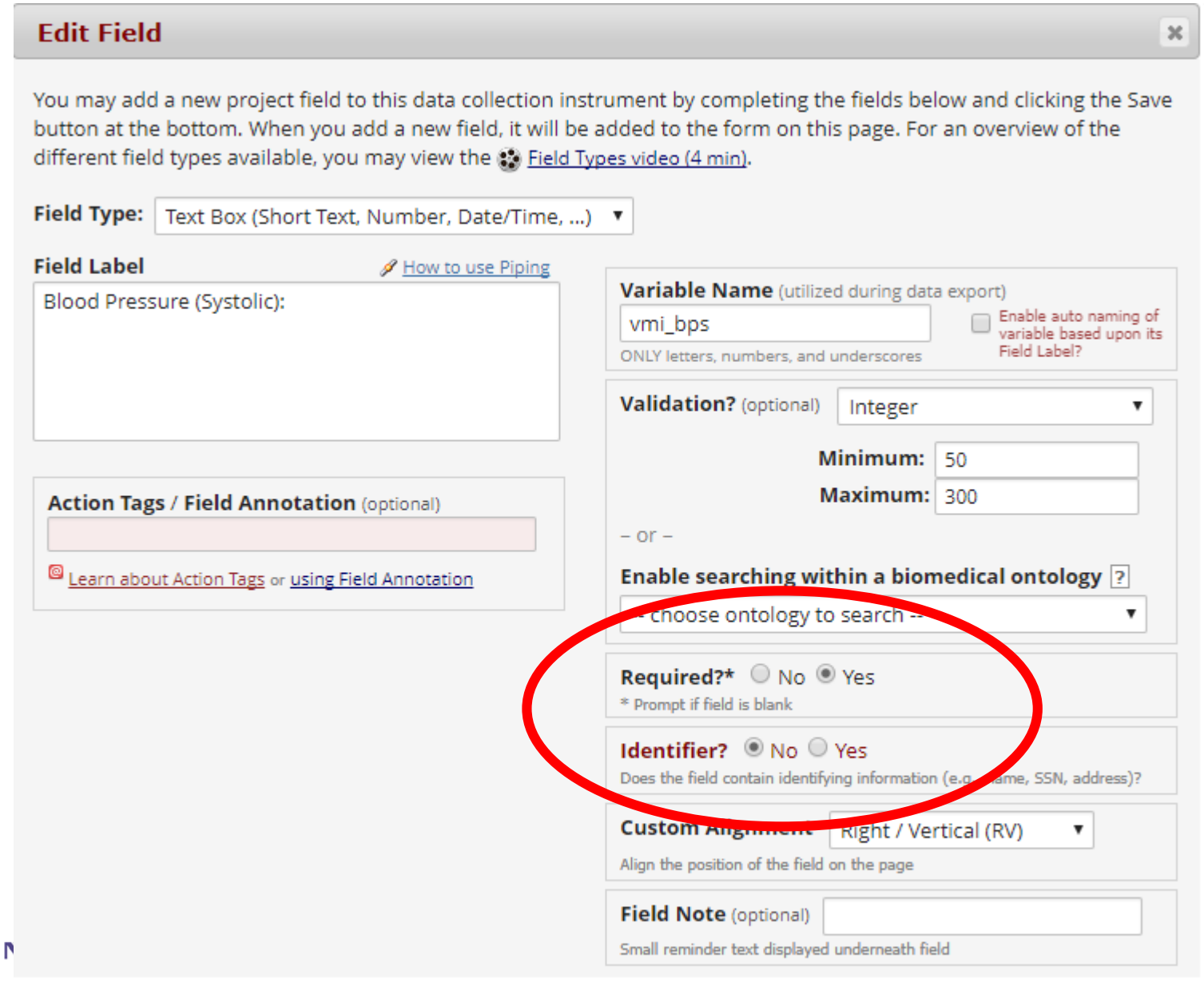
Statistically Speaking…

- Validation feature is invaluable in ensuring high-quality data for analyses
- Prevents many headaches later…
- Example:
  - Excel vs. REDCap

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



Required and Identifier Fields



Required and Identifier Fields

- **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), Identifier

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)

Field Matrix Setup

Matrix Header Text (optional)

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

Matrix Rows

Each row represents a different field with its own label and variable name.

Enable auto naming of variable based upon its Field Label?

Field Label	Variable Name (ONLY letters, numbers, and underscores)	Required?*	Field Annotation ?
Cancer	cancer_hx		
Heart disease	heart_hx		
Lung disease	lung_hx		
Circulatory problems	circ_hx		
Mental health disorders	mh_hx		

Add another row

Matrix Column Choices

Choices (one choice per line)

0, No
1, Yes

How do I manually code the choices?

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?

Matrix of Fields: Example

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

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

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

Advanced Branching Logic Syntax (How do I use the advanced syntax?)

Show the field ONLY if...

— OR —

Drag-N-Drop Logic Builder

Displaying field choices for the following data collection instrument:

Enrollment Checklist

Field choices from other fields
(drag a choice below to box on right)

- studyid = (define criteria)
- hypertensive = Yes (1)
- hypertensive = No (0)
- age_18 = Yes (1)
- age_18 = No (0)
- premeno = Yes (1)
- premeno = No (0)
- negpregnant = Yes (1)

Drag and Drop

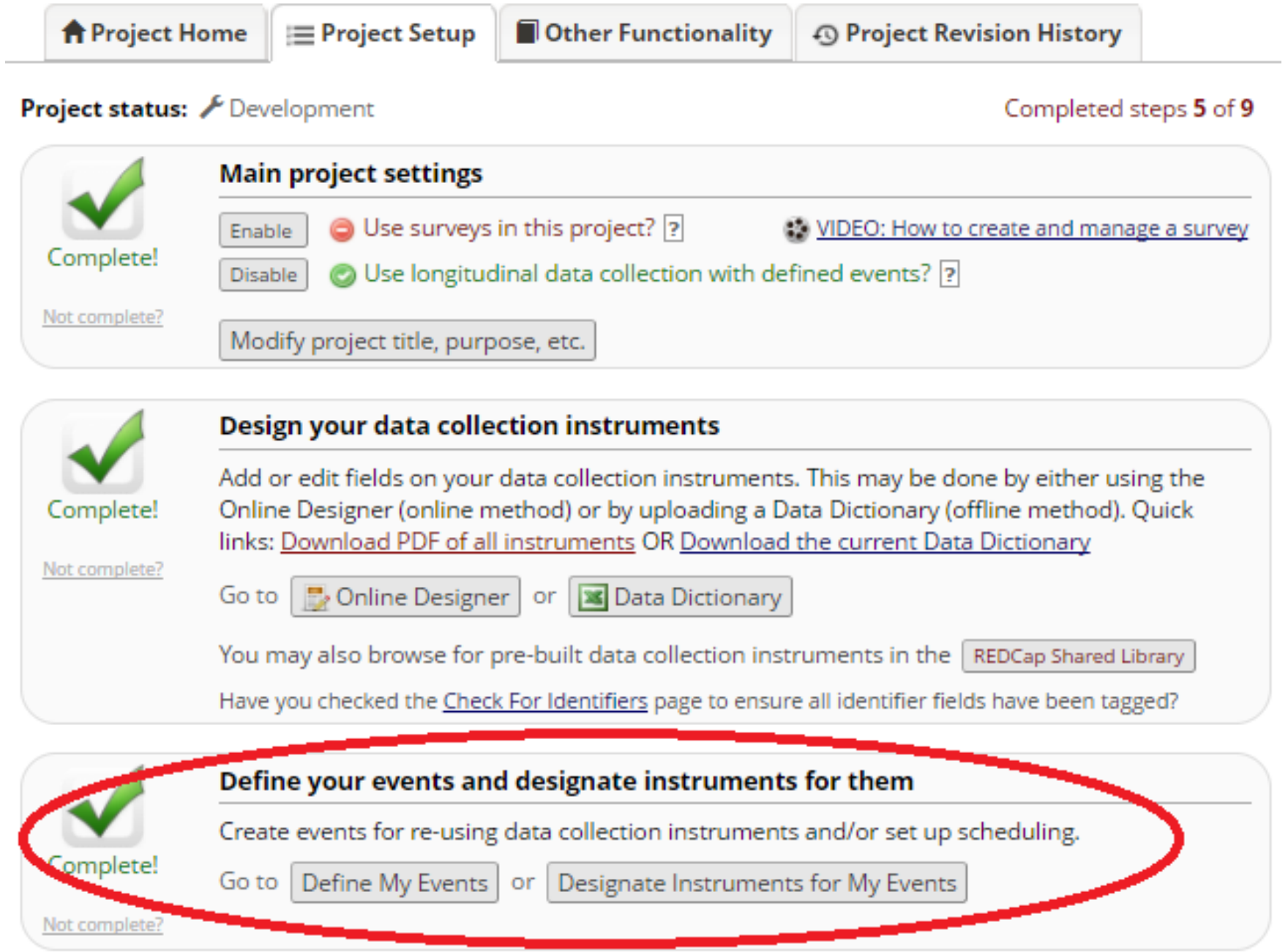
Show the field ONLY if...

- ALL below are true
- ANY below are true

Clear logic

Save Cancel

‘Arms’ and Events


Project Home
Project Setup
Other Functionality
Project Revision History
Project status: Development
Completed steps 5 of 9
Main project settings
Enable
Use surveys in this project?
VIDEO: How to create and manage a survey
Disable
Use longitudinal data collection with defined events?
Modify project title, purpose, etc.
Complete!
Not complete?
Design your data collection instruments
Add or edit fields on your data collection instruments. This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). Quick links: Download PDF of all instruments OR Download the current Data Dictionary
Go to Online Designer or 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

‘Arms’ and Events

- **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)

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

Designate Instruments for Events

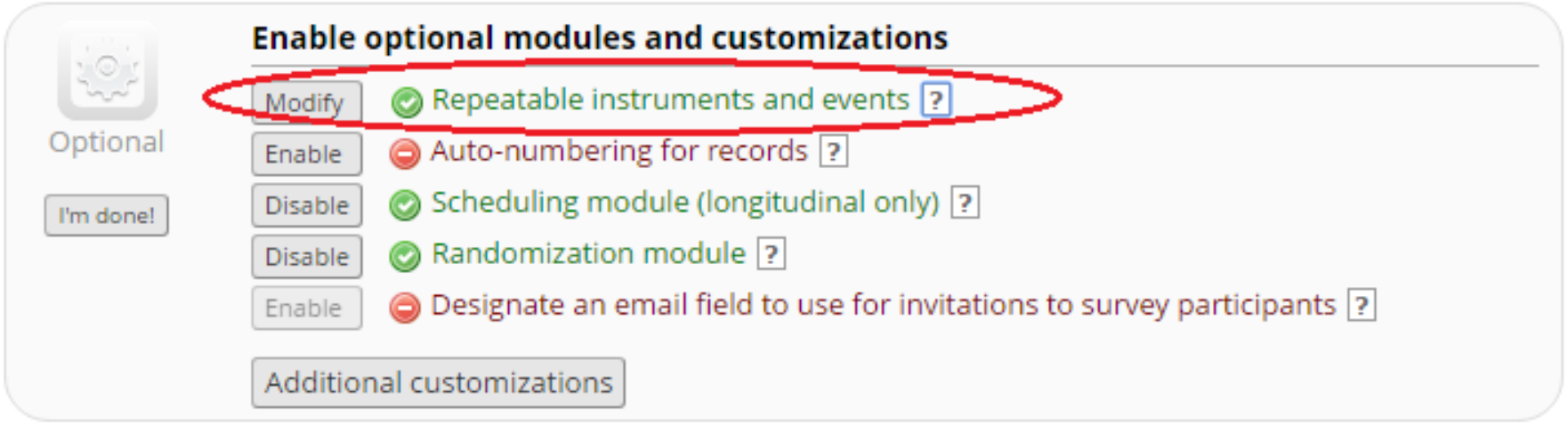
Arm name: **Prenatal**

Begin Editing | Save

Data Collection Instrument	Consent (1)	V1 Baseline (2)	V2 Prenatal (3)	V3 Prenatal (4)	V4 Prenatal (5)	V5 Prenatal (6)	V6 Prenatal (7)	V7 Prenatal (8)	V8 Prenatal (9)	V9 Prenatal (10)	V10 Prenatal (11)	V11 Prenatal (12)
Screen Consent Eligibility	✓											
Consent Change		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Participant Status	✓											
Visit Compliance		✓										
SSRI Dose Trajectory	✓											
Concomitant Medications	✓											
Diagnosis Trajectory	✓											
Concentration		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Blood Draw		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Vitals		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Visit Medical Information		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Alcohol Cigarette And Other Drug Use		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Abbreviated Asberg Side Effect (ASE)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Rx Drug Change Intake												

Repeatable Instruments and Events

- Ability to repeat a single instrument (e.g., Adverse Events) or an entire event of instruments (e.g., Clinic visits) an unlimited number of times without having to specify the amount needed
- Able to implement with surveys



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

Highest level privileges:

- Project Design and Setup ☑
- User Rights ☑
- Data Access Groups ☑

Privileges for data exports (including PDFs and API exports), reports, and stats:

- Data Exports ○ No Access ○ De-Identified* ◉ Remove all tagged Identifier fields ○ Full Data Set
  * De-identified means that all free-form text fields will be removed, as well as any date/time fields and Identifier fields.
- Add / Edit Reports ☑
  Also allows user to view ALL reports (but not necessarily all data in the reports)
- Stats & Charts ☑

Other privileges:

- Manage Survey Participants ☐
- Calendar ☐
- Data Import Tool ☐
- Data Comparison Tool ☐
- Logging ☑
- File Repository ☑
- Data Quality ☑ Create & edit rules ☑ Execute rules
  What is Data Quality?
- Data Resolution Workflow ○ No Access
  What is Data Resolution Workflow?

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 data imports or data exports.*

	No Access	Read Only	View & Edit	Edit survey responses
Screen Consent Eligibility	○	◉	○	
Consent Change	○	◉	○	
Participant Status	○	◉	○	
Visit Compliance	○	◉	○	
SSRI Dose Trajectory	○	◉	○	
Concomitant Medications	○	◉	○	
Diagnosis Trajectory	○	◉	○	
Concentration	○	◉	○	
Blood Draw	○	◉	○	
Vitals	○	◉	○	
Visit Medical Information	○	◉	○	
Alcohol Cigarette And Other Drug Use	○	◉	○	
Abbreviated Asberg Side Effect (ASE)	○	◉	○	
Rx Drug Change Intake	○	○	◉	
Edinburgh Postnatal Depression Scale (EPDS) (survey)	○	◉	○	☐
Generalized Anxiety Disorder (GAD-7)	○	◉	○	☐

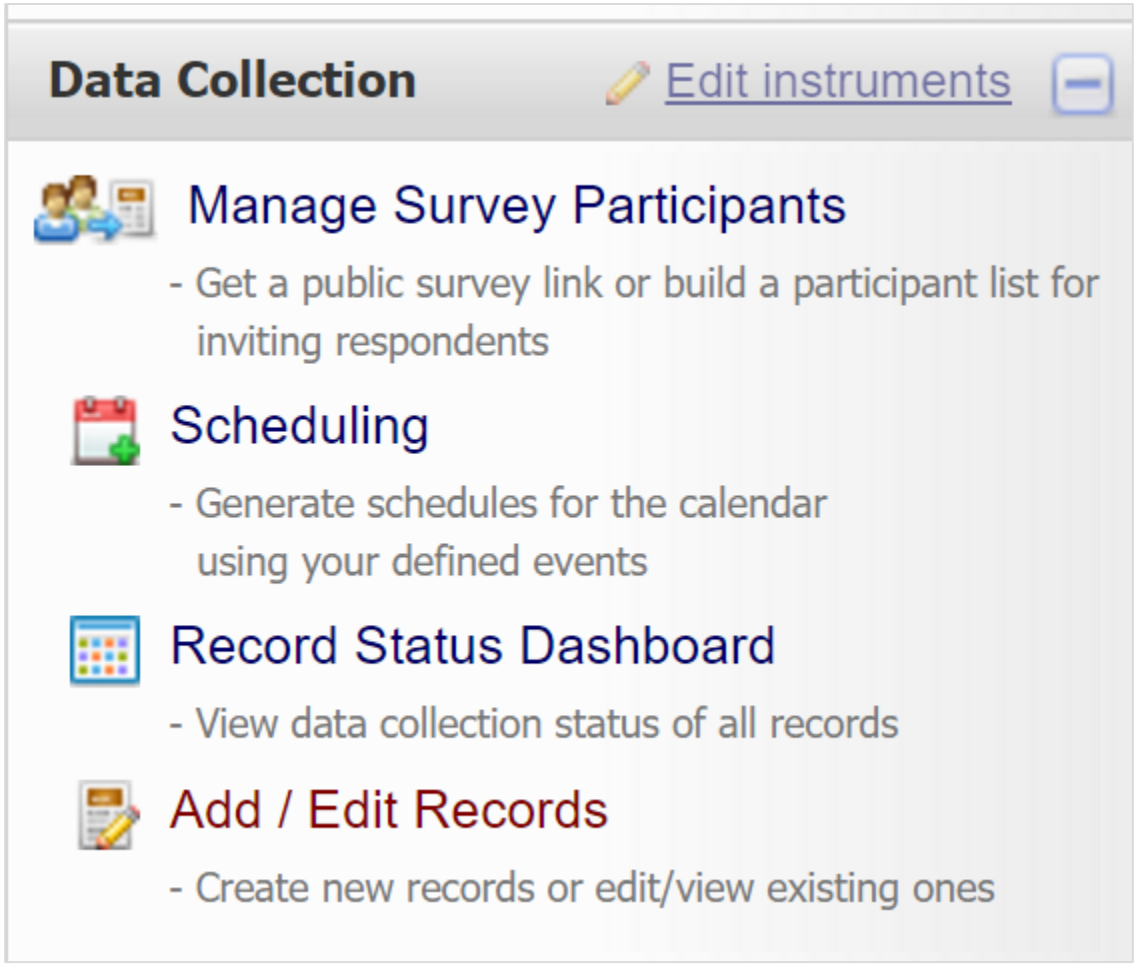
Northwestern Medicine
Feinberg School of Medicine

Northwestern Medicine®
Feinberg School of Medicine

Post Database Development…

…Data Entry, Quality Control, and Reporting

Data Entry


Data Collection
Edit instruments
Manage Survey Participants
- Get a public survey link or build a participant list for inviting respondents
Scheduling
- Generate schedules for the calendar using your defined events
Record Status Dashboard
- View data collection status of all records
Add / Edit Records
- Create new records or edit/view existing ones

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 reco 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

Data Search	
Choose a field to search (excludes multiple choice fields)	-- select search field -- ▼
Search query Begin typing to search the project data, then click an item in the list to navigate to that record.	

Record Home Page

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 Define My Events page.

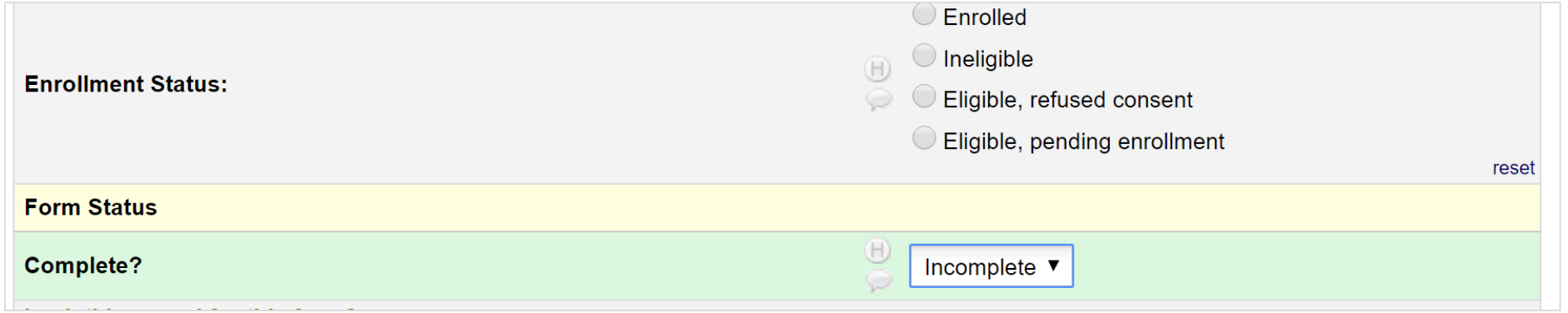
Legend for status icons:

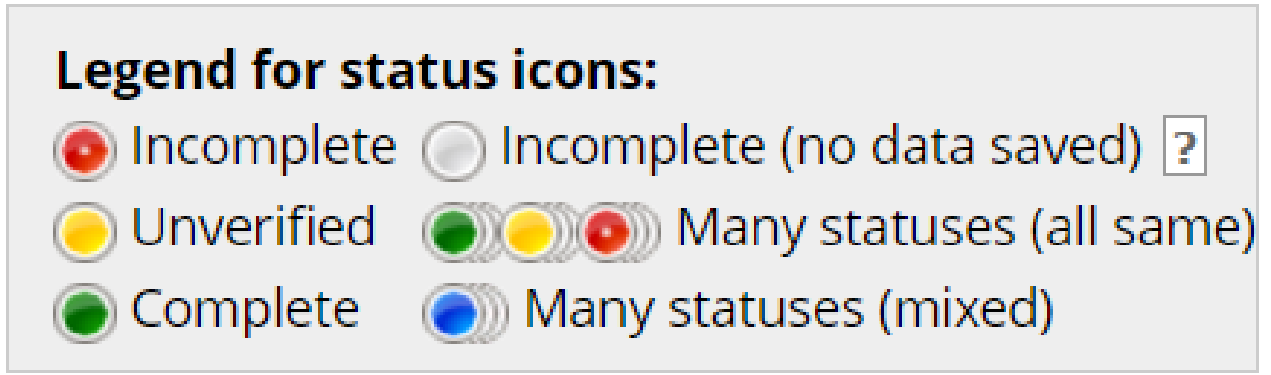
- Incomplete
- Incomplete (no data saved) ?
- Unverified
- Many statuses (all same)
- Complete
- Many statuses (mixed)

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												
Visit Compliance												
SSRI Dose Trajectory												
Concomitant Medications												
Diagnosis Trajectory												
Concentration												
Blood Draw												
Vitals												
Visit Medical Information												
Alcohol Cigarette And Other Drug Use												
Abbreviated Asberg Side Effect (ASE)												
Edinburgh Postnatal Depression Scale (EPDS) (survey)												
Generalized Anxiety Disorder (GAD-7) (survey)												
Quick Inventory Depressive Symptomatology (QIDS) (survey)												
Global Health (survey)												
Demographics (survey)												
Adverse Childhood Experience (ACE) (survey)												
Chronic Medical Conditions (CMC) (survey)												
Mood Disorder Questionnaire (MDQ) (survey)												
Mini International Neuropsychiatric Interview (MINI)												
Antidepressant Treatment History Form (ATHF)												

Da

Data Resolution Workflow

VIDEO: Data Resolution Workflow

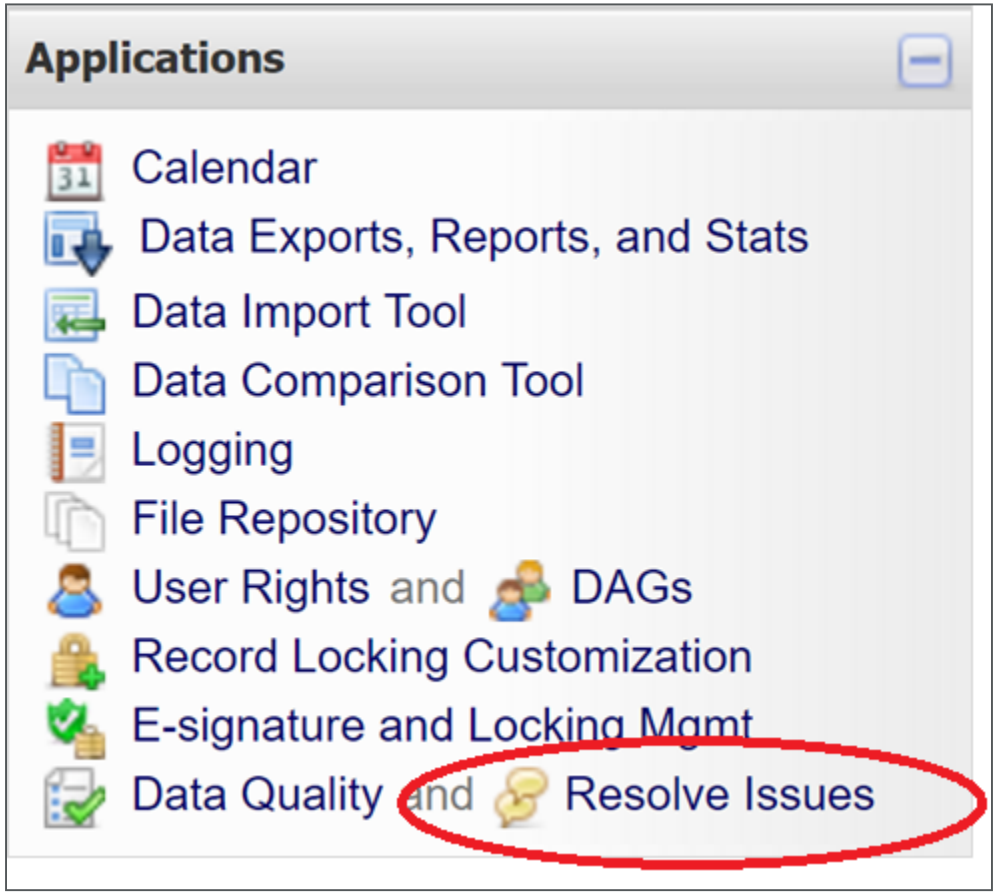
This pop-up displays the Data Resolution Workflow for the specified record for a given field and/or Data Quality rule. Users with appropriate user privileges may open data queries to begin a documented process of resolving an issue with the data. Opened data queries may thus be responded to by users 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):

Verified data value | Cancel

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

Data Resolution Dashboard

Filters: Closed / resolved issues (237) ▼ | All fields and rules ▼ | Jody ▼ | jdc800 (Jody Ciolino) ▼

Click button to view data query	Record	Data Quality rule and/or Field	User Assigned	Days Open	First Update	Last Update
2 comments	18819705 (Garbe Jody	Field: **followup** (Participant follow-up time:)	jdc800	8.7	jdc800 (02/07/2015 2:58pm): "52-week study at the patient level Study began 02/2006 and ended 11/2007"	jdc800 (02/16/2015 8:25am): "updated after form changes"
2 comments	19059639 (Gome Jody	Field: **followup** (Participant follow-up time:)	jdc800	8.7	jdc800 (02/07/2015 3:26pm): "Study lasted (08/2000-07/2006) about 6 years. Participant follow-up was 30 days."	jdc800 (02/16/2015 8:27am): "updated after form changes"
2 comments	19066368 (Gaziar Jody	Field: **followup** (Participant follow-up time:)	jdc800	8.6	jdc800 (02/07/2015 3:42pm): "Follow-up was about 8 years and length of study was about 9 years."	jdc800 (02/16/2015 8:14am): "Updated after form changes made."
3 comments	19070889 (ASTE Jody	Field: **followup** (Participant follow-up time:)	jdc800	8.6	jdc800 (02/07/2015 4:10pm): "July 1998-March 2005 (7 years)"	jdc800 (02/16/2015 8:20am): "updated after form changes."

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 record to overlay onto the plots below — -- select record --

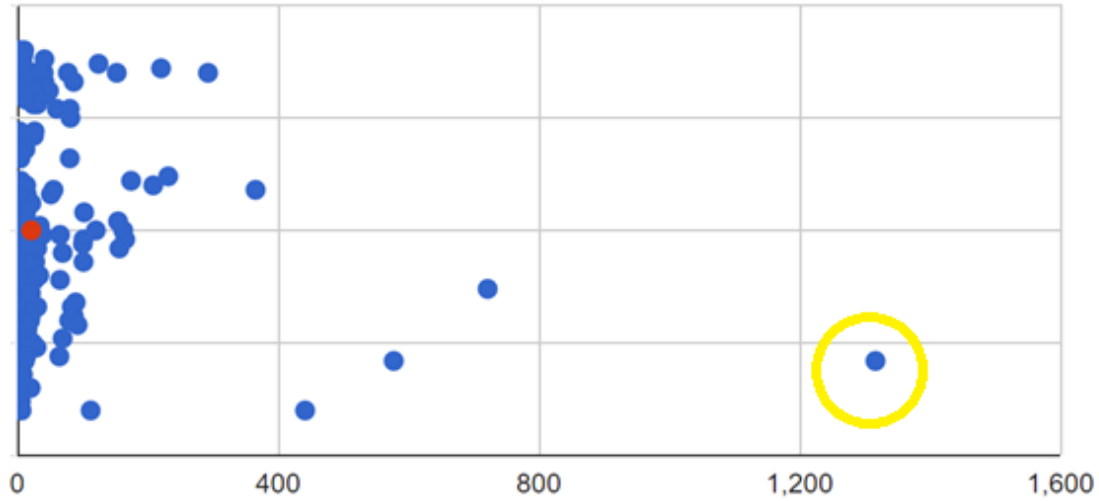
Viewing options: Show plots & stats | Show plots only | Show stats only

How many centers? Refresh Plot

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								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

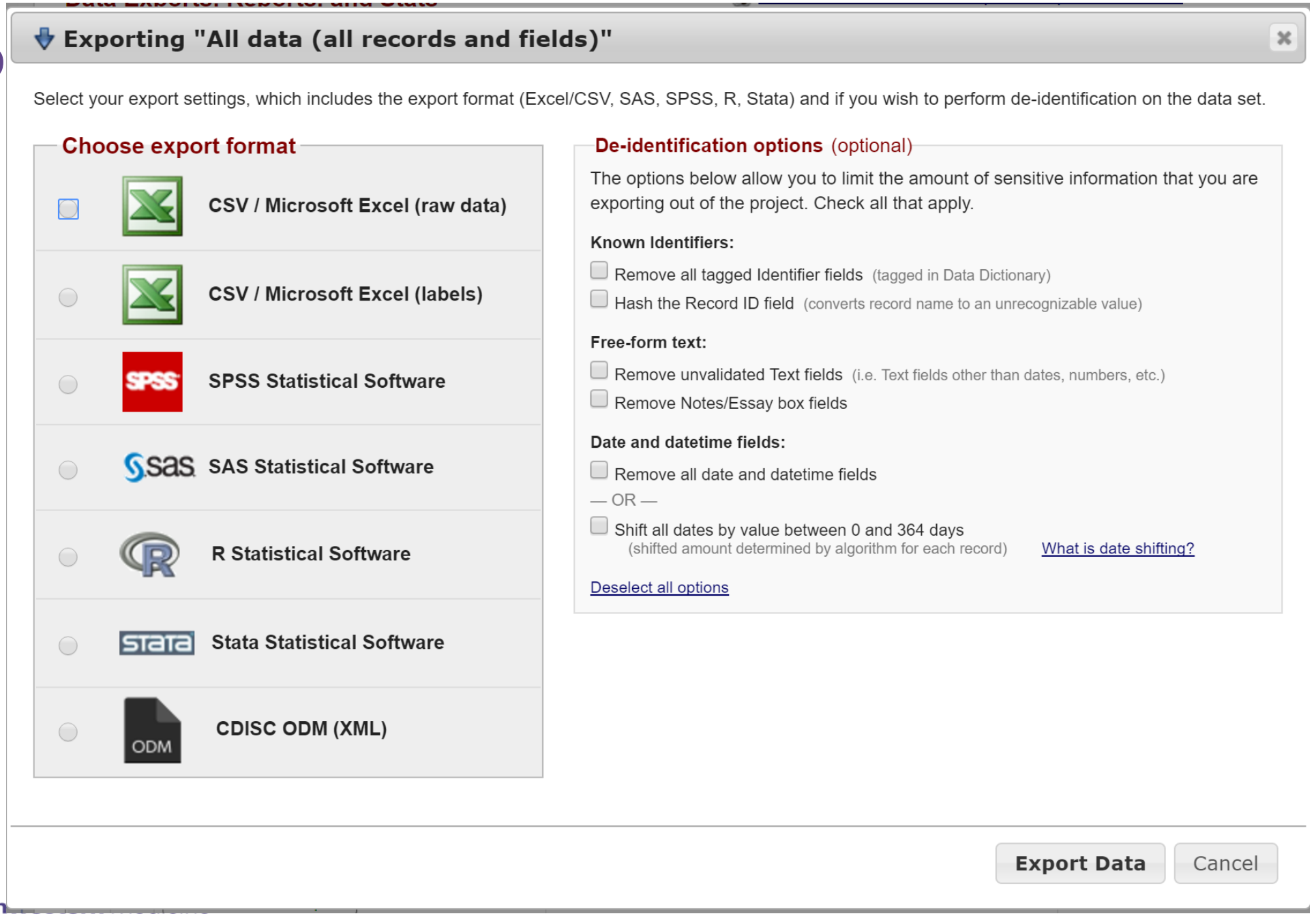


Download image

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

Data Export

D


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)
SPSS Statistical Software
SAS Statistical Software
R Statistical Software
Stata Statistical Software
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

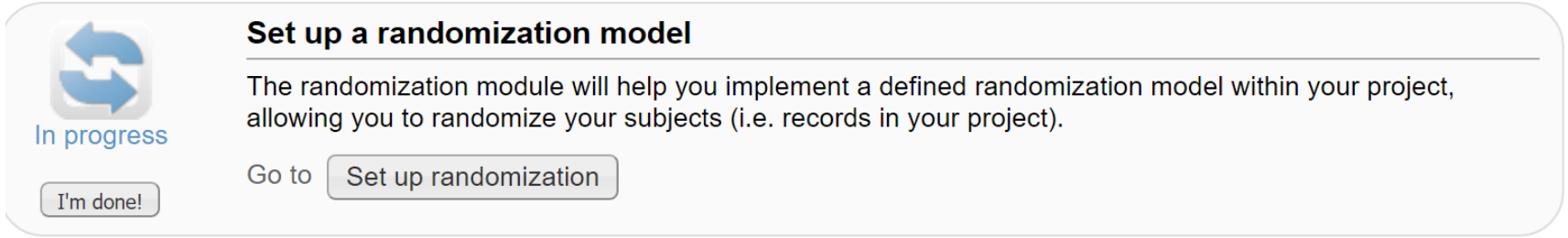
Northwestern Medicine®
Feinberg School of Medicine

Advanced REDCap Features

- Randomization
- API

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)



Setup | Dashboard

STEP 1: Define your randomization model

This step will allow you to define the randomization model you will be implementing and all its parameters, which includes defining strata (if applicable) and optionally randomizing subjects per group/site (if a multi-site study).

NOTE: This section is currently locked and uneditable because the randomization setup process has already been completed. If you wish to modify the randomization setup below, you will need to click the Erase Randomization Model button below.

A) Use stratified randomization? ☐

It is often necessary to ensure equal treatment among a number of factors. Stratified randomization is the solution to achieve balance within one or more subgroups, such as gender, race, diabetics/non-diabetics, etc. By choosing strata (criteria fields), you may then be able to ensure balance within those subgroups. Tell me more

B) Randomize by group/site? ☐

If this is a multi-center/multi-site project (or something similar), you may want to stratify the randomization by each group/site. You can select an existing multiple choice field that represents the groups/sites, OR you can use Data Access Groups to stratify by group/site.

C) Choose your randomization field

This is the field where the allocated randomization (treatment) group will be saved and stored, and is where the Randomize button will appear on your data collection form.

treatmnt (Participant allocation)

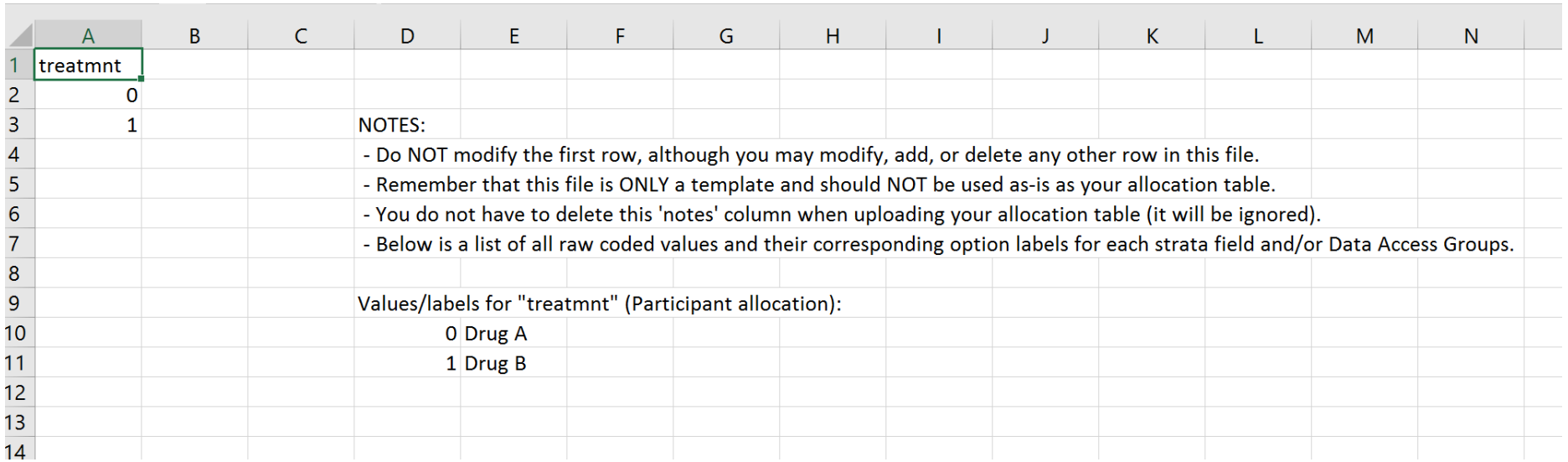
for Baseline (Arm 1: Arm1) ▼

Save randomization model | Erase randomization model

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)



	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	treatmnt													
2	0													
3	1			NOTES:										
4				- Do NOT modify the first row, although you may modify, add, or delete any other row in this file.										
5				- Remember that this file is ONLY a template and should NOT be used as-is as your allocation table.										
6				- You do not have to delete this 'notes' column when uploading your allocation table (it will be ignored).										
7				- Below is a list of all raw coded values and their corresponding option labels for each strata field and/or Data Access Groups.										
8														
9				Values/labels for "treatmnt" (Participant allocation):										
10				0	Drug A									
11				1	Drug B									
12														
13														
14														

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 drop-out and drop-in of subjects).
- Record names (e.g., study ID) should NOT be included as a column in your allocation table, but only the fields listed in the example files from Step 2 above.

Not uploaded yet

Upload allocation table (CSV file) for use in DEVELOPMENT status

Choose File No file chosen

Upload File

Not uploaded yet

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
- 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)

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

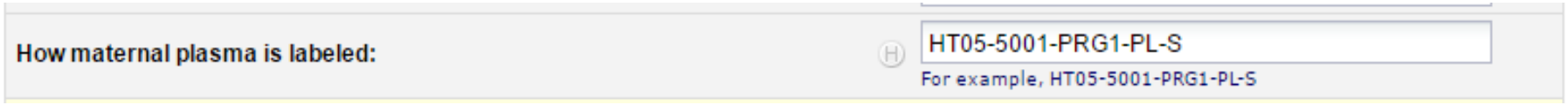
- To use the REDCap API, users must be granted ‘tokens’ by a REDCap administrator that is specific to each username and project
- Each user running any code using the API must request their own API token, which should be treated like a password
- Token must be included in all API requests
- REDCap API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

API: An Example

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

- Complex specimen labeling

Core Database:



- 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

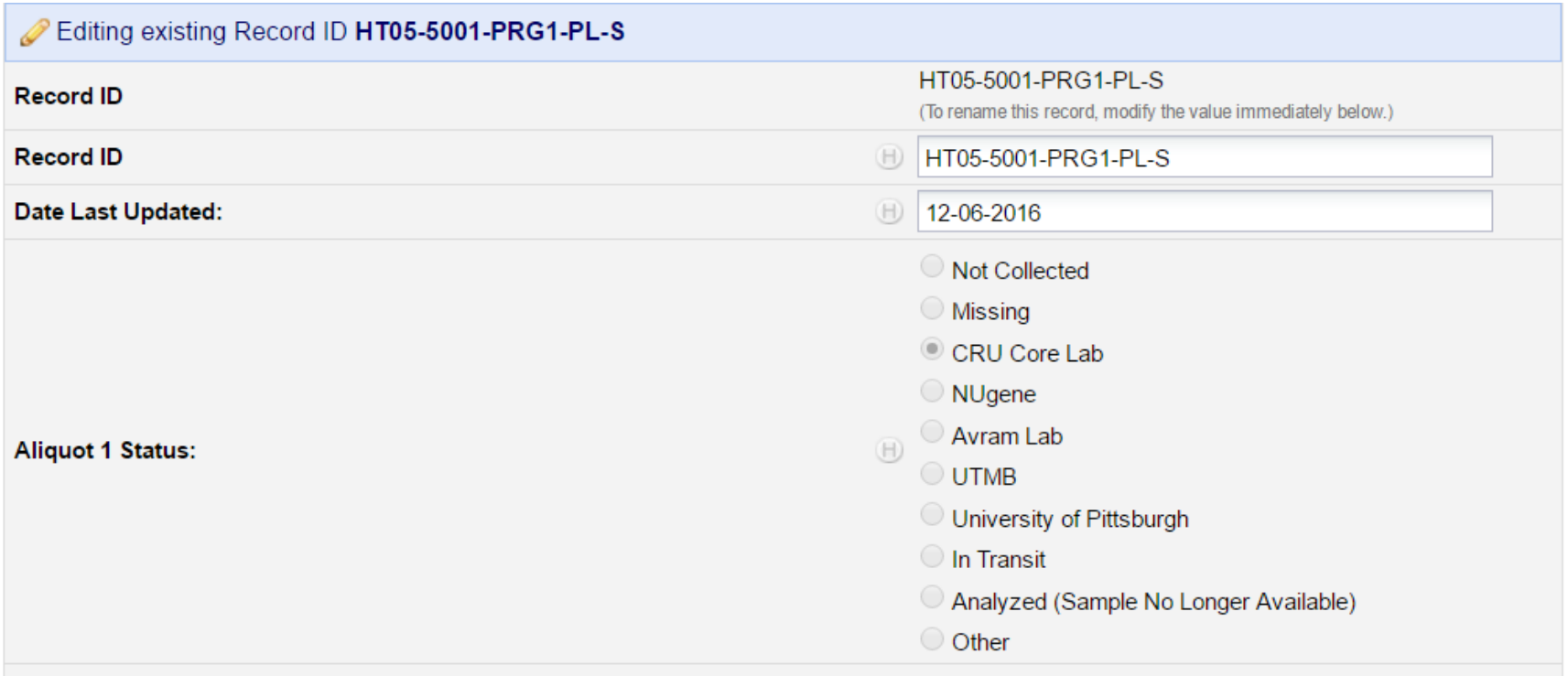
Specimen

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



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 OPTI-MOM project-->API

redcap_url <- "https://redcap.nubic.northwestern.edu/redcap/api/"
token_ex <- "XXXXXXXXXXXXXXXXX"

# rcon is the connect for data EXPORT from OPTI-MOM
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","p11bl","plm0lbl","plm0_11bl","plm0_251bl","plm0_51bl",
        "plm0_751bl","plm11bl","plm21bl","plm2_51bl","plm31bl","p1p1bl","plm41bl",
        "p141bl","plm51bl","plm61bl","p1241bl","p1t1bl","planes1bl","csf1bl","p1dell1bl",
        "cv1bl","ca1bl","fdna1bl","blood_draw_complete")]

# Data cleaning--filter out those without complete blood draw information
bd2=bd1[bd1$blood_draw_complete==2& !is.na(bd1$blood_draw_complete),
        c(c("mdnalbl","p11bl","plm0lbl","plm0_11bl","plm0_251bl","plm0_51bl",
        "plm0_751bl","plm11bl","plm21bl","plm2_51bl","plm31bl","p1p1bl","plm41bl",
        "p141bl","plm51bl","plm61bl","p1241bl","p1t1bl","planes1bl","csf1bl","p1dell1bl",
        "cv1bl","ca1bl","fdna1bl"))]

# 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
token_im="XXXXXXXXXXXXXXXXXXXXXXXX"

# 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.
```

Northwestern Medicine®
Feinberg School of Medicine

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
- FDA has yet to approve that REDCap as compliant with 21 CFR Part 11 →REDCap alone (as a mode of direct data entry) may not be suitable for FDA-governed clinical trials

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**

REDCap at Northwestern

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

Create Free One-week REDCap Trial Account

1. Go to https://redcapdemo.vanderbilt.edu/trial/
2. Enter information where prompted
3. Check your e-mail for e-mail with the subject 'REDCap Trial Account'
4. Click the link to set your password
5. You will be logged in and
   - You may log into the demo site (https://redcapdemo.vanderbilt.edu/) for one week using your e-mail address and password

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.
- University of Iowa REDCap wiki
- Clinical Research Data Management MOOC on Coursera (6 week free course with hands-on applications in REDCap).
  - https://www.coursera.org/learn/clinical-data-management

BCC: Biostatistics Collaboration Center

Contact Us

- Request an Appointment
  - http://www.feinberg.northwestern.edu/sites/bcc/contact-us/request-form.html
- General Inquiries
  - bcc@northwestern.edu
  - 312.503.2288
- Visit Our Website
  - http://www.feinberg.northwestern.edu/sites/bcc/index.html

Biostatistics Collaboration Center |680 N. Lake Shore Drive, Suite 1400 |Chicago, IL 60611

Statistically Speaking Lecture Series

- October 30:
  - David Aaby, MS
  - Using R for Statistical Graphics
- November 1:
  - Lauren Balmert, PhD
  - Time-to-Event Analysis

- http://www.feinberg.northwestern.edu/sites/bcc/education/lecture/2017.html

Your feedback is important to us! (And helps us plan future lectures).

Complete the evaluation survey to be entered in to a drawing to win 2 free hours of biostatistics consultation.