

REDCAP

LONGITUDINAL STUDIES CLASS (203)



Learning Objectives



Longitudinal features

- ▶ Setup
- ▶ Logic
- ▶ Data entry



Repeatable forms

- ▶ Setup
- ▶ Data entry



Determining the best model for your project

- ▶ Data entry vs data analysis
- ▶ Export consequences

ITHS' Focus

- Speeding science to clinical practice for the benefit of patients and communities.
- Promotes translation of scientific discovery by:
 - ❑ Fostering innovative research
 - ❑ Cultivating multi-disciplinary partnerships
 - ❑ Training the next generation of researchers
- More information: www.iths.org



Laboratory

Clinic

Community



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ACCELERATING RESEARCH. IMPROVING HEALTH.

General Workflow Models

Classical model

- *Longitudinal mode turned off*
 - *Each form can be filled out once per record*
 - *Simplest and easiest*
-

Longitudinal model (Single arm)

- *Longitudinal mode turned on*
 - *Single arm with a number of events defined*
 - *Instruments can be linked to multiple events*
-

Longitudinal model (Multiple arms)

- *Longitudinal mode turned on*
- *Multiple arms each with a number of events defined*
- *Instruments can be linked to multiple events in each arm*
- *The event setup can differ widely per arm*
- *Each record can only “live” in one arm at a time*

Longitudinal Setup

Enable Feature



Enable longitudinal mode

Setup Arms



Setup the desired number of arms

Setup Events



Setup the appropriate number of events per arm

Link instruments



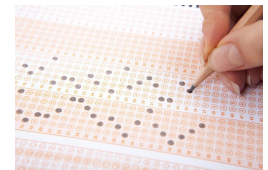
Link up the proper instruments to each event in each arm

Check Dependents



Setup features dependent on a correct longitudinal model

Run Tests



Test your model

Each step requires the previous steps, so follow this order

Longitudinal Setup

Enable Longitudinal mode

Setup Arms

Setup Events

Link Instruments

Setup Dependent Features

Test Your Model



Enable Longitudinal Mode

- ▶ Hit the “Enable” button to turn on longitudinal mode
 - ▶ Found in the project setup page
 - ▶ Disable longitudinal mode hides features

Main project settings

Complete! Not complete

☒ Use surveys in this project? [VIDEO: How to create and manage a survey](#)

☐ Use longitudinal data collection with defined events?

Main project settings

Complete! Not complete

☒ Use surveys in this project? [VIDEO: How to create and manage a survey](#)

☒ Use longitudinal data collection with defined events?

Longitudinal Setup

Enable Longitudinal mode

Setup Arms

Setup Events

Link Instruments

Setup Dependent Features

Test Your Model



Setup Arms

- ▶ Location:
 - ▶ Navigate to the Project Setup page
 - ▶ Click on the “Define My Events” Button
- ▶ Basic setup:
 - ▶ Single arm is the default
 - ▶ To add additional arms use the “+Add New Arm” tab
- ▶ “Quick” setup:
 - ▶ Use the “Upload arms (CSV)” option
 - ▶ Download a template with the “Download arms (CSV)” option
- ▶ Rename your arm(s) as needed
- ▶ Order of arms is determined by number not name
- ▶ Do not change order if you have real data in the project

Longitudinal Setup

Enable Longitudinal mode

Setup Arms

Setup Events

Link Instruments

Setup Dependent Features

Test Your Model



Setup Events

- ▶ Also found in “Define My Events”
- ▶ Basic setup:
 - ▶ Each arm needs to have at least 1 event
 - ▶ To add extra events use the “Add new event” button after define the event name
- ▶ “Quick” setup:
 - ▶ Use the “Upload events (CSV)” option
 - ▶ Download a template with the “Download events (CSV)” option
 - ▶ Pro tip: only the event name and arm number are mandatory for the “Upload events (CSV)” option
- ▶ The event name and arm number automatically combine into the “unique event name”.
 - ▶ Keep event names short

Longitudinal Setup

Enable Longitudinal mode

Setup Arms

Setup Events

Link Instruments

Setup Dependent Features

Test Your Model



Link Instruments

- ▶ Assign instruments to appropriate event(s)
- ▶ Needs to be done for each arm
- ▶ Always link the first instrument to the first event
 - ▶ Due to the record ID requirement
- ▶ Basic setup:
 - ▶ Click on "Begin editing"
 - ▶ Select the instruments you want to link
 - ▶ Click on the "Save" Button
- ▶ "Quick" setup:
 - ▶ Use "Upload instrument-events mappings (CSV)" option
 - ▶ Download a template with the "Upload instrument-events mappings (CSV)"

Longitudinal Setup

Enable Longitudinal mode

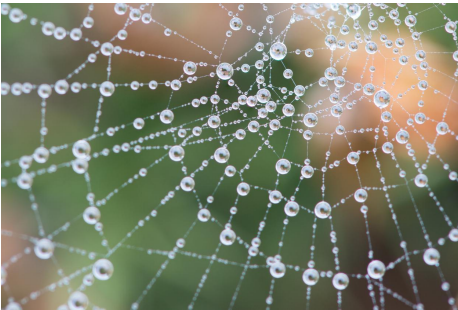
Setup Arms

Setup Events

Link Instruments

Setup Dependent Features (1/2)

Test Your Model



Setup Dependent Features

- ▶ Surveys
 - ▶ Automatic survey invitations
 - ▶ Survey queue
 - ▶ Public survey link
- ▶ Repeatability forms
 - ▶ Repeatability instruments
 - ▶ Repeatability events
- ▶ Reports
- ▶ Branching logic
- ▶ Calculations

Longitudinal Setup

Enable Longitudinal mode

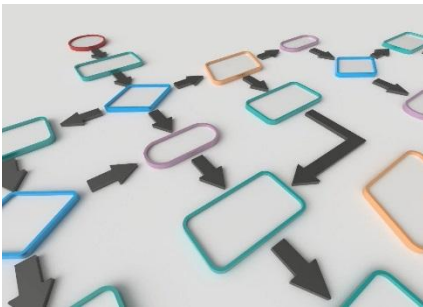
Setup Arms

Setup Events

Link Instruments

Setup Dependent Features (2/2)

Test Your Model



Branching Logic

- ▶ Classic Branching logic
 - ▶ Define the **variable**
 - ▶ Put in an **operator**
 - ▶ Declare you **comparison value**

[age_of_child] >= '18'

- ▶ Longitudinal Branching Logic
 - ▶ Define the **event**
 - ▶ Define the **variable**
 - ▶ Put in an **operator**
 - ▶ Declare you **comparison value**

[baseline_arm_1][age_of_child] >= '18'

Longitudinal Setup

Enable Longitudinal mode

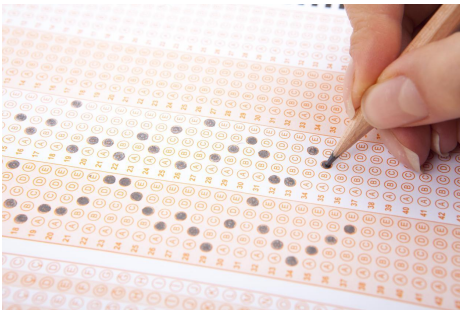
Setup Arms

Setup Events

Link Instruments

Setup Dependent Features

Test Your Model



Test Your Model

- ▶ Create a couple of test records
 - ▶ Use test data as close to real as possible
 - ▶ Simulate the workflow you intend to use
- ▶ Pay extra attention to the following features:
 - ▶ Survey mechanics
 - ▶ Branching logic
 - ▶ Calculations

Scheduling Module

Location

- *Enabled in the project setup page*
 - *Button in “Optional modules and customizations” section*
 - *Scheduling application found under “Data collection”*
 - *Calendar application found under “Applications”*
-

Setup

- *Enable “Scheduling module”*
 - *Navigate to the “Define My Events” page*
 - *Add “Days Offset” & “Offset Range”*
 - *“Days Offset” governs the order of events*
 - *“Offset Range” is used for schedule generation*
-

Use

- *Generate a schedule for each record in the “Scheduling” application*
 - *Adjust the schedule if necessary*
- *View all scheduled records together in the “Calendar” application*

Longitudinal Data Entry

Adding new records

- *Navigate to the “Add / Edit Records” menu*
 - *Create a new record*
 - *In case of multiple arms, you’ll have to select the appropriate arm before creating a record*

Record home page

- *Page provides an overview for the data entry progress for a single record*
- *Clicking on any dot will take you directly to that particular form in the corresponding event*
- *General & event specific actions are located on this page*

Record Status Dashboard

- *Dashboard provides an overview for the data entry progress of all records*
- *Organised by event*
- *Use the “Create custom dashboard” option to craft your own custom overviews*

Infinitely Repeating Instruments or Events



Repeating Instruments

- ▶ Repeat any instrument as many times as needed
- ▶ Works in both classic and longitudinal mode
- ▶ Use for “fuzzy” data entry like “adverse events”

Repeating Events

- ▶ Only works for longitudinal mode
- ▶ Repeat any event as many times as needed
- ▶ Use for situations where the number of needed events differs per record. e.g. “Chemotherapy cycles”

Limitations

- ▶ Adding a repeating instrument to a repeating event is not allowed
- ▶ Use of repeating function will make analysis more challenging



Infinitely Repeating Setup



- ▶ Done after setup of:
 - ▶ Instruments
 - ▶ Longitudinal model
- ▶ Navigate to the “optional modules” section in the project setup page
 - ▶ Click on the “Modify” button next to the “Repeatable instruments and events” button
- ▶ In the resulting pop-up, select from the following for each event:
 - ▶ Not repeat anything
 - ▶ Repeat the entire event
 - ▶ Repeat instruments
 - ▶ Select the instruments to repeat
 - ▶ Use of a custom label is recommended
 - ▶ Use the variable name of a variable within the repeated instrument
 - ▶ Example labels:
 - ▶ Visit date: [visit_date]
 - ▶ Score: [score_total]

Using Repeating Instruments

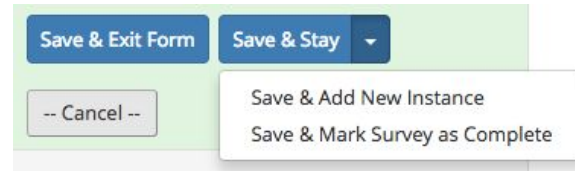
- ▶ Instruments can be repeated by:

- ▶ Users
- ▶ Survey participants



- ▶ Users should look for:

- ▶ The "plus" symbol in the record home page
- ▶ The "Add New" button in the record homepage
- ▶ The "Save & Add New Instance" option in the "Save & Stay" button on an instrument page



- ▶ Survey participants should look for a button at:

- ▶ Next to the submit button
- ▶ Below the survey completion text

- ▶ The text and location of the button can be configured in the survey settings of any repeating survey

Using Repeating Events



- ▶ Events can only be repeated by users
- ▶ User should look at the “+Add new” button in the record home page
- ▶ If you want to send out any survey in a repeated event, you’ll have to schedule that invitation manually. You can do that via:
 - ▶ The compose survey invitation in a form
 - ▶ The participant list
- ▶ Automated invitations are currently not available for repeated events



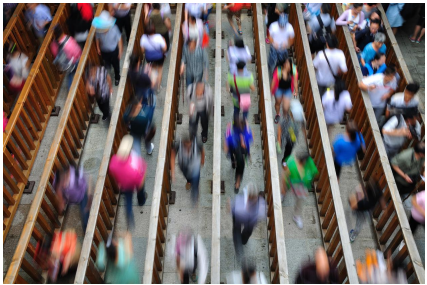
Export consequences

For longitudinal projects and repeatable instruments/events



- ▶ Classic projects
 - ▶ Single row of data per record
 - ▶ Smaller export files

**Exports will have
1 row per record**



- ▶ Longitudinal projects
 - ▶ 1 row per event, per record
 - ▶ Only if data is in the event
 - ▶ Sparse matrix

**Exports will have
Multiple rows per
record**



- ▶ Repeatable instruments/events
 - ▶ 1 row per repeat, per record
 - ▶ Bigger exports files
 - ▶ Unwieldy reports
 - ▶ Very sparse matrix

**Talk to your
analyst/statistician**

Ease of Data Entry VS Ease of Analysis

Design focused on **Easy Data Entry**

- Tends to require more work to analyze
- Has greater flexibility for data entry

Design focused on **Easy Data Analysis**

- Rigid data entry
- Better quality data

Solution?

- ▶ Talk to the parties involved
- ▶ Determine priorities for your study
- ▶ And if all else fails, ☐ Compromise

Thank You

Questions?

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