Longitudinal Projects

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

General Workflow Models

Classic model

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

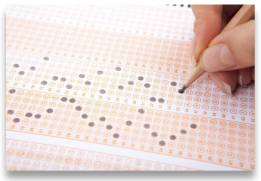
Longitudinal model (Single arm)

- *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	Setup Arms	Setup Events	Link instruments	Check Dependents	Run Tests
					
Enable longitudinal mode	*Setup the desired number of arms*	*Setup the appropriate number of events per arm*	*Link up the proper instruments to each event in each arm*	*Setup features dependent on a correct longitudinal model*	*Test your model*

Each step requires the previous steps, so follow this order!

Longitudinal Setup

Enable Longitudinal mode

Setup Arms

Setup Events

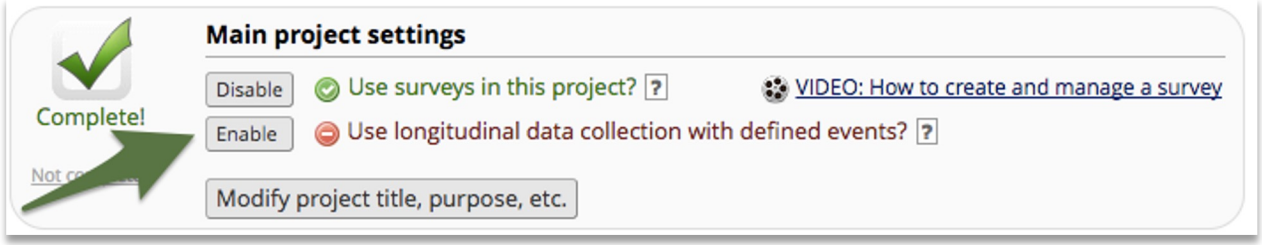
Link Instruments

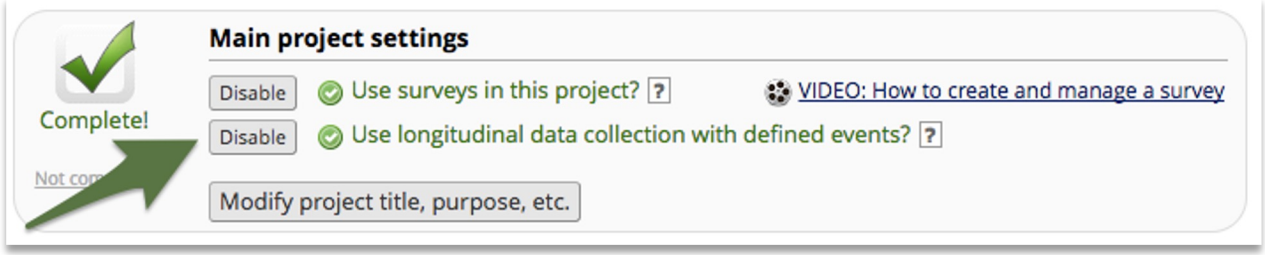
Setup Dependent Features

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





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
- Repeatable forms
  - Repeatable instruments
  - Repeatable events
- Reports
- Branching logic
- Calculations

Longitudinal Setup

Enable Longitudinal mode

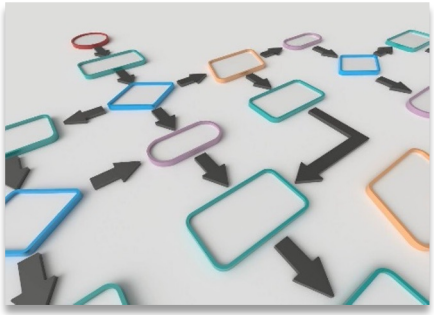
Setup Arms

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

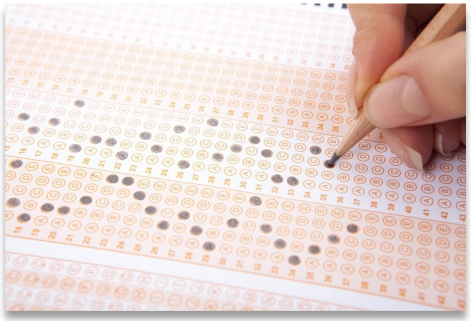
Setup Arms

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*
- *Organized 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

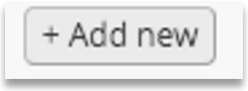
- Adding a repeating instrument to a repeating event is not allowed
- Use of repeating function will make analysis more challenging

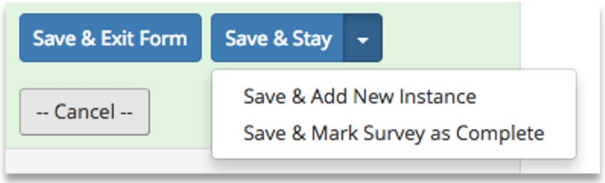
Infinitely Repeating Setup

- 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 option
  - The participant list
- Automated invitations are currently not available for repeated events

Useful Smart Variables and Special Functions

- Repeating Instruments and Events
  - [current-instance]
  - [previous-instance]
  - [next-instance]
  - [first-instance]
  - [last-instance]
- Event and Arm
  - [event-id], [event-name]
  - [arm-number], [arm-label]
  - [first-event-name], [next-event-name], [previous-event-name]
- Datediff function
  - datediff([date1], 'today', 'd')

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

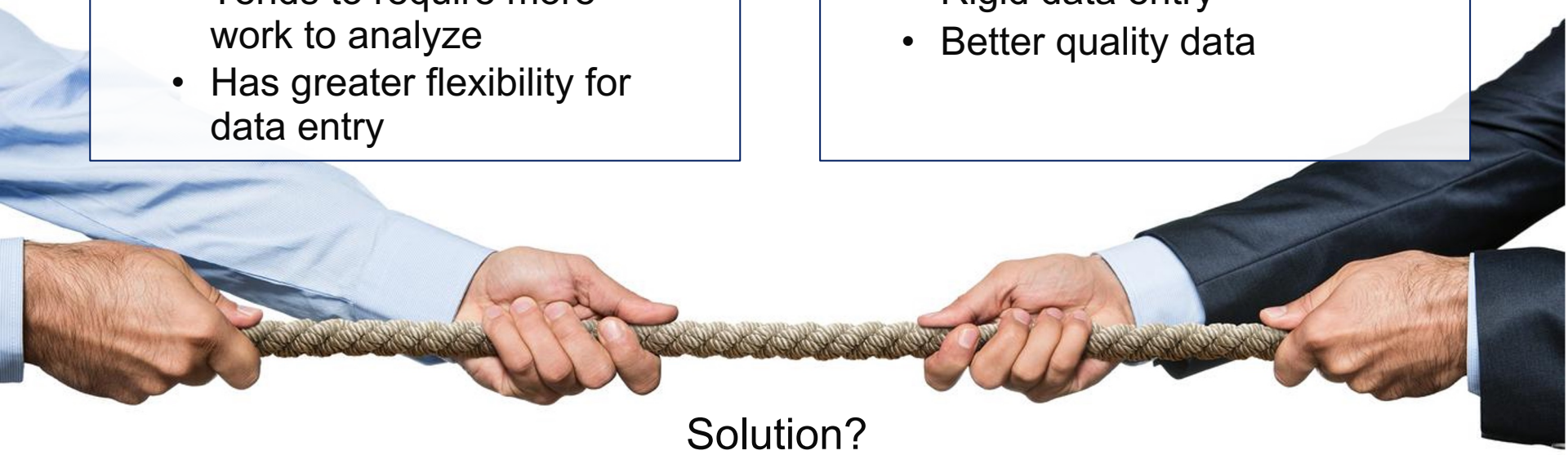
Ease of Data Entry vs Ease of Analysis

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

Guide adopted from