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

[Diagram: Laboratory, Clinic, Community]
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

<table>
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<tr>
<th>Enable Feature</th>
<th>Setup Arms</th>
<th>Setup Events</th>
<th>Link instruments</th>
<th>Check Dependents</th>
<th>Run Tests</th>
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<tbody>
<tr>
<td>Enable longitudinal mode</td>
<td>Setup the desired number of arms</td>
<td>Setup the appropriate number of events per arm</td>
<td>Link up the proper instruments to each event in each arm</td>
<td>Setup features dependent on a correct longitudinal model</td>
<td>Test your model</td>
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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

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

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

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
  ► Unwieldly 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
Questions?
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