Introducing TFL Designer: Community Solution to Automate Development of Mock-up Shells and Analysis Results Metadata

PharmaSUG 2023, Hands on Training, HT-355

May 16, 2023
Current State: Analysis Results Deliverables

- Manual process in designing TFL shells/layout and ADaM specifications
- Programmer writes the SAS code to generate analysis deliverables (sometime with macros or re-using the code)
- Too much variability across studies, disease areas, and organization
- Static results with No or limited linking facility (e.g., to Protocol, SAP, ADaM data)
- There is no industry standards for analysis results
CDISC Analysis Result Standards – Coming Soon!

All You Need to Know about the New CDISC Analysis Result Standards!

PharmaSUG 2023: Paper # MM327

Bhavin Busa, Richard Marshall, Bess LeRoy
Analysis Results Standard Public Repo on GitHub

- https://github.com/cdisc-org/analysis-results-standard

**Model:** representations of the model (YAML, JSON, Mermaid ER, YUML, SVG)

**Workfiles:** CMAP, examples

**Project:** Auto-generated content (Python classes/API, documentation, model structures)

**To come:** Utilities, API Dev
ARS Model Representation using CMAP (DRAFT)
# Analysis Results and Associated Metadata Example

**Table 2** Baseline Demographics and Clinical Characteristics, Safety Population

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Dataset</th>
<th>Variable</th>
<th>Value</th>
<th>Sex</th>
<th>Label</th>
<th>Value</th>
<th>Name</th>
<th>Label</th>
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</thead>
<tbody>
<tr>
<td>Table 2</td>
<td>Baseline Demographics and Clinical Characteristics, Safety Population</td>
<td>ADSL</td>
<td>TR01X</td>
<td>Drug Name Dosage X</td>
<td>SEX</td>
<td>M</td>
<td>Male</td>
<td>53</td>
<td>Count</td>
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<td>M</td>
<td>Male</td>
<td>61.6</td>
<td>Percent</td>
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<td>TR01X</td>
<td>Drug Name Dosage X</td>
<td>SEX</td>
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<td>Female</td>
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<td>TR01X</td>
<td>Drug Name Dosage X</td>
<td>SEX</td>
<td>F</td>
<td>Female</td>
<td>38.4</td>
<td>Percent</td>
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</tbody>
</table>
Future State: Analysis Results Deliverables

Open-source Tools

Sponsor
Study
MDR

Protocol,
CRF & SAP

TFL Designer*

ADaM Specs

ADaM Programs

ADaM Datasets

ADaM Define + ARM

TFL Shells & Extended ARM + ARD

TFL Programs

TFL Outputs

CSR

Analysis Results Standards

Analysis Results Standards (ARM-TS & ARD) & TFL Display Templates

Design

Specify

Build/Execute

Report

= Automated Process

Submission of Datasets & CSR
XPT files, Define, ADRG, Analysis codes
Streamlining Analysis Data Flow

Keeping End in Mind
TFL Designer – Key Highlights

- Digitizing your analysis results (TFL)
- Aligned with CDISC Analysis Results Standards (ARM-TS and ARD)
- Central repository for your TFL standards, display templates, conventions and metadata
- Automate generation of TFL shells and provides machine-readable metadata
- Open-source (CDISC COSA approved) & Enterprise versions
Hands-on Training
TFL Designer (Community version – Sandbox environment)