TFL Designer Community – Demo and Q/A

Bhavin Busa
COSA Spotlight
March 26, 2024
CDISC Analysis Result Standards – Releasing April 2024!
Creating Analysis Results Metadata: JSON

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Drug Name Dosage X N = XXX</th>
<th>Drug Name Dosage Y N = XXX</th>
<th>Placebo N = XXX</th>
<th>Active Control N = XXX</th>
<th>Total Population N = XXX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Male</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Female</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Age, years, mean (SD)</td>
<td>X.X (Y.I)</td>
<td>X.X (Y.I)</td>
<td>X.X (Y.I)</td>
<td>X.X (Y.I)</td>
<td>X.X (Y.I)</td>
</tr>
<tr>
<td>Age, years, median (IQR)</td>
<td>X.X (Y.I)</td>
<td>X.X (Y.I)</td>
<td>X.X (Y.I)</td>
<td>X.X (Y.I)</td>
<td>X.X (Y.I)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>White</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Asian</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Other</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
</tbody>
</table>

Source: [Include Applicat source, datasets and/or software tools used].

*(Difference is shown between treatment arms (e.g., difference is shown between Drug Name dosage X vs. placebo)).
Abbreviations: N, number of patients in treatment arm; n, number of patients with given characteristic; SD, standard deviation

```json

"name": "FDA Standard Safety Tables and Figures - Integrated Guide, Table 2",
"id": "FDA_STF_T2",
"listOfPlannedAnalyses": {
  "listItems": [
    "name": "Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Trial CDISCIPLOT011",
    "level": 1,
    "order": 1,
    "outputId": "0_FDA_STF_T2",
    "sublist": {
      "listItems": [
        {"name": "Count of Subjects by Treatment",
         "level": 2,
         "order": 1,
         "analysisId": "A_SAF_CNT_USUBJID_TRT"
        },
        {"name": "Count of Subjects (Total Population)",
         "level": 2,
         "order": 2,
         "analysisId": "A_SAF_CNT_USUBJID"
        },
        {"name": "Sex, n (%)",
         "level": 3,
         "order": 3,
         "listItems": [
           {"name": "Summary of Subjects by Treatment",
            "level": 3,
            "order": 1,
            "analysisId": "A_SAF_SUM_USUBJID_TRT_SEX"
           },
           {"name": "Summary of Subjects (Total Population)",
            "level": 3,
            "order": 2,
            "analysisId": "A_SAF_SUM_USUBJID_SEX"
           }
         ]
      }
    }
  }
}
```

---

The document contains a table listing characteristics such as sex, age, and race, along with their respective counts and means. It also includes JSON code to define the list of planned analyses for the dataset, including specific counts and summaries by various levels and order specifications.
Leveraging ARS Metadata to Drive Results Automation
Analysis Results Standard Model and User Guide

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

Analysis Results Standard (ARS)

Schema Diagram

Classes

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NamedObject</td>
<td>An object with a name</td>
</tr>
<tr>
<td>ReportingEvent</td>
<td>A set of analyses and outputs created to meet a specific reporting requirement</td>
</tr>
</tbody>
</table>

Notes to Readers

- This is the draft Version 1.0 of the Analysis Results Standard User Guide.
- This document is based on ADaM v2.1 and Analysis Results Metadata (ARM) v1.0 for Define-XML v2.0

Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>2023-08-22</td>
<td>Internal Review Draft</td>
</tr>
</tbody>
</table>

https://wiki.cdisc.org/display/ARSP/Analysis+Results+User+Guide
ARS Model Representation using CMAP
ARS model is complex!

How do I operationalize it and generate analysis results metadata prospectively?
Analysis Results Workflow w/ TFL Designer

Sponsor Study MDR

Industry Standards
Sponsor Standards
Study Definitions

SDTM, ADaM, ARS Model, & TFL Templates

Protocol, CRF & SAP

TFL Designer*

Design

ADaM Specs → ADaM Programs

TFL Shells & Extended ARM + ARD

ADaM Datasets

ADaM Define + ARM

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

Specify

Build/Execute

Report

= Automated Process
SDTM, ADaM, ARS Model, & TFL Templates

API

Select TFL of Interest

Select Analysis Concepts, Methods, Terminology & TFL Display (Template)

Customize TFL Layout & Metadata

Machine-readable CDISC ARS (JSON & Excel) + TFL Shells (RTF & PDF)

Study ADaM, ARD and TFL outputs

Automation Engine (SAS, R or other Software products)
TFL Designer – Key Highlights

- Web-based solution
- Digitizes your analysis results (TFL)
- Aligned with CDISC Analysis Results Standards
- Central repository for your TFL standards, display templates, conventions and metadata
- Automates generation of TFL shells and provides machine-readable metadata
- Community & Enterprise versions
Key Functionalities

- Central repository for your TFL standards/templates, conventions and metadata
- Access to library of TFL templates (community* and user generated) by disease areas, TA, and indication
- Access to CDISC Standards (SDTM, ADaM, CT) via API to CDISC Library
- Develop new mock-up shells, edit/delete items
- Automatically populate items based on user inputs
- Export TFL shells in RTF & PDF formats
- Export analysis results metadata per the CDISC ARS model in JSON and Excel formats

* including FDA STF-IG
[Will include PMDA, & PHUSE display templates in future updates]
TFL Designer: Contributing to Open-source Community

- Operationalize CDISC ARS
- TFL Display Templates
- ARS Metadata in JSON and Excel
- Shareable TFL codes (SAS & R community)
Live Demo
TFL Designer

TFL Designer, available as both a Community and Enterprise version, is a leading Software as a Service (SaaS) solution that simplifies clinical trial reporting. This platform automates the creation of TFL shells and provides machine-readable metadata, which can then be seamlessly ingested for downstream automation in the programming of the TFLs. It digitizes analysis results, ensuring alignment with CDISC Analysis Results Standards (ARS), and offers a central repository for TFL templates, conventions, and metadata.

Why TFL Designer?

- Digitizes TFL analysis results
- Provides a centralized repository for TFL standards and templates
- Aligned with CDISC Analysis Results Standards and Model
- Automates TFL shell generation and provides machine-readable metadata
TFL Designer (Community version)

https://tfldesigner.org/
Download files

http://bit.ly/3uKMAAav