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

PharmaSUG 2023, Hands on Training, HT-355

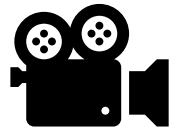
May 16, 2023

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!



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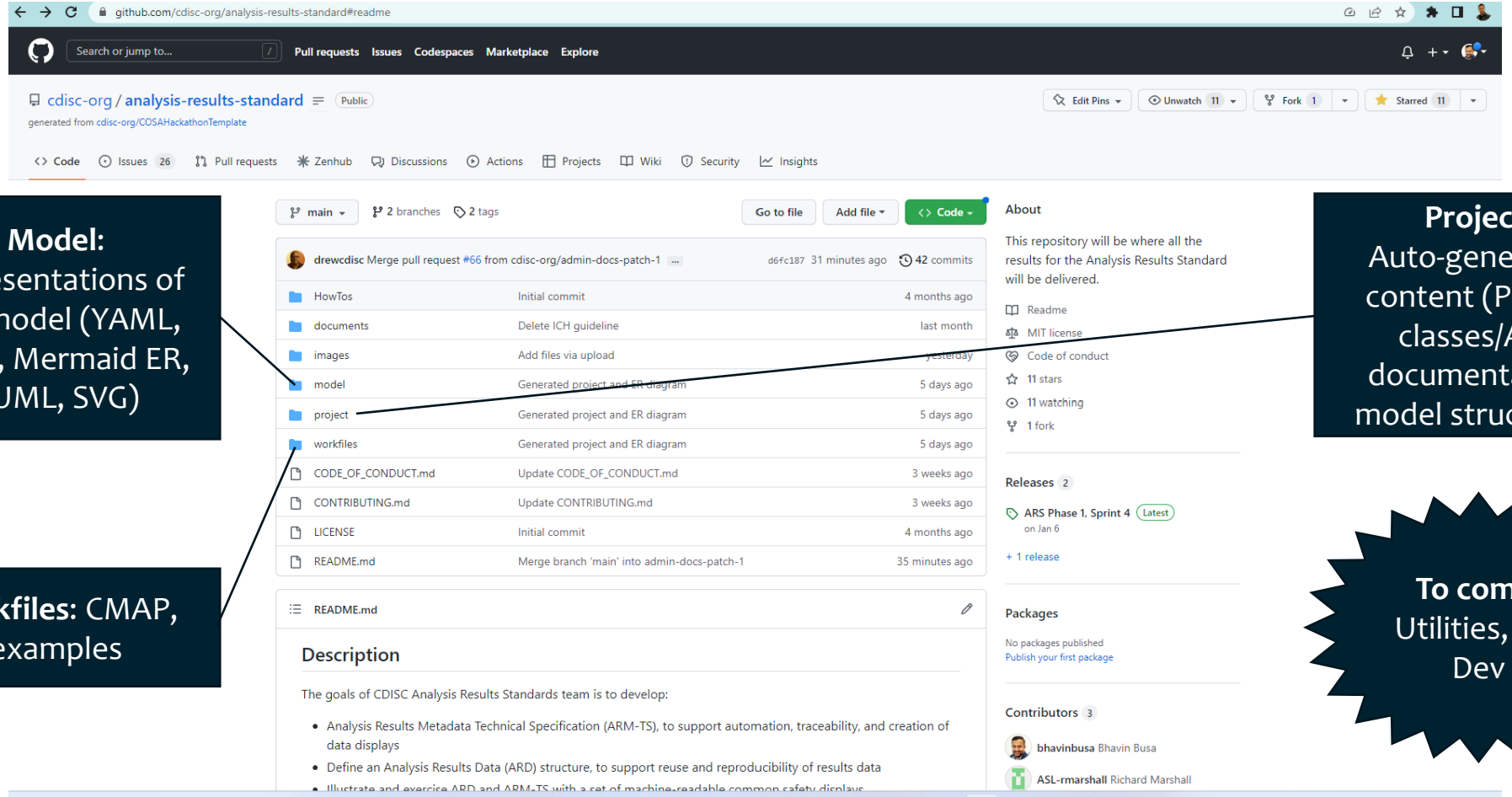
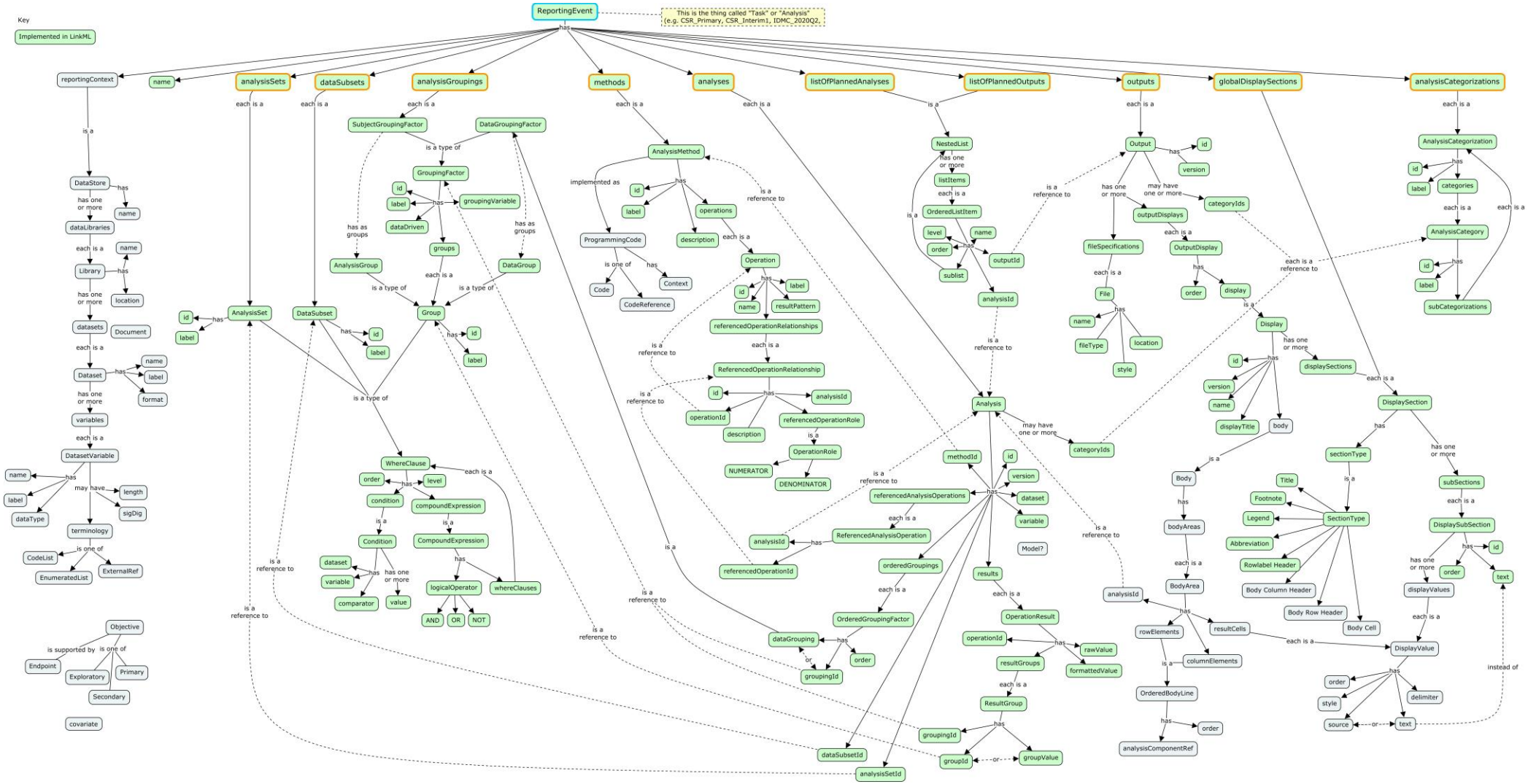
Analysis Results Standard Public Repo on GitHub

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



ARS Model Representation using CMAP (DRAFT)



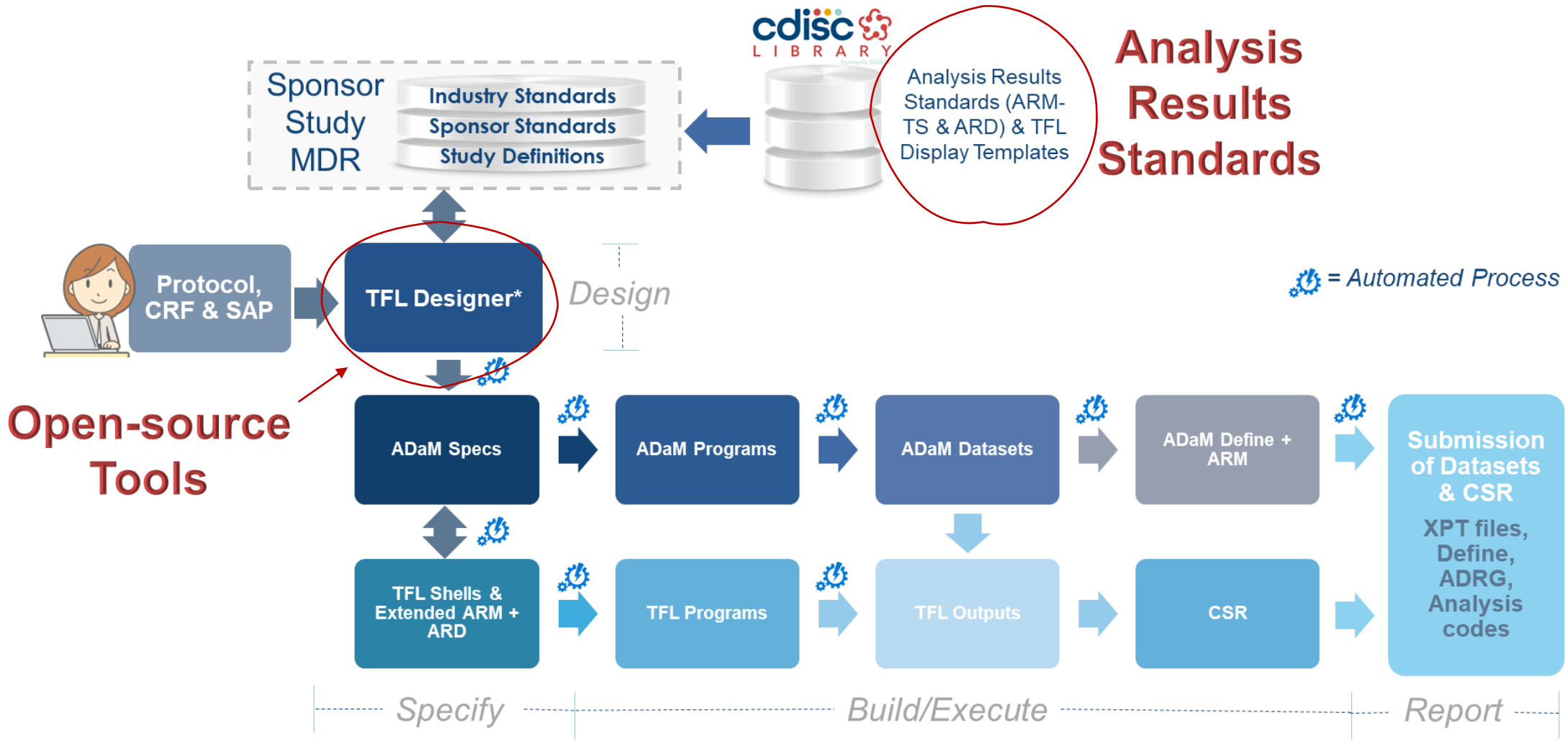
Analysis Results and Associated Metadata Example

Identifiers		Analysis Group			Result Variable			Results Statistic		
Name	Title	Dataset	Variable	Value	Variable	Value	Label	Value	Name	Label
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	M	Male	53	Count	n
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	M	Male	61.6	Percent	%
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	F	Female	33	Count	n
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	F	Female	38.4	Percent	%

Analysis Results Metadata

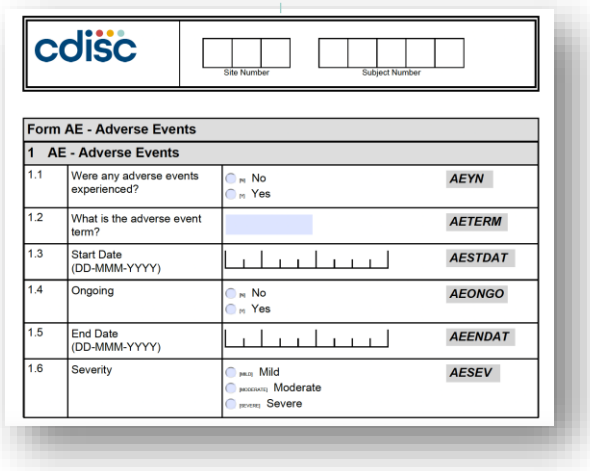
Analysis Results Data

Future State: Analysis Results Deliverables



Streamlining Analysis Data Flow

CDASH (Collection) → SDTM (Tabulation) → ADaM (Analysis) → Analysis Results → TFL



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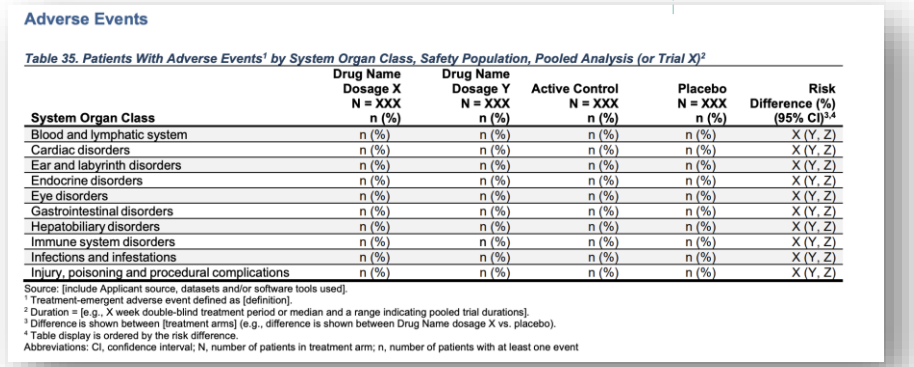
Site Number | Subject Number

Form AE - Adverse Events

1 AE - Adverse Events

1.1	Were any adverse events experienced?	No / Yes	AEYN
1.2	What is the adverse event term?		AETERM
1.3	Start Date (DD-MMM-YYYY)		AESTDAT
1.4	Ongoing	No / Yes	AEONGO
1.5	End Date (DD-MMM-YYYY)		AEENDAT
1.6	Severity	Mild / Moderate / Severe	AESEV



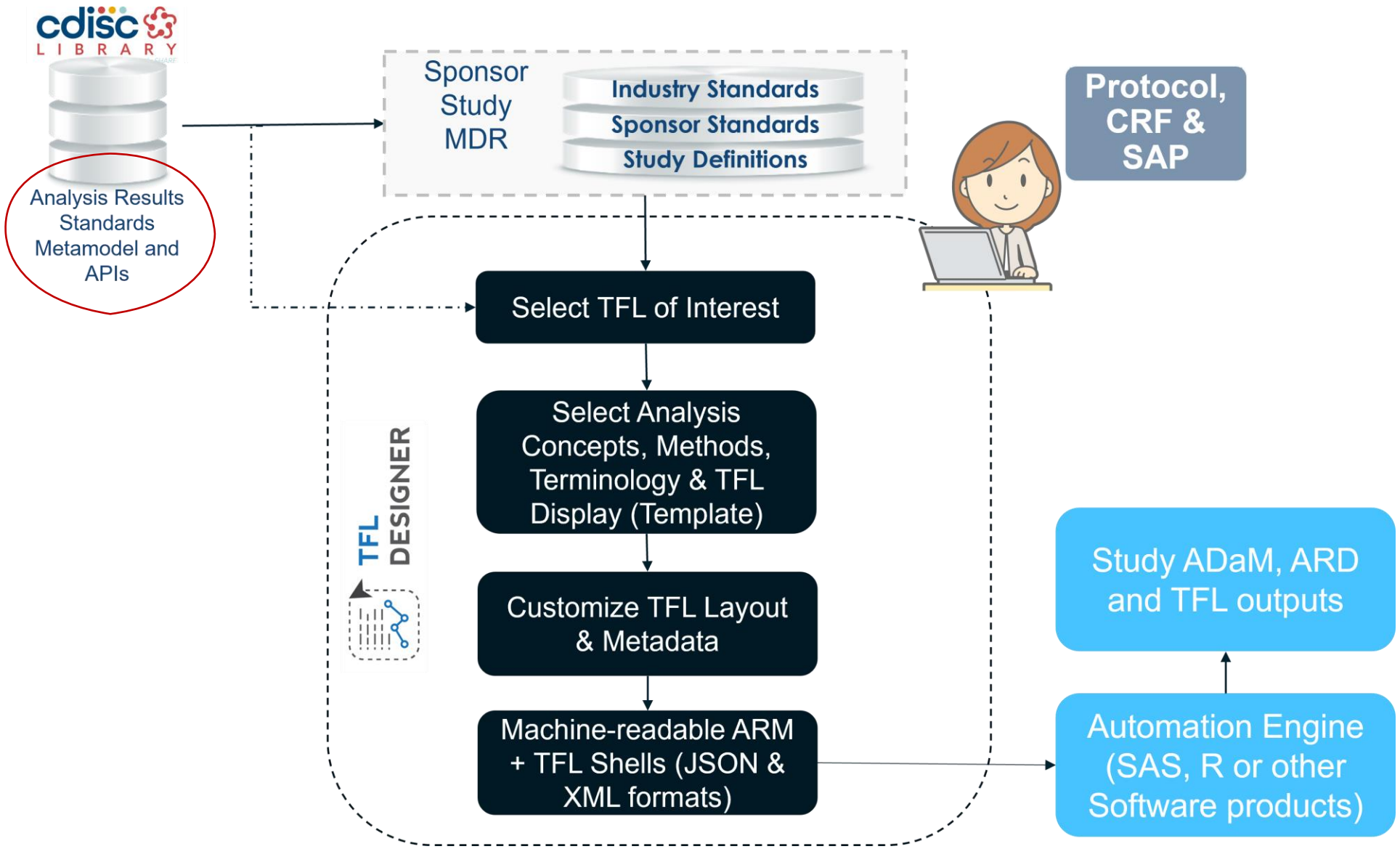
Adverse Events

Table 35. Patients With Adverse Events[1] by System Organ Class, Safety Population, Pooled Analysis (or Trial X)[2]

System Organ Class	Drug Name Dosage X N = XXX n (%)	Drug Name Dosage Y N = XXX n (%)	Active Control N = XXX n (%)	Placebo N = XXX n (%)	Risk Difference (%) (95% CI)[3,4]
Blood and lymphatic system	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cardiac disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Ear and labyrinth disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Endocrine disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Eye disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Gastrointestinal disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Hepatobiliary disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Immune system disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Infections and infestations	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Injury, poisoning and procedural complications	n (%)	n (%)	n (%)	n (%)	X (Y, Z)

Source: [include Applicant source, datasets and/or software tools used].
[1] Treatment-emergent adverse event defined as [definition].
[2] Duration = [e.g., X week double-blind treatment period or median and a range indicating pooled trial durations].
[3] Difference is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo).
[4] Table display is ordered by the risk difference.
Abbreviations: CI, confidence interval; N, number of patients in treatment arm; n, number of patients with at least one event

Keeping End in Mind


cdisc LIBRARY
Analysis Results Standards Metamodel and APIs
Sponsor Study MDR
Industry Standards
Sponsor Standards
Study Definitions
Protocol, CRF & SAP
Select TFL of Interest
Select Analysis Concepts, Methods, Terminology & TFL Display (Template)
Customize TFL Layout & Metadata
Machine-readable ARM + TFL Shells (JSON & XML formats)
TFL DESIGNER
Study ADaM, ARD and TFL outputs
Automation Engine (SAS, R or other Software products)

TFL
DESIGNER

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

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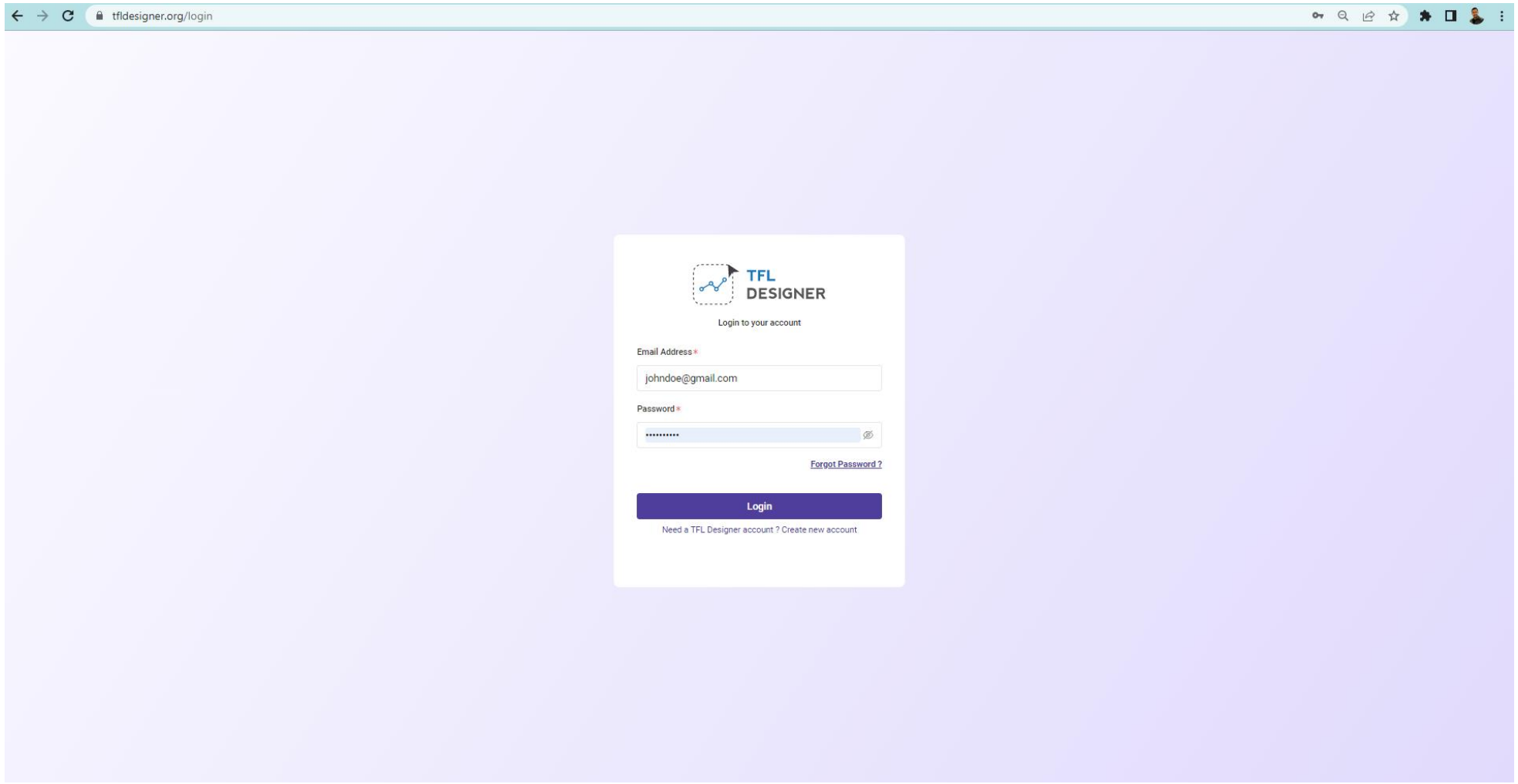
Hands-on Training

TFL Designer (Community version – Sandbox environment)



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