TFL Designer Community – Demo and Q/A

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COSA Spotlight

March 26, 2024

CDISC Analysis Result Standards – Releasing April 2024!

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Creating Analysis Results Metadata: JSON

Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses (or Trial X)

Characteristic	Drug Name Dosage X N = XXX n (%)	Drug Name Dosage Y N = XXX n (%)	Placebo N = XXX n (%)	Active Control N = XXX n (%)	Total Population N = XXX n (%)
Sex, n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Male	n (%)	n (%)	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)	n (%)	n (%)
Age, years	**X.X (Y.Y)**	**X.X (Y.Y)**	**X.X (Y.Y)**	**X.X (Y.Y)**	**X.X (Y.Y)**
Mean (SD)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)
Median (min, max)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)
Age groups (years), n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
≥17 to <65	n (%)	n (%)	n (%)	n (%)	n (%)
≥65	n (%)	n (%)	n (%)	n (%)	n (%)
≥65 to <75	n (%)	n (%)	n (%)	n (%)	n (%)
≥75	n (%)	n (%)	n (%)	n (%)	n (%)
Race, n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
American Indian or Alaska Native Asian	n (%)	n (%)	n (%)	n (%)	n (%)
Black or African American	n (%)	n (%)	n (%)	n (%)	n (%)
Native Hawaiian or Other Pacific Islander	n (%)	n (%)	n (%)	n (%)	n (%)
White	n (%)	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)	n (%)

Source: [include Applicant source, datasets and/or software tools used].
[1] 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

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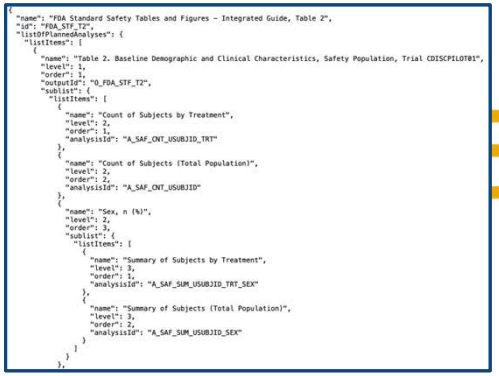
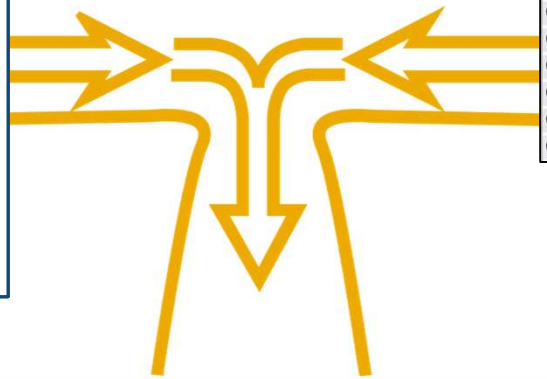
Leveraging ARS Metadata to Drive Results Automation

ARS Metadata



ADaM Dataset

USUBJID	ARM	AGE	AGEGR1	AGEU	RACE	SEX
01-701-1015	Placebo	63	<65	YEARS	WHITE	F
01-701-1023	Placebo	64	<65	YEARS	WHITE	M
01-701-1028	Xanomeline High Dose	71	65+	YEARS	WHITE	M
01-701-1033	Xanomeline Low Dose	74	65+	YEARS	WHITE	M
01-701-1034	Xanomeline High Dose	77	65+	YEARS	WHITE	F
01-701-1047	Placebo	85	65+	YEARS	WHITE	F



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An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_1	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	72	72
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An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_1_n	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_2	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	76	76
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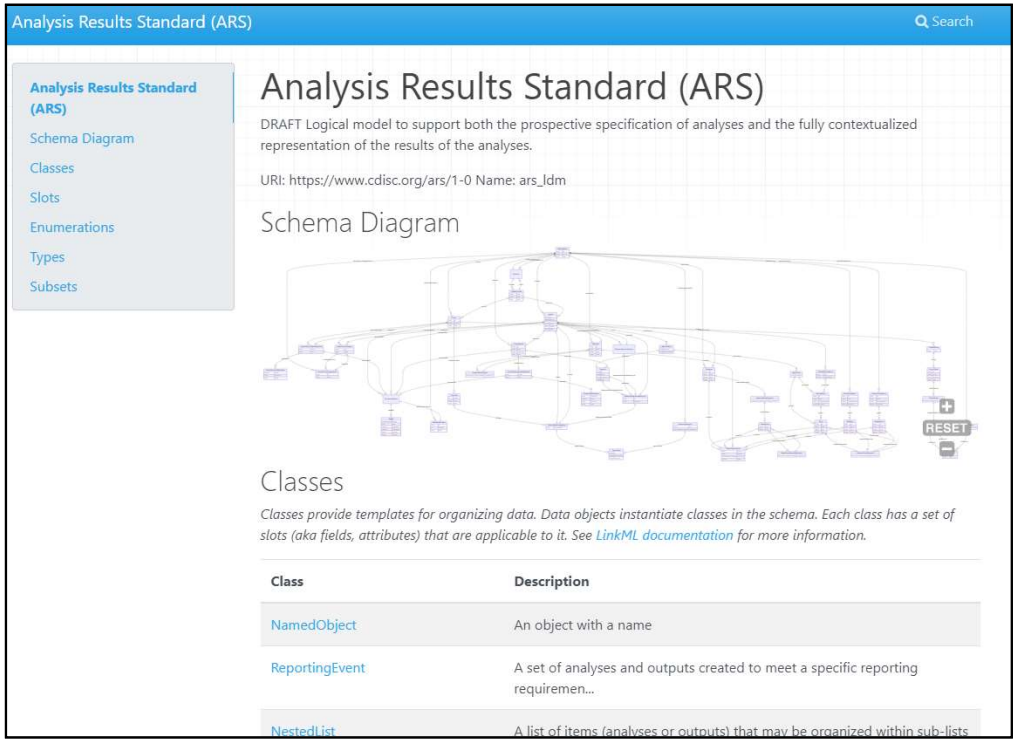
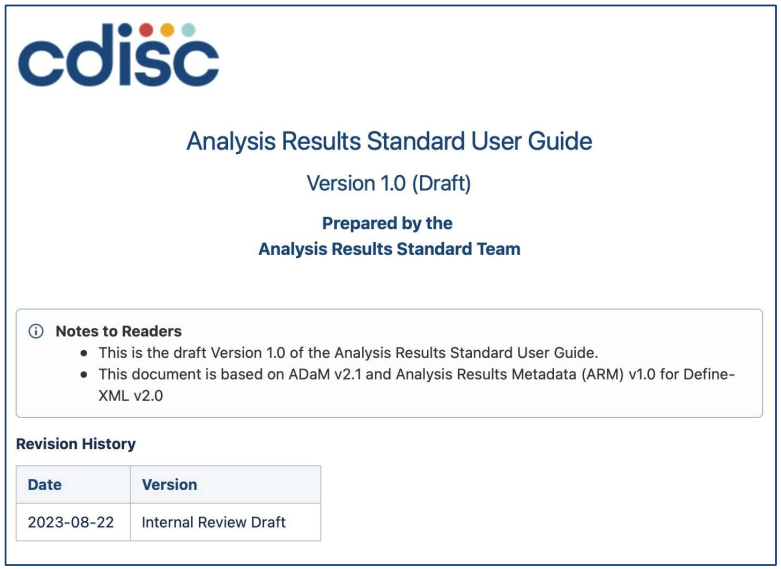
An03.02_AgeGrp_ByTrt	Mth01_CatVar_ByGrp_2_pct	AnlsGrouping_02_Trt	AnlsGrouping_02_Trt_3	AnlsGrouping_03_AgeGp	AnlsGrouping_03_AgeGp_2	86.90476	(86.9)

Analysis Results Dataset

Analysis Results Standard Model and User Guide

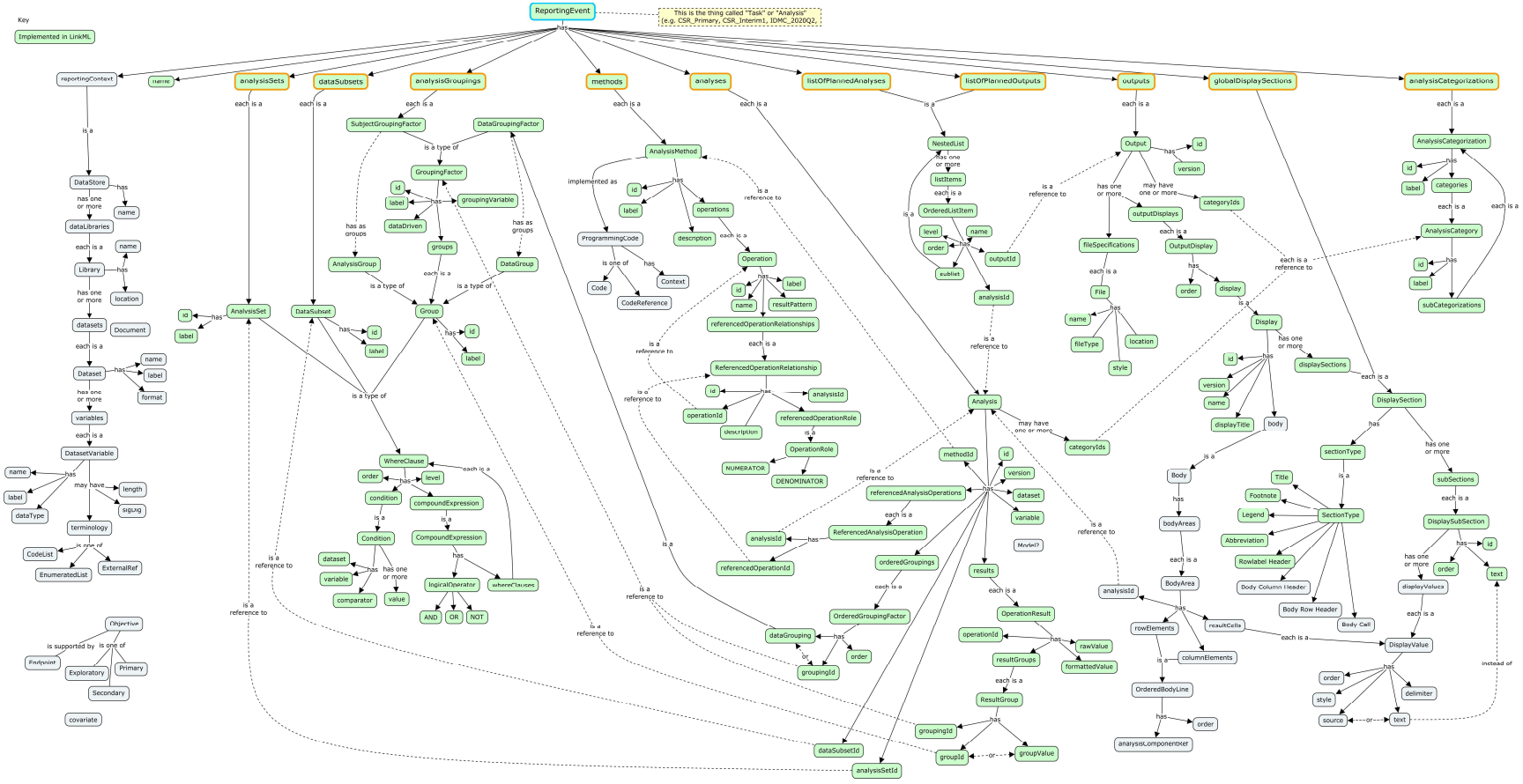
https://cdisc-org.github.io/analysis-results-standard/





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?

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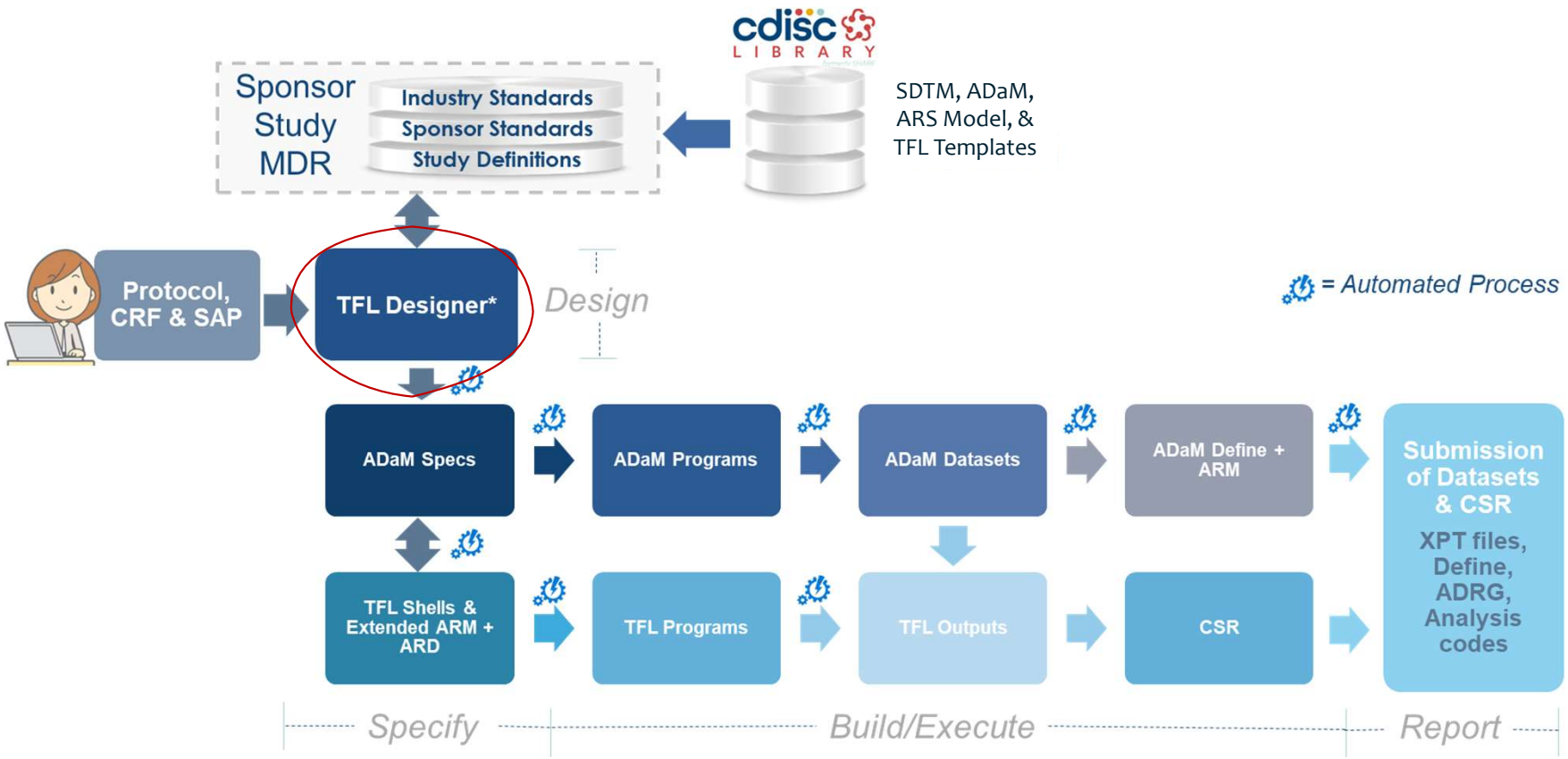
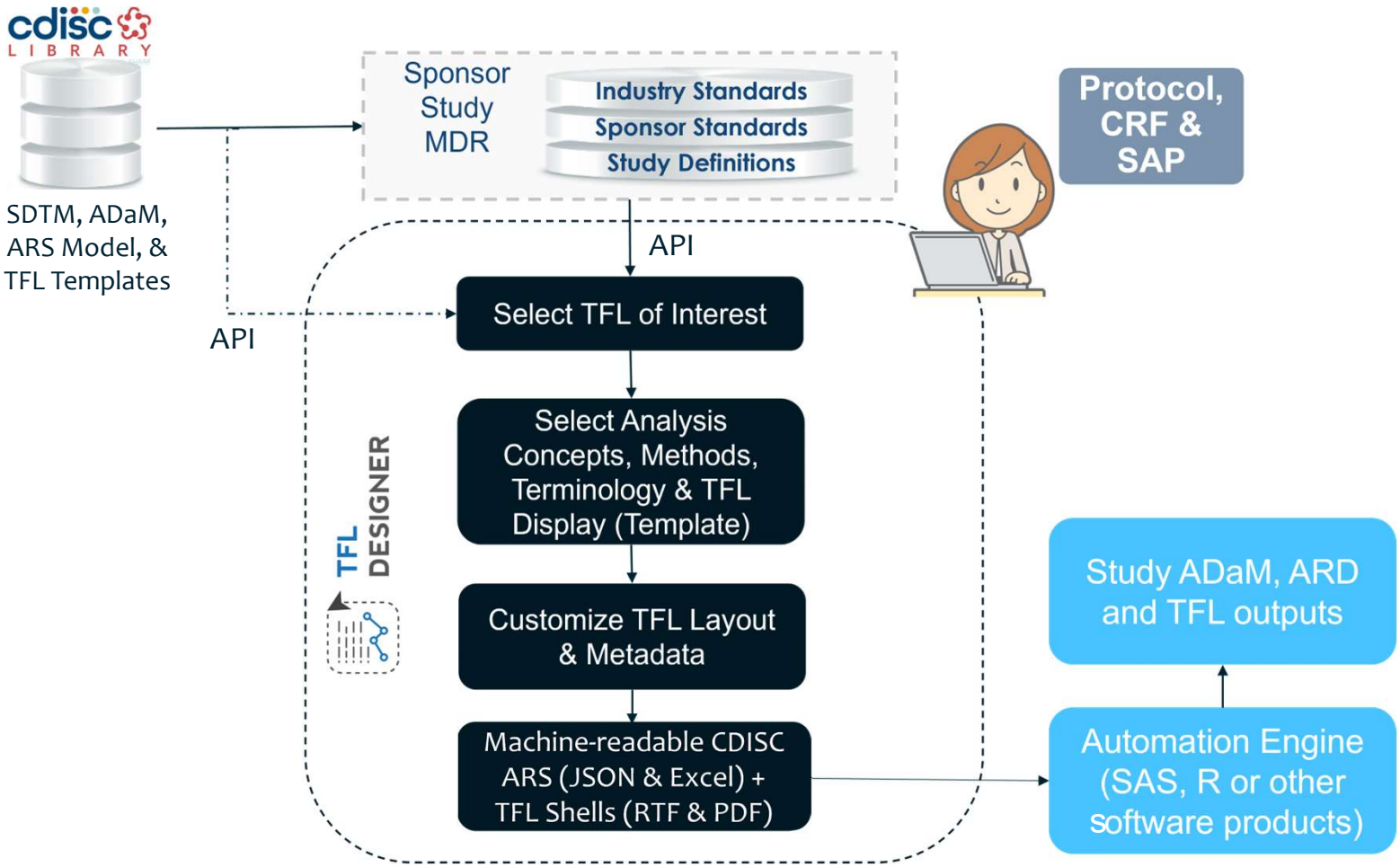
Analysis Results Workflow w/ TFL Designer




cdisc LIBRARY
SDTM, ADaM, ARS Model, & TFL Templates
Sponsor Study MDR
Industry Standards
Sponsor Standards
Study Definitions
Protocol, CRF & SAP
API
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)
TFL DESIGNER
Study ADaM, ARD and TFL outputs
Automation Engine (SAS, R or other software products)

TFL DESIGNER

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

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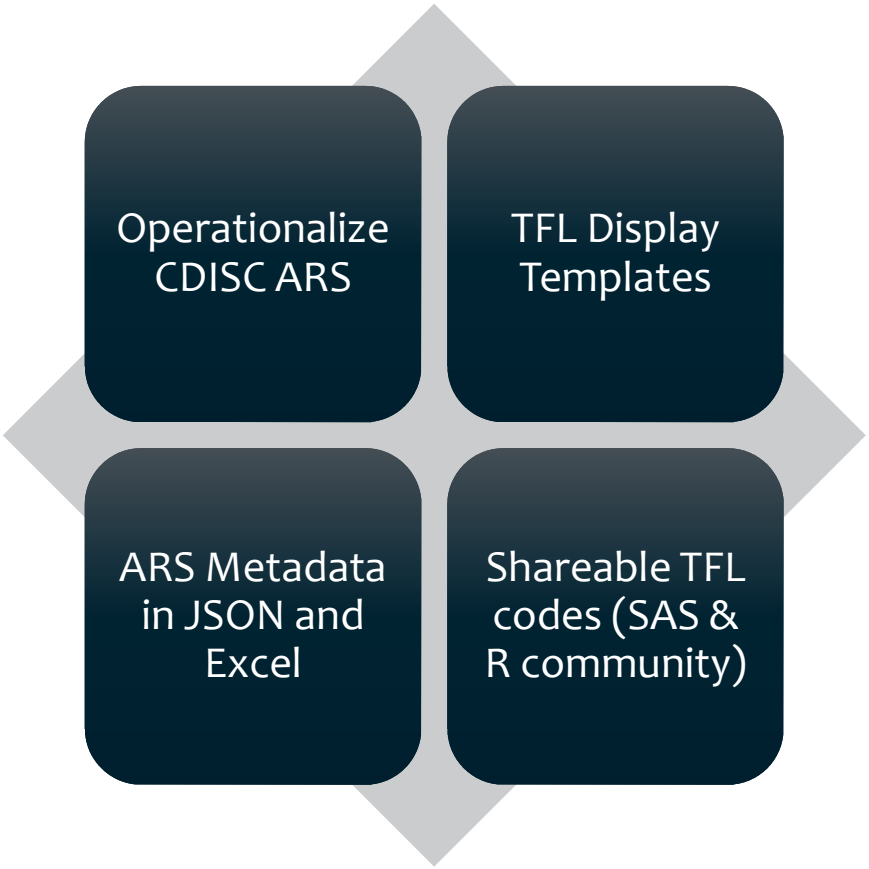
TFL DESIGNER®

Key Functionalities

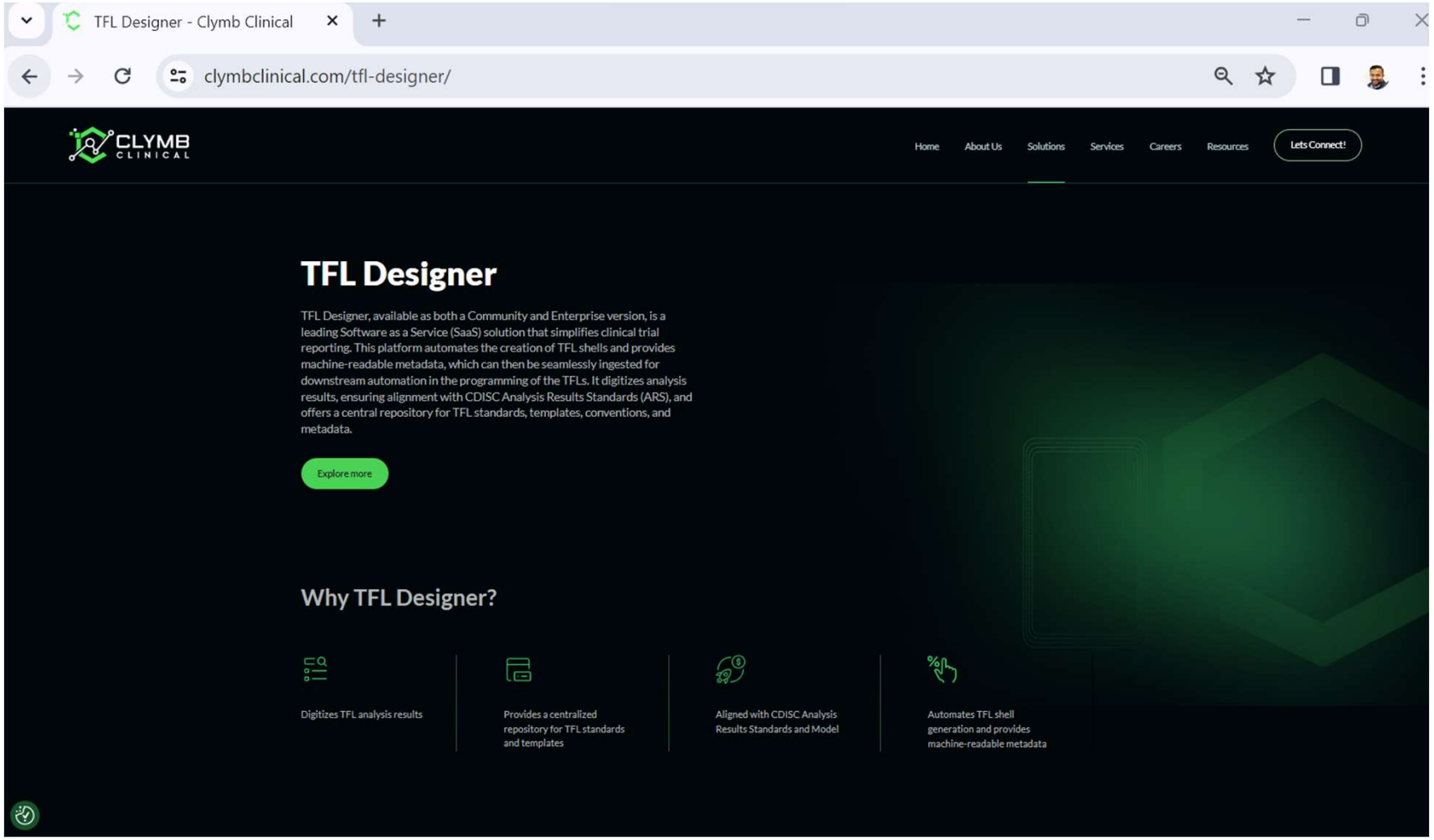
- *Central repository for your TFL standards/templates, conventions and metadata*
- *Access to library of TFL templates (community* and user generated) by disease areas, TA, and indication*
- *Access to CDISC Standards (SDTM, ADaM, CT) via API to CDISC Library*
- *Develop new mock-up shells, edit/delete 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



Live Demo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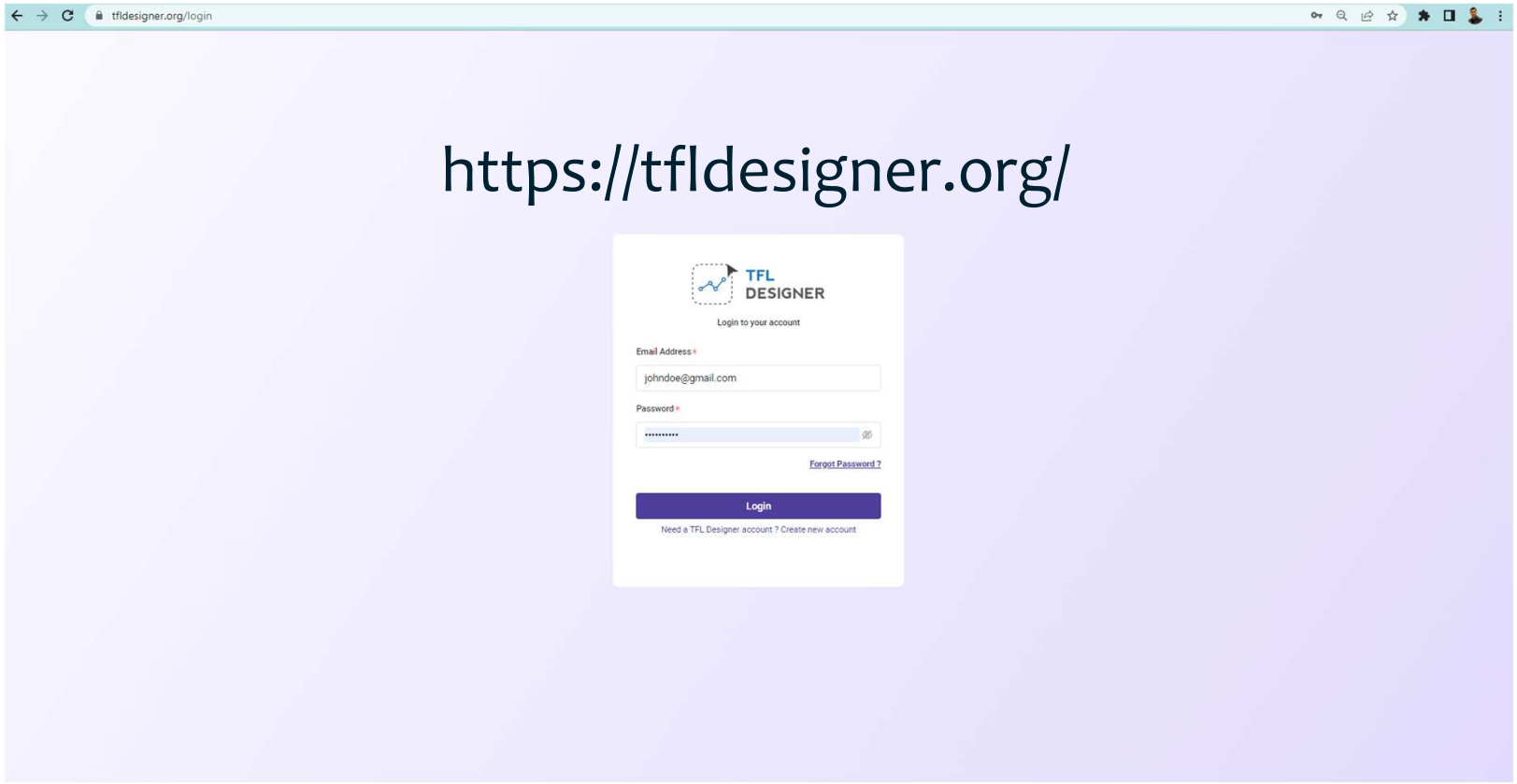
TFL Designer
TFL Designer, available as both a Community and Enterprise version, is a leading Software as a Service (SaaS) solution that simplifies clinical trial reporting. This platform automates the creation of TFL shells and provides machine-readable metadata, which can then be seamlessly ingested 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 standards, templates, conventions, and metadata.
Explore more
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)



Download files

http://bit.ly/3uKMAAv

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