



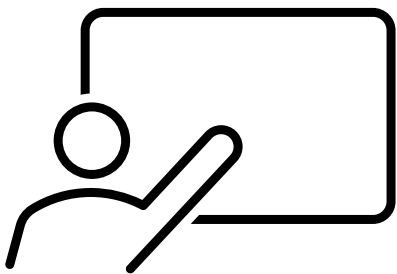
TFL Designer: Automating TFL Design & Generation for Clinical Trial Analysis

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Paper # SDo8

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Poll Summary*



* Results from the live poll
(n=253 responders)
conducted during the TFL
Designer Virtual Design
Thinking Workshop (Part I),
13th Sep 2022, Bhavin Busa

Who attended the workshop:

- Clinical / Statistical Programmer (**63%**)
- Biostatisticians (**14%**)
- Data Standards Expert (**13%**)
- Other (**12%**)

Top 5 pain points:

1. Too much variability across studies / disease areas / organizations
2. No industry-wide standards exist
3. TFL metadata and shells are not machine-readable
4. Multiple manual steps in the process
5. Limited or no automation exist

Programming is more of a Science (**50%**) than it is an Art (**39%**)!



74% organizations have TFL standards or templates

Who generates TFL shells (mock-ups)?
57% - Biostatistician
31% - Biostats & Programmers

87% responders confirmed their TFL shells are NOT machine-readable

65% responders uses MS Word / RTF for TFL shells generation

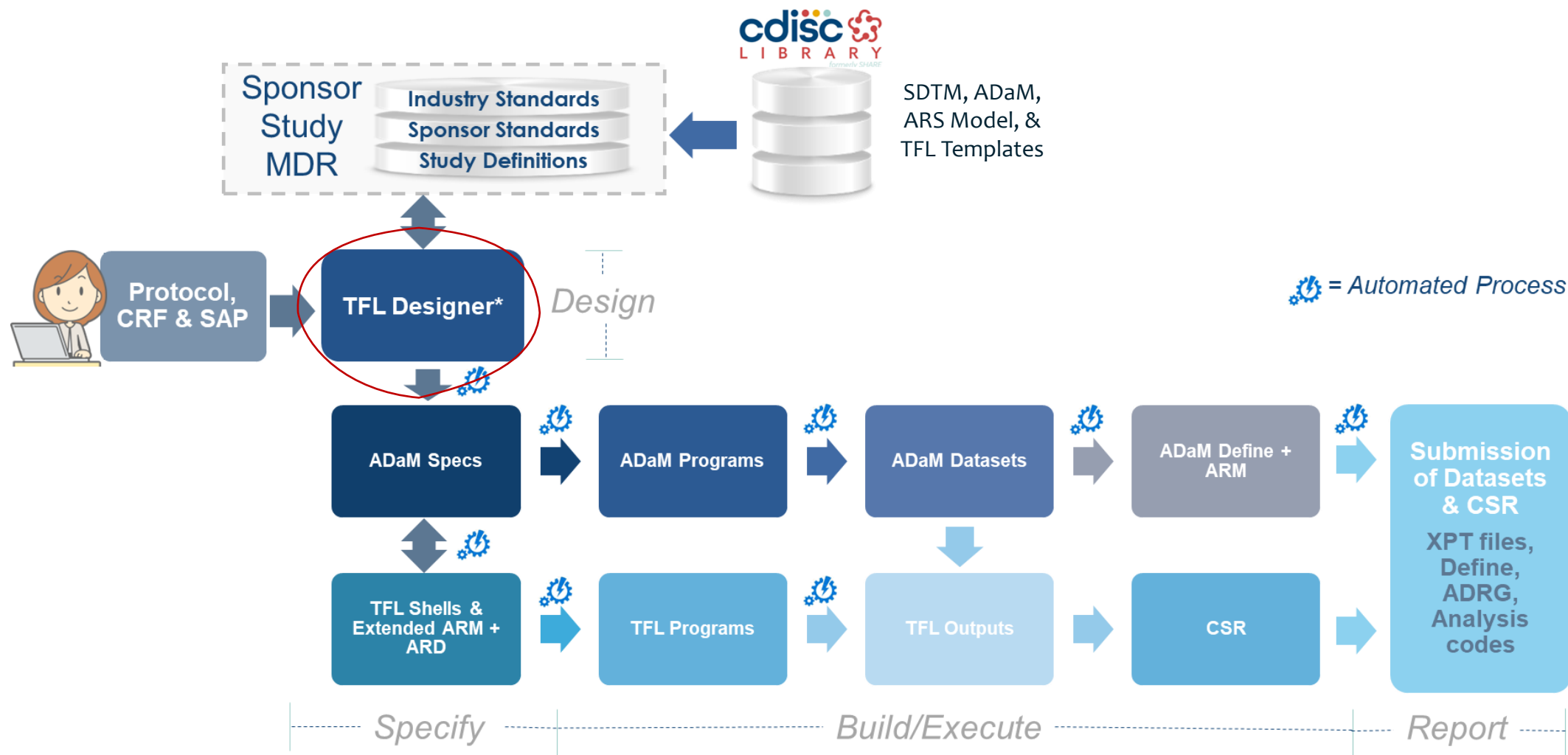
40% annotate their TFL mock-up shells to provide results metadata information

76% do not generate analysis results metadata prospectively to use in their TFL program

82% confirmed not having machine-readable TFL analysis results metadata

Out of the responders who use machine-readable ARM: MS Excel (**14%**) and SAS (**10%**) are top 2 format choices

Analysis Results Workflow w/ TFL Designer





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 ARM
+ TFL Shells (JSON &
XML formats)

TFL
DESIGNER

Study ADaM, ARD
and TFL outputs

Automation Engine
(SAS, R or other
Software products)



TFL Designer – Key Highlights

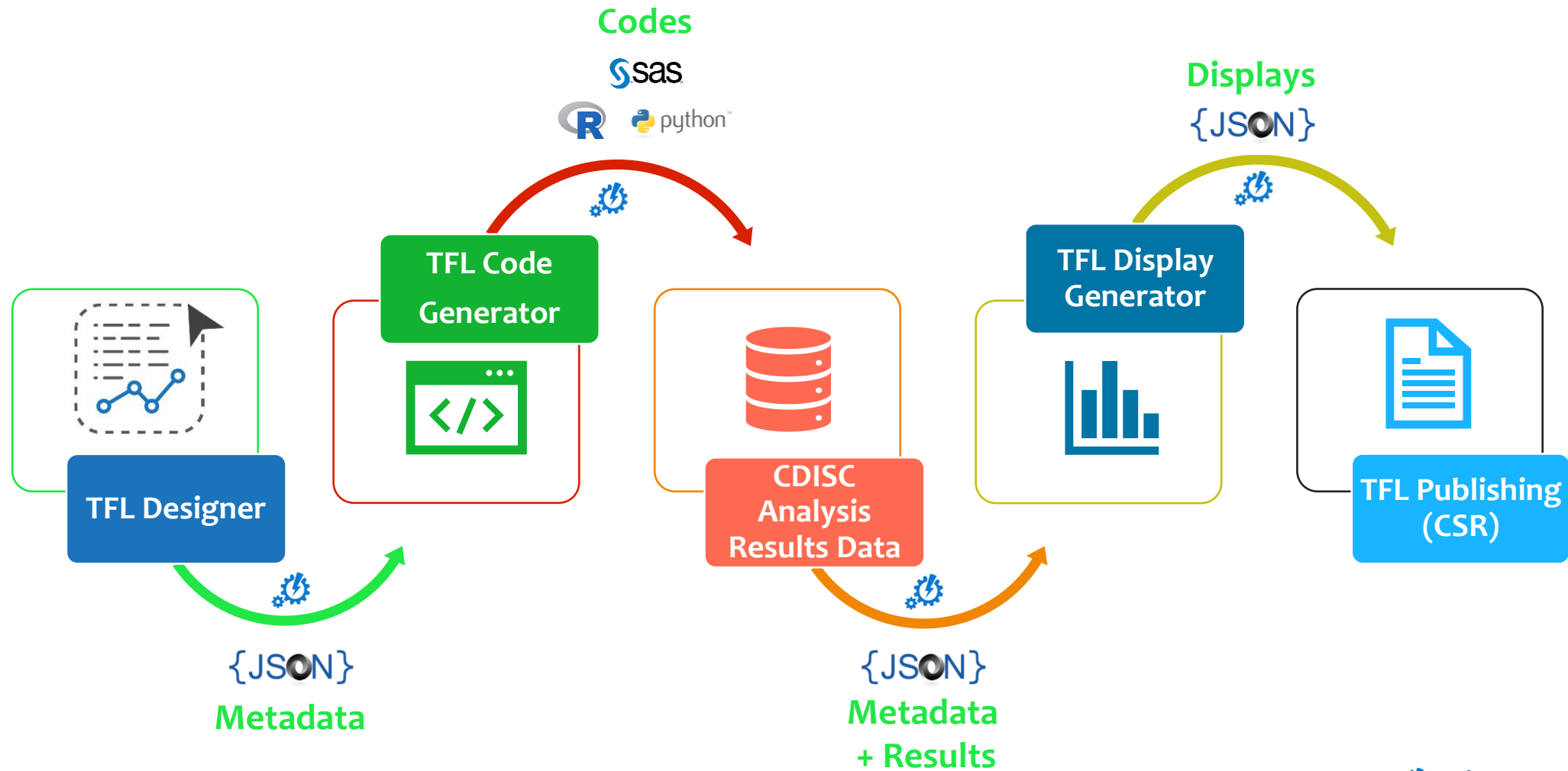
- Software as a Service (SaaS) Solution
- Digitizes your analysis results (TFL)
- Aligned with CDISC Analysis Results Standards
- Central repository for your TFL standards, display templates, conventions and metadata
- Automates generation of TFL shells and provides machine-readable metadata
- Community & 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 and import analysis results metadata in various machine-readable formats*

** including FDA STF-IG, PMDA, & PHUSE display templates*

TFL / Analysis Results – Clymb's Development

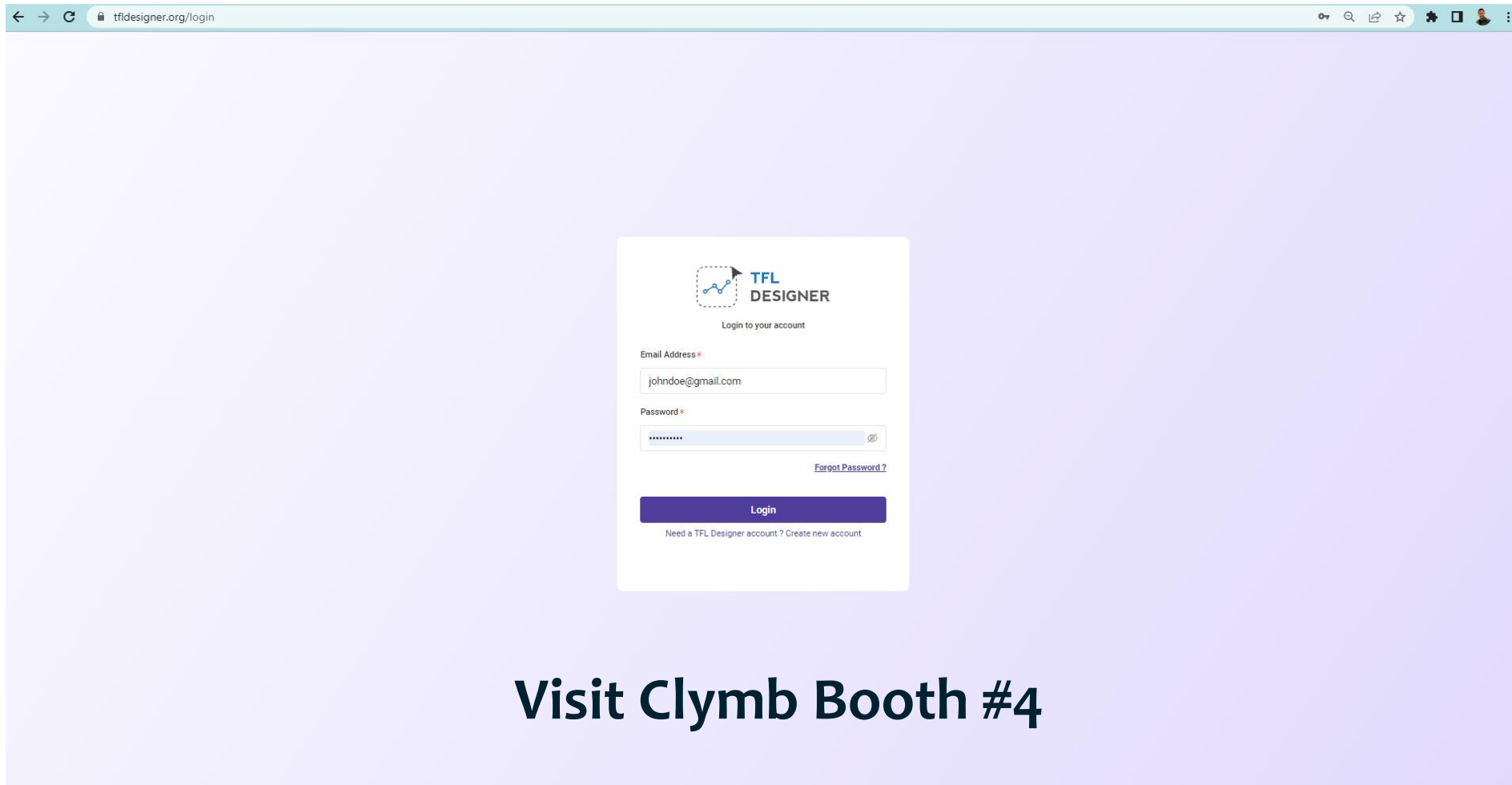




What are we trying to accomplish?

- Build an industry leading software solution that automates TFL design and generation process [community & enterprise versions]
- Partner with companies to improve their internal TFL standards and processes
- Quantify process improvements and continue to build future state automation (target 40-50% efficiency)
- Accelerate study timelines to allow your team to get data quicker
- CDISC 360 Vision: From PoC to Reality

TFL Designer (Community) Demo



A screenshot of a web browser displaying the login page for TFL Designer. The browser's address bar shows the URL `tfldesigner.org/login`. The page has a light purple background. In the center, there is a white login card. At the top of the card is the TFL Designer logo, which consists of a blue line graph icon and the text "TFL DESIGNER". Below the logo is the text "Login to your account". The card contains two input fields: "Email Address" with the value "johndoe@gmail.com" and "Password" with masked characters. To the right of the password field is a "Forgot Password?" link. Below the input fields is a purple "Login" button. At the bottom of the card, there is a link that says "Need a TFL Designer account? Create new account".

tfldesigner.org/login

 **TFL
DESIGNER**

Login to your account

Email Address *

johndoe@gmail.com

Password *

[Forgot Password?](#)

Login

Need a TFL Designer account? [Create new account](#)

Visit Clymb Booth #4



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