

# **Open-source TFL Designer:** Virtual Workshop

Bhavin Busa Workshop 1 13<sup>th</sup> September 2022

#### Meet the Speaker



Bhavin Busa is Project Owner of TFL Designer. He has built and implemented multiple system-level compliant tools toward data analytics/visualization, programming, and data standardization. A philanthropist, tech innovator and CDISC volunteer, Bhavin has worked with CDISC Standards for over 15 years, serves on the Board of CDISC Open-Source Alliance and is co-leading CDISC Analysis Results Standards team. He is also a Steering Committee member at PHUSE and co-chair PHUSE US Connect.

Bhavin participated on the <u>CDISC 360 project</u> and coauthored the 360 White Paper. He thinks open-source technologies have the potential to be a game changer in our industry to help get things done faster and more efficiently.

#### **Global & Diverse Community Representation!**



- 38 countries across 6 continents
- 800+ Registered
- 250+ Organizations
  - Large, Mid and Small Pharma/Biotech
  - CROs
  - Software vendors
  - Academic Institution

#### **Workshop Agenda**

- Workshop 1: 13<sup>th</sup> Sep 2022 11:00AM to 12:30PM EST (Today!)
  - Problem Statement
  - CDISC 360 PoC recap and Future State with Standards & Open-source tools
  - Introduction to CDISC Analysis Results Standards (Bess LeRoy)
  - Open-source TFL Designer (Initial concept/wireframe)
  - User Stories and User Requirements (your input needed here!)
  - High-level Development Roadmap
  - Sign-up and next steps

- Workshop 2: 6<sup>th</sup> Oct 2022 11:00AM to 12:30PM EST
  - Summarize use cases and userrequirements
  - Address questions from the previous meeting
  - Technology stack
  - Governance structure
  - Development Roadmap
  - Collaboration expectations
  - Sign-up and next steps

## **Active Participation**





Feedback on initial concept



Input on User Stories and User Requirements



Lucky Draw - \$100 Amazon Gift Card

#### Why Open-source and why this Workshop?



- "More perspectives make better software"
- Bringing together global community: crowdsourcing to establish an industry-wide standard!
- Community support needed:
  - Support from CDISC (COSA) & PHUSE
  - Collaboration partners: Sponsor companies, vendors, Microsoft, etc.
  - Contributors and thought leaders in the space

#### What's in for you?

- Be part of the greater good!
- Help shape-up a solution for the industry
- Be the early adopters
- Participate in beta-version testing
- Learn new skills
- Network and meet smart people
- You don't need to be a software developer (although developers are welcome!)
- Stay connected



# Poll Time!

- What is your current role in the organization?
- Biostatistician
- Clinical/Statistical Programmer
- Data Standards Expert
- Data Engineer
- Product Developer
- Open-source Enthusiast / Developer
- Other

#### Current State: TFL / Analysis Results Generation Process

Manual process in designing TFL shells/layout and ADaM specifications

Programmer writes the SAS code to generate analysis deliverables (sometime with macros or reusing the code)

Static results with No or limited linking facility (e.g., to Protocol, SAP, ADaM data)

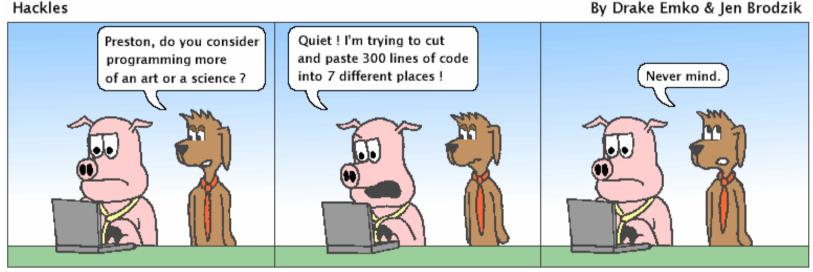
There is no industry standards for analysis results



# Poll Time!

- What do you think is not working out (pain points) in the TFL/analysis results generation process? [You can select more than one choices]
- No industry-wide standards exist
- Too much variability across studies / disease areas / organizations
- Limited reusability (mostly "copy-paste" programming)
- Static outputs with no traceability to the source data / SAP / Protocol
- Limited or no automation exist
- Multiple manual steps in the process
- TFL metadata and shells are not machine-readable
- None current process is working well
- Other

## **Challenging the Status Quo**



http://hackles.org Copyright @ 2001 Drake Emko & Jen Brodzik

"copy-paste programming" to "meta-programming"



# Poll Time!

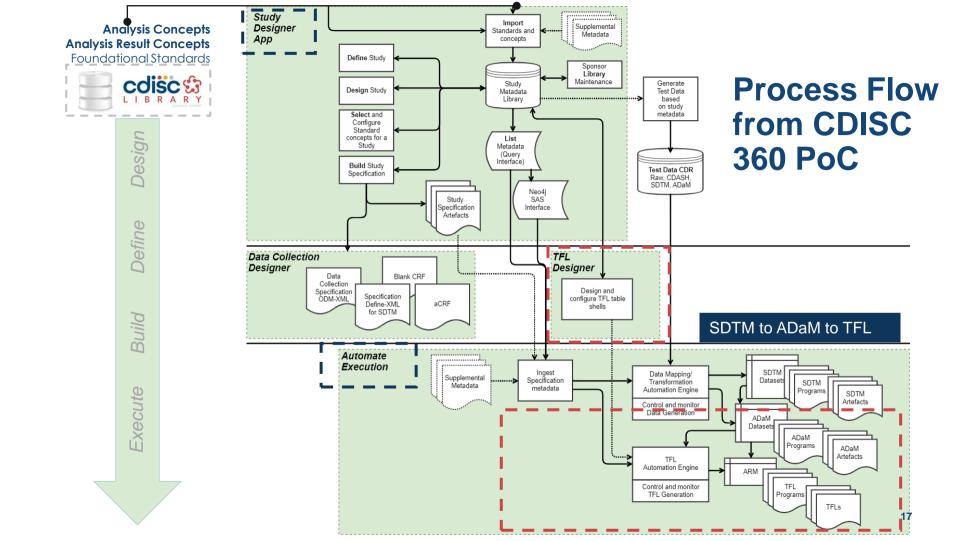
- Do you consider programming more of an art or a science?
- Art
- Science
- None

#### CDISC 360 Proof of Concept (PoC) Project

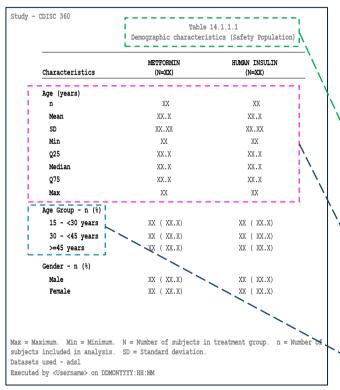
- CDISC 360 PoC project demonstrated endto-end automation of study specification, data processing and analysis using a metadata-driven approach
- CDISC is working on adding a conceptual layer to the analysis standards (e.g., CDISC Analysis Results Standards) and are developing a Safety User Guide

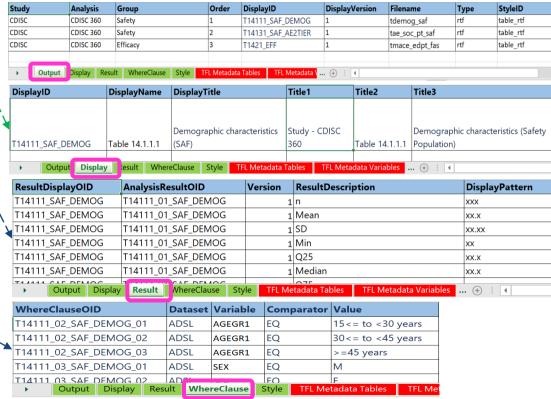


Reference: CDISC 360 Project White Paper

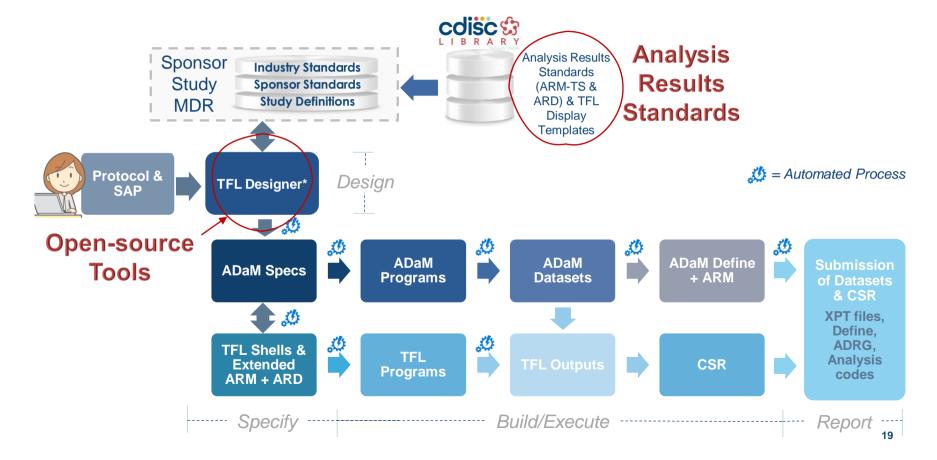


# **CDISC 360: Extended Analysis Results Metadata Sample**





#### **Future State: Analysis Datasets and TFL Generation**









#### With Standards - Science will Prevail!\*



# With Standards and Open-Source Tools - Science will Prevail! ^

#### Introduction to CDISC Analysis Results Standards

Bess LeRoy, Head of Standards Development, CDISC

#### **Analysis Results Current State**

- Static results created for Clinical Study Report
- May be hundred of tables in PDF format, often difficult to navigate
- Variability between sponsors
- Expensive to generate and only used once, no or limited reusability

#### **Analysis Ready ADaM Dataset**

| Table 3.1.1: ADHYPO Analysis Dataset |         |         |        |              |         |                    |  |
|--------------------------------------|---------|---------|--------|--------------|---------|--------------------|--|
| Row                                  | STUDYID | USUBJID | MIDS   | CEDECOD      | WASAEYN | ASTDTM             |  |
| 1                                    | XYZ     | 000001  | НҮРО 1 | Hypoglycemia | Y       | 07Sep2012 22:29:00 |  |
| 2                                    | XYZ     | 000001  | НҮРО 2 | Hypoglycemia | N       | 10Sep2012 09:12:00 |  |
| 3                                    | XYZ     | 000001  | НҮРО 3 | Hypoglycemia | N       | 10Sep2012 23:05:00 |  |
| 4                                    | XYZ     | 000001  | НҮРО 4 | Hypoglycemia | N       | 11Sep2012 15:24:00 |  |
| 5                                    | XYZ     | 000001  | НҮРО 5 | Hypoglycemia | N       | 18Sep2012 11:39:00 |  |
| 6                                    | XYZ     | 000002  | НҮРО 1 | Hypoglycemia | N       | 22Oct2012 13:28:00 |  |
| 7                                    | XYZ     | 000002  | НҮРО 2 | Hypoglycemia | N       | 25Oct2012 13:59:00 |  |
| 8                                    | XYZ     | 000002  | НҮРО 3 | Hypoglycemia | N       | 17Nov2012 05:01:00 |  |
|                                      |         |         |        |              |         |                    |  |



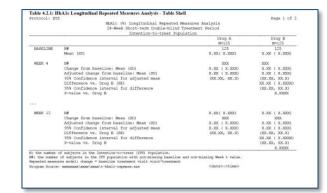
| BASSLINS N    | Intention-to-treat Popula  | Drug A  |   |
|---------------|--|---|---|
| BASSLINE >    |  | N=125   | Drug B<br>N=125   |
| ,             | Officer (SD)   | 125<br>X.XX(X.XXX)  | 1.25<br>X.XX ( X.XXX)   |
|               | Hamps from baseline: Mean (SI)<br>highered change from baseline: Mean (SI)<br>60% Confidence interval for adjusted mean<br>difference ws. Drug B (SE)<br>64% Confidence interval for difference—<br>vealue ws. Evug B  | X.30X ( X.300X)<br>X.30X ( X.300X)<br>(XX.30X, XX.3X)                         | 300X<br>X.30X ( X.300X)<br>X.30X ( X.300X)<br>(00.30X, 30X.X)<br>30X.30X ( X.300X)<br>00X.30X, 30X.X)<br>X.3000X                            |
|               |  |   |   |
|               | Hearing from baseline: Hearn (ZD) ddjusted change from baseline: Hearn (ZD) ddjusted change from baseline: Hearn (ZD) ddjusted mean ifference w. Turny B (ZB) ddjusted mean ddference interval for difference decontinuous interval for difference decontinuous cuty B | X.30X ( X.300X)<br>200X<br>X.30X ( X.30X)<br>X.30X ( X.30X)<br>(XX.30X, XX.X) | X.30X ( X.300X)<br>X00X<br>X.30X ( X.300X)<br>X.30X ( X.300X)<br>(0X.30X, 30X.X)<br>XX.30X ( X.300X)<br>(0X.30X, 30X.X)<br>XX.30X ( X.300X) |
| the number of | abjects in the Intention-to-treat (ITT) Population.<br>subjects in the ITT population with non-missing baseline an<br>model; chapts = baseline treatment visit visit*treatment   | d non-missing Week t value.   | 0.0000  |

**Static Display** 



#### **Analysis Results Current State**

| Row | STUDYID | USUBJID | MIDS   | CEDECOD      | WASAEYN | ASTDTM             |
|-----|---------|---------|--------|--------------|---------|--------------------|
| 1   | XYZ     | 000001  | НҮРО 1 | Hypoglycemia | Y       | 07Sep2012 22:29:00 |
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**ADaM Dataset** 



ARM for Define-XML

**Static Display** 

| Table 4.2.2: HbA1c Longit | udinal Repeated Measures Analysis Results Metadata  |                              |
|---------------------------|---|------------------------------|
| Metadata Field            | Metadata  |                              |
| DISPLAY IDENTIFIER        | Table 4.2.1/Figure 4.2.1  | <u> </u>                     |
| DISPLAY NAME              | Mean Change from Baseline in HbA1c (Percent) Longitudinal Repeated Measures Analysis, 24-Week Short | -term Double-blind Treatment |
|                           | Period, Intention-to-treat Population   |                              |
| RESULT IDENTIFIER         | Treatment difference results (LSMean, confidence interval, p-value)                                 |                              |
| PARAM                     | HbA1c (%)   |                              |
| PARAMCD                   | HBA1C   |                              |
| ANALYSIS VARIABLE         | CHG (Change from baseline)  |                              |
| ANALYSIS REASON           | SPECIFIED IN SAP  |                              |
| ANALYSIS PURPOSE          | PRIMARY OUTCOME MEASURE   | ARM v1                       |
| ANALYSIS DATASET          | ADHBA1C   |                              |



#### **Analysis Results Current State**

- ARM v1.0 describes metadata about analysis displays and results (at a high level), no formal analysis and results model or results data
- Lack of features to drive automation
- Limited regulatory use cases
- Limited traceability

| Table 4.2.2: HbA1c Longitue | dinal Repeated Measures Analysis Results Metadata   |
|-----------------------------|---|
| Metadata Field              | Metadata  |
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| ANALYSIS PURPOSE            | PRIMARY OUTCOME MEASURE   |
| ANALYSIS DATASET            | ADHBAIC   |



### **Shifting the Paradigm**

| Tabl | e 3.1.1: A | <b>DHYPO</b> | Analysi | s Dataset    |         |                    |
|------|------------|--------------|---------|--------------|---------|--------------------|
| Row  | STUDYID    | USUBJID      | MIDS    | CEDECOD      | WASAEYN | ASTDTM             |
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| 8    | XYZ        | 000002       | НҮРО 3  | Hypoglycemia | N       | 17Nov2012 05:01:00 |
|      | 2          | 000002       |         |              |         | 171.0.2012 00.0    |

**ADaM Dataset** 



### **Shifting the Paradigm**

| Table 3.1.1: ADHYPO Analysis Dataset |         |         |        |              |         |                    |
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|                                      |         |         |        |              |         |                    |



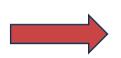
**ADaM Dataset** 

| Metadata Field     | Metadata  |                     |  |  |  |
|--------------------|---|---------------------|--|--|--|
| DISPLAY IDENTIFIER | Table 4.2.1/Figure 4.2.1  |                     |  |  |  |
| DISPLAY NAME       | Mean Change from Baseline in HbA1c (Percent) Longitudinal Repeated Measures |                     |  |  |  |
|                    | Period, Intention-to-treat Population                                       |                     |  |  |  |
| RESULT IDENTIFIER  | Treatment difference results (LSMean, confidence i                          | interval, p-value)  |  |  |  |
| PARAM              | HbA1c (%)   |                     |  |  |  |
| PARAMCD            | HBA1C   |                     |  |  |  |
| ANALYSIS VARIABLE  | CHG (Change from baseline)  |                     |  |  |  |
| ANALYSIS REASON    | SPECIFIED IN SAP  |                     |  |  |  |
| ANALYSIS PURPOSE   | PRIMARY OUTCOME MEASURE   | ARM v1              |  |  |  |
| ANALYSIS DATASET   | ADHBA1C   | 7 (1 (1) 1 )        |  |  |  |
|                    |   |                     |  |  |  |
|                    | APM Extension Tech  | nical Consideration |  |  |  |
|                    | ARM Extension Tech  | nicai opecincation  |  |  |  |



### **Shifting the Paradigm**

| Row | STUDYID | USUBJID | MIDS   | CEDECOD      | WASAEYN | ASTDTM             |
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| Metadata Field     | Metadata  |                     |  |  |  |
|--------------------|---|---------------------|--|--|--|
| DISPLAY IDENTIFIER | Table 4.2.1/Figure 4.2.1  |                     |  |  |  |
| DISPLAY NAME       | Mean Change from Baseline in HbA1c (Percent) Longitudinal Repeated Measures A |                     |  |  |  |
|                    | Period, Intention-to-treat Population   |                     |  |  |  |
| RESULT IDENTIFIER  | Treatment difference results (LSMean, confidence in                           | nterval, p-value)   |  |  |  |
| PARAM              | HbA1c (%)   |                     |  |  |  |
| PARAMCD            | HBA1C   |                     |  |  |  |
| ANALYSIS VARIABLE  | CHG (Change from baseline)  |                     |  |  |  |
| ANALYSIS REASON    | SPECIFIED IN SAP  |                     |  |  |  |
| ANALYSIS PURPOSE   | PRIMARY OUTCOME MEASURE   | ARM v1              |  |  |  |
| ANALYSIS DATASET   | ADHBA1C   | 7 (1 (1))           |  |  |  |
|                    |   |                     |  |  |  |
|                    | ARM Extension Techr   | nical Specification |  |  |  |

#### **ADaM Dataset**

| b:Observation | qb:Table   | dim.population | dim.treatment | dim.parameter  | dim.sex | dim.agecat | dim.statistic | analysisResul |
|---------------|------------|----------------|---------------|----------------|---------|------------|---------------|---------------|
| 1001          | dm.summary | errolled       | Treatment A   | param.subjects | sex.ALL | agecat ALL | stat,freq     | 100           |
| 1002          | dm.summary | enrolled       | Treatment.A   | param.subjects | sex.F   | agecat.ALL | stat,freq     | 60            |
| 1003          | dm.summary | enrolled       | Treatment.A   | param.subjects | sex.F   | agecat.ALL | stat.percent  | 60            |
|               | dm.summary | errolled       | Treatment.A   | param.subjects | sex.M   | agecat.ALL | stat.freq     | 40            |
| 1005          | dm.summary | errolled       | Treatment.A   | param.subjects | sex.M   | agecat.ALL | stat.percent  | 40            |
| 1006          | dm.summary | enrolled       | Treatment.B   | param.subjects | sex.ALL | agecat.ALL | stat.freq     | 50            |
| 1007          | dm.summary | enrolled       | Treatment.B   | param.subjects | sex.F   | agecat.ALL | stat.freq     | 30            |
| 1008          | dm.summary | enrolled       | Treatment.B   | param.subjects | sex.F   | agecat.ALL | stat.percent  | 60            |
| 1009          | dm.summary | enrolled       | Treatment.B   | param.subjects | sex.M   | agecat.ALL | stat.freq     | 20            |
| 1010          | dm.summary | enrolled       | Treatment.B   | param.subjects | sex.M   | agecat.ALL | stat.percent  | 40            |
| 1011          | dm.summary | enrolled       | Treatment ALL | param.subjects | sex.ALL | agecat.ALL | stat,freq     | 150           |
|               | dm.summary | enrolled       | Treatment.ALL | param.subjects | sex.F   | agecat.ALL | stat.freq     | 90            |
| 1013          | dm.summary | enrolled       | Treatment ALL | param.subjects | sexF    | agecat.ALL | stat.percent  | 60            |
| 1014          | dm.summary | errolled       | Treatment.ALL | param.subjects | sex.M   | agecat.ALL | stat,freq     | 60            |
| 1015          | dm.summary | enrolled       | Treatment ALL | param.subjects | sex.M   | agecat.ALL | stat.percent  | 40            |
| 1016          | dm.summary | itt            | Treatment.A   | param.age      | sex.ALL | agecat.ALL | stat,freq     | 100           |
| 1017          | dm.summary | itt            | Treatment.A   | param.age      | sex.ALL | agecat.ALL | stat,mean     | 40.7          |
|               | dm.summary | itt            | Treatment.A   | param.age      | sex.ALL | agecat.ALL | stat.stdev    | 10.7          |
|               | dm.summary | itt            | Treatment.A   | param.age      | sex.ALL | agecat.ALL | stat.median   | 37.0          |
|               | dm.summary | itt            | Treatment.A   | param.age      | sex.ALL | agecat.ALL | stat.min      | 21.0          |
| 1021          | dm.summary | itt            | Treatment.A   | param.age      | sex.ALL | agecat.ALL | stat.max      | 66.0          |
| 1022          | dm.summary | itt            | Treatment.B   | param.age      | sex.ALL | agecat.ALL | stat.freq     | 50            |
| 1023          | dm.summary | Rt             | Treatment.B   | param.age      | sex.ALL | agecat.ALL | stat,mean     | 41.2          |
| 1024          | dm.summary | itt            | Treatment.B   | param.age      | sex.ALL | agecat.ALL | stat.stdev    | 10.3          |
| 1025          | dm.summary | itt            | Treatment.B   | param.age      | sex.ALL | agecat.ALL | stat.median   | 36.0          |
| 1026          | dm.summary | itt            | Treatment.B   | param.age      | sex.ALL | agecat.ALL | stat.min      | 23.0          |
| 1027          | dm.summary | itt            | Treatment.B   | param.age      | sex.ALL | agecat.ALL | stat.max      | 67.0          |
| 1028          | dm.summary | itt            | Treatment.ALL | param.age      | sex.ALL | agecat.ALL | stat.freq     | 150           |
| 1029          | dm.summary | itt            | Treatment.ALL | param.age      | sex.ALL | agecat.ALL | stat.mean     | 40.9          |
| 1030          | dm.summary | itt            | Treatment ALL | param.age      | sex.ALL | agecat.ALL | stat.stdev    | 10.4          |
|               | dm.summary | itt            | Treatment.ALL | param.age      | sex.ALL | agecat.ALL | stat.median   | 37.0          |
| 1032          | dm.summary | itt            | Treatment.ALL | param.age      | sex.ALL | agecat.ALL | stat.min      | 21.0          |
| 1033          | dm.summary | at             | Treatment ALL | param.age      | sex.ALL | agecat.ALL | stat.max      | 67.0          |

#### **Automation**



Reuse Traceability

| HbAic (%) Longitudinal Repeated Measures Analysis<br>24-Neek Short-term Double-blind Treatment Period<br>Intention-to-treat Pevulation |   |  |   |  |  |  |
|--|---|--|---|--|--|--|
|  | W   | Drug A<br>N=125  | Drug B<br>N=125   |  |  |  |
| BASELINE   | N♥<br>Mean (SD)   | 125<br>X.XX( X.XXX)  | 125<br>X.XX ( X.XXX)  |  |  |  |
| WEEK 4   | NH change from baseline: Mean (SD) Adjusted change from baseline: Mean (SD) Adjusted change from baseline: Mean (SD) SS confidence interval for adjusted mean Difference vs. Drug B (SE) SS Confidence interval for difference P-value vs. Drug B   | X.30X ( X.X0X)<br>X.30X ( X.X0X)<br>X.30X ( X.X0X)<br>(XX.XX, XX.X)  | 300X<br>X.3X ( X.300X)<br>X.3X ( X.300X)<br>(30X.3XX, XX.XX)<br>30X.3XX ( X.300X)<br>(30X.3XX, XX.XX)<br>X.3000X                                      |  |  |  |
|  |   |  |   |  |  |  |
| WEEK 12  | He change from baseline: Heam (ED) adjusted change from baseline: Heam (ED) adjusted change from baseline: Heam (ED) 95% confidence interval for adjusted mean bifference vs. Drug B (EE) 55% Confidence interval for difference P-value vs. Drug B | X.30X ( X.300X) 300X X.30X ( X.300X) X.30X ( X.300X) X.30X ( X.300X) | X.XX ( X.XXXX) XXX ( X.XXXX) X.XX ( X.XXXX) XX.XX ( X.XXXX) XX.XX ( X.XXXX) XX.XX ( X.XXXXX) XX.XX ( X.XXXXX) XX.XXX ( X.XXXXXXXXXXXXXXXXXXXXXXXXXXXX |  |  |  |
| : the number<br>peated measu   | of subjects in the Intention-to-treat (ITT) Population. of subjects in the ITT population with non-missing baseline a res model: change = baseline treatment visit visit*treatment : popococon/popul/tobalc_repmess.ass                             | and non-missing Week t value.  |   |  |  |  |





#### **Analysis Results Desired Future State**

- Formal model for describing analyses and results as data
- Facilitate automated generation of results
- From static to machine readable results
- Improved navigation and reusability of analyses and results

- Support storage, access, processing and reproducibility of results
- Traceability to Protocol/SAP and to input ADaM data
- Open-source tools to design, specify, build and generate analysis results



#### **Analysis Results Standards Goals**



Analysis Results Metadata Technical Specification (ARM-TS), to support automation, traceability, and creation of data displays



Define an Analysis Results Data (ARD) structure, to support reuse and reproducibility of results data



Illustrate and exercise ARD and ARM-TS with a set of machine-readable common safety displays





# Poll Time!

- Does your organization have TFL standards or templates?
- Yes
- No
- Not sure

- Who generates TFL shells (mock-up) in your organization?
- Biostatistician
- Clinical/Statistical Programmer
- Biostatistician and Clinical/Statistical Programmer
- Other

- How do you generate your TFL shells?
- MS Word / RTF (Manually or copy-paste)
- MS Excel (Manually or copy-paste)
- Proprietary tool (home-grown)
- Proprietary tool (in-licensed)
- Other

- Is your TFL mock-up shells machine-readable?
- Yes
- No
- Not sure

- Do you annotate your TFL mock-up shells to provide results metadata information?
- Yes
- No
- Not sure

- Do you generate analysis results metadata (not just the Titles and Footnotes) to ingest in your TFL program for automation?
- Yes
- No
- Not sure

- Is your TFL analysis results metadata machine-readable?
- Yes
- No
- Not Applicable

- In which format is your <u>machine-readable</u> analysis results metadata?
- Excel/CSV
- RTF
- SAS
- XML
- JSON
- Other
- Not Applicable

**Open-Source TFL-Designer** 

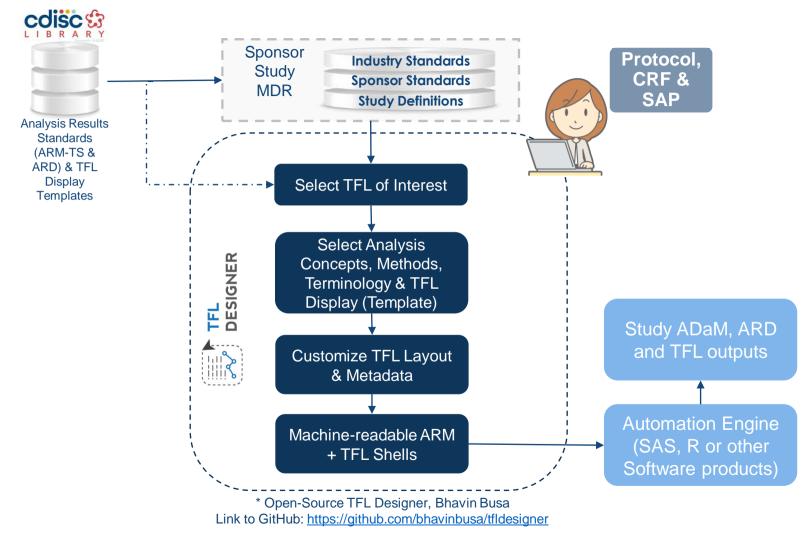




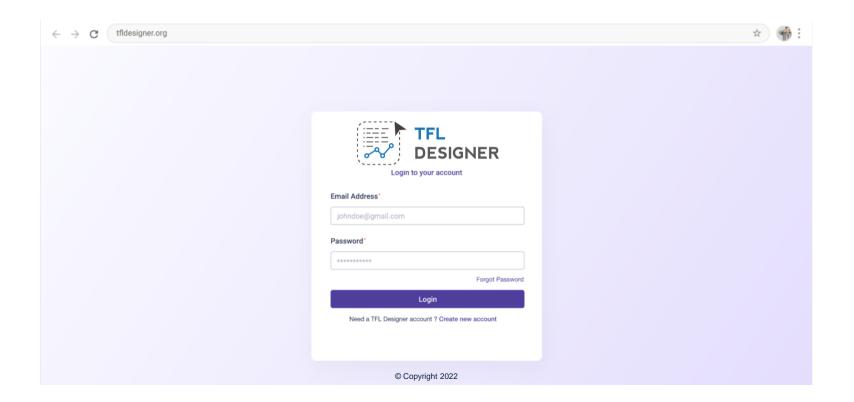




- Open-source tool to design tables, figures, and listings (TFL) and generate associated metadata to support clinical trial data analysis and reporting
- MIT license
- CDISC COSA approved
- GitHub: <a href="https://github.com/bhavinbusa/tfldesigner">https://github.com/bhavinbusa/tfldesigner</a>



### **Open-source TFL Designer - Wireframe**





Need your input!

 Please provide at least one user story for a TFL Designer in the text box below

**A user story is a** short, simple description of a feature told from the perspective of the person who desires the new capability, usually a user or customer of the system. User stories typically follow a simple template:

As a < type of user >, I want < some goal > so that < some reason >

#### **User Stories (Examples) for TFL Designer**

 As a Biostats/Stats Prog, I want to use an automated tool to design TFL shells and generate machine-readable metadata for downstream programming activities.

 As a Biostats/Stats Prog, I want to have a web-based solution to access all my study-level TFL shells and analysis results metadata.



## Need your input!

 Please provide user requirements for a TFL Designer in the text box below

A **user requirements**, often referred to as user needs, describe what the user does with the software/system, such as what activities that users must be able to perform.

#### **User Requirements (Examples) for TFL Designer**

- Secure log-in to cloud-based application
- Access to scalable and validated 21
   CFR Part 11 compliant solution
- Access to library of TFL templates (community and user generated)
- Ability to connect to CDISC Library via API

- Develop new mock-up shells, edit/delete items
- Automatically populate items based on user inputs
- Review of TFL shells in the system
- Export and import machinereadable TFL shells and analysis results metadata (XML, JSON)

# Unique Value Proposition

By the people, for the people

Open-source offering

Governance and Technical Boards

Integrate with the current industry workflow

Align with CDISC standards and future updates

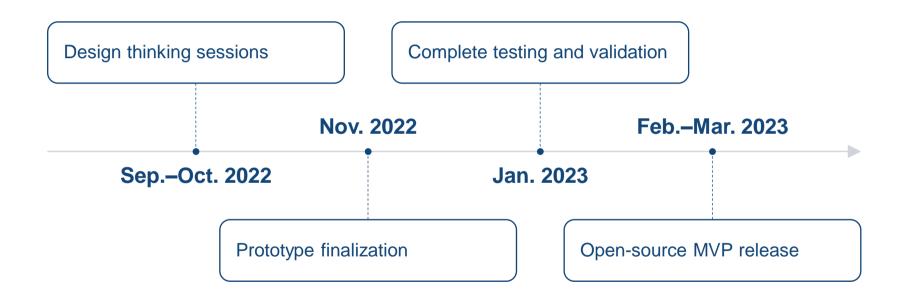
In line with the regulatory and industry requirements

Incorporate and support machine-learning & automation

Software/tool agnostic

Enterprise Version & Professional services offering

#### **High-level Open-source MVP Development Roadmap**





## Sign up!

https://forms.gle/iB5aHhqz8rdL6CVw7

#### **Next Steps**

- Sign-up for future collaboration and communication <u>https://forms.gle/iB5aHhqz8rdL6CVw7</u>
- Stay in-touch via Slack channel (details will be shared during Workshop 2)
- Attend Workshop 2 on 6<sup>th</sup> Oct 2022 at 11:00AM 12:30PM EST [Invite will be sent out to everyone who registered for Workshop 1]
- Announcement of lucky winner (US \$100 Amazon Gift Card)

#### References

- CDISC 360 White Paper: <a href="https://www.cdisc.org/cdisc-360">https://www.cdisc.org/cdisc-360</a>
- CDISC COSA: <a href="https://cosa.cdisc.org/">https://cosa.cdisc.org/</a>
- Link to TFL Designer GitHub: <a href="https://github.com/bhavinbusa/tfldesigner">https://github.com/bhavinbusa/tfldesigner</a>
- CDISC Analysis Results Standards: <a href="https://www.cdisc.org/standards/foundational/analysis-results-standard">https://www.cdisc.org/standards/foundational/analysis-results-standard</a>
- FDA Standard Safety Tables and Figures: Integrated Guide: https://www.regulations.gov/docket/FDA-2022-N-1961/document
- General Output Tips and Considerations (PHUSE White Paper)
- TFL Designer Workshop Registration page: <a href="https://www.cdisc.org/events/webinar/tfl-designer-virtual-workshop">https://www.cdisc.org/events/webinar/tfl-designer-virtual-workshop</a>

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