



**TFL**  
**DESIGNER®**

# Open-source TFL Designer: Virtual Workshop

Bhavin Busa

Workshop 2

06<sup>th</sup> October 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 [CDISC 360 project](#) and co-authored 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

Recording: <https://www.cdisc.org/events/webinar/tfl-designer-virtual-workshop>

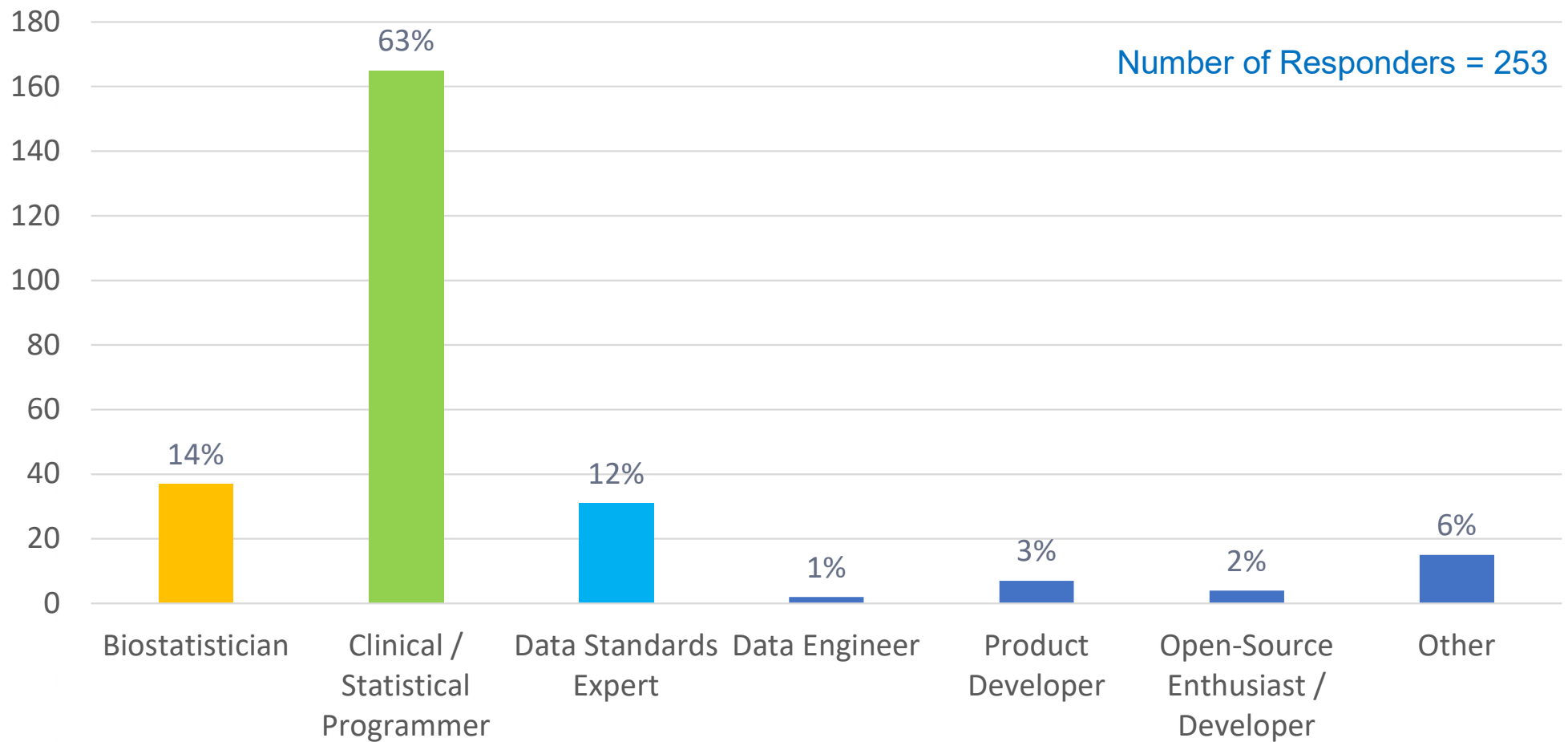
• **Workshop 2:** 6<sup>th</sup> Oct 2022 11:00AM to 12:30PM EST

- Review Poll Results
- Summarize user-stories and user-requirements
- Development Approach and Technology Stack
- Development Roadmap
- Governance & User Community
- Collaboration Expectations
- Sign-up, Resources and References
- Next Steps
- Q&A session



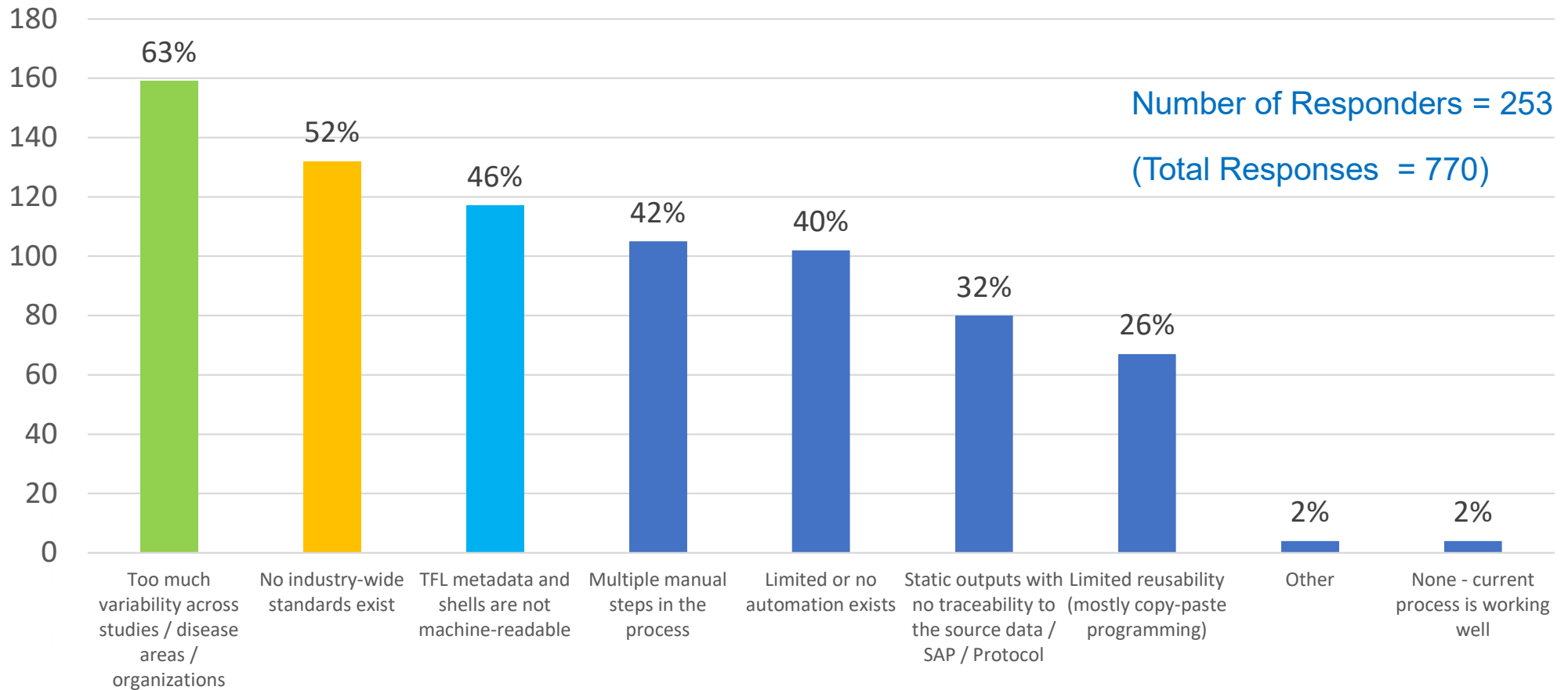
Poll Results!

## 1. What best describes your current role in your organization?\*



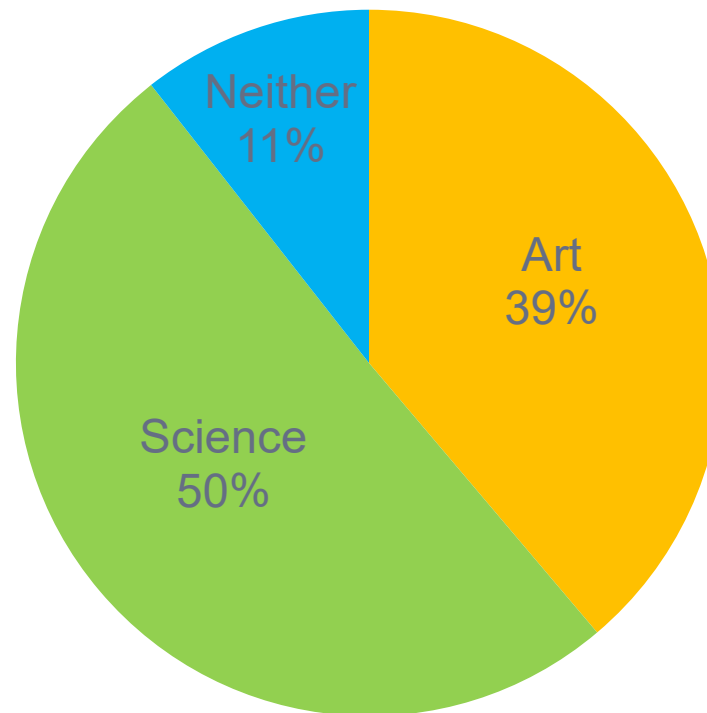
\* Results from the live poll conducted during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> Sep 2022, Bhavin Bura

## 2. What do you think is not working out (pain points) in the TFL/analysis results generation process? (select all that apply)\*



\* Results from the live poll conducted during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> Sep 2022, Bhavin Busa

### 3. Do you consider programming more of an art or a science?\*

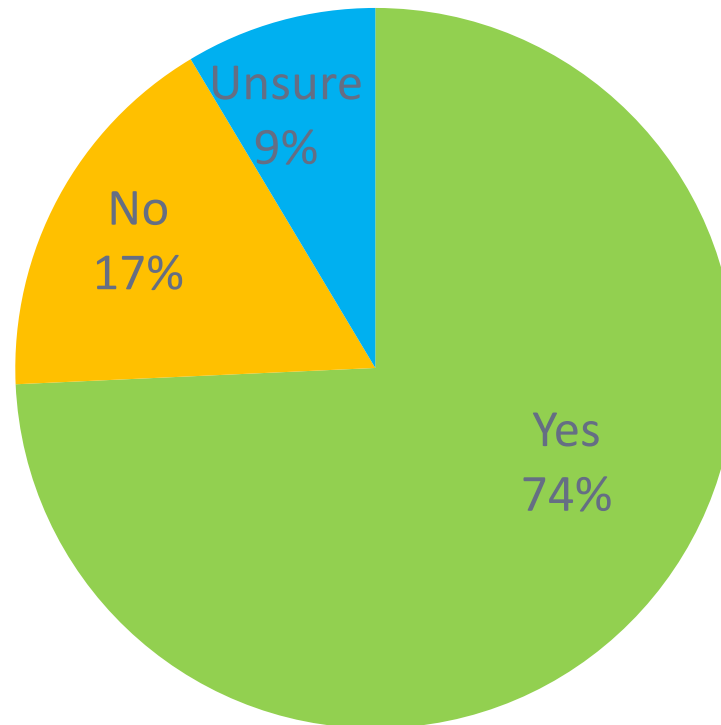


Number of Responders = 255

*\* Results from the live poll conducted during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> Sep 2022, Bhavin Busa*



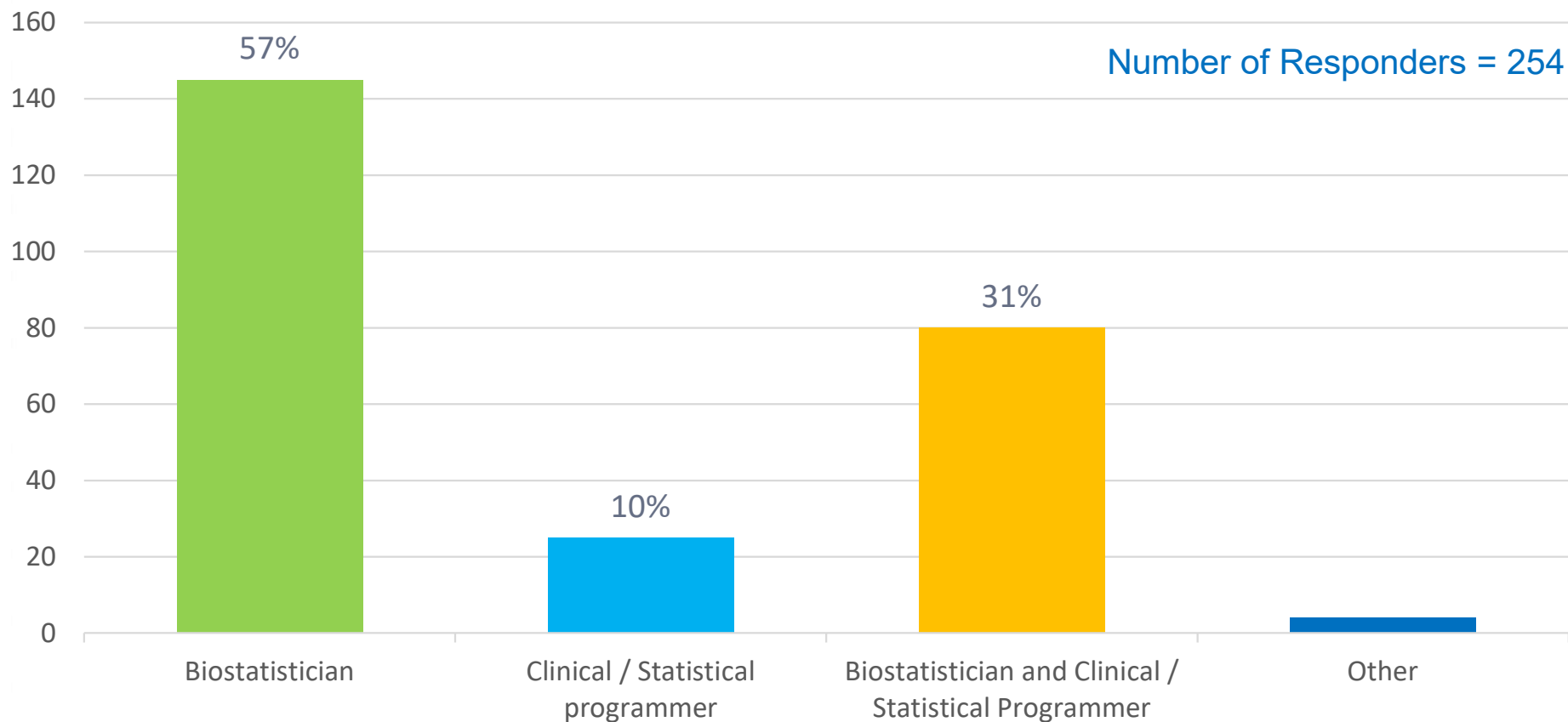
4. Does your organization have TFL standards or templates?\*



Number of Responders = 245

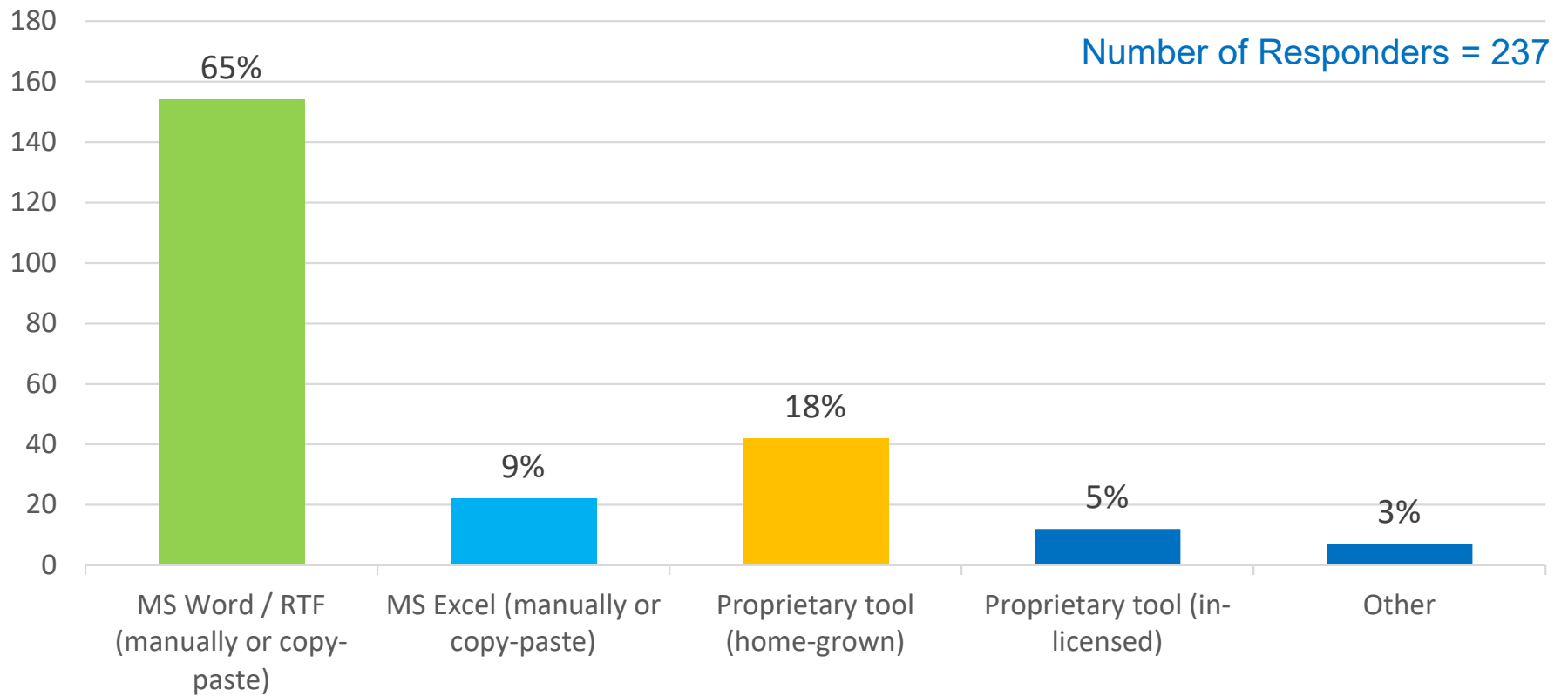
*\* Results from the live poll conducted during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> Sep 2022, Bhavin Busa*

## 5. Who generates TFL shells (mock-ups) in your organization\*



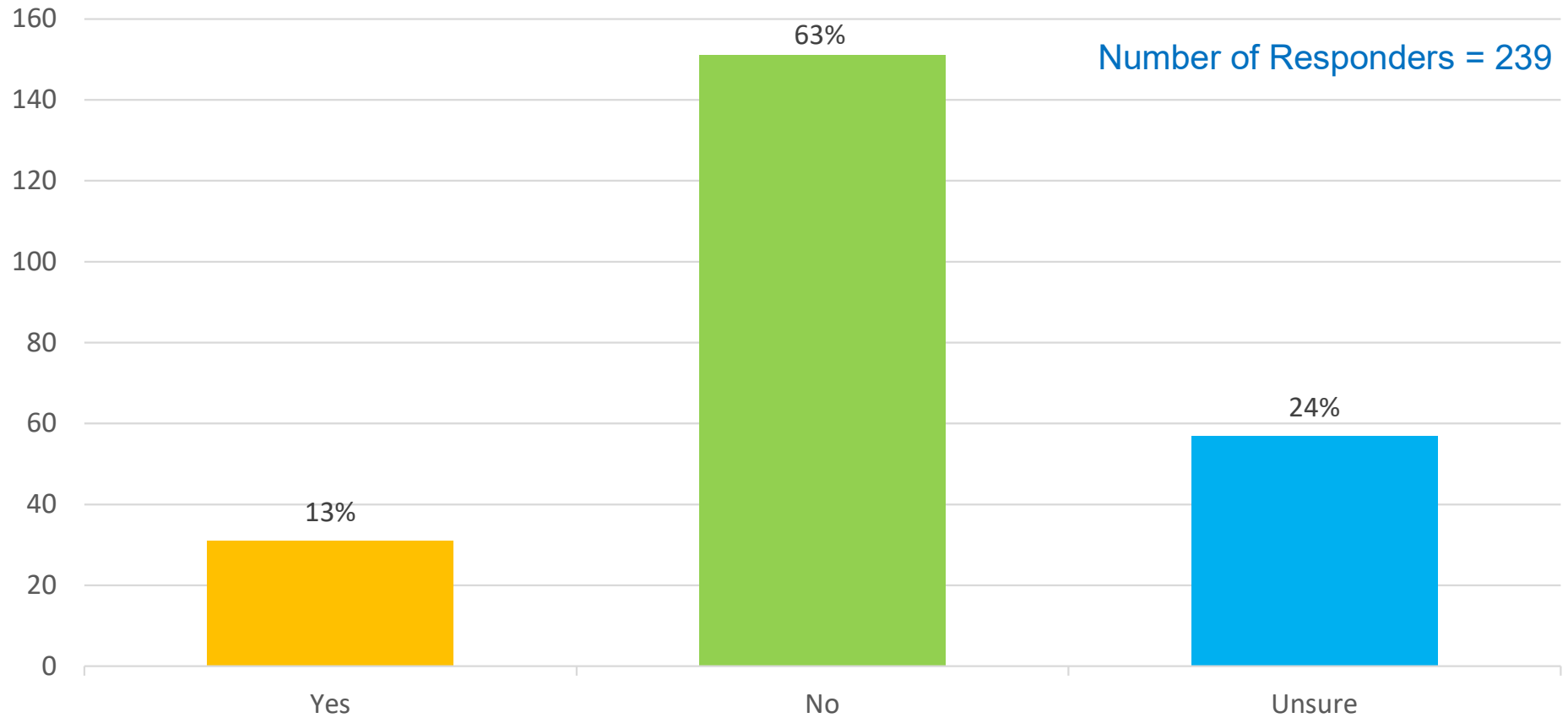
\* Results from the live poll conducted during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> Sep 2022, Bhavin Busa

## 6. How do you generate your TFL shells?\*



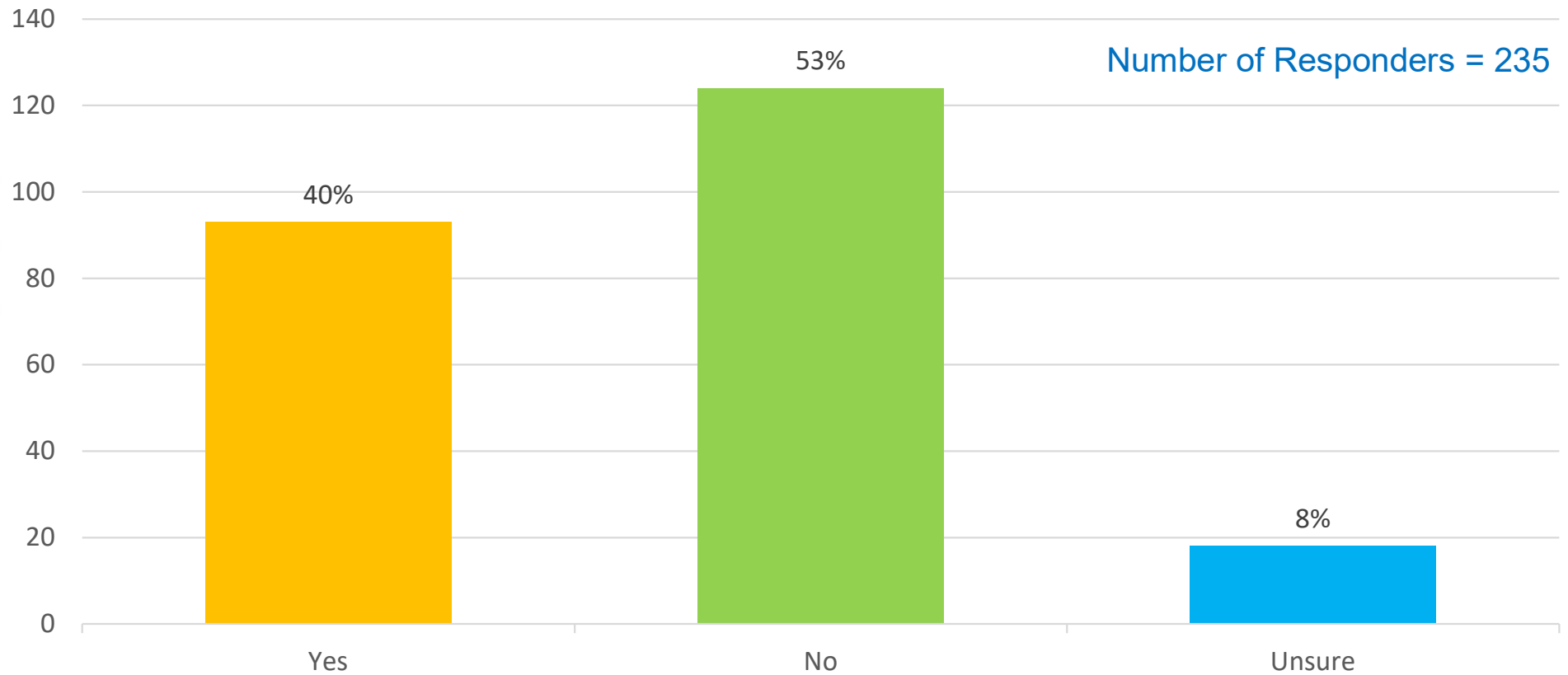
*\* Results from the live poll conducted during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> Sep 2022, Bhavin Busa*

## 7. Are your TFL mock-up shells machine-readable?\*

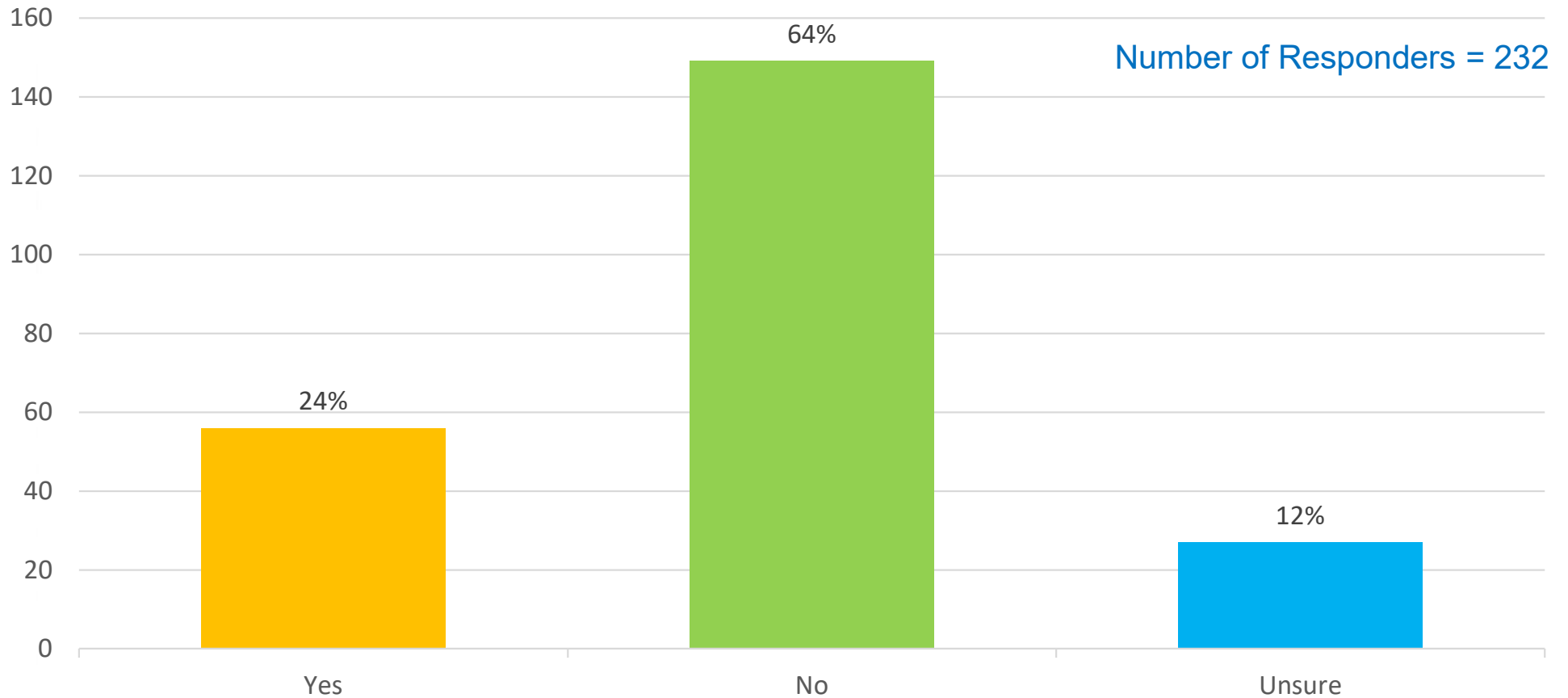


*\* Results from the live poll conducted during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> Sep 2022, Bhavin Busa*

8. Do you annotate your TFL mock-up shells to provide results metadata information?\*

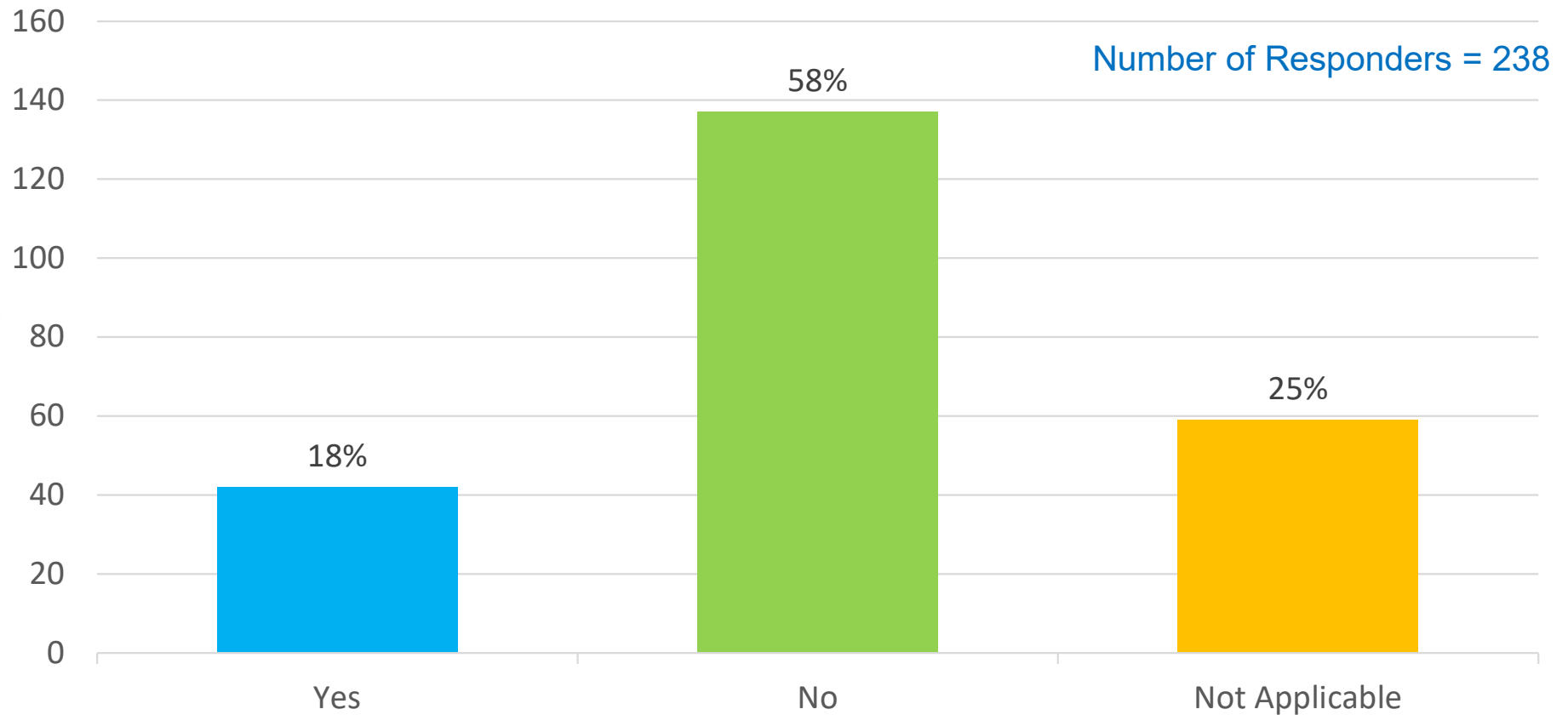


### 9. Do you generate analysis results metadata (not just the Titles and Footnotes) to ingest in your TFL program for automation?\*



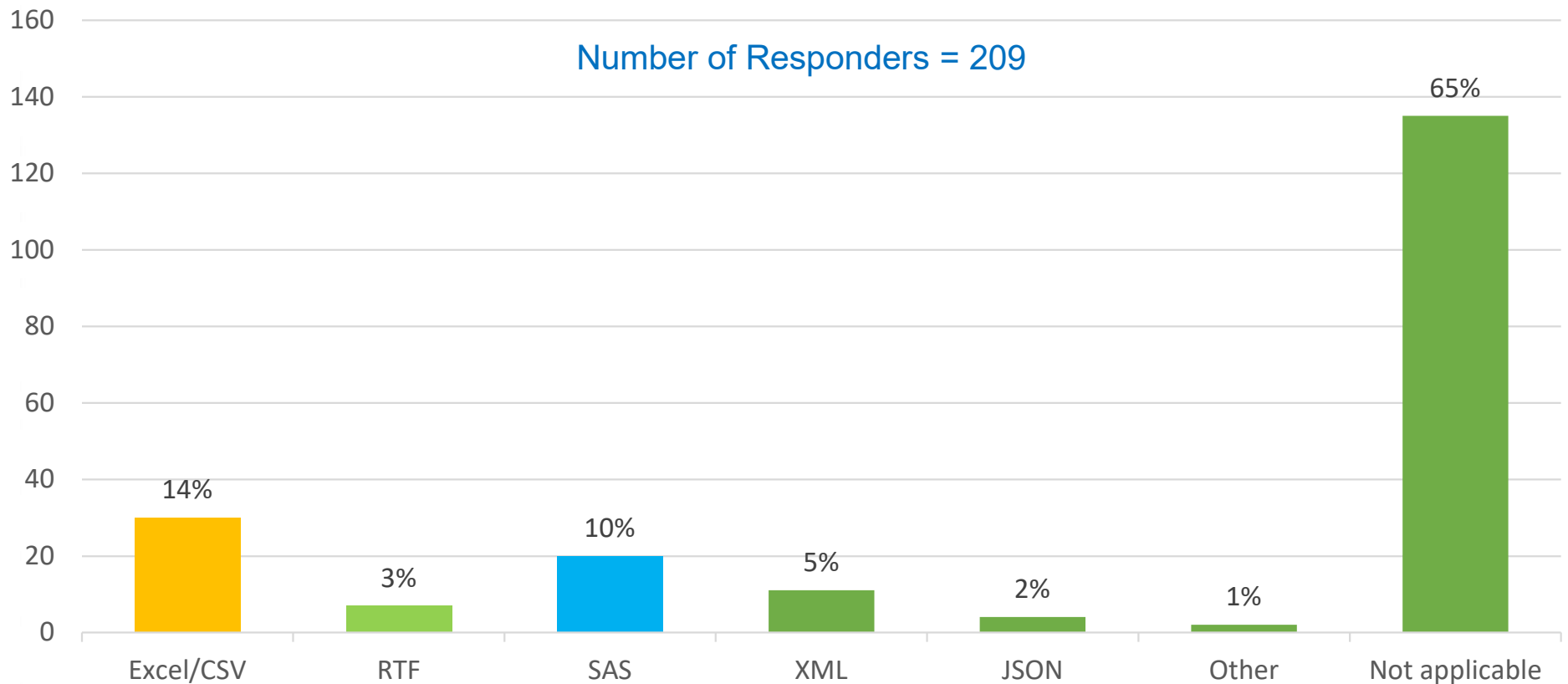
\* Results from the live poll conducted during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> Sep 2022, Bhavin Busa

## 10. Is your TFL analysis results metadata machine-readable?\*



*\* Results from the live poll conducted during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> Sep 2022, Bhavin Busa*

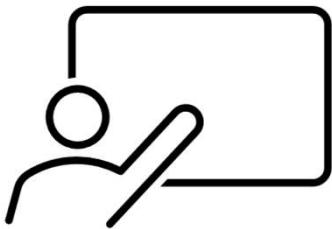
## 11. In which format is your machine-readable analysis results metadata?\*



\* Results from the live poll conducted during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> Sep 2022, Bhavin Busa



## Poll Summary\*



\* Results from the live poll conducted during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> 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%** organization 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

# Summary of User Stories\*

## Automate TFL shell and metadata generation



## TFL Library, Templates, Standards and more



## Share, Review and Maintain



## Import and Export TFL Metadata & Shells



## Application host



## Version control / Audit Trail



## Ingest ADaM Metadata



## Traceability to ADaM / SDTM or CRF data



## Annotate TFL Shells



## Automate generation of TFL code and output



## Repeat Tables



## Machine-learning functionality



## Miscellaneous



miro

\* User Stories provided by the attendees during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> Sep 2022, Bhavin Busa

# Summary of User Requirements\*



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\* User Requirements provided by the attendees during the Open-source TFL Designer Virtual Design Thinking Workshop (Part I), 13<sup>th</sup> Sep 2022, Bhavin Busa

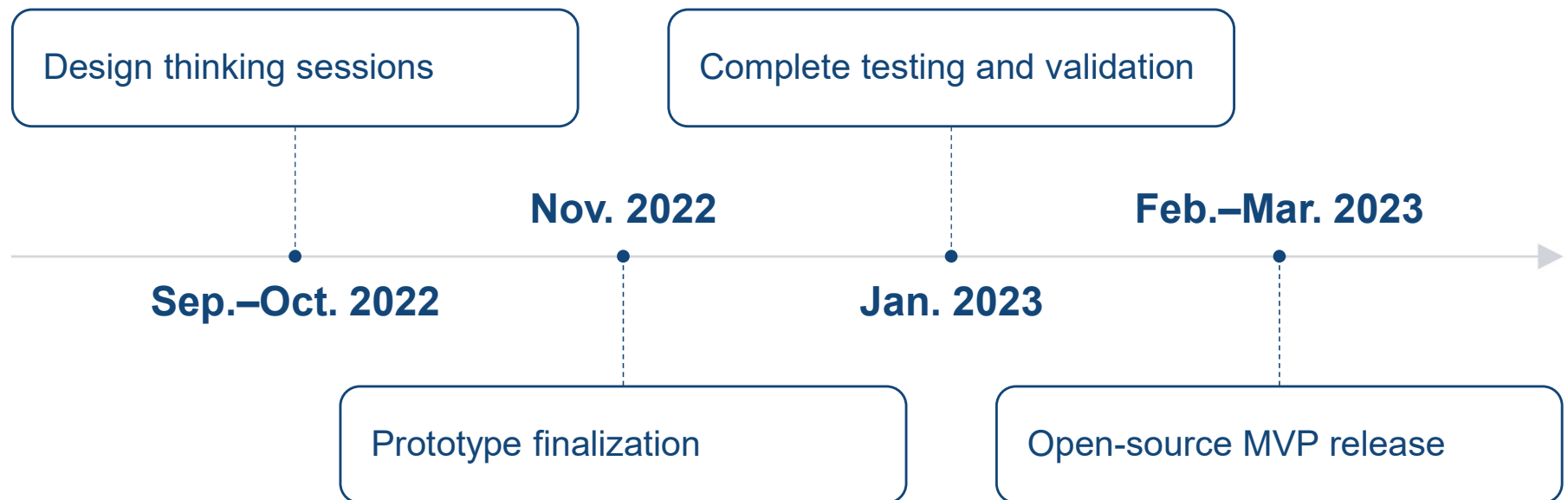
## User Requirements (Examples) for TFL Designer

- *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 machine-readable TFL shells and analysis results metadata (XML, JSON)*

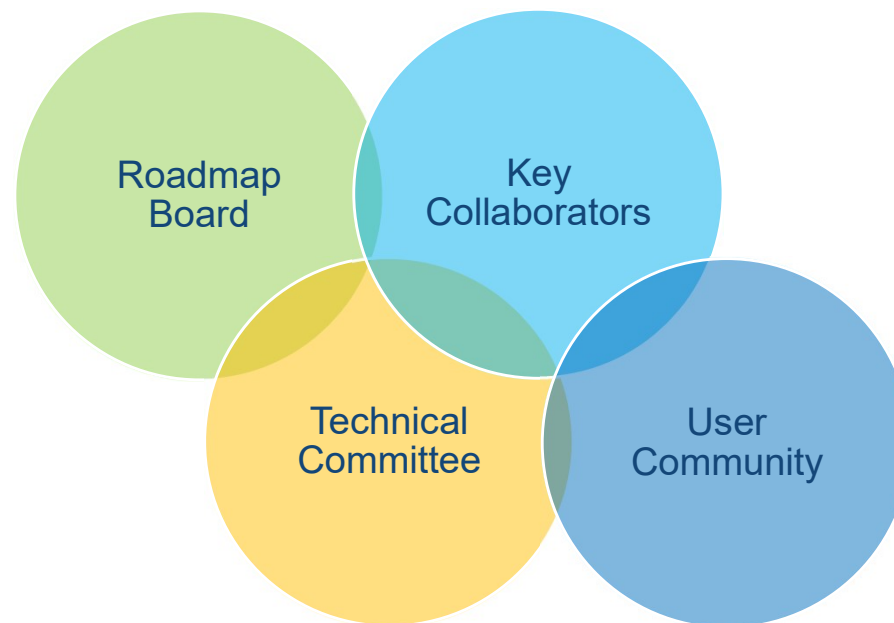
# Development Approach & Technology Stack

- Hosting and Repo: GitHub
- Agile Method (Atlassian JIRA Software for project tracking)
- TFL Designer built on following tools/technologies:
  - React JS
  - jQuery
  - Fast API/Django (Python)
  - Atlas MongoDB
  - Azure or AWS S3 (TBD)
- API to CDISC Library
- Integration with SAS and R packages
- Custom APIs and Integration for Sponsor-specific implementation

# High-level Open-source MVP Development Roadmap



# TFL Designer Governance and Membership

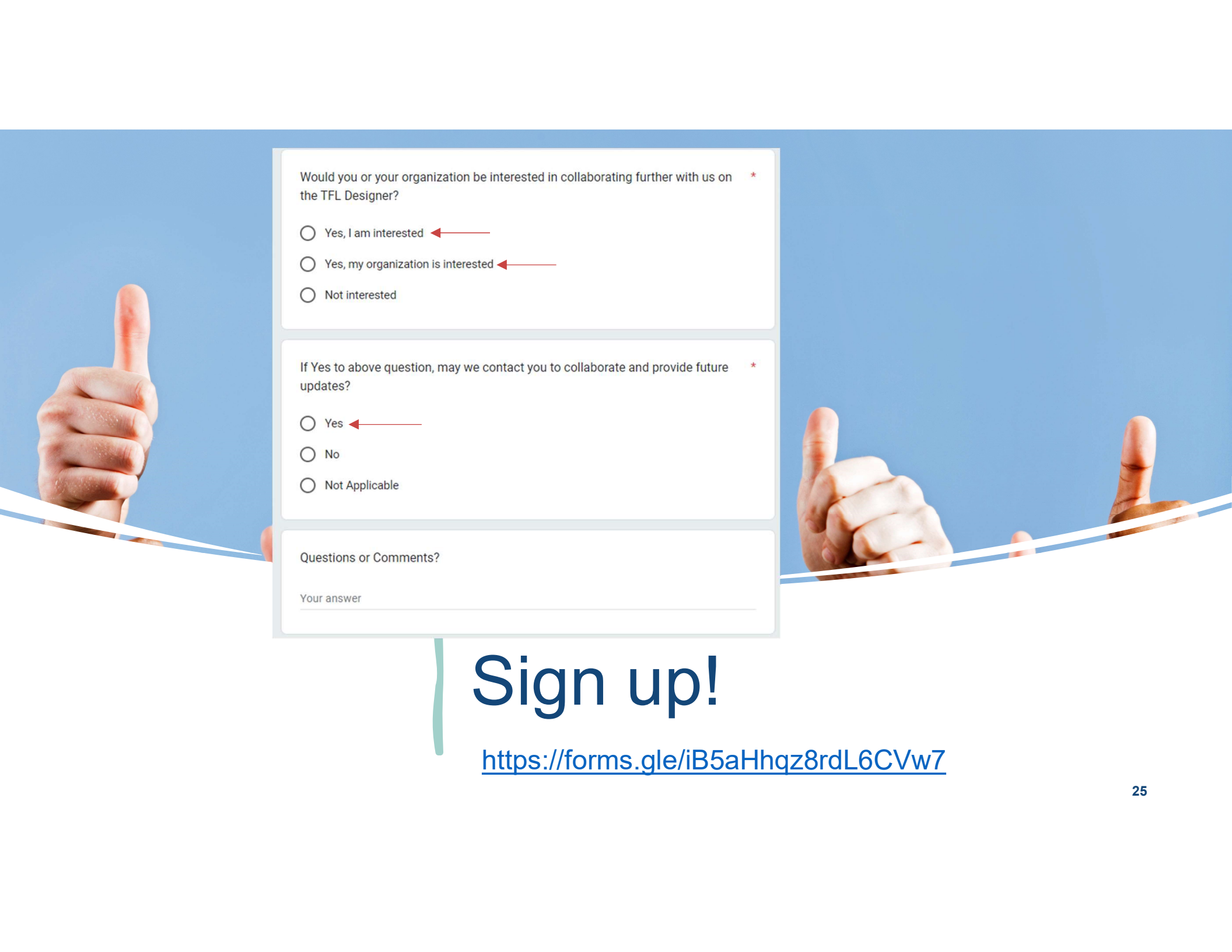


## Joining TFL Designer User Community



Communication and staying in touch via TFL Designer Slack channel (Sign up required)





Would you or your organization be interested in collaborating further with us on the TFL Designer? \*

- ☒ Yes, I am interested
- ☒ Yes, my organization is interested
- ☐ Not interested

If Yes to above question, may we contact you to collaborate and provide future updates? \*

- ☒ Yes
- ☐ No
- ☐ Not Applicable

Questions or Comments?

Your answer

# Sign up!

<https://forms.gle/iB5aHhqz8rdL6CVw7>

## **What's in for you and your organization?**

- Huge Benefits in your Clinical Trial Quality, Speed and Efficiency
- Early adapters will have enhanced ability to dictate layout and structure for their own needs!
- Ability to get a huge head start on inevitable automation that will take place
- Immense cost savings across all functions

# Collaboration Expectations [@Organization Level]

- Pilot study or studies
  - See the TFL Designer work on your study!
- Share TFL standards and templates
- Monthly meetings to discuss progress and updates
  - Integrate with leadership from both sides to talk about progress and continuous improvement
- Gather input to make edits and optimize tool
  - Collaborators and early adapters will have input to optimize and make edits for their needs
- Set short-term and long-term goals for each collaborator
  - Tailor the expectations to your needs and goals
- Enable your business owners to succeed

## TFL Designer Resources

- TFL Designer GitHub: <https://github.com/bhavinbusa/tfldesigner>
- Workshop (Part I and II) slides, poll results, user stories and requirements available on [TFL Designer GitHub](#)
- TFL Designer workshop (Part I) recording available at: [TFL Designer Virtual Workshop | CDISC](#)
- TFL Designer workshop (Part II) recording available at: [TFL Designer Virtual Workshop - Part II | CDISC](#)

## References

- CDISC 360 White Paper: <https://www.cdisc.org/cdisc-360>
- CDISC COSA: <https://cosa.cdisc.org/>
- CDISC Analysis Results Standards:  
<https://www.cdisc.org/standards/foundational/analysis-results-standard>
- 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](#))

## Next Steps

- Announcement of lucky winner (US \$100 Amazon Gift Card) via Email (Oct 14<sup>th</sup>, 2022)
- Send out Slack invite (Oct 14<sup>th</sup>, 2022)
- 1x1 meetings with individuals who signed-up (Oct/Nov 2022)
  - Email will be sent to sign-up via Calendly
- User Community in-person meet-up at CDISC Interchange, COSA booth on Oct 26<sup>th</sup>-27<sup>th</sup> (Email me if you are going to be there)
- User Community monthly virtual meet-up (Nov 2022, Date/time: TBD)

# Q&A Session

## Contact Info

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- Connect on LinkedIn at: <https://www.linkedin.com/in/bhavinbusa/>