

Driving Efficiency and Automation in TFL Generation: A Case Study of Establishing an Oncology TFL Library & Analysis Results Metadata Repository

Authors: Bhavin Busa (Clymb Clinical) & Salil Parab (Xencor, Inc)

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

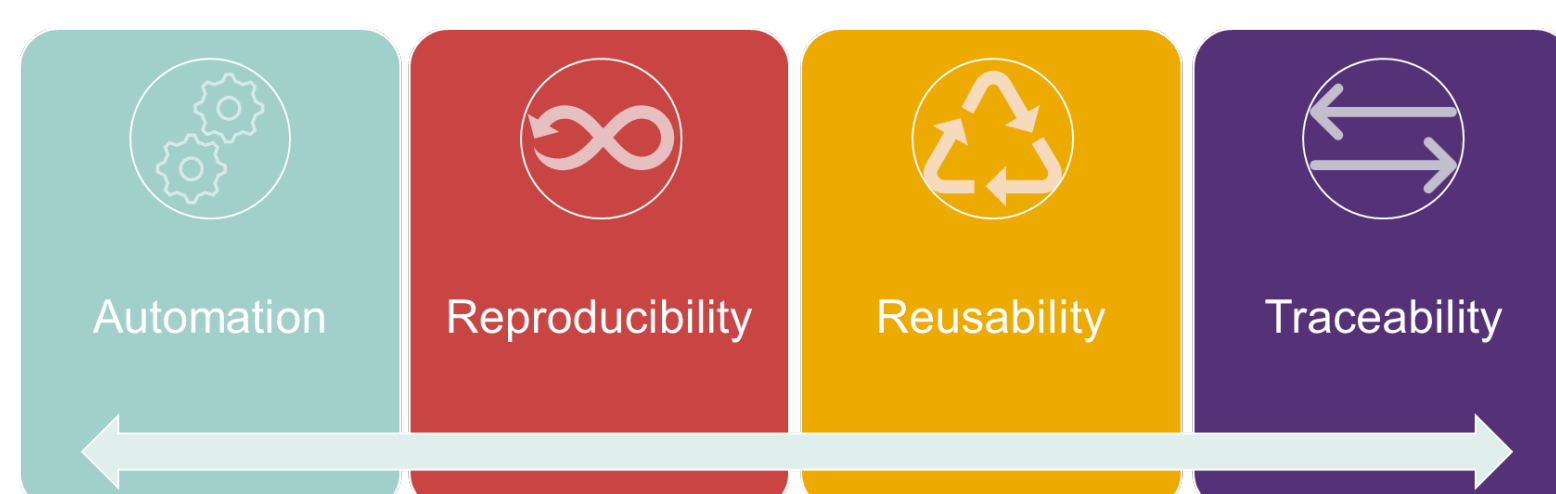
Static results with No or limited linking facility (e.g., to Protocol, SAP, ADaM data)

There is no industry standards for analysis results

Analysis Results Generation: Top 5 pain points

CDISC Analysis Results Standard (ARS)¹: The CDISC ARS Model have been developed to provide a logical model that fully described analysis results and associated metadata to support automation, consistency, reuse, and traceability of results data.

[¹ CDISC ARS Documentation: <https://cdisc-org.github.io/analysis-results-standard/>]



Xencor Case Study: Xencor, a biotech company focused on oncology and autoimmune indications, faced similar challenges. A small team supported various regulatory submissions, including DERC, DSUR, IB, and CSR, with manual processes dominating TFL generation.

Standardization and automation were critical to improving their operations.

TFL Shells Development and Review Challenges:

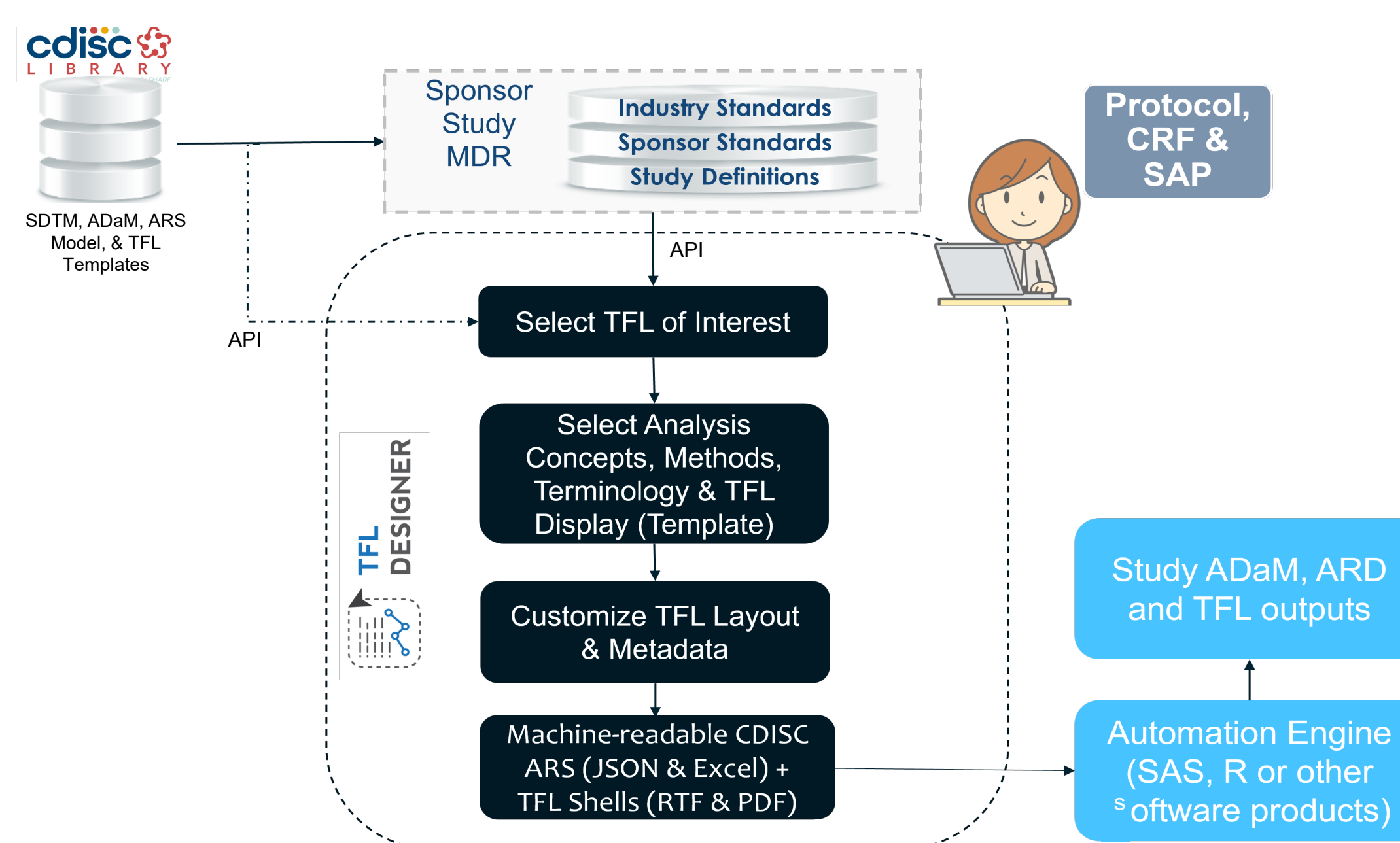
- Manual using MS Word.
- Repetitive tasks & time consuming.
- Hyperlinking TOCs and annotating is not fun.
- Tedious review process.

Broader Industry Challenges:

- Difficulty in maintaining consistency across oncology pipelines.
- Heavy reliance on manual processes resulted in inefficiencies and increased costs.

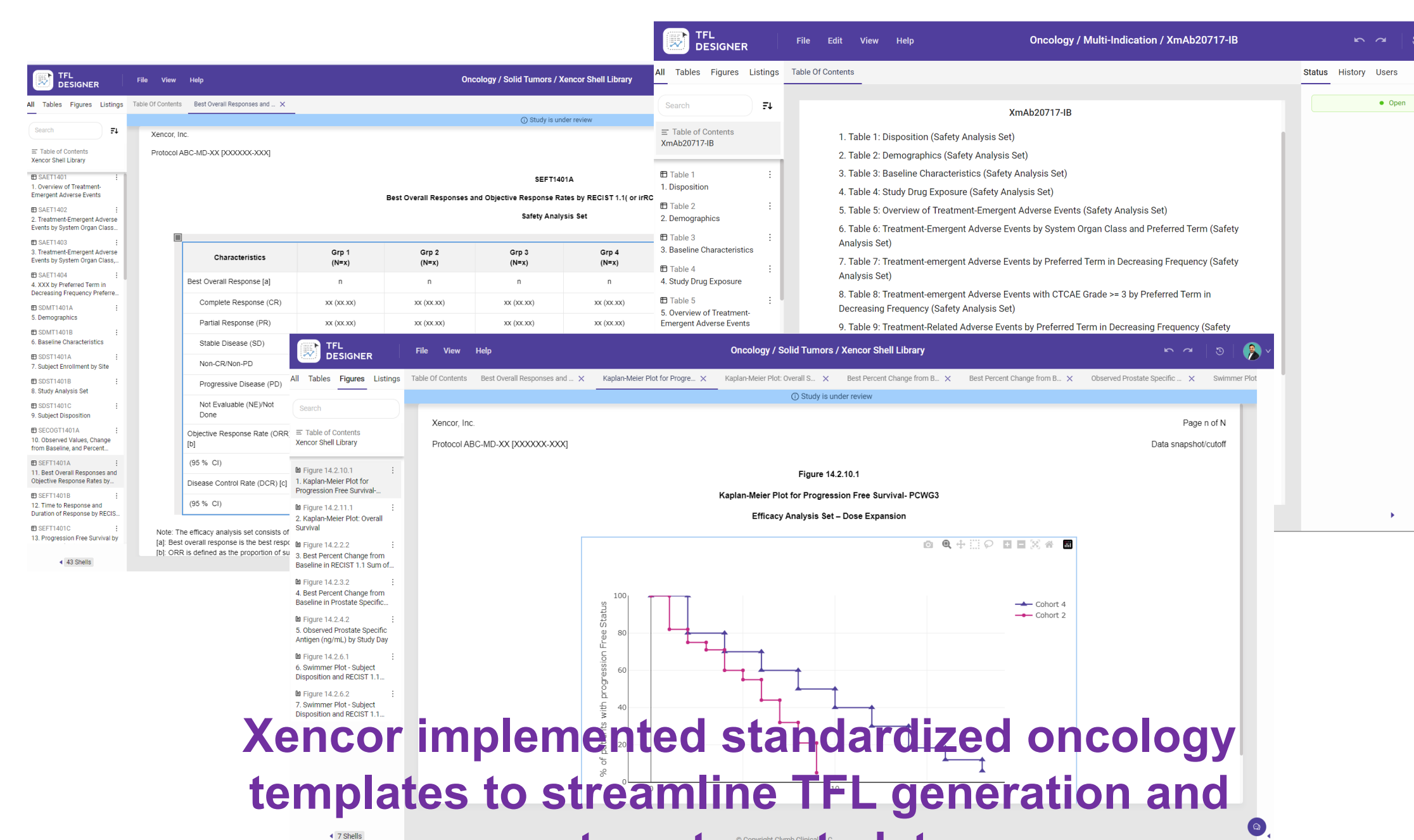
TFL Designer (Community, free version)²: This platform automates the creation of TFL shells and provides machine-readable metadata, which can then be seamlessly ingested for downstream automation in the programming of the TFLs.

[² TFL Designer Community <https://tfl designer.org/>]



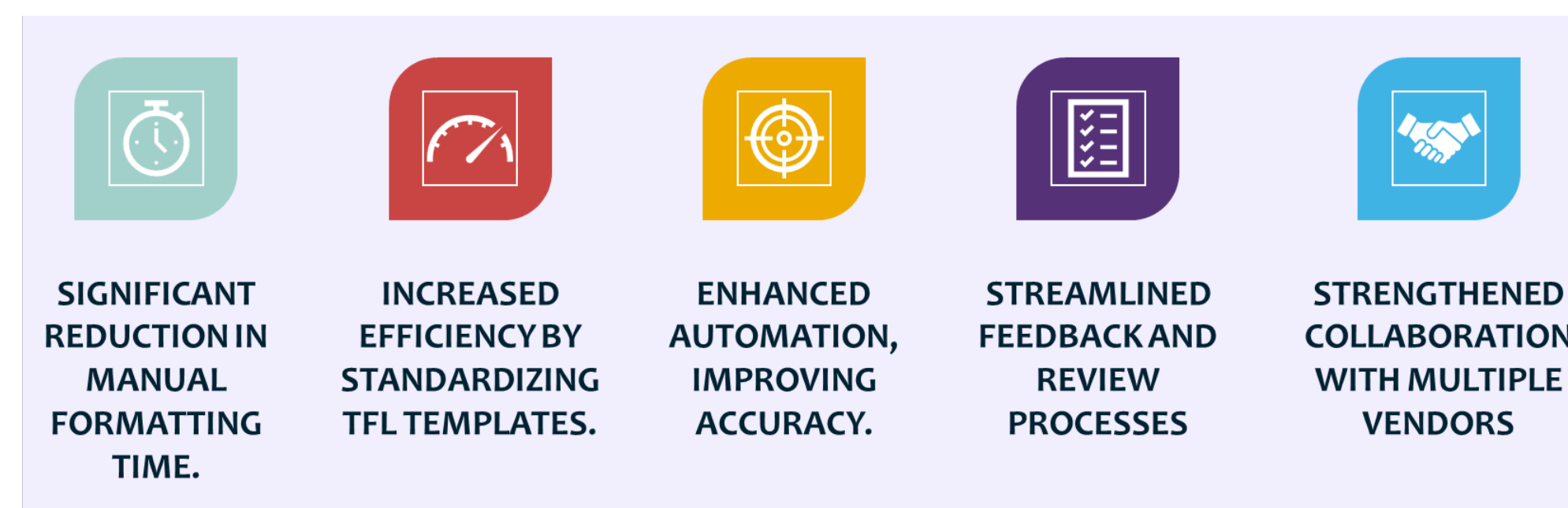
TFL Designer Implementation at Xencor:

- Automated formatting of TFL shells.
- Created a repository for TFL standardization and templates.
- Streamlined review and feedback processes for TFL mock shells.
- Automated TFL metadata creation, reducing manual errors.
- Improved collaboration with vendors/CROs by establishing consistent standards.



Xencor implemented standardized oncology templates to streamline TFL generation and automate metadata

Improvements:



Improvements after implementing TFL Designer at Xencor

Lessons Learned:

Xencor's Experience:

- Embrace new tools that enhance automation and efficiency.
- Proactively train teams to adopt new technologies.
- Be prepared to answer questions and provide support during implementation.
- Justify the cost through real improvements in efficiency, standardization, and automation.

General Recommendations:

- Involve stakeholders from the beginning to ensure buy-in and collaboration.
- Regularly update the TFL repository to incorporate the latest standards and lessons learned.
- Leverage machine learning and automation tools to further reduce manual effort and increase accuracy.

Conclusion:

The integration of the TFL Designer at Xencor and the development of the Oncology TFL Library and Analysis Results Metadata Repository have driven significant improvements in efficiency and automation in TFL generation.

By embracing CDISC ARS standards and automated workflows, Xencor has enhanced consistency and reduced manual effort, setting a precedent for future implementations across other therapeutic areas.

Acknowledgments & References

Acknowledgments: We would like to thank the teams at Xencor, Clymb Clinical, and all stakeholders involved in this initiative.

Contact: bhavin@clymbclinical.com; sparab@xencor.com