Paper SD09

Introducing TFL Viewer: Centralized Platform for TFL Review, Collaboration, and Approval

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ABSTRACT

Why go through hundreds of RTF and PDF files when you can manage, review, and approve tables, figures, and listings (TFLs) on a unified web-based platform? In this paper, we will introduce TFL Viewer, highlighting features like version control, easy navigation, and comment tracking to simplify the review process. Currently, feedback from reviewers is often disorganized, with comments added to individual Word documents or manually collated into Excel, making it difficult to track and incorporate feedback.

TFL Viewer centralizes this process, allowing teams to collaborate more effectively by consolidating comments in one place and streamlining review cycles. The tool also allows users to publish selected TFLs into a single report for submission to the Clinical Study Report (CSR), format TFLs for in-text CSR integration, and more. Add-on functionality includes AI-powered features to further streamline the generation of statistical reports and sections of the CSR.

INTRODUCTION

In clinical trials, TFLs are essential for summarizing study results and supporting regulatory submissions. The conventional approach to reviewing TFLs involves scattered RTF and PDF files, manual feedback tracking via emails and Excel spreadsheets, and an overall lack of integration with clinical data systems across various stakeholders. This fragmented approach leads to inefficiencies, potential inconsistencies, and prolonged timelines.

The TFL Viewer [1] aims to address these challenges by offering a centralized, web-based platform where clinical stakeholders, including Biostatisticians, Statistical Programmers, Clinicians, and Medical Writers, can collaborate effectively. By providing real-time collaboration, automation, and version tracking, the tool significantly improves workflow efficiency and data integrity.

Clymb leverages a suite of modern technologies to develop TFL Viewer, ensuring seamless and efficient user experience. The front-end is built using React JS for an intuitive interface, while Python powers various backend functionalities. Data integrity and scalability are maintained through a robust NoSQL database, such as MongoDB. Additionally, Git is employed for version control, ensuring systematic development and collaboration.

Designed to support the integration of CDISC Analysis Results Dataset (ARD) in Dataset-JSON format, TFL Viewer can efficiently process and render displays directly from structured machine-readable results data. While the current implementation relies on RTF/PDF outputs from study teams, the platform is built with the future in mind. As the industry shifts toward CDISC Analysis Results Standard (ARS) model [2, 3, 4], TFL Viewer will seamlessly adapt to ingest study ARD in Dataset-JSON format. This transformation towards the generation of machine-readable structured ARD will significantly enhance downstream usability, paving the way for CSR automation through Gen-AI-driven solutions.

STREAMLINING ANALYSIS RESULTS REVIEW AND APPROVAL

TFL Viewer offers a comprehensive suite of functionalities designed to streamline the review and approval process for Tables, Figures, and Listings. By serving as a centralized hub, it eliminates the need for managing multiple static documents and enables efficient collaboration. Users can engage in real-time commenting and annotation, assign tasks, and track feedback, ensuring transparency and accountability throughout the review cycle.

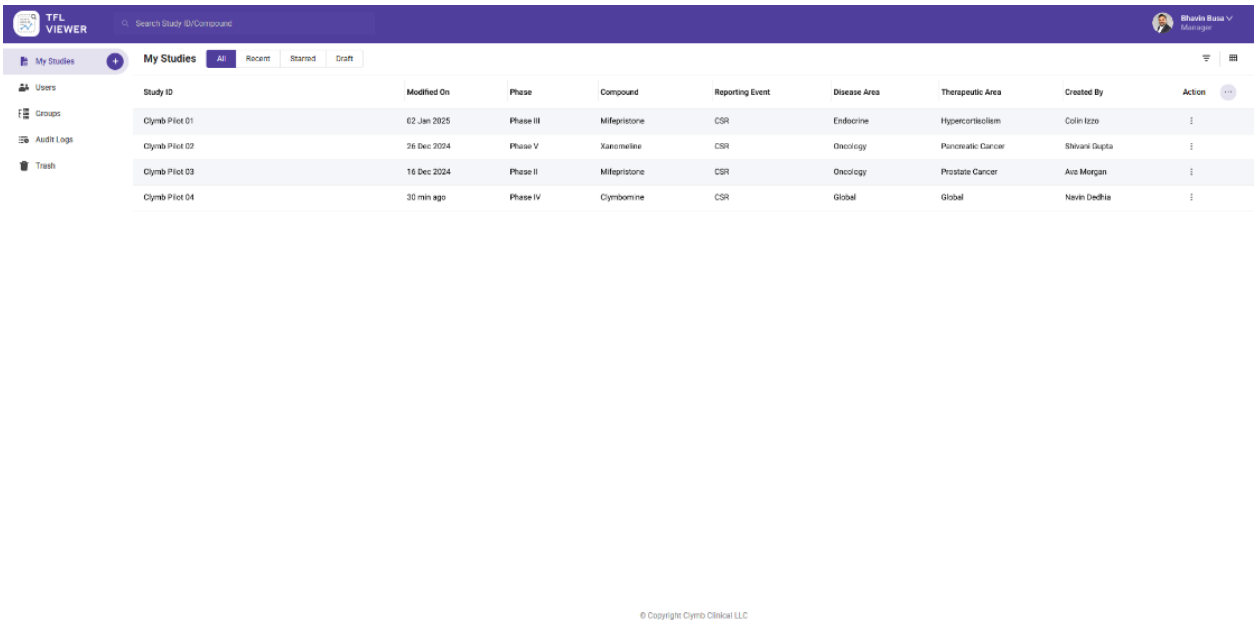

Figure 1: TFL Viewer Study Dashboard

The intelligent navigation and search features allow users to quickly locate specific TFLs using advanced filtering, hyperlinking, and keyword searches, significantly reducing time spent searching through documents.

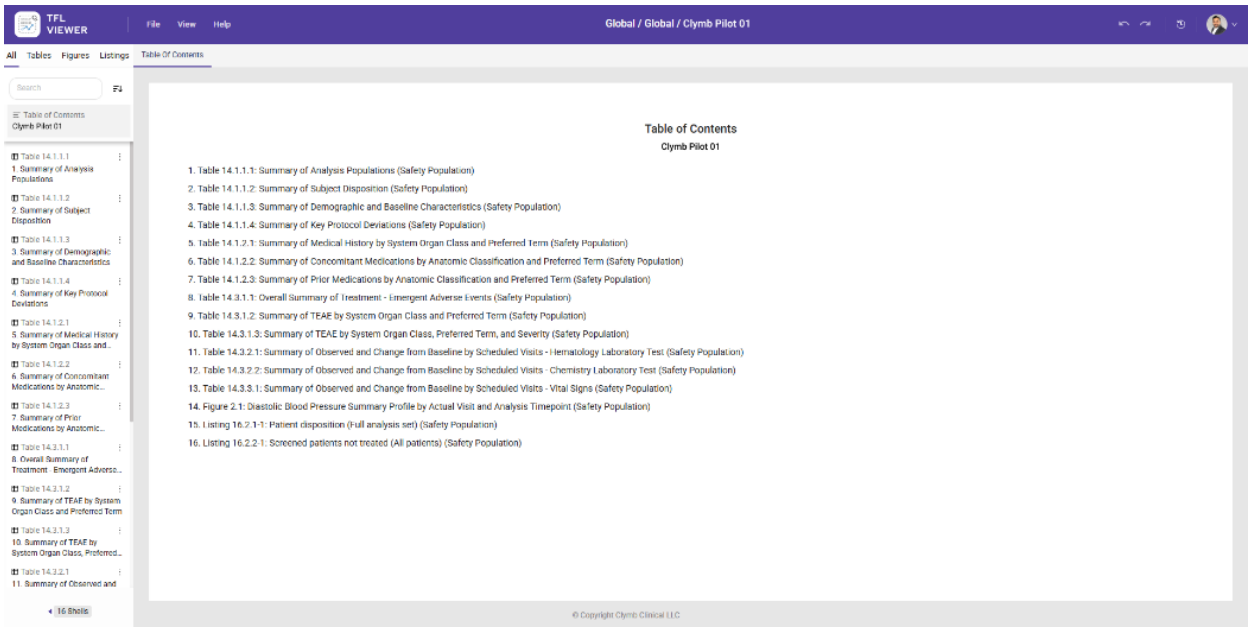

Figure 2: TFL Viewer Intelligent Navigation, Filtering and Search capabilities

Furthermore, the platform integrates automated quality checks to validate adherence to formatting standards, regulatory guidelines, and data consistency, helping reduce errors before submission. A robust version control and comparison system ensures that all changes are tracked, allowing users to compare iterations and restore previous versions as needed.

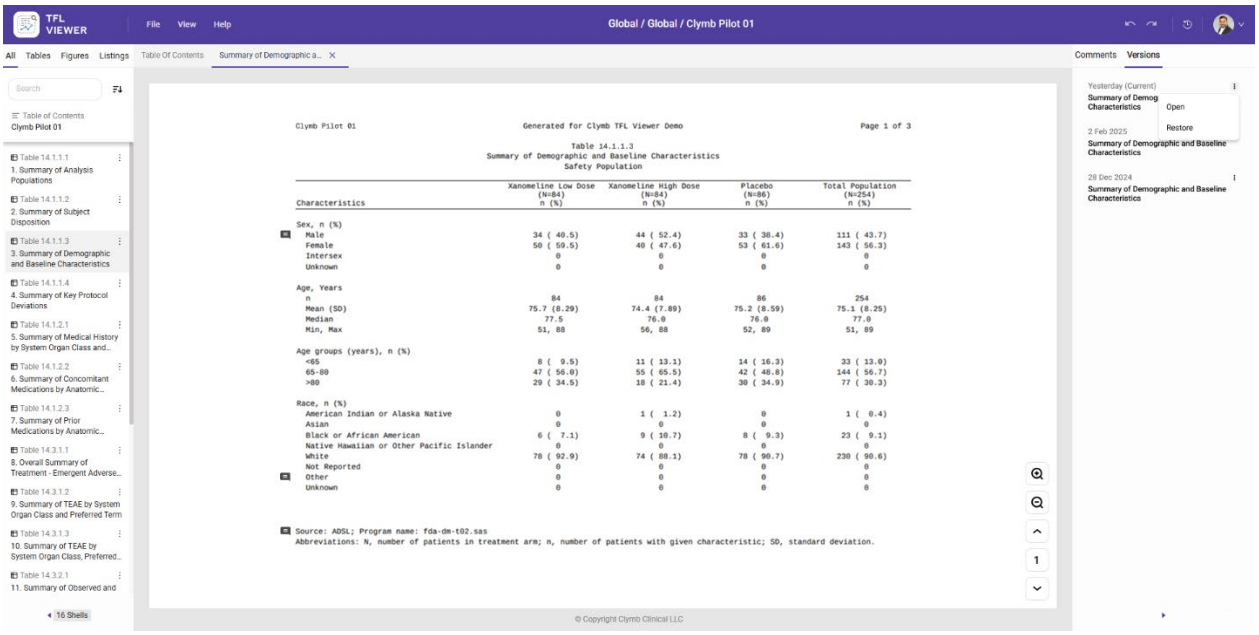

Figure 3: TFL Viewer Version control, Comparison, and Restore capabilities

TFL Viewer also enhances actionable feedback management, allowing comments and review notes to be stored systematically while providing task assignments and notifications for efficient resolution. Moreover, the tool could also integrate with statistical programming environments, streamlining workflows and supporting regulatory compliance.

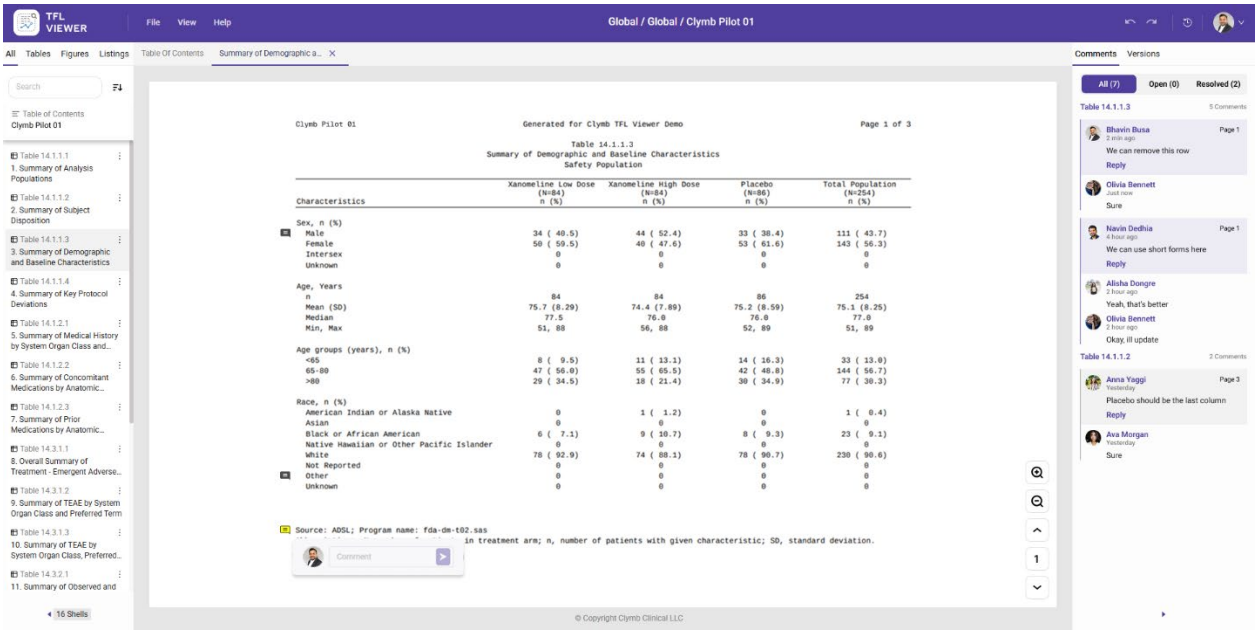

Figure 4: TFL Viewer Comments, Review, and Resolution capabilities

Additionally, export and integration capabilities facilitate seamless compatibility with existing statistical and regulatory requirements, ensuring that TFLs can be compiled into a single document (Word or PDF) for publishing.

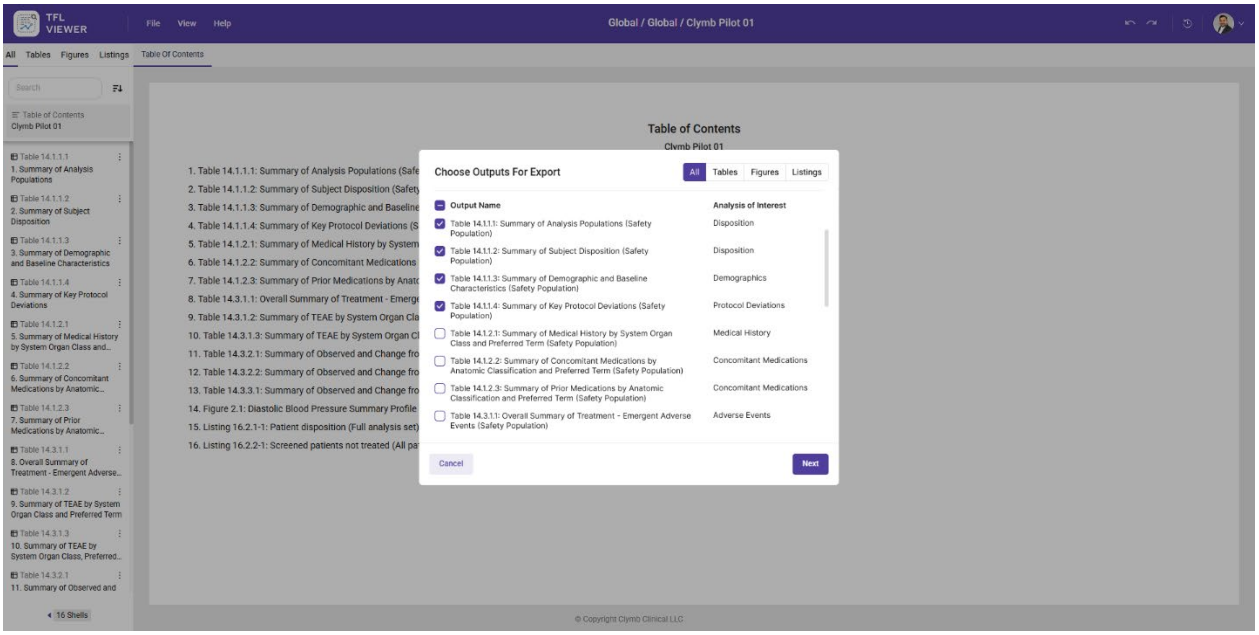

Figure 5: TFL Viewer Export of TFLs capabilities

Looking ahead, TFL Viewer will incorporate AI-powered enhancements, leveraging automation to generate statistical reports and sections of Clinical Study Reports (CSR). These forward-looking features will revolutionize the efficiency and accuracy of clinical trial documentation.

EMPOWERING INDUSTRY WITH SMARTER TFL REVIEWS

TFL Viewer provides numerous advantages to pharmaceutical and biotechnology companies by streamlining the TFL review and approval process. By accelerating review cycles, it reduces the time required for TFL approvals by up to 30%, enabling faster decision-making and improving overall study efficiency.

The platform enhances data quality by implementing automated validation checks that ensure consistency, compliance, and accuracy, minimizing errors that could impact regulatory submissions. Collaboration among cross-functional teams is significantly improved by centralizing feedback, reducing reliance on fragmented document-based reviews, and fostering efficient communication.

Additionally, TFL Viewer mitigates risks by maintaining a comprehensive audit trail and version history, supporting regulatory compliance through secure and structured document management. Lastly, it optimizes costs and resource allocation by reducing manual effort associated with feedback collation and version tracking, allowing teams to focus on more critical analytical and scientific tasks, ultimately driving efficiency and productivity in clinical trial reporting.

ADVANCING TFL AUTOMATION: CLYMB'S INNOVATION PATHWAY

Clymb is actively developing a Gen-AI-driven model designed to process study-level ADaM and ARD data. This model utilizes metadata to contextualize generated results in relation to patient-level data, enabling automated generation of key CSR sections. Additionally, it empowers users to interact with the results dynamically, allowing for in-depth exploration and drill-down into patient-level details to enhance data interpretation. Clymb is presenting on this topic at US Connect 2025, highlighting advancements in Gen-AI-driven automation for statistical reporting and CSR generation [5]. This presentation, led by Navin

Dedhia from Clymb, will demonstrate how AI and metadata-driven solutions, along with the CDISC ARS model and ARD, has the potential to advance efficiency and accuracy of clinical trial reporting.

Beyond TFL Viewer, Clymb is driving automation through TFL Designer, an advanced solution that utilizes metadata to generate ready-to-use R and SAS code for TFL and ARD creation. As part of this initiative, Clymb has developed two key automation tools: siera and atlas. Siera is an open-source R package designed to ingest ARS metadata and generate R scripts, enabling meta-programming and facilitating the automated creation of ARD and TFLs. In parallel, atlas, a SAS-based automation engine, equips users with ready-to-use SAS scripts for ARD and TFL outputs by leveraging Clymb's reporting macro library. At Clymb, we are aiming to modernize statistical programming workflows, enhancing efficiency, consistency, and reproducibility in clinical trial reporting.

CONCLUSION

TFL Viewer offers a centralized platform and streamlines the review and approval of analysis results. By providing an intuitive, collaborative environment equipped with intelligent navigation, automated quality checks, and version control, the platform significantly enhances efficiency, data integrity, and regulatory compliance. As the industry transitions towards metadata-driven automation, a solution such as TFL Viewer aims to support this evolution and provide integration capabilities with structured data formats like CDISC ARD in Dataset-JSON. Moreover, with AI-driven enhancements on the horizon, the platform is set to redefine how results are reviewed and utilized, paving the way for more efficient, automated clinical trial reporting and CSR generation.

REFERENCES

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CONTACT INFORMATION

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