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Verify: A First-in-Class Review and Validation Platform for Biometrics in Clinical Research

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ABSTRACT

Double programming of TLFs is one of many redundancies in the development and review of analysis outputs in clinical research. Overlapping review responsibilities begin with S&P and end with medical writing; iterative table review for each deliverable in each study; multiple disparate communication channels; each duplicative by design. The maintenance and perpetuation of each of these inefficiencies has direct time and financial costs, and indirect costs (burnout, turnover, boredom with repetitive tasks), which detract from a bottom line.

Verify provides a first-in-class, standalone suite of AI-enabled verification and validation checks and a process map designed to minimize silos and redundancies. Leveraging novel technologies that optimize the strengths of human and machine, Verify provides a platform to streamline TLF development, validation, and review cycles, enabling significant reduction in validation timelines. This demonstration provides an overview of Verify functionality, including new GenAI validation enhancements and extended tools for end-to-end QC management.

INTRODUCTION

The landscape of clinical validation processes is evolving rapidly as advancements in AI and data management reshape how statistical outputs are reviewed and validated. Verify is a comprehensive platform designed to address these challenges by providing a unified workspace for managing, developing, and validating statistical outputs. By leveraging Machine Learning (ML) and Natural Language Processing (NLP), Verify automates key aspects of validation, including format, within-table, and across-table consistency checks, while unifying communication and QC progress tracking into one collaborative platform. This reduces validation timelines, increases efficiency, and allows programmers, statisticians, and other subject matter experts (clinicians, pharmacokineticists, medical writers, et al.) to focus on more complex, high-order analysis tasks. In this paper, we delve into the limitations and challenges of the current state of clinical validation and how Verify addresses these issues.

CURRENT LANDSCAPE OF TLF VALIDATION

Despite the critical nature of ensuring accurate and timely validation, current methods are highly manual, time-consuming, and fragmented across multiple platforms. Below, we outline key obstacles that many organizations face in managing clinical validation and review, which underscore the need for more streamlined, automated methods.

LABOR-INTENSIVE PROCESSES

The review of TLFs, including double programming and visual review, is a traditionally resource-intensive process that has multiple SMEs doing similar, if not identical, types of review. This is a strategy that requires significant manual effort and time, which is inefficient and paradoxically leads to increased risk of human error. This dependence on manual review over programmatic solutions diverts focus from more critical analysis tasks. In addition, review tasks such as cross-validation and consistency checks are often performed iteratively, when a machine-driven process would be both more accurate and faster. Similarly, at the end of the review process, when time is most valuable in a deliverable cycle, human attention is most divided (over an entire TLF set), increasing the risk of detecting late-stage errors. Taken together, these factors can necessitate high-stakes rework and extend timelines, adding to the overall cost of clinical trials.

STUDY-SPECIFIC CONFIGURATION

Despite a standard framework for TLFs, each study often requires unique coding and configuration, making it difficult to standardize processes across multiple TAs and studies. Study-specific configurations further add to the complexity of validation efforts and hinders scalability and transferability.

FRAGMENTED COMMUNICATION

Communication across multiple platforms – such as emails, spreadsheets, and marked-up PDFs – creates fragmented workflows. This can lead to duplicate comments from multiple reviewers, versioning issues with updating outdated outputs and trackers, loss of institutional memory over long study phases, and delays in decision-making.

USING VERIFY FOR AI-ENABLED CLINICAL VALIDATION PROCESSES AND DYNAMIC COLLABORATION

EXTENSIVE AI-ENABLED VALIDATION CHECK LIBRARY

Verify transforms validation workflows by ingesting any number of TLF output files, supporting documents such as tables of contents (TOC), mock shells, and ADaM datasets, and converting them into a dynamic database. This enables automated validation checks that would otherwise require double programming plus manual review, and supports early-stage remediation of errors and discrepancies.

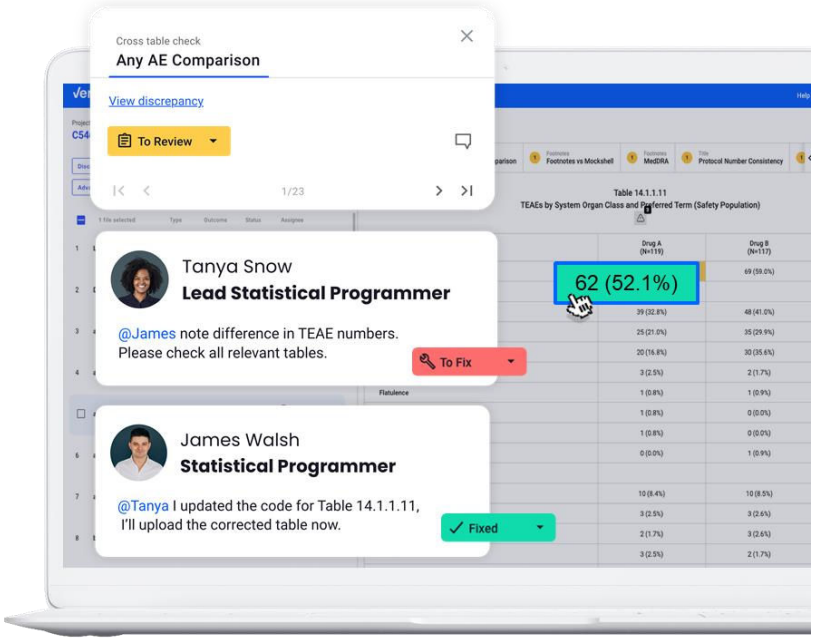
Verify's AI-enabled validation checks include:

- Format Checks, which validate format, titles and footnotes, and TLF structural characteristics.
- Reference Checks, which validate consistency of TLFs against reference documentation such as mock shells and TOCs.
- Within-Table Checks, which validate arithmetic and hierarchies within TLFs.
- Cross-Table Checks, which ensure cross-table consistency.
- Table vs. ADaM Checks, which validateTLFs using ADaM datasets.

REAL-TIME DYNAMIC COLLABORATION

The centralized workspace facilitates dynamic collaboration between users with all clinical review roles, ensuring that everyone has access to the most up-to-date information and minimizing delays caused by traditional communication methods. Users engage and communicate within Verify, including adding comments and feedback directly onto digitized TLFs, assigning tasks, sharing files, updating status and priority levels, and tracking overall submission readiness. Automated progress tracking helps eliminate multiple offline QC trackers by assigning files to users at each review stage and calculating overall progress based on user activities *within the Verify platform*.

All updates, actions, and changes are automatically recorded in the Activity Log, which provides a transparent record of validation processes and can be exported as a comprehensive audit trail. By maintaining immutable historical records of review actions and decisions, Verify aids in preserving traceability and institutional memory over long study phases, enabling continuity even when teams change.



AI-enabled validation checks identify discrepancies within and across TLFs. Within the Verify workspace, programmers and clinical reviewers view digitized TLFs and discrepancies identified by Verify, and assign remediation tasks in real time. Analysis and review activities are automatically recorded and saved within the platform.

THE ROLE OF HUMAN EXPERTISE

While AI and machine learning offer significant improvements in automation and efficiency, human expertise will always remain a critical component of the validation process. Verify recognizes the distinctions between skill sets that human experts and machines bring to clinical research and the high value that each adds. Verify supports biometrics teams in employing a balanced approach to clinical validation, wherein AI and automation handle the repetitive checking with the speed and accuracy best suited to a machine, and experts provide human-in-the loop (HITL) feedback and focus on higher-level analysis.

CONCLUSION

The clinical validation landscape is at a pivotal point where AI technologies are set to redefine how TLFs are developed and reviewed. Platforms like Verify are leading the charge by providing a unified workspace that not only automates routine tasks but also fosters transparent and traceable collaboration between stakeholders. The future of TLF validation lies in embracing these AI techniques to reduce manual errors, streamline processes, and significantly decrease validation timelines.

CONTACT INFORMATION

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