Session Report

Lean Writing Implementation: A Success Story

Speaker
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On May 3rd, Sarah Wilson, MS, shared her success story in transforming the writing workflow at her organization by streamlining the creation of Clinical Study Reports (CSRs), Clinical Study Protocols (CSPs), Investigator's Brochures (IB), and standard operating procedures (SOPs) to ensure compliance with the FDA's stringent requirements. This ultimately improved the quality and efficiency of document submissions. Sarah Wilson is the Director and Head of Medical Writing at Alkermes and a dedicated member of the medical writing community.

The Need for Change: As technology and regulatory processes advance, the need for more efficient and concise documentation becomes apparent. FDA reviewers no longer read documents from front to back but navigate electronically, focusing on specific sections. This shift required a new writing approach that prioritized clarity, efficiency, and quick accessibility. Additionally, the EU CTR 2014/536 transparency rule introduced a significant challenge by demanding previously confidential documents, such as clinical study protocols (CSPs) and clinical study reports (CSRs), to be made public. This required careful redaction to protect commercially confidential (CCI) and personally identifiable information (PII) without compromising transparency.

Step One included outlining the project's scope by revising templates for redundancy, updating style guides, implementing Quality Control (QC) and submission readiness checklists, creating a "drop-in" table process, and improving methods for delivery of tables, figures, and listings (TFL) and CSR appendices. As a successful visionary, Sarah knew she needed support within her organization. Thus, she identified stakeholders across critical functional areas and secured resources by emphasizing the long-term benefits of lean writing.

Step Two began with forming a cross-functional project team to set and finalize clear project goals with realistic deadlines.

Goal #1 was to update CSR, CSP, and IB templates using a lean writing approach, including use of crosslinks and hyperlinks to appendices, thus reducing redundancy and the risk of errors.

Goal #2 was to develop and implement the "drop-in" table process. The tables are in a ready-to-use format, which streamlines their integration into documents and reduces the need for extensive quality checks.

Goal #3 involved training new and established writers, biostatisticians, and QC members.

Step Three: Execution lasted 18 months, starting with the CSR template, "drop-in" tables, and corresponding SOPs. Then extending to the IB and CSR templates, and QC and formatting checklists.

Step Four: Adopting and Maintaining Lean Writing approach was accomplished through continuous training of personnel

within the entire organization and its departments. Regular training sessions ensured that everyone was equipped to adopt these new practices. Additionally, continuous improvement assessment was vital to gathering feedback from stakeholders and making ongoing adjustments. This iterative approach ensured that lean writing became part of Alkermes' documentation culture.

Step #5: Measure Success—The lean writing project at Alkermes significantly improved the quality and efficiency of their clinical regulatory documents, reducing processes from eight months to seven weeks.

The successful implementation of lean writing at Alkermes not only met regulatory standards but also inspired a more efficient and effective approach to document creation, motivating the audience with the potential for similar improvements in their own organizations and setting a new standard for medical writing excellence.

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