Streamlining eRegulatory Compliance: Integrating Single Source of Truth for Accurate Document Access Across Expansive Study Teams

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Introduction:

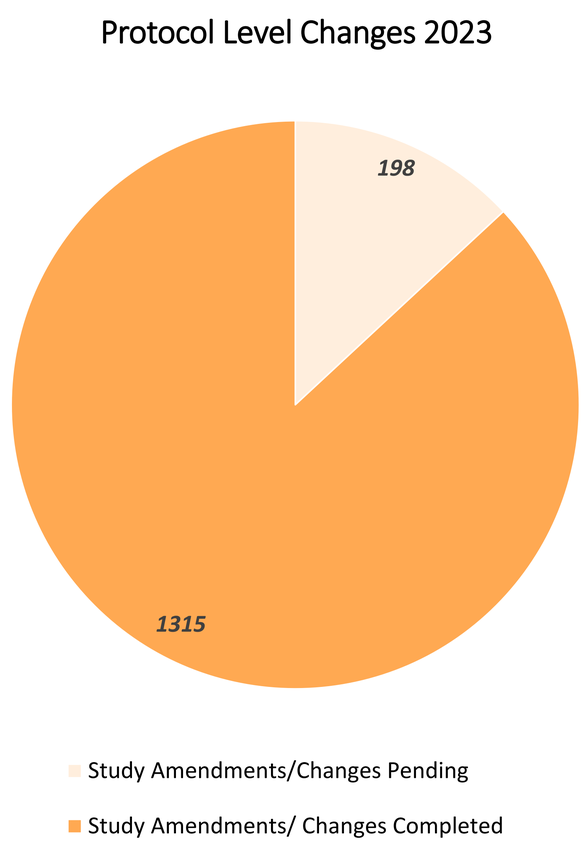
The efficacy of study operations hinges on the ability to access regulatory documents across various sites and stakeholders. This study explores the integration and implementation of an advanced eRegulatory system, and a clinical trial management system (CTMS) designed to be both accessible and precise within a network of clinical study sites. In close collaboration with WCG Velos and Complion, KUCC began working to integrate both systems for their network of sites, simplifying the process of making key documents processed by the Department of Regulatory Affairs readily available to study teams, as the current process included many duplicative steps with susceptibility to errors.

The integration proved crucial for streamlining the document management workflow, providing real-time access to accurate data without the traditional reliance on attaching newly approved documents to email correspondence and uploading documents in multiple systems, which is often time-consuming and prone to errors. This shift has significantly alleviated the duplication of effort, thus expedited the document retrieval process and reduced the risk of inaccuracies.

The findings demonstrate the transformative potential of integrated eRegulatory systems like Complion in enhancing the efficiency of multi-site clinical studies, paving the way for a more streamlined, error-resistant future in clinical research management.

Objective:

The primary objectives of this eRegulatory integration project were to achieve substantial time savings and a marked reduction in document-related errors. A pivotal goal was the seamless provision of access to accurate and up-to-date documents directly from Complion, thereby minimizing the duplication of document uploads which is inefficient and prone to error. With the implementation of this system, we aimed to manage over 1,500 study changes per year efficiently, streamlining operations across our network of sites and ensuring that our large study teams operate with the most current information without the guesswork.



Methods:

KUCC identified key documents to be linked from the eBinder to CTMS. Complion and WCG Velos collaborated to map these documents in their systems. When a key document has been identified in the ebinder by regulatory personnel, a link to the key document is automatically uploaded to the CTMS. This allows the study teams access to the most updated version in real-time. Key study documents identified for integration included the protocol, consent form, investigator brochure, patient materials, and 1572.

Outcome:

With this integration, our teams have efficiently managed over 1,500 changes in study
protocols and personnel, significantly saving time and improving document accuracy. We plan to provide an estimate of time savings per year in the poster presentation.

Future Directions:

From a project management perspective, the streamlined process ensuring all stakeholders have access to the most up-to-date information is a best practice that can be shared with other cancer centers and will benefit the greater community.