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Life Science's Process and Artifact Generation Automation

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ABSTRACT

A metadata-driven platform is paving the way for end-to-end automation of the Clinical Drug Development Process. Leveraging Artificial Intelligence (AI) and Machine Learning (ML) concepts with a focus on standards and metadata management, this platform aims to enhance the curation of metadata and streamline the delivery of artifacts ranging from protocols through Clinical Study Reports (CSRs). The primary objective of this platform is to have Subject Matter Experts focus on curation of metadata needed to guide the automated production of artifacts, that are generated repetitively as part of Clinical Study Lifecycle. This focus consequently enhances the value of the metadata and related transformations making it possible to extend the capabilities of the platform to cover additional artifacts, processes, and use cases.

INTRODUCTION

Clinical data operations, from data collection to analysis and submission is part of the larger Clinical R&D process. Historically, while this process has always been driven by metadata, this metadata has been derived manually by study team members and consumers. As an example, the clinical trial protocol is reviewed and from it is pulled details relevant to various study team members in guiding their activities and the generation of related artifacts. These manually generated details (as specifications) require review and approval. The generation of the artifacts themselves (e.g., Case Report Forms (CRFs), database screens/tables, datasets, TFLs, various reports including CSRs) has also been manually generated thereby requiring independent methods of QC/validation adding further to the time and cost of production.

The challenges associated with proper and timely metadata management alone are enough to discourage those looking for greater efficiency and quality of clinical study lifecycle deliverables. But it IS possible. It is not in the distant future.

DEMONSTRATION

This presentation will demonstrate a platform capable of achieving both enhanced quality and streamlined efficiencies across several different artifact-generation processes including:

- **METADATA MANAGEMENT**

  Metadata management is a critical support function of this automation platform. Metadata is gathered, governed and maintained in a custom metadata repository as fuel for automation. To support generation of artifacts, metadata is of both structural and transformational types. Programmers accustomed to coding, see this useful and effective as "coders of metadata" or metadata curators where their contributions are leveraged potentially across the entire platform and study lifecycle. Their expertise is essential to ensuring that metadata-driven transformations are properly defined and tested in the platform.

  The platform performs automatic impact analysis for any change requests proposed. It also curates publicly available literature and previous request history for better comprehensive decision support. This process is more efficient, supports quick-decision making and becomes less error-prone.

  Flexibility still exists within the platform to allow for study-specific deviations or for the introduction of new entities/attributes; however, governance tools enable metadata governance team members to identify these altered/new items in deviations reports. Both deviations and impact analysis reports are interactive and allow reviews/recipients to initiate deviations management, e.g., proposing deviations be introduced as updates (versioned) to the standard, allowed as deviations, or reverted to comply with the standard. Impact analysis reports

allow for those impacted by an approved change to choose to accept or to reject the update for their projects and/or other hierarchical levels of the repository.

- **DATA MAPPING, DATASET GENERATION AND ANALYSIS**

  Mapping datasets, e.g., raw to SDTM (or SDTM to ADaM), is another time-consuming task supported by this automation platform. With AI-enabled technology, automapping (or automated generation of dataset specifications to get from source to target) is not only possible, but also becomes increasingly intelligent via guided, supervised learning with use over time, reducing time to generation as well as the QC cycles required.

  The platform has considered functionalities to automate the process of generating both ADaM and TFLs platform macros and transformational metadata to support ETL-like conversion processes. Every step of the conversion process is traceable and documented.

- **DATA VISUALIZATION**

  While data visualization may be worth more than a thousand words, users of this platform also would appreciate, how data entity recognition can be leveraged to recognize data and propose the most commonly/effectively used Data Visualization reports.

CONCLUSION

Advancements in technology are making it possible to combine high-powered servers with effective metadata management and AI-enabled software systems into a powerful automation platform capable of supporting highly efficient artifact generation. This platform addresses large amount of the historically manual and repetitive processes typically associated with artifact generation off-of regurgitated metadata originated in the protocol. By leveraging this metadata directly and using a combination of both structural and transformational metadata, artifacts can be generated more quickly and with a greater degree of accuracy. With a focus on metadata as fuel for this automation platform, the quality of the metadata is of primary concern and lies at the front of the platform. This enables artifacts to be generated earlier in the study life cycles, allowing more time for data review and analysis, and potentially for extending the platform coverage to support additional use cases/capabilities.

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DISCLAIMER

The scope of this paper is to present the opinions and suggestions of the authors. The interpretations of standards and procedures contained in this paper are those of the authors only. Any views and recommendations stated within this paper are those of the author, and they do not represent the position of Geninvo.

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