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Leverage Automation to Accelerate the Creation of Submission Ready Artifacts

Serena Peirson, Accenture, New York, USA
Lourdes Devenney, Accenture, Pennsylvania, USA

ABSTRACT

This paper describes the current landscape on how users reach "submission ready" artifacts and how current process/resources can be leveraged to automate the use of metadata across the full clinical trial process not just to support submissions. Through our experience in collaborating with multiple pharma organizations to deliver automated-metadata-driven processes and SCE products, we are in a unique position to present a broad and deep industry-wide perspective enabling in-depth discussion within the landscape and the future direction of the industry. The paper also presents how the Life Sciences industry "currently" creates these deliverables and introduces some of the newer ideas organizations have been entertaining. Ultimately, we will discuss a view on how to reach true automation leveraging governed metadata, to enable metadata-driven processes throughout the entire clinical trial lifecycle, resulting in decreased cycle times leading to submissions.

INTRODUCTION

The industry is amid a progression from current state to the future desire enabling full automation through the re-use of Industry Standards across the clinical trial life cycle – not just for submissions. Organizations can define metadata upfront providing the ability to accelerate the generation of "submission ready" artifacts earlier in the process while decreasing cycle time for submissions. This paper explores considerations for achieving automation of submission ready artifacts using standard data definition metadata.

STATUS QUO

Most organizations outsource study management; however, organizations may have a mix of internally-managed and outsourced studies. Unless organizations have a relationship with established or preferred vendors for the majority of their studies, they are presumably leveraging a small macro library and doing one-off programming for study specific outputs. These outputs are typically produced based on database lock milestones.

Organizations are currently performing some of these activities during the Study Lifecycle:

Protocol authoring is done manually.	Standard Libraries are housed in individual operational systems (e.g. Data Collection in EDC, TFLs in a Macro Library or SCE.)	Study Teams work in reactionary mode vs. indicative or predicative management.	Downstream activities for close out are done per Lead per operational system.	Submission inventory is done in separate systems than Study mgmt.
Inputs to the Protocol are done via conversations and meetings with SMEs.	Metadata and Data Traceability are hard to establish since many operational systems support one Study.	Little visibility across operational systems on impact of change.	Close out requirements across systems is managed manually and independently.	New technology benefits are seldom taken into consideration for submission artifact packaging.
Inputs for Study Design are done via manual and individual research.	Impact Assessment for Study changes/amendments are done manually.		System reconciliation is a manual and massive effort.	
Inputs for Study Population, Design and Schedule of Activities are done in silos.	Studies are built manually in each operational system.			

UPON THE HORIZON

Teams are entertaining efficiency options such as the use of macro/program libraries agreed upon within each organization. Teams are also introducing the use of metadata to enable efficiencies, such as automation, and drive programming of individual standards. These efficiency activities may affect automation of only some parts of the Study Lifecycle and are seldom maximized and leveraged across Teams, activities, and systems.

FUTURE STATE

The production of any Study artifact can be automated based on the metadata traceability and Study requirements. Teams have the ability to identify end-to-end metadata traceability by leveraging historical information, Standards and existing libraries to attain automation of Submission-Ready Artifacts.

During Study Design, a requirements are identified to assess viability of the Study.. Objectives, endpoints, rationale, participants' intervention groups and duration are defined as part of these requirements. Study Design is the first place where Teams may leverage inputs from their organization and industry to perform early definitions of metadata. Innovative technology may be used to look across these inputs and establish a foundation for defining traceability of data collection and analysis reports to be produced by the Study.

Study specific input data and criteria that will dictate the setup, conduct, analysis and reporting activities in aid of the study objectives while also supporting metadata and mappings that define relationship and transformation paths to convert each piece of information into the downstream outputs for systems such as Electronic Data Capture (EDC) and Statistical Computing Environment (SCE).

Organizations that store and govern this metadata can constantly enhance the Library with end-to-end metadata traceability leveraging each Study requirement. Automation can then be realized for areas that are core to a Study as well as those areas that are predictable and where metadata traceability is defined.

Through the creation of metadata and data traceability upfront, teams can generate a high percentage of Study artifacts such as Define-XML, Annotated CRFs, SDTM Domains, ADaM Datasets, and TFLs earlier in the process, in addition to maximizing collaboration for producing Study Startup artifacts while patient data is being collected.

The Study Lifecycle in the future state relies on continuous learning and machine learning:

Study Design	Study Start up	Study Conduct	Study Closeout	Submissions
Authoring of Protocol and other Study artifacts can be automatically created using historical information, Study requirements, and metadata traceability	One source of truth for Standards Library	Study Teams concentrate on continuous enhancement of the Standards Library and predicative management	Close activities across operational systems are centralized and simplified using technology to review and track for completion	Content for Submission artifacts has been reviewed throughout Start up and Conduct Phase, thus streamlining finalization process
Access to historical information facilitates Study assessments and foundation for Study Start up	Metadata and Data Traceability are pre-defined and a Library is maintained based on continuous machine learning	Visualizations across operational systems and across Studies is possible	Reconciliation across systems is automated using metadata traceability	High percentage of Artifacts can be produced automatically in submission-ready format
Collaboration is maximized with the use of innovative technologies	Impact Assessment shows gaps and risks for the end-to-end data flow automatically based on Library references and traceability	Change Management is done as a result of Protocol enhancements and not for omissions or lack of analysis and reporting traceability		
Predictive modeling of the Study is automated using Standards Library and historical information	A high percentage of Study build is automated from pre-defined Study Specifications using Standards metadata and traceability	Review of Submission artifacts is done early in the process thus preventing delays		

CONCLUSION

When organizations understand the trend across similar Studies and start leveraging a baseline set of metadata, they can then utilize metadata Standards to create submission-ready artifacts earlier in the process. Organizations can also then re-allocate resources to support more complex and study-specific analyses and reporting requirements. These process and organization enhancements would significantly decrease cycle time for submissions while utilizing resources more efficiently.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the authors at:

Serena Peirson
Accenture – New York, USA
Serena.peirson@accenture.com

Lourdes Devenney
Accenture – Pennsylvania, USA
Lourdes.devenney@accenture.com