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Study Builder: Centralized Study Specifications from Data Collection to Reporting

Jenna Lo, Accenture, Boston, MA USA

ABSTRACT

There are many challenges with study design and build today, including the extensive time it takes to draft study specifications and build operational systems. Unfortunately, there is a lot of time wasted on manual activities, communication inefficiencies, and dispersed inputs. How can these challenges be addressed so that treatments and cures can be delivered to patients faster? Accenture has been working with several major pharmaceutical companies to develop and build a new product called Study Builder. Study Builder will provide a centralized location for creating study specifications from data collection all the way down to reporting.

INTRODUCTION

The purpose of this paper is to describe Accenture's vision of the Study Builder product – a tool with three major goals:

1) Facilitate collaboration and outcome driven study design
2) Leverage automation to drastically accelerate standards-driven specification generation and operational system build time
3) Establish an end-to-end traceability and automation framework to track and produce deliverables from protocol through to submission artifact.

This vision was developed in collaboration with several major pharmaceutical companies to address key challenges study designers and builders experience today.

CHALLENGES WITH STUDY DESIGN AND BUILD TODAY

Drug development, starting with discovery and ending with higher quality of life in patients, is a very long process. This has created many initiatives toward reducing this time and cost and creating more streamlined processes so that treatments can be delivered to patients faster. One step in the drug development process is study design. Currently, it is taking a very long time to draft study specifications and build the operational systems once a protocol has been approved (~2 months!) due to manual efforts, communication inefficiencies, and dispersed inputs. This bottleneck leads to…

MANUAL ACTIVITIES

There are many activities in the study design and build lifecycle that are being performed manually. After a protocol has been approved, key information for study design is manually transferred from the protocol document to the study specification draft. If there are any amendments to the original protocol document, a complex impact assessment to downstream activities and documents is performed by a person. After the study specification has been approved, the corresponding operational systems are built manually by data managers and programmers. These manual efforts pose risks to human error and potential discrepancies between the approved protocol, study design, and operational systems, which can lead to lost traceability between important deliverables and undesired audit findings. Also, manual efforts contribute directly to the extensive duration of these processes.

COMMUNICATION INEFFICIENCIES

Many components as well as stakeholders are involved in the study design and build lifecycle which are typically allocated to multiple groups of individuals based on their expertise. Although this work may be appropriately allocated, there is inefficient communication across these groups. Document reviews and comments are facilitated via email, which has led to overwritten updates and lost decisions and change tracking.

DISPERSED INPUTS

Standard forms, data models, codelists, and other key standards are developed and maintained by a special group within companies. The intent of these standards for study design and build is to provide a starting place for the study specification and save time. However, extra time is wasted on transferring these standards from other operational systems into the teams' work areas. Study designers and builders are not aware of all standards available to use and are creating new forms when one may already exist. Moreover, since these standards libraries live in a separate area or system, many companies are unable to link their standards to the specification process in real-time, which has led to creating an additional standards library

in their downstream operational system. In this case, companies face the challenge of maintaining two standards libraries which has a risk of falling out of sync.

HOW CAN THESE CHALLENGES BE ADDRESSED?

It is an exciting time in technology. Automation and machine-learning can be leveraged to reduce the manual effort needed for any particular activity. Latest technology has enabled the ability to create a system to facilitate a more collaborative environment for all teams as well as integrate with existing systems so that all components can be accessed and viewed in one place. The combination of automation, machine-learning, and custom systems with built-in integration has fueled the concept and vision of Study Builder.

STUDY BUILDER VISION

Study Builder is a system where study designers can import protocol information and access standards needed to design a study. It is also a dedicated place for all teams to view study specifications needed to build operational systems. After these specifications have gone through a draft, review, and approval cycle, this information can be used to automate the build of operational systems via a machine-readable study specification. Since Study Builder is tying together study design, study specification creation, and operational system build, this will enable clearer traceability from the protocol all the down to the individual artifacts of a study.

DESIGN THE STUDY

Study Builder will streamline steps in the study design process for study designers. Study attributes and protocol requirements such as schedule of activities can be loaded into Study Builder through the master data management system, or via a file upload to easily populate what has been defined for the study. Once these attributes are available, study designers can review and make updates as needed through a user-friendly user interface where all updates are audited. By providing this mechanism to upload study attributes and protocol requirements, this will reduce the amount of manual effort that needs to be executed by the study designer and leave more time for other activities. Moreover, objectives, endpoints, and inclusion/exclusion criteria included in the protocol requirements can be used to as a starting point for creating the trial design domains (e.g. Trial Summary (TS)), which saves additional time for the study designer.

CREATE SPECIFICATIONS BY LEVERAGING EXISTING STANDARDS

Study Builder will help facilitate the creation of the DAS, DRM, and SDTM specifications. Standards such as edit checks, data review models (DRMs), and SDTM datasets can be ingested into the Study Builder system and associated to corresponding specifications. These standards can be integrated from any metadata registry (MDR) system for a seamless sync enabling the study designer to create the specification and associate standards in one localized place. Once the draft is ready, reviewers and approvers will be able to perform their activities in the Study Builder tool. Approved specifications along with operational metadata can be exported out of Study Builder and sent directly to the data managers to initiate build of the operational systems needed.

AUTOMATE BUILD OF OPERATIONAL SYSTEMS

Since there is a tight link from the ingested standards to the approved specifications, this information can be leveraged to automate the build of the operational systems, saving even more time in the study design and build process. In addition, to ensure compliance between the protocol, study design, specification, and build, Study Builder will provide a capability that allows users to generate a comparison report to address any unexpected discrepancies that may occur during these workstreams.

CURRENT PROGRESS

Due to this shared interest and priority in addressing these key challenges, Accenture has kicked off discussions with several major pharmaceutical companies and started product development activities.

ACCENTURE LIFE SCIENCES CLOUD (ALSC) COALITION

The ALSC Coalition is a group of pharmaceutical clients that work with Accenture on endorsing business objectives and proposed strategic initiatives for the ALSC's platform of technologies and products. Based on the priorities Accenture has heard from the ALSC Coalition, Accenture has jump started discussions for Study Builder. Accenture is currently working on confirming use cases and high-level features for the first version.

AGILE METHODOLOGY

Accenture is implementing Agile Methodology for the product development of Study Builder with heavy engagement from the ALSC Coalition. Prototypes will be developed and shared at a high frequency, and then translated into beta releases for hands-on user experience, feedback, and alignment.

CONCLUSION

Accenture is targeting to address challenges that are faced in study design and build today by working with the ALSC Coalition to build the Study Builder product. Study Builder will facilitate collaboration and outcome driven study design, leverage automation to drastically accelerate standards-driven specification generation and operational system build time,

and establish an end-to-end traceability and automation framework to track and produce deliverables from protocol through to submission artifact.

CONTACT INFORMATION

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

Jenna Lo
Accenture – Boston, MA USA
jenna.lo@accenture.com