Executive Summary

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TransCelerate's Digital Data Flow Solution Framework and Conceptual Design

Contents

Introduction:

This document describes a potential Solution Framework and Conceptual Design that would optimize processes and automate asset development from study concept finalization through study start-up (SSU). This package articulates the overall vision for the solution and will enable technology providers to create an innovative, central protocol platform that will be accessible, open, flexible and vendor-agnostic toward downstream clinical applications.

The solution we advocate would enable interoperability across multiple systems in a clinical study, improve efficiency and data quality, and reduce cycle times. It is our intention that this platform will eventually form the center of a broader ecosystem of applications, which will include upstream data sources to inform study design and modeling, and downstream systems to manage studies, collect data and report study results.

Purpose:

The short-term aim of TransCelerate's Digital Data Flow (DDF) initiative is to optimize study SSU processes and automate system configuration and readiness.

The Solution Framework and Conceptual Design document is the first description of the proposed study start-up digital data flow solution and will serve as the basis for further design work, and prototyping of solutions. The Solution Framework describes the scope of the design and ten key design principles to be followed. The Conceptual Design includes descriptions of key features, processes (user narratives), the common data model, and the system architecture.

Current State:

The current state typically involves disconnected study design services and assets, and transcription or re-entry of the same information into many systems across Sponsors, Contract Research Organizations, and vendors. The SSU workflow is not automated, which makes it inefficient, redundant and increases risk of error. Sponsors are not able to utilize resources efficiently due to the siloed, document-based environment. This inefficiency results in systems configuration falling onto the critical path for study start-up and adds risks for transcription errors and unnecessary delays.

Solution / Future State:

The future technology solution would enable interoperability across multiple systems in a clinical study, improve efficiency and data quality, and reduce cycle times. The proposed system would capture digitized protocol elements and present them in standardized formats to enable automated configuration of downstream systems and efficient consumption of protocol information across the study ecosystem.

The platform of solutions would:

- Automate the workflow for configuration of all systems that support both data collection and study operations.
- Utilize a study builder to capture structured elements of a study protocol including Study Objectives, Endpoints and Schedule of Activities (SoA).

- Link the study builder to a study design repository that would store therapeutic area (TA)-specific standard design templates and other elements in a Common Data Model.
- Enable the use of simulation and machine learning to support protocol designers by leveraging operational data, real world data, or historical clinical study data or other knowledge bases from internal or external data sources.

A Common Data Model (CDM) would constitute a key component of the platform, enabling the platform to be utilized by different study sponsor organizations and a broad range of vendor types and vendor systems. Utilizing controlled terminology will be critical in order to facilitate downstream automation.

The initial, principal release of a DDF platform should support automated study-specific configuration of the Electronic Data Capture (EDC) system.

Subsequent releases should expand this scope to include additional systems:

- Other data collection (for laboratory or non-CRF data)
- Clinical Trial Management System (CTMS)
- Interactive Response Technology (IRT)
- Electronic Trial Master File (eTMF)
- Project- or resource management systems (Portfolio Project Management).

The platform architecture supports extension to a broader spectrum of potential data sources and client systems and a broad range of use cases including, for example, “downstream” outputs into study documents (e.g., Clinical Study Reports) and applications such as trial registries, eConsent, the Shared Investigator Platform. The architecture should also support inputs from a variety of “upstream” sources, as mentioned above.

Solution Framework:

TransCelerate’s DDF project expects to enable development of a core technology platform (study builder, study design repository, and connections from the builder to the design and other metadata repositories). This platform will eventually form the center of a broader ecosystem of applications which will include upstream data sources to inform study design and modeling, and downstream systems.

We envision that a study builder would provide an interrogative user interface and have modular architecture to provide flexible integration to sponsors’ existing technology platforms. Additionally, the platform must be system agnostic, with all content and transactions exposed via open application programming interfaces (APIs).

Conceptual Design:

In order to facilitate automated study-specific systems configuration, a study builder platform would be required to assemble structured study elements from existing standards repositories according to the study design. User narratives describe the technology-enabled business process the platform will support, as well as the associated data flows.

Implementation of the described study builder would constitute a significant shift to current practices, allowing study teams to begin work in the platform much earlier, and would require data managers and systems specialists to maintain libraries of pre-specified study objects and design elements.

Interfaces to Collaborative and Initiatives:

This initiative is being developed in collaboration with CDISC and their 360 Project, as well as other ongoing engagement with many other relevant internal and external initiatives. Particularly germane initiatives include TransCelerate's Common Protocol Template (CPT) and eSource projects, and the International Council for Harmonization's M11 work on "Clinical electronic Structured Harmonized Protocol (CeSHarP)."

Conclusion:

The study builder platform will enable the automation of critical portions of SSU workflow to increase efficiency and decrease the risk of error. It will also enable sponsors to utilize resources more efficiency by eliminating redundant activities that stem from the current siloed, document-based environment.

The project would also create an incentive for sponsors to rigorously adopt existing data standards, consistent terminology and design templates. Such alignment to standards would enable technology vendors to develop solutions that would meet the needs of a broad range of study sponsors.

Furthermore, we envision that the DDF study builder could form the center of a broader ecosystem of technology solutions that will evolve over time. In totality, the visions expressed by TransCelerate's DDF project team, and the Solution Framework and Conceptual Design, offers an opportunity to finally transition from the manual, repetitive, SSU processes of the past, to a truly digital, automated future achieved by other modern industries.