Digital Data Flow (DDF) Initiative Overview

The Digital Data Flow (DDF) Initiative aims to catalyze digital transformation; breaking the protocol document paradigm to enable seamless data flow

Digitized Protocols

Enabling the use of technologies that identify and assemble study elements using a common, industry-standard digital language allows industry to move to digital protocols

Advanced Analytics

Better enabling the use of advanced analytics such as Artificial Intelligence and Machine Learning to improve study designs

Connectivity of Data and Processes

Enabling traceability, automated flow of content to key clinical documents, and automation to clinical & operational systems (e.g.. EDC, CTMS)

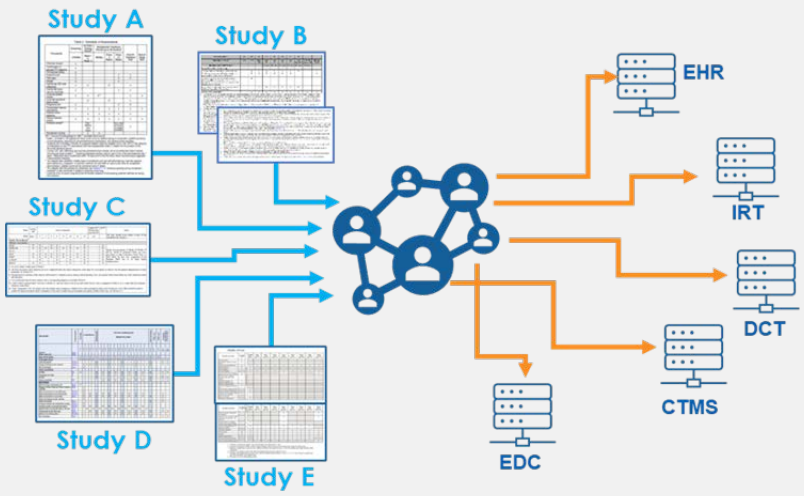
Open & Flexible Solution

A functioning, example solution to enable exchange of protocol info between systems that is vendor agnostic, flexible, and provided in open source

VISION: From Documents to Data: Write Once, Read Many Times

TODAY

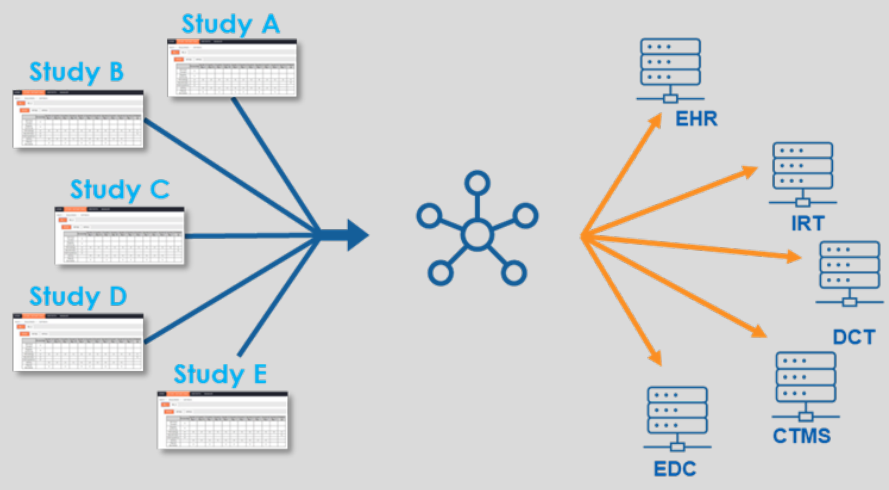
Many-to-many manual process; Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems



- *Schedule of Activities (SoA) specified **inconsistently** in study protocols (e.g., sections, rows, columns, footnotes)*
- ***Manual** process to configure systems/tools*
- ***No reliable method** to synchronize updates from a single source of truth*

TOMORROW

Digitalized one-to-many process; Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems



- ✓ ***Digitized design** specification per study*
- ✓ ***Consistent** method of study spec exchange*
- ✓ *Streamlined, **automated** start-up (reduce effort, cycle time, and complexity)*
- ✓ ***Improve** quality and compliance. Minimize protocol violations*

TransCelerate BIOPHARMA INC.

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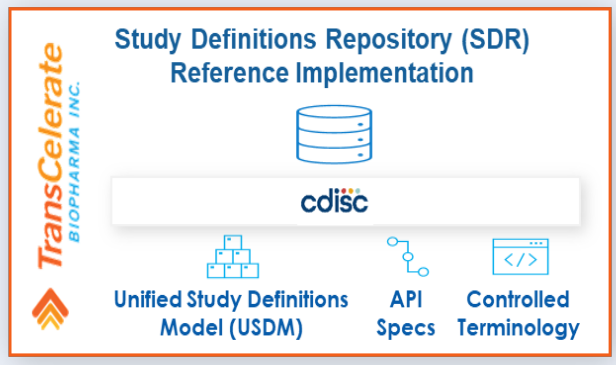
Understanding Key Concepts

The Digital Data Flow Initiative offers a **mechanism to digitize clinical study components** to enable interoperability and reuse, starting with study design.

In collaboration with Clinical Data Interchange Standards Consortium (CDISC) and other stakeholders, TransCelerate has developed a standard data model that creates **a new digital language for specifying protocol information**, as well as a **demonstrated way to connect systems** that produce, exchange or consume this information.



Unified Study Definitions Model (USDM)

An industry standard for study definitions (protocol information) promulgated and maintained by CDISC

Study Definitions Repository Reference Implementation (SDR RI)

A functioning, example approach that utilizes USDM to manage the information flow of protocol data between upstream and downstream systems

Study Builder/ Digitized Study Design Solution

An application or piece of software utilized by a study team to design a study and/or author a study protocol

Controlled Terminology

CDISC developed set of codelists and valid values for terms used in a study

Application Programming Interface (API) Specifications

CDISC developed coding language to connect and exchange data between systems

Biomedical Concepts

CDISC and other organizations developed definitions of discrete units of biomedical information that would need to be measured for a study participant

Key Focus Areas on the DDF Roadmap

Digitization of Study Elements and Downstream EDC Automation (Current/Completed)

- ✓ Support electronically populating and configuring EDC/CRFs based on the digital protocol specification
- ✓ Use digital protocol specification to demonstrate (as a proof of concept) the population of elements in a human readable protocol document

Complete Protocol Digitization & Regulatory Alignment (In Progress)

Includes collaboration through HL7 Vulcan Working Group between ICH M11 & CDISC

- ➢ Complete (100%) digitization of all protocol elements in alignment with M11 and relevant CDISC SDTM domains
- ➢ Begins with gap analysis between USDM and ICH M11 content model, CDISC SDTM, and Global Trial Registry Reporting
- ➢ Goal to capture "breadth" of ICH M11 completely within USDM, followed by greater "depth" of structured content within model (e.g. structured I/E criteria)

Expand Downstream Connectivity (In Progress)

Includes collaboration with expanding community of tech solution providers across range of clinical solutions

- ➢ Further develop USDM to enable downstream connectivity with priority systems, enabling a future state of "write once, read many times"
- ➢ Work collaboratively with vendor ecosystem to better understand existing gaps & development requirements for the USDM

Alignment with Point of Care (In Progress)

Includes collaboration with Vulcan FHIR Accelerator

- ➢ Comparative assessment of USDM and FHIR
- ➢ Alignment of DDF and FHIR resources for end-to-end enablement of EHR workflow set-up and eSource