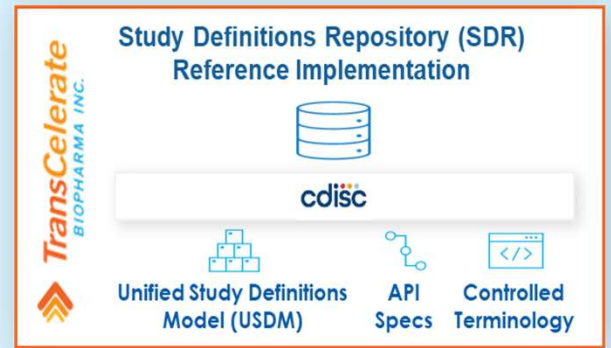


The Digital Data Flow Initiative offers a **mechanism to digitize clinical study components** to enable interoperability and reuse, starting with study design.

In collaboration with TransCelerate and other stakeholders, Clinical Data Interchange Standards Consortium (CDISC) 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 utilizing standards to manage information flow of protocol data between upstream & 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

Conformant Systems

Systems that provide and expose a conformant implementation of the USDM API specification and all conformance rules – such a system is able to ingest and/or produce USDM conformant data, facilitating interoperability with other conformant systems. Systems can achieve conformance through internal data re-design, or through the implementation of an Adapter at the system interface

Consuming Systems

Systems that consume digitized protocol information in order to execute a study start-up or study execution task based on the study definition (e.g. EDC, CTMS, Data Hubs)



Repositories

Systems that store information and provide it to other systems/processes which use it to perform a task (e.g. Meta Data Repository (MDR), Data Hubs). May perform a role in governing study metadata



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