Paper DS07

The Revolution of Digitized Study Designs: Standards, Use Cases and Tools

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ABSTRACT

The TransCelerate Digital Data Flow project is focused on enabling downstream automation by digitization of study designs. Their collaboration with CDISC in this project resulted in a new CDISC data model called the Unified Study Definitions Model (USDM), which is directly linked to other standards like SDTM, IDMP, ICH M11, and more. Further collaboration with Vulcan and ICH is aiming at showcasing how the digitized study design information can be submitted in ICH M11 format.

This paper aims to give an expert view on how the USDM can be utilized in the study design and protocol writing phase, and how it enables automation of a number of downstream processes like EDC set-up, creation of SDTM submission datasets and EHR to sponsor processes.

INTRODUCTION

For many years now, our industry is preparing the designs of a clinical study in a document format: the clinical study protocol. This protocol is subsequently interpreted by different downstream processes like operational processes, site monitoring, data management, data analysis, and reporting. The resulting interpreted details of the study design information are then stored in corresponding solutions dedicated to the specific process.

This manual interpretation process takes time and is typically repeated for every process. Moreover, the textual interpretations for different processes can result in errors and discrepancies between processes. This may result in protocol deviations and extended time needed in the submission phase to resolve discrepancy issues.

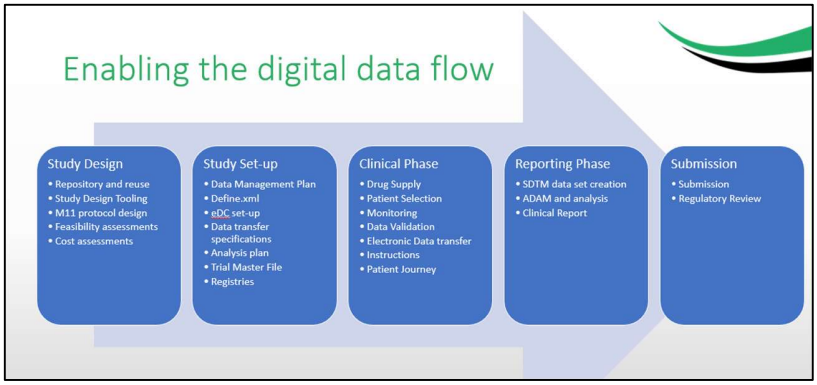
The above issue was recognized by the pharmaceutical industry around 2019 resulting in the TransCelerate Digital Data Flow project (DDF). The project recognized that an industry standard for study design would help in enabling the digitized study design and the system agnostic exchange of information between systems. For this, CDISC was engaged in 2021 to build the Unified Study Definitions Model (USDM), together with a corresponding API and controlled terminology. In 2025, version 4.0 of this model was released. This version is seen as the first stable version covering all different aspects of a study design. The industry is now in the stage of adoption of this data model.

Around the same time that TransCelerate started with the DDF project, also regulatory agencies joined with ICH to develop a protocol template to inform the industry of their study design requirements and improve the efficiency in evaluating study designs. This resulted in the ICH M11 guideline including the corresponding protocol template and technical specifications. The USDM data model is aligned to different standards including ICH M11, but also CDISC SDTM, IDMP, CTIS, ClinicalTrials.gov and FHIR.

USDM USE CASES

As presented in Figure 1, the USDM enables many digital data flow use cases in different stages of the clinical study process. The mentioned use cases in this figure are not exhaustive. However, it shows how a uniform data model and corresponding agnostic exchange mechanism can support many different activities. CDISCs 360i project that started in January 2025, uses USDM as well as a starting point to enable and automate the data flow from design to submission

Figure 1: USDM Use cases



REPOSITORY, REUSE, AND DESIGN AUTOMATION

The USDM is designed to store specific study details. However, to ensure consistency within and between studies, it is evident that a repository is needed to store the preferred or required configurations for a company, therapeutic area, or intervention.

The USDM is logically structured to include the relationships between different information items and is therefore well-suited as a basis for repositories. When utilized for a specific study, the corresponding structure can then be copied, and no additional mapping is needed.

Repositories based on USDM structures that might be beneficial in this aspect are:

- Objectives & Endpoints
- Populations & Eligibility Criteria
- Biomedical Concepts
- Procedures
- Interventions
- Timings
- Document structures (like M11)
- Estimands

For example, when an Objectives, Endpoints repository is built then the relationship between them is included. Moreover, the endpoint can already be linked to the corresponding assessment in the form of a biomedical concept and the corresponding digitized timing information. The selection of this endpoint then subsequently can inform the basic build of the schedule of activities as it includes a required assessment and a required time point for the study. Likewise, selecting specific eligibility criteria may inform corresponding screening assessments to be included in the schedule of activities.

During the ClinLine Break & Learn webinar of February 2026, we talked more about how to build a modern flexible repository. See https://clinline.org/break-learn/ for the 30-minute recording.

FEASIBILITY ASSESSMENTS

Other USDM use cases that have a lot of interest from the industry, are the study feasibility assessments. If you dive deeper into this topic, you will learn that study feasibility assessments in general include different aspects like costs, patient burden, and patient recruitment feasibility.

The study costs and patient burden can be estimated based on the digitized timings and assessments stored in USDM. The patient recruitment feasibility can be based on the number of patients that might be eligible for a clinical trial which is defined by the eligibility criteria. Depending on the strictness of these eligibility criteria, more or less patients can be included. By digitizing these criteria using the USDM syntax template capability, information sources like site patient databases, electronic health records, and registries can utilized to calculate the number of patients that are likely to be eligible for the study. Our white paper for the US Connect in 2025 gives more detail on how this can be achieved (See chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://phuse.s3.eu-central-1.amazonaws.com/Archive/2025/Connect/US/Orlando/PAP_RE03.pdf).

EDC SET-UP AND SDTM DOMAIN CREATION

All activities specified in the study design schedule of activities can be specified in USDM on a highly detailed level using the CDISC Biomedical Concepts, procedures and exact timing details. This includes sub-timing details, like pre-dose grouping of activities, measurement repeats, and combinations of sampling procedures with lab analyte assessment details. The CDISC Biomedical Concept SDTM specializations are very helpful in informing the EDC set-up and the corresponding creation of SDTM domains based on the collected patient data. In addition, SDTM trial design domains can be directly created as demonstrated in the video that is available from our open source USDM to SDTM trial design domain tool (See https://github.com/ClinLine/USDM_SDTM_mapper).

CONCLUSION

As illustrated by the above use cases, the USDM with its capabilities enables us to digitize the data flow and optimize efficiencies downstream. Especially in combination with the ICH M11 guideline, which was finalized in November 2025, the need for adopting the CDISC USDM is currently acknowledged by the industry. The starting point for adoption can vary based on the most valuable use case for the specific pharmaceutical, biotech or vendor company. Although starting with one or two use cases is recommended from an implementation perspective, the combination of multiple use cases will eventually result in significant reductions of time and effort in the evaluation of new drugs for unmet needs.

REFERENCES

CDISC DDF Reference architecture Github: https://github.com/cdisc-org/DDF-RA
TransCelerate DDF project: https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/
ICH M11: https://ich.org/page/multidisciplinary-guidelines#11

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