

USDM in Action

Use Cases Supporting the DDF Vision

Use Cases

Retrospective

Prospective

Protocol 'Store'

Past Protocols

The storage of past sponsor protocols in to support a variety of use cases such as:

- Therapeutic area specific content
- Standard inclusion and exclusion criteria.
- Libraries of objectives, endpoints and estimands.
- Asses the past to prevent protocol amendments.
- General search across the library

Study Design

Protocol Authoring

Support the authoring of new protocols including complex studies such as Master, Umbrella etc.

This would include analyzing previous protocol information to inform design choices (see Protocol Store).

Writing associated SAP, Informed Consent, Monitoring Plan, Drug Plan etc via content reuse.

Study Build

Build of the study based on the protocol including all detailed procedures and assessments to allow for immediate deployment.

Feasibility & Cost

Support study feasibility and complexity evaluations.

Determine the cost of the study including such items as vendor and CRO costs and support the laboratory RFP process

Regulatory Authority

Approval for the execution of the study including IND, CTA etc and discussions with regulatory authorities

Stakeholder Views

Tailored views for stakeholders such as IRB and ethic committees.

Study Start-up

Deployment

Deployment of the study across the enterprise using the USDM to support electronic configuration rather than manual data entry including Data collection systems (incl. EDC), CTMS, IRT, Data transmission specifications and more

TMF

Linking the protocol to the specification of milestones and essential documents

Data Collection Strategy

Ensure all data that is needed for analysis is collected. Remove unnecessary procedures & data collection to reduce trial cost and patient burden.

Trial Registries

Registration of the study with registries such as CT.gov, CTIS etc.

Training

Provision of training materials to those involved in the study including sites

Site Support

Provision of tailored information to sites regarding study execution.

Study Execution

Amendments

Support the amendment process with the ability to indicate the precise changes to the user community.

Ensure fewer amendments (see Protocol Store).

Subject Information

Provision of improved information to subjects regarding study execution, improve expectation management.

Drug & Study Materials

Assist in the planning and provision of study drug, materials and supplies

Subject Recruitment

Support the identification of subjects to help improve subject recruitment to the study. Help support EHR participation identification.

Analysis & Reporting

Automation

Provide a solid foundation for the automation of analysis and reporting outputs such as TLFs and CSRs.

SDTM

Creation of 'T' domains. Auto generation of data domains

ADaM

Use the protocol statistical metadata to assist in the derivation of analysis datasets

Statistical Analysis Plan

Use the protocol as the initial source of the SAP to ensure consistency with objectives, endpoints, estimands

Regulatory Submission

Submission

Preparation of the submission by the sponsor

Regulatory Review

Review of the submission by the regulatory authority and discussions / questions with the sponsor

Statistical and Safety Review

Support the comparison of data by arm or study design.

Allow for the verification of planned (protocol) data versus actual (study data) captured data

Across The Lifecycle

Dashboards

The display of protocol related information sourced from one or more protocols in ways which have not been achievable before

Comparison

Compare and verify differences across versions and similar protocols

Unified Study Definitions Model (USDM)

Controlled Terms

Unstructured Content

Populations, Inclusion & Exclusion, Interventions & Indications, Estimands, Objectives & Endpoints

Study, Identifiers, Amendments

Study Designs, Arms, Epochs

Procedures, Biomedical Concepts

Detailed Study Logic, Encounters

Study Details

The overall study, its various versions, identifiers and associated governance. Also includes the amendments made to the study

Study High Level Design

The single or set of study designs making up the study detailing the epochs, arms etc.

Study Science

The detailed description of the study science: the populations and the associated inclusion and exclusion criteria, the indications being studied, the interventions being used and the objectives, endpoints and the associated estimands.

Detailed Study Logic

A precise definition of the study logic including support for the Schedule of Activities.

Unstructured Content

The ability to support one or more document presentations of the USDM content including the ICH M11 protocol template, sponsor templates and other documents.

Procedures and Biomedical Concepts

The detail around the procedures and observations to be performed as part of the detailed study designs.

Controlled Terms

The controlled terminology needed to define the semantics within the model. Managed in the same manner as all CDISC CT and aligned with the M11 template standard.

'DDF In Action'

Indicates that a poster touching on the use case described will be presented at the respective event.

- Europe, Copenhagen
- US, New jersey

NOTE: The use cases presented are illustrative and the list is not intended to be exhaustive.