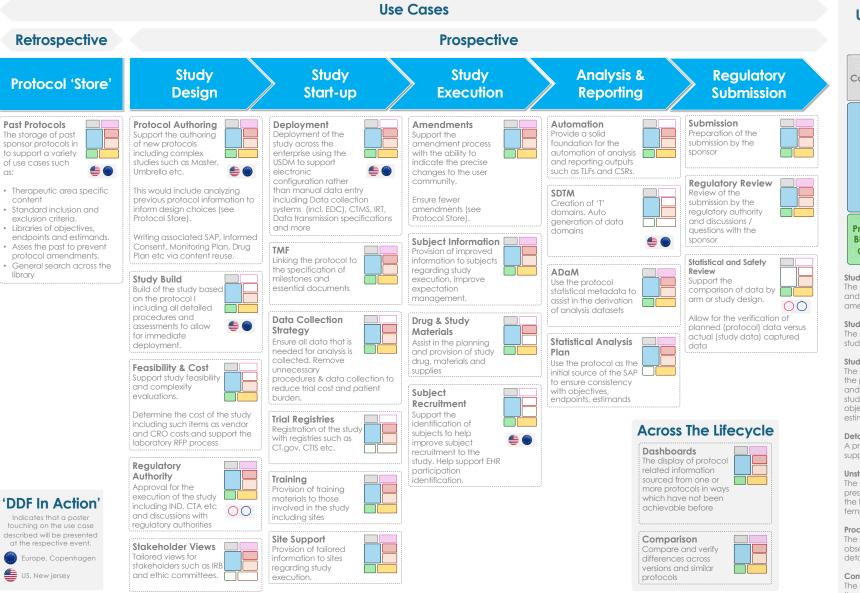


# USDM in Action Use Cases Supporting the DDF Vision





# Unified Study Definitions Model (USDM)

Unstructured **Controlled Terms** Content Populations. Study, Identifiers. Inclusion & Amendments Exclusion, Interventions & Indications. Estimands. Study Designs, **Objectives** Arms, Epochs & Endpoints Procedures, Detailed Study Logic, **Biomedical Encounters** Concepts

# 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.

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