

PP14: CDISC USDM & ICH M11: Practical electronic Protocols

With CDISC's Unified Study Definition Model (USDM) and ICH's M11 Clinical Electronic Structured Harmonized Protocol (CeSHArP) both being released this month we are witnessing a revolution in how sponsor companies operate. Say goodbye to outdated silos and hello to dynamic, data-centric workflows! These powerful standards, working in tandem, promise to transform industry operations. This poster details the connection between USDM and the M11 template and discusses the implementation efforts already underway.

ICH M11 Protocol Template

The ICH M11 Working Group has developed a specification that specifies a comprehensive clinical protocol organization with standardized content with both required and optional components.

The two main components of the specification are:

A template that includes the identification of document headers, common text and a set of data fields and terminologies for creating protocol documents

A technical specification that uses an open, non-proprietary standard to enable electronic exchange of clinical protocols



Scan the QR code to visit the ICH M11 WG webpage

Unified Study Definitions Model

CDISC's USDM is a logical model providing machine-readable structure for clinical trial protocols and their extended study definitions. Beyond capturing standard protocol information, the USDM accommodates enhanced detail for Schedule of Activities components, creating a more comprehensive representation of clinical study design.

By maintaining study definitions and protocols in electronic form, the USDM enables a wide range of automated downstream applications, embodying the "write-once, use many" principle that increases efficiency throughout the clinical trial process.

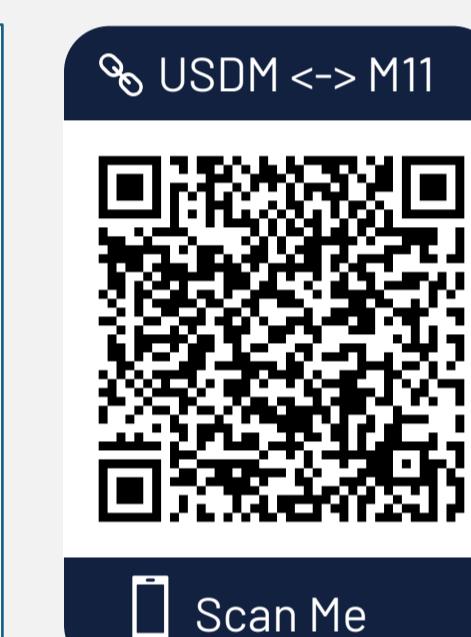
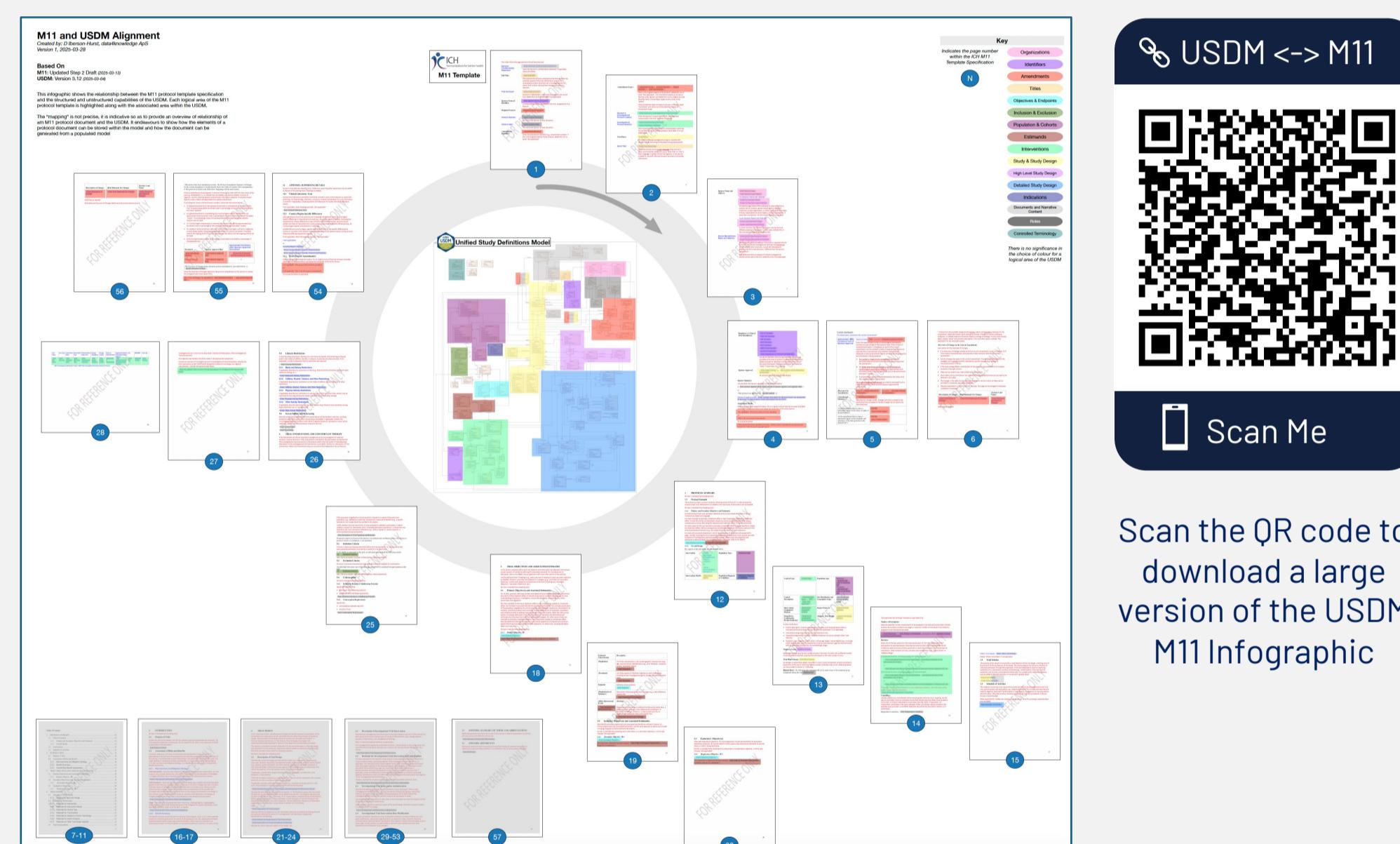


Scan the QR code to download a large version of the Use Case infographic

USDM & M11

USDM Offers Full Support For M11

The infographic below shows the crucial relationship between the M11 Template Specification and the USDM, clearly demonstrating how USDM provides comprehensive support for ICH's innovative M11 standard. It breaks down each M11 element, precisely identifying where and how it's supported within the USDM framework—creating a visual roadmap for seamless integration between the standards.



Scan the QR code to download a large version of the USDM M11 Infographic

From Theory to Reality

ICH M11, USDM, and FHIR M11 message integration has moved beyond concept to practical implementation at two HL7 connectathons in 2024.

The Dallas and Atlanta events showcased transmission of M11 protocols between systems—proving these standards work together. This same technology is already driving innovation in the FDA PRISM pilot.

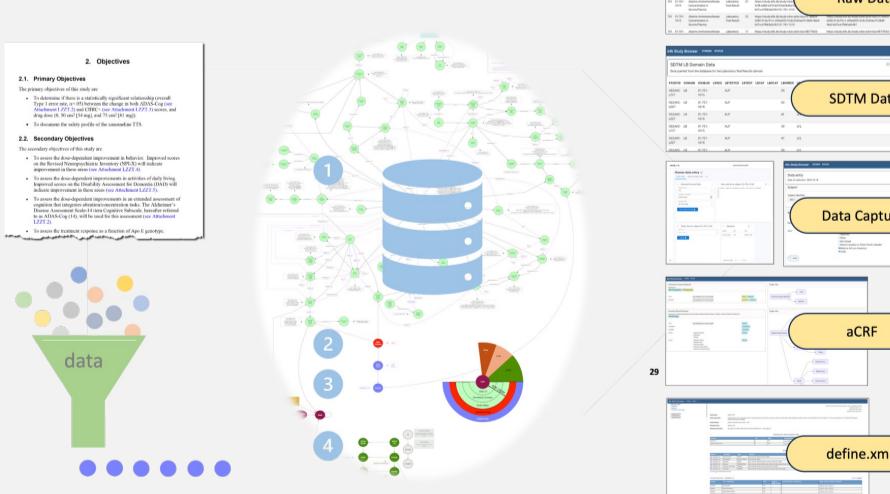
FHIR Schedule of Activities Message

At the January 2025 HL7 virtual Connectathon, teams showcased the seamless integration of USDM with the Schedule of Activities (SoA) message standard.

The demonstration proved that critical Schedule of Activities data stored in USDM can now be flawlessly transmitted to receiving systems through the HL7 SoA message pathway.

Unleashing USDM

USDM isn't just another standard—it's a versatile powerhouse with countless applications! The d4k technology demonstrator takes USDM to the next level by extending the model into operational territories never before explored.



This groundbreaking demonstrator reveals how USDM creates the solid foundation needed to revolutionize downstream processes including the auto generation of SDTM datasets.