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 Say goodbye to outdated silos and hello to dynamic, data-centric workflows!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.
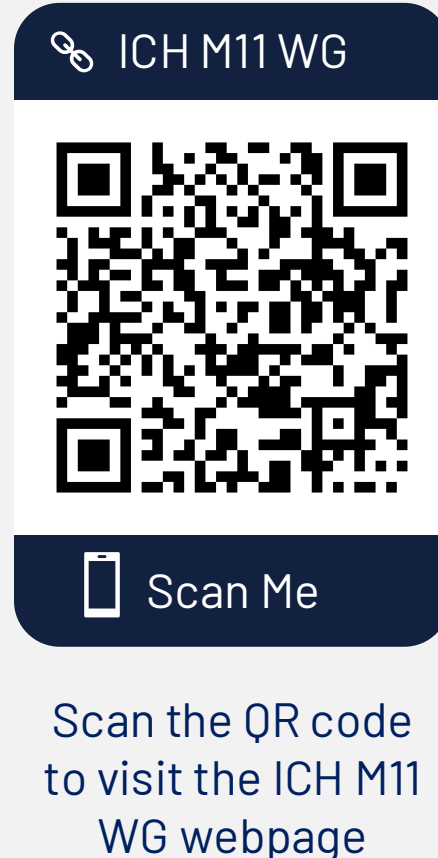
ICH M11 Protocol Template

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
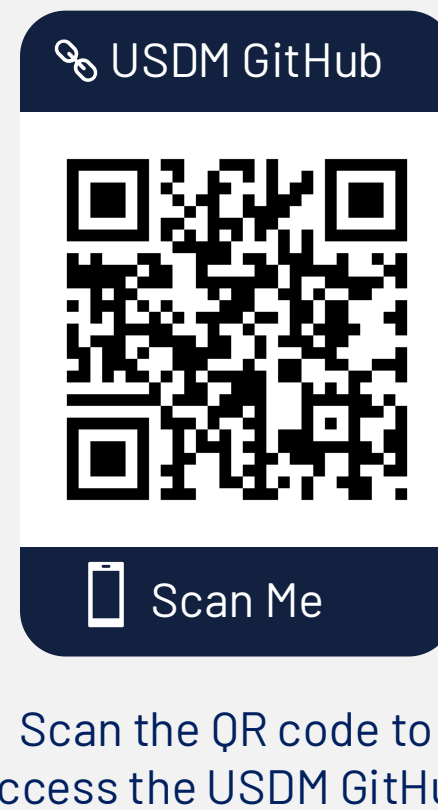
🔗 ICH M11 WG

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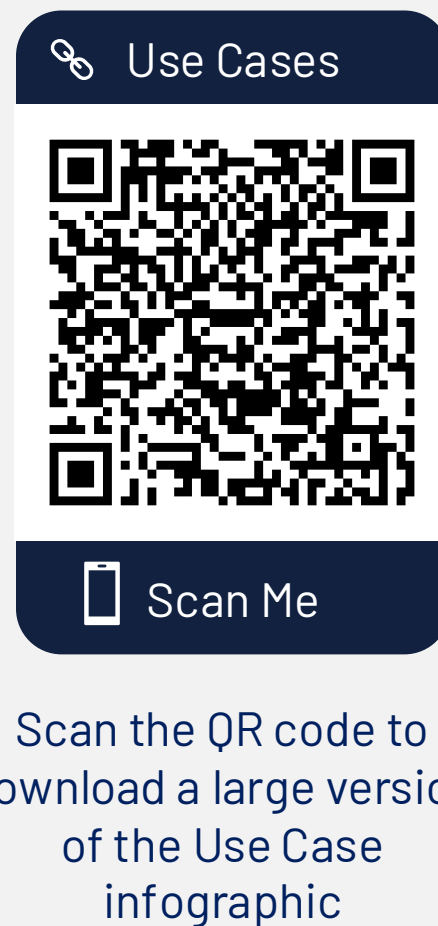Scan the QR code to visit the ICH M11 WG webpage

Unified Study Definitions Model

CDISC's USDM is a logical model for clinical trial protocols and study definitions. It captures standard protocol information plus enhanced Schedule of Activities details, creating a comprehensive study design representation.
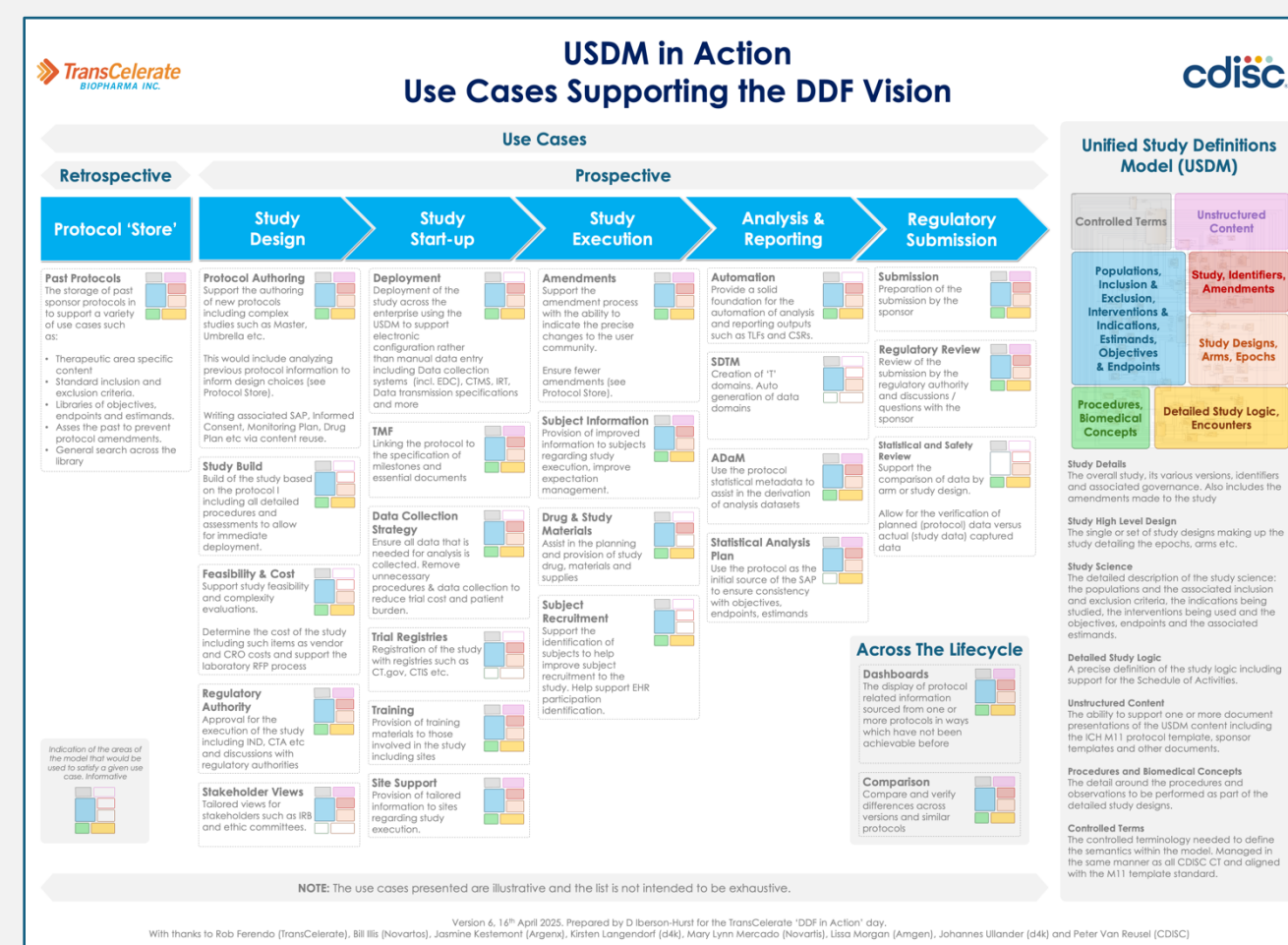
The USDM enables automated downstream applications supporting multiple use cases, embodying the "write-once, use many" principle that increases clinical trial efficiency.

🔗 USDM GitHub

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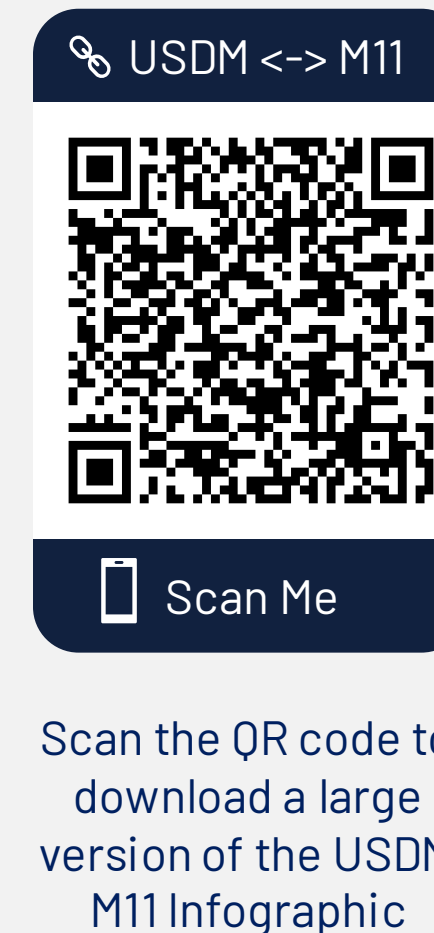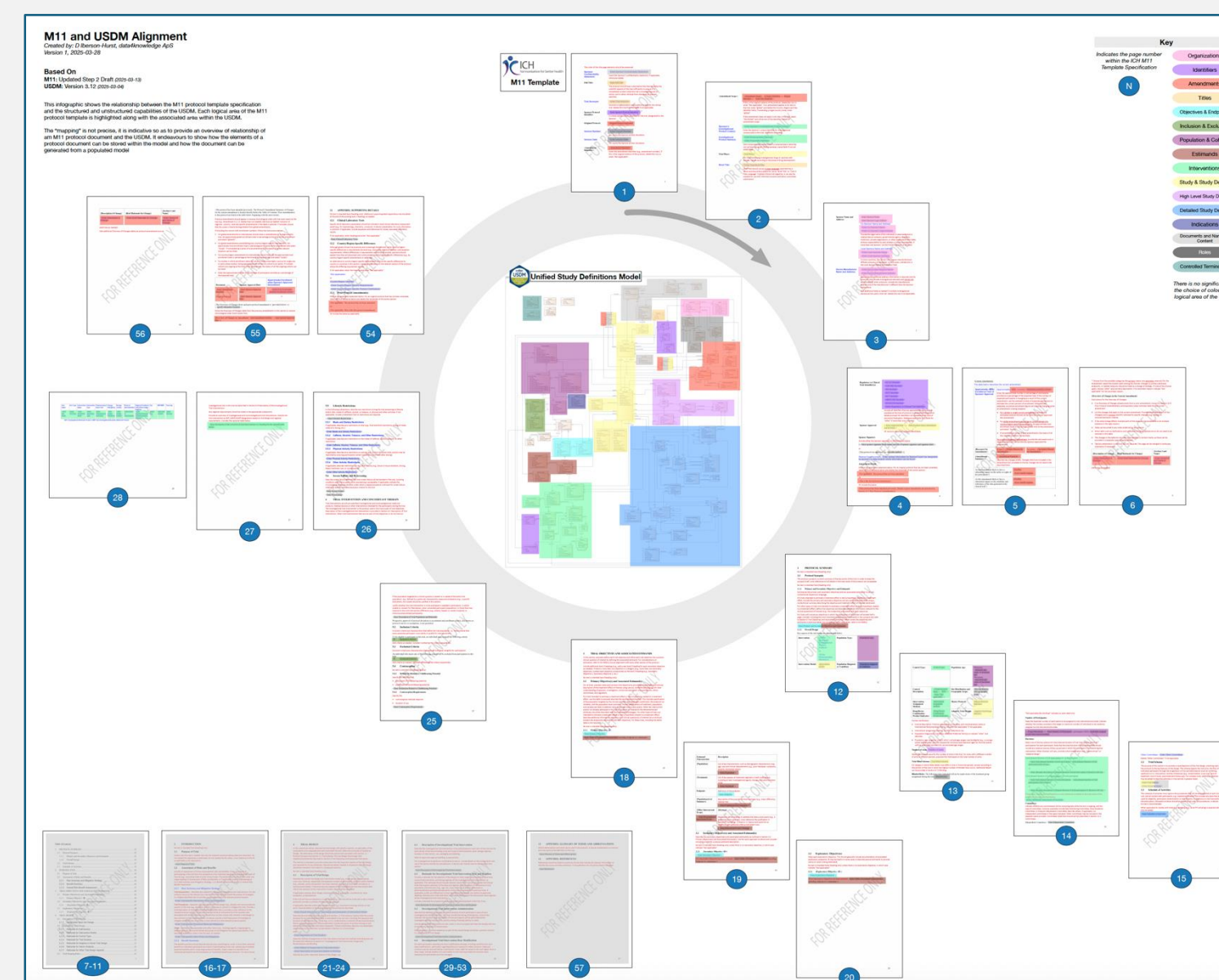Scan the QR code to access the USDM GitHub

🔗 Use Cases

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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.

🔗 USDM <-> M11

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

Business Drivers

The combination of USDM and M11 provides the electronic, foundation for clinical trial execution despite implementation challenges. Digital study definitions offer:

Costs: Significant reduction of effort from days to hours while reducing the number of study amendments.
Quality and Clarity: Eliminating ambiguity and transcription errors through precision while providing traceability.
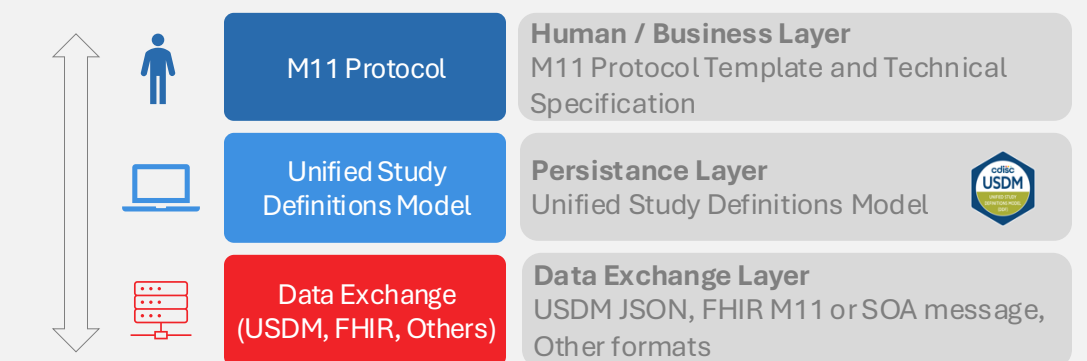**Capacity:** Running more trials with existing resources
Automation: Many opportunities including generating SDTM and submission artifacts automatically
Enable: Creating a single source of truth powering cross-study AI analytics for breakthrough insights

USDM Data Exchange

The USDM seamlessly integrates with the ICH M11 standard and allows for data exchange in a variety of formats:
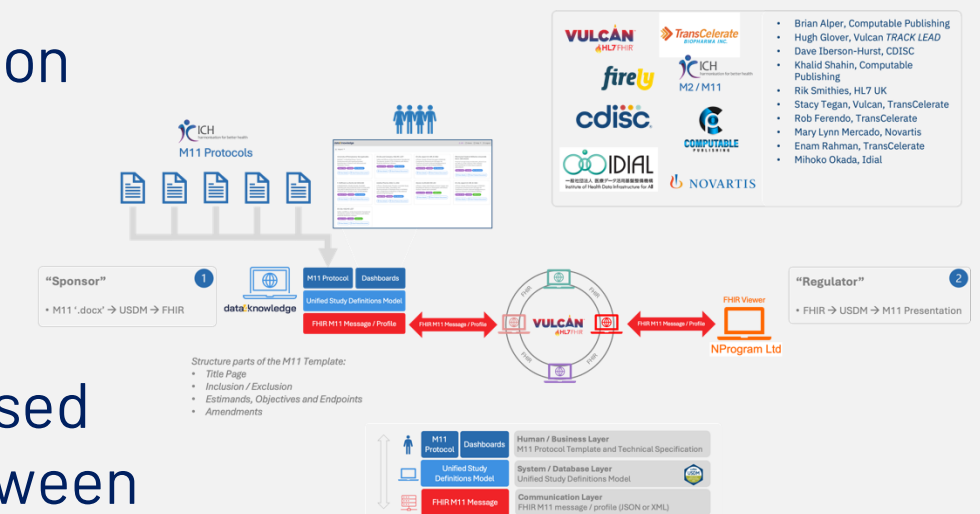
CDISC USDM: Native JSON serialization.
HL7 FHIR Messages: Import/export to HL7 Vulcan M11 FHIR message; export to HL7 FHIR SoA message .
Other Formats: Support for the TransCelerate CPT protocol template, ClinicalTrials.gov registry, EMA CTIS structures, and CDISC SDTM Trial Design Domains.

From Theory to Reality

ICH M11, USDM, and FHIR integration has moved beyond concept to practical implementation at HL7 connectathons

2024 Dallas and Atlanta: showcased transmission of M11 protocols between systems. This was used in the FDA PRISM pilot.
2025 Virtual: showcased the seamless integration of USDM with the Schedule of Activities (SoA) FHIR message proving that critical SoA data in USDM can be transmitted through the HL7 FHIR

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

data4knowledge