Digital Data Flow, ICH M11 Current State and Aligning TMF Standards Development Nick Hargaden and David Iberson-Hurst



15 May 2025



Meet the Speakers

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Disclaimer and Disclosures

- The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC or the speakers' employers
- The author(s) have no real or apparent conflicts of interest to report.



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NEWSPAPER HEADLINE

TMF IS DEAD, LONG LIVE THE DIGITAL TMF

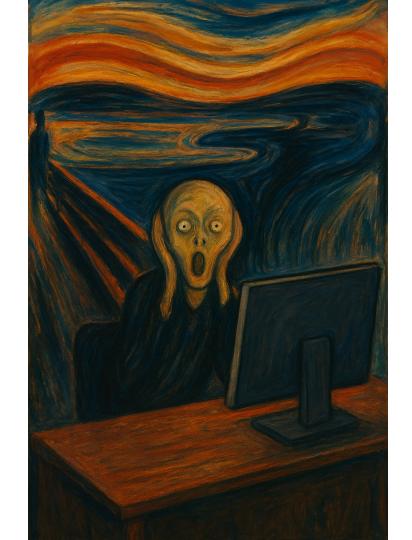
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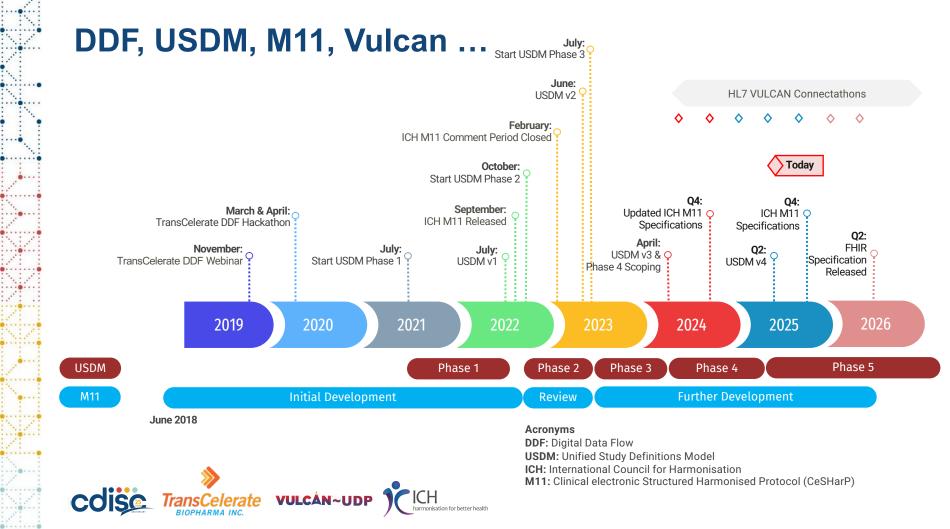


Agenda

- 1. DDF and USDM: a primer and where are we today
- 2. Visualizing USDM some concrete examples
- 3. Q&A what could USDM mean for TMF



A Primer on DDF and USDM



USDM

TransCelerate

Protocol 'Store

· Therapeutic area specific

endpoints and estimands.

Asses the past to preven

protocol amendments.

· General search across the

Past Protocols

The storage of past

sponsor protocols in

exclusion criteria.

used to satisfy a given use

library

· Libraries of objectives,

of use cases such

USDM in Action **Use Cases Supporting the DDF Vision**



Unstructured

Content

Study, Identifiers

Amendments

Study Designs

Arms, Epochs

Detailed Study Logic,

Encounters

Unified Study Definitions Model (USDM)

Controlled Terms

Populations,

Inclusion &

Exclusion.

Interventions &

Indications.

Estimands.

Objectives

& Endpoints

Procedures

Biomedical

Concepts



Retrospective

Study Design

Protocol Authorina

Support the authoring

studies such as Master,

This would include analyzina

inform design choices (see

Plan etc via content reuse.

Build of the study based

including all detailed

assessments to allow

Feasibility & Cost

Support study feasibility

laboratory RFP process

Stakeholder Views

Determine the cost of the study

including such items as vendor

and CRO costs and support the

previous protocol information to

Writing associated SAP, Informed

Consent, Monitoring Plan, Drug

of new protocols

Umbrella etc

Protocol Store).

Study Build

on the protocol l

procedures and

for immediate

deployment

evaluations.

Regulatory

including complex

Study Start-up

Deployment

study across the

USDM to support

and more

Deployment of the

enterprise using the

configuration rather

than manual data entry

including Data collection

Linking the protocol to

the specification of

essential documents

Data Collection

Ensure all data that is

needed for analysis is

procedures & data collection to

reduce trial cost and patient

collected. Remove

Trial Registries

CT.gov, CTIS etc.

Training

execution

Registration of the study

with registries such as

Strategy

unnecessary

burden.

systems (incl. EDC), CTMS, IRT,

Data transmission specifications

Study Execution

Amendments

amendment process

indicate the precise

changes to the user

amendments (see

Subject Information

Provision of improved

information to subjects

regarding study

expectation

management

Drug & Study

Assist in the planning

drug, materials and

and provision of study

Materials

Subject

execution, improve

Protocol Store)

with the ability to

Support the

Ensure fewer

Prospective

Use Cases

Analysis & Reporting

Automation

Provide a solid

Creation of 'T'

domains. Auto

generation of data

SDTM

domains

ADaM

foundation for the

automation of analysis

and reporting outputs

such as TLFs and CSRs.

Regulatory Submission

Preparation of the submission by the



regulatory authority and discussions / auestions with the







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

Regulatory Review Review of the





Study High Level Design

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

The overall study, its various versions, identifiers

and associated governance. Also includes the

amendments made to the study

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.

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.

QR Code for Image



Tailored views for stakeholders such as IRB and ethic committees.



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











improve subject recruitment to the study. Help support EHR participation

Recruitment Support the identification of subjects to help identification.

Across The Lifecycle

achievable before	Dashboards The display of protocol related information sourced from one or more protocols in ways which have not been achievable before	
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NOTE: The use cases presented are illustrative and the list is not intended to be exhaustive

Version 6, 16th April 2025. Prepared by D Iberson-Hurst for the TransCelerate 'DDF in Action' day. With thanks to Rob Ferendo (TransCelerate), Bill Illis (Novartos), Jasmine Kestemont (Argenz), Kirsten Langendorf (d4k), Mary Lynn Mercado (Novartis), Lissa Morgan (Amgen), Johannes Ullander (d4k) and Peter Van Reusel (CDISC)



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USDM & TMF

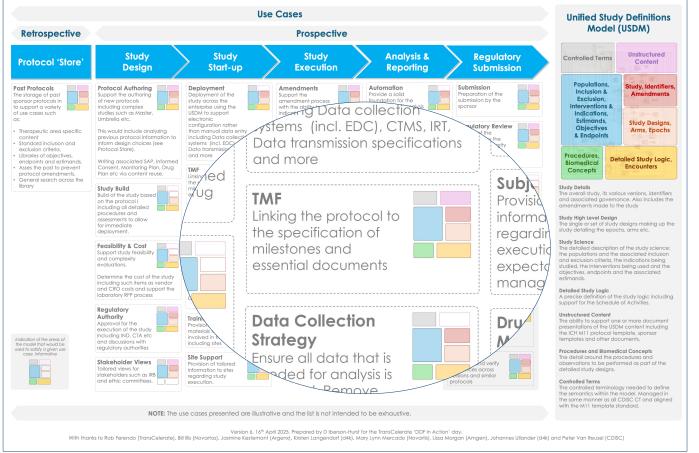
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USDM in Action Use Cases Supporting the DDF Vision



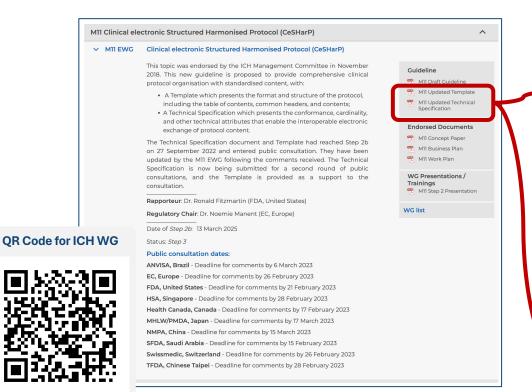




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ICH M11 Updated Draft Released



cdisc

ICH M11 Templ

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED
PROTOCOL
(CESHARP)
M11 TEMPLATE

NOT FOR COMMENT - FOR REFERENCE ONLY

Updated Step 2 Draft 13 March 2025

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.



INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CcSHarp)

M11 TECHNICAL SPECIFICATION

Updated Step 2 Draft - For Second Public Consultation

14 March 2025

Structured v Unstructured

The order of the title page elements should be p

Structured

Sponsor Confidentiality Statement: <Enter Sponsor Confidentiality Statement>

Insert the Sponsor's confidentiality statement, if applicable, otherwise delete.

Full Title: <Enter Full Title>

The protocol should have a descriptive title that identifies the scientific aspects of the trial sufficiently to ensure it is immediately evident what the trial is investigating and on whom, and to allow retrieval from literature or internet

searches.

Trial Acronym: <Enter Trial Acronym>

Acronym or abbreviation used publicly to identify the clinical trial. Delete this line from the table if not applicable.

Sponsor Protocol <Enter Sponsor Protocol Identifier>

Identifier:

A unique alphanumeric identifier for the trial, designated by the

ponsor.

Original Protocol: [Original Protocol Indicator]

Version Number: <Enter Version Number>

For use by the Sponsor at their discretion.

Version Date: <Enter Version Date>

For use by the Sponsor at their discretion.

{Amendment Identifier:}

{[Amendment Identifier]}

Enter the amendment identifier (e.g., amendment number). If this is the original instance of the protocol, delete the row or

enter "Not applicable".

Unstructured

If the trial allows for some investigators or allow them to adjust investigational trial intervention), the means of maintaining the blinding for other investigators or staff should be explained. Measures to prevent unblinding by laboratory measurements or while performing study assessments, if used, should be described.

{<Enter Measures to Maintain Blinding>}

.7.4 {Emergency Unblinding at the Site}

Describe the criteria for breaking the trial blind or participant code. Describe the circumstances that would require breaking the blind, either for an individual participant or all participants, and specify who will be responsible for this decision. Include the procedure for emergency unblinding as well as documentation of unblinding, Indicate to whom the intentional and unplanned unblinding should be reported.

{<Enter Emergency Unblinding at the Site>}

.8 Investigational Trial Intervention Adherence

Describe the measures to monitor and document participants' adherence with investigational trial intervention (e.g., trial intervention accountability records, diary cards, or investigational trial intervention concentration measurements).

List what documents are mandatory to complete (e.g., participant drug log) and what source data/records will be used to document investigational trial intervention adherence.

<Enter Investigational Trial Intervention Adherence>

6.9 Description of Noninvestigational Trial Intervention

As stated in Section 6 Trial Intervention and Concomitant Therapy, noninvestigational interventions are pre-specified products used in the trial but are not part of trial objectives and hence, are not investigational trial interventions.

<Enter Description of Noninvestigational Trial Intervention>

6.9.1 {Background Trial Intervention}

Describe any background intervention(s), including administration and any conditions for use.

{<Enter Background Trial Interventions>}

6.9.2 {Rescue Therapy}

List all permitted rescue medications, treatments, and/or procedures, including any relevant instructions on administration and any conditions of use.

If administration of rescue therapy leads to the temporary discontinuation of trial intervention or a participant's withdrawal from the trial, refer to Section 7 Participant Discontinuation of Trial Intervention and Discontinuation or Withdrawal from Trial.

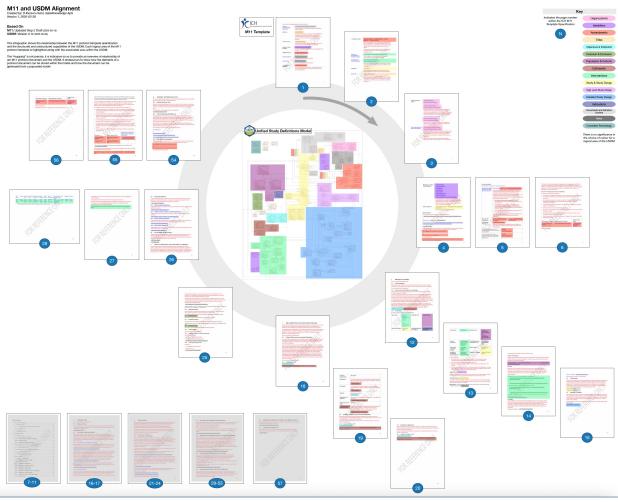
{<Enter Rescue Therapy>}



ICH M11 & USDM

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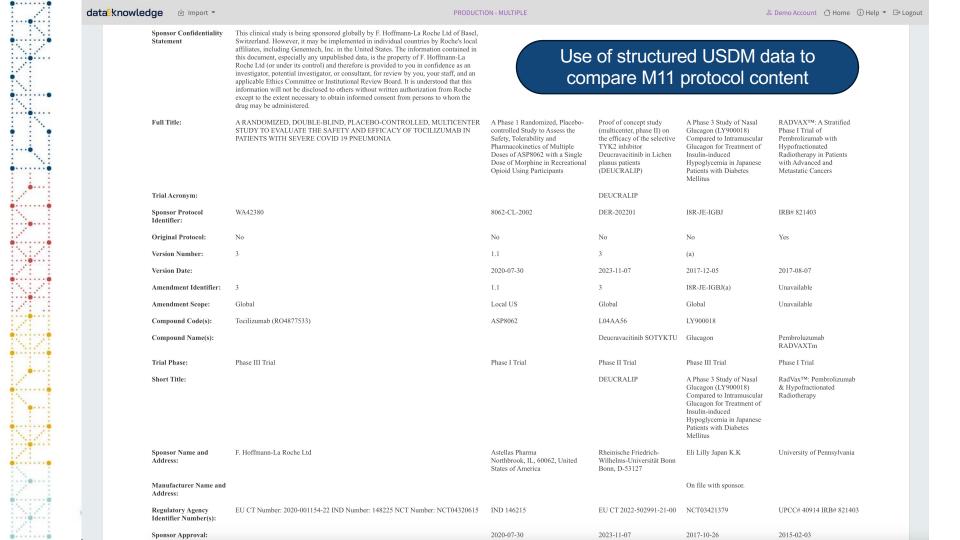


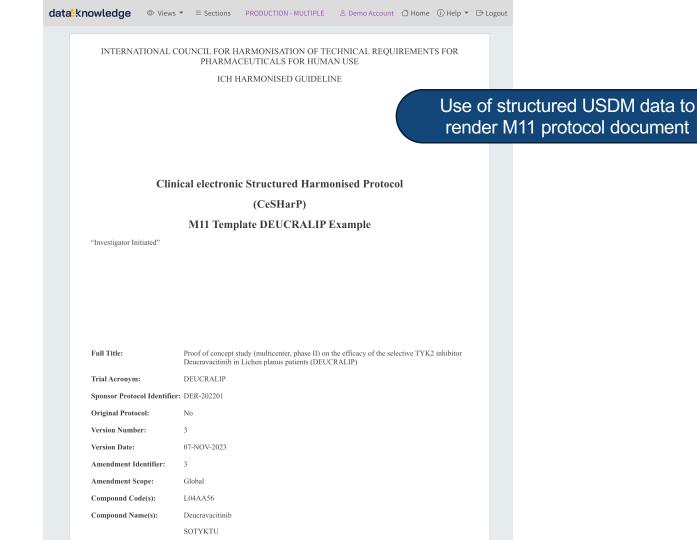


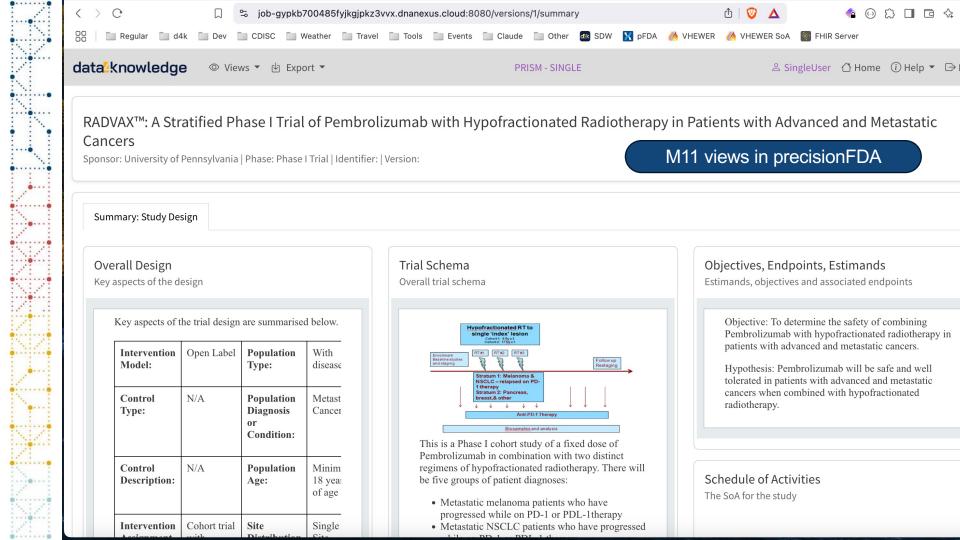


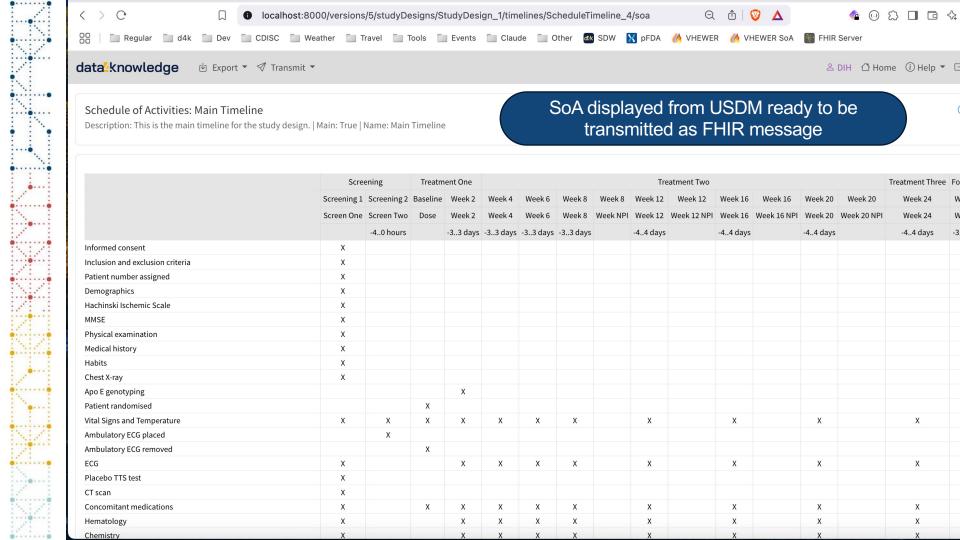
Visualizing the USDM

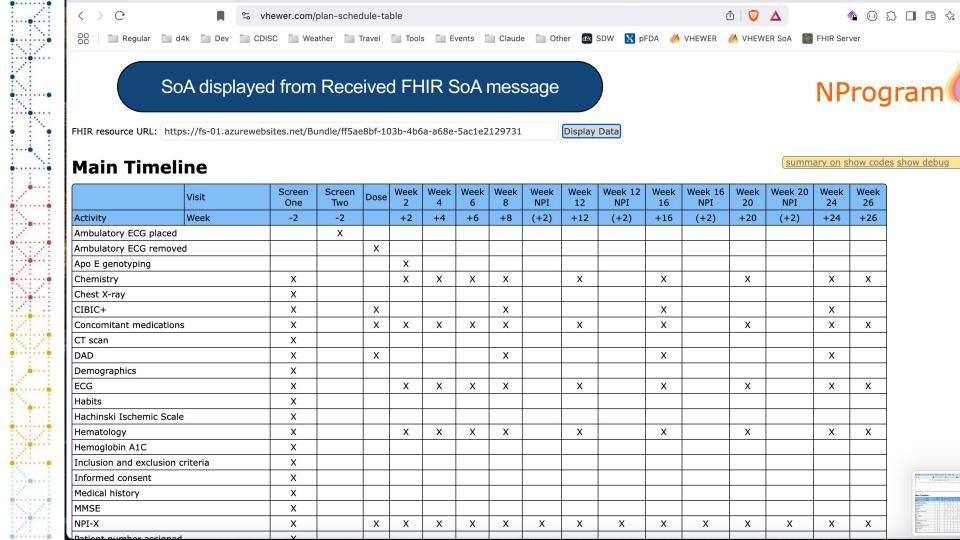
Some examples













Q&A

What could USDM mean for TMF practices

Thank You!

