

Utilizing The Digital Protocol (UDP)

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Path to Today: Evolution of Protocol Initiatives



Common Protocol Template

Model protocol structure and content, globally aligned regulator requirements



ICH M11



ICH M11

Common approach for dividing protocol content into structured elements



Unified Study Definition Model



Unified Study Definition Model

Common detailed data model that addresses granularity, relationships, etc.



Digital Data Flow, Protocol Digitization



Clinical Data Standards & Terminology



UDP: Utilizing the Digital Protocol

Compatible exchange mechanisms to maximize value across stakeholders across the research to care continuum



Fast Healthcare Interoperability Resources

A Collaboration for Connectivity and Compatibility

Regulatory Bodies

FDA

EMA
EUROPEAN MEDICINES AGENCY

Pmda

+14
Regulatory
Members

>20
Observing
Authorities



M11 Technical Specification & Guidelines

Consistency

VULCAN ~UDP

UDP: Utilising the Digital Protocol



Integration Through FHIR

- Use Cases & Reference Applications
- FHIR Implementation Guides



Digital Data Flow (DDF)

- USDM: Operational Model
- Controlled Terminology





FHIR (Fast Healthcare Interoperability Resources) is a specification that is a standard for exchanging healthcare information electronically. FHIR R4 is the modernization of and best feature reutilization from HL7s v2, v3, and CDA products. Development of resources follows an 80/20 rule and aims to focus on what is required in 80% of existing systems and to regard the remaining 20% as edge cases. The 20% can then be dealt with through the extension mechanism built into FHIR.

FHIR aims to simplify implementation without sacrificing information integrity. It leverages existing logical and theoretical models to provide a consistent, easy-to-implement, and rigorous mechanism for exchanging data between healthcare applications.

Why?

Interoperability out-of-the-box, Using established systems to exchange data across the research to care continuum

How?

FHIR is built on web standards (e.g., XML, JSON, HTTP, and OAuth)

What?

FHIR is a flexible standard with over 150 resources to cover a wide array of use cases

Who?

FHIR has a diverse global community (hospitals, academia, vendors, biopharma, regulators)

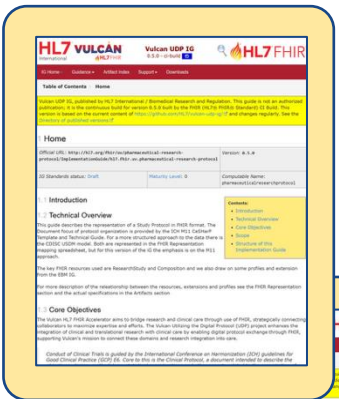
Vulcan UDP Plan for Clinical Study Protocol FHIR Implementation Guides



Base

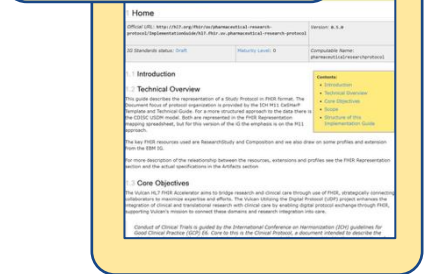
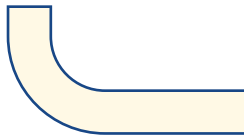
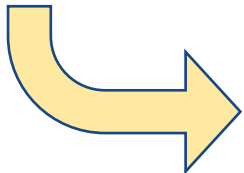
- ✓ Addresses sponsor-to-regulator exchange per requirements presented in ICH M11
- ✓ Establishes foundational practices for leveraging FHIR for Clinical Study Protocols
- ✓ Provides the linkage to standard managed outside of HL7: ICH M11 (and thus to controlled terminology), USDM; links to additional standards can be added via IG lifecycle processes if applicable

Child IGs: Use case specific Implementation Guides can be created that reference the Base IG and add only what details are needed for the particular use case. These may define additional terminology.

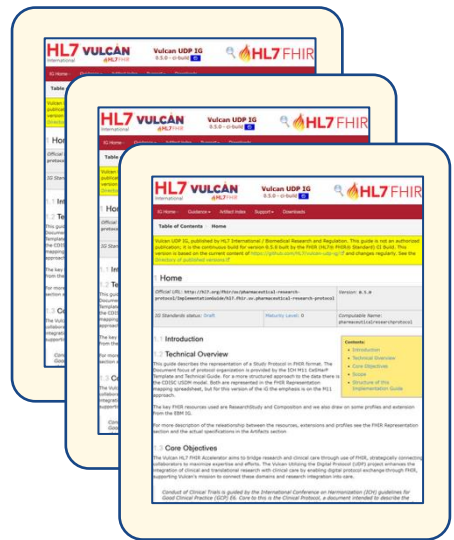


SoA

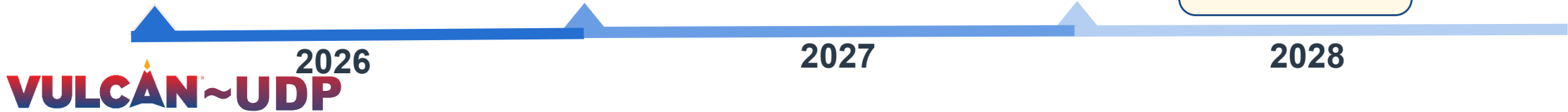
Implementation is described by identifying parts of the base IG that are relevant and any other IGs that are relevant. The child IG may then provide profiles for all of these elements to enforce validation against key attributes and excluding others and by appropriate binding of terminology.



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The Power of the Digital Protocol

ICH M11 Aligned Document Transmission

- Align with evolving regulatory requirements
- Secure transfer of sensitive information
- Efficient exchange with additional stakeholders

Streamlined Structured Document Creation

- Standardized templates for protocols
- Automated population of key fields using metadata
- Reduced human errors
- Real time updates/input
- Improved collaboration/version control
- Reduced time spent drafting protocols

Efficiencies, Automation, and Analytics

EHR Integration

Expedited Recruitment

Site System Integration

Budgeting and Forecasting

Improved Operational Efficiency

Pooled Analysis of Protocols

Above the waterline are use cases currently addressed by this Implementation guide.

Below the waterline are an illustration of future use cases for which UDP may develop an implementation guide

FEvIR Platform by Computable Publishing

other tools available at the Connectathon

“Bring Your Own Protocol” or use sample M11 protocols

Join us at the May connecathon

The May HL7 WGM & Connectathon is a working week where ideas and solutions get challenged, tested and moved forward.

- Roll up your sleeves in Connectathon tracks
- Collaborate face-to-face with the global HL7 community
- Move implementation guides and FHIR solutions from draft to reality





Get Involved



Get to know the ICH M11 Template, Guideline and specification.



Find out more about USDM and the Digital Data Flow initiative



Find out more about UDP and the monthly project meetings



Learn about HL7 FHIR and how to get started with a FHIR IG



Connect with Vulcan!

