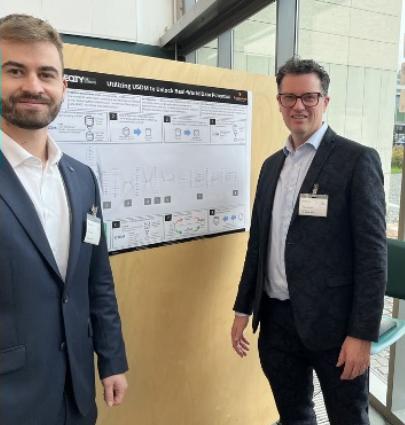
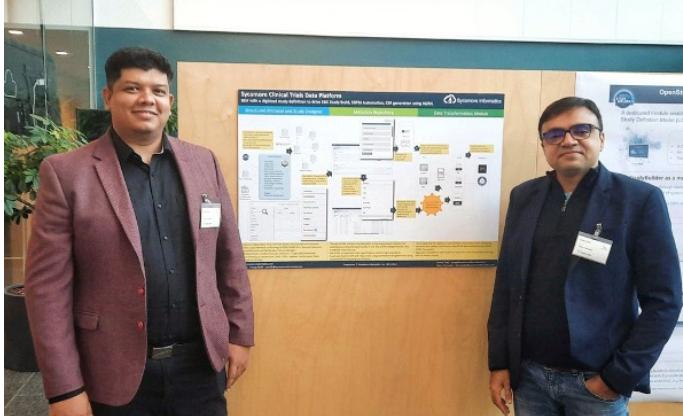


The TransCelerate/CDISC Digital Data Flow Project: Practical Electronic Study Designs

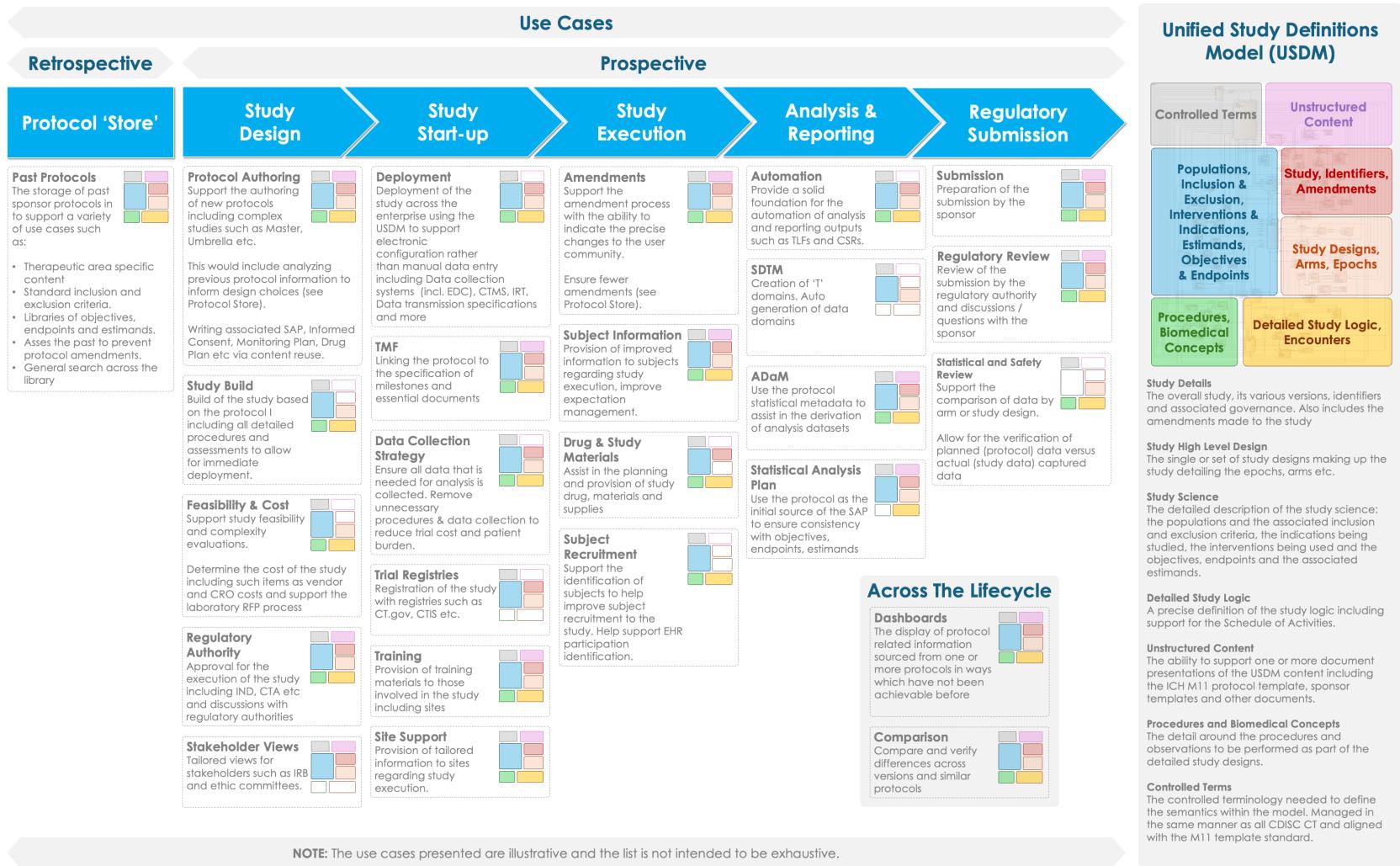
Dave Iberson-Hurst, USDM Product Owner, CDISC
PHUSE EU Connect 2024, DS09





USDM in Action

Use Cases Supporting the DDF Vision



Retrospective

Use Cases

Prospective

Unified Study Definitions
Model (USDM)

“DDF in Action”: Sponsor Presentations

- **Eli Lilly:**
The Digital Schedule of Activities
- **Roche:**
How can we unlock the power of data and technology to transform study design and protocol generation?
- **Novo Nordisk:**
Adoption of Digital Data Flow



Procedures and Biomechanical 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.

“DDF in Action” Posters

Novo Nordisk: Copenhagen

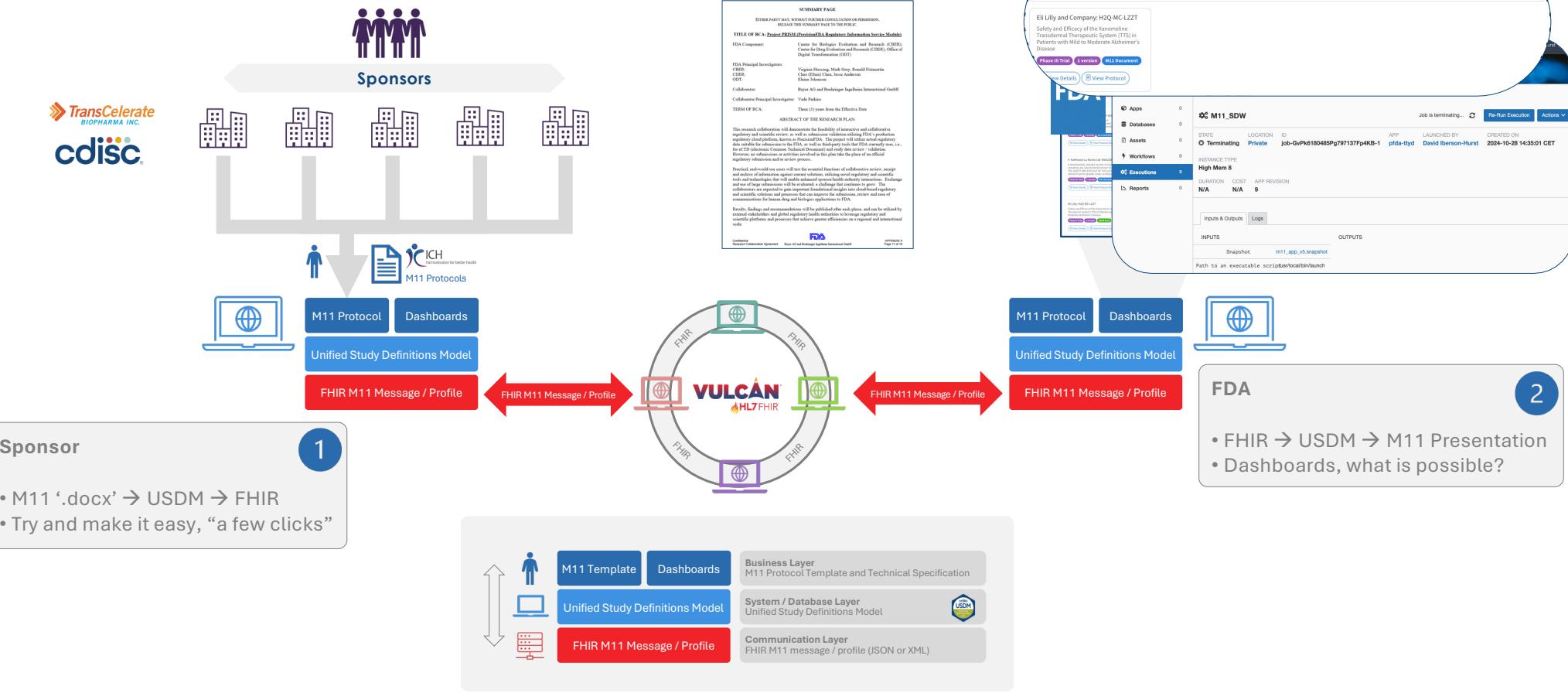
- **data4knowledge:**
One model USDM at the Center
- **EQTY Lifesciences and ClinLine:**
Utilizing USDM to unlock real world data potential
- **Novo Nordisk:**
OpenStudyBuilder: A USDM compatible SDR solution
- **Nurocor:**
Nurocor Clinical Platform: Making DDF a reality today
- **Sycamore Informatics:**
Sycamore Clinical Trials Data Platform
- **TransCelerate:**
Study Definitions Repository (SDR)

J&J: New Jersey

- **EZ Research Solutions:**
The power of seamless innovation (USDM, AI, Automation and Collaboration)
- **NNIT:**
FHIR and USDM in action
- **Novo Nordisk:**
OpenStudyBuilder: A USDM compatible SDR solution
- **Nurocor:**
Nurocor Clinical Platform: Making DDF a reality today
- **Tata Consultancy Services (TCS):**
AI Enabled Trial Design Dataset Automation
- **Sycamore Informatics:**
Sycamore Clinical Trials Data Platform
- **PFMD and CTDN:**
Applying USDM resources to Protocol Eligibility Criteria also supports clinical trial matching, patient and site enrollment and inclusiveness use cases
- **Contentrules and Futurpositif:**
USDM enables content reuse from the study protocol
- **TransCelerate:**
Study Definitions Repository (SDR)

PRISM M11 Use Case

(PrecisionFDA Regulatory Information Service Module)



Removing Silos

2. Objectives

2.1. Primary Objectives

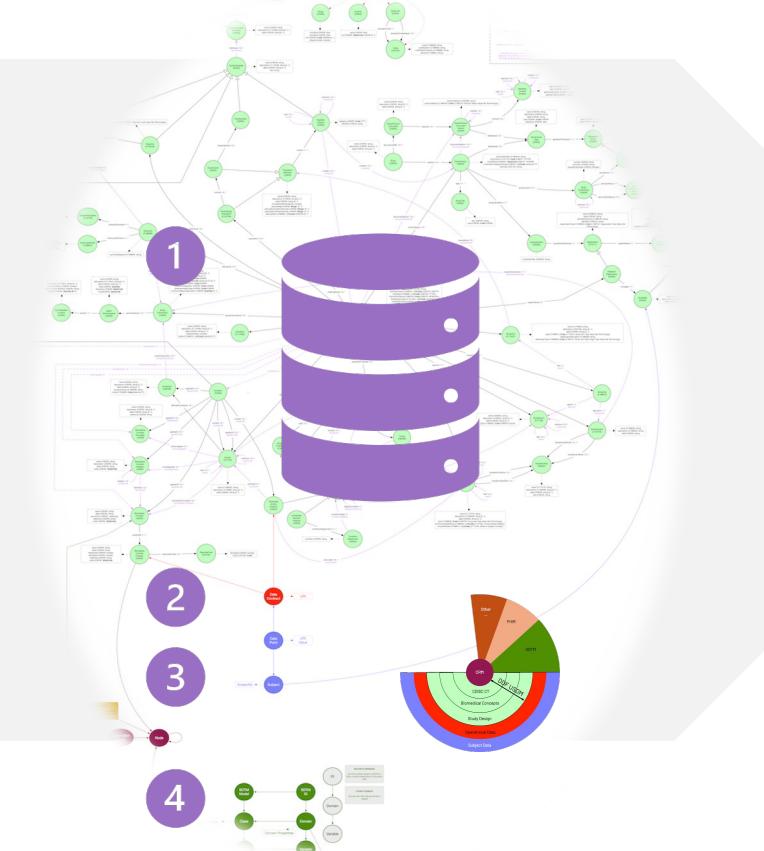
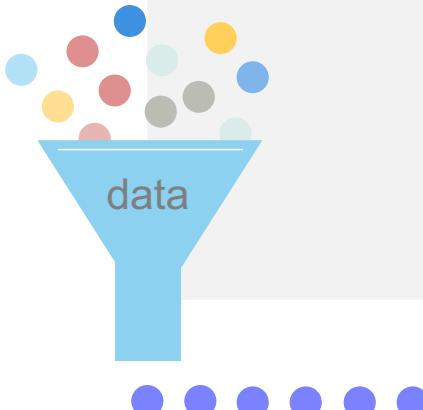
The primary objectives of this study are

- To determine if there is a statistically significant relationship (overall Type I error rate, $\alpha = 0.05$) between the change in both ADAS-Cog (see Attachment LZT12) and CIBIC+ (see Attachment LZT13) scores, and drug dose (0, 50 cm² [54 mg], and 75 cm² [81 mg]).
- To document the safety profile of the xanomeline TTS.

2.2. Secondary Objectives

The secondary objectives of this study are

- To assess the dose-dependent improvement in behavior. Improved scores on the Revised Neuropsychiatric Inventory (NPI-X) will indicate improvement in these areas (see Attachment LZT14).
- To assess the dose-dependent improvements in activities of daily living. Improved scores on the Disability Assessment for Dementia (DAD) will indicate improvement in these areas (see Attachment LZT15).
- To assess the dose-dependent improvements in an extended assessment of cognition that integrates attention/concentration tasks. The Alzheimer's Disease Assessment Scale-14 item Cognitive Subscale, hereafter referred to as ADAS-Cog (14), will be used for this assessment (see Attachment LZT12).
- To assess the treatment response as a function of Apo E genotype.



2024 EU PHUSE Connect, Strasbourg

Raw Data

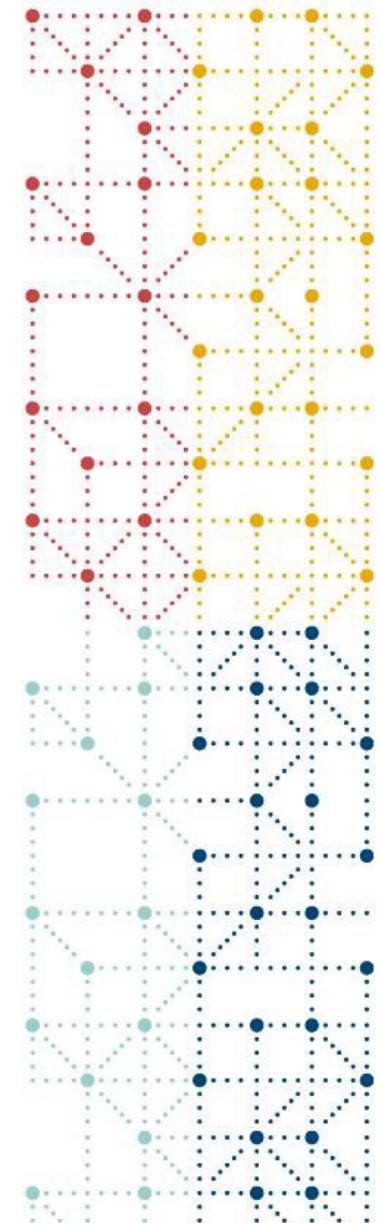
SDTM Data

Data Capture

aCRF

define.xml





Thank You



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[Dave Iberson-Hurst](#)

