Digital Data Flow (DDF) Solution Showcase

March 27, 2025

Presenting Organizations:
data4knowledge & Contentrules / futurpositif

.

Agenda

Topic

- Welcome, Background, Webinar Logistics & Ground Rules
- Presenting Company 1: data4knowledge – 30 mins
- Presenting Company 2: Contentrules/futurpositif – 30 mins
- Q & A with Panelists
- Closing

TransCelerate BIOPHARMA INC.

Today's Presenters

data4knowledge & Contentrules/futurpositif

Johannes Ulander

Partner, data4knowledge

Kirsten Walter Langendorf

Partner, data4knowledge

Regina Lynn Preciado

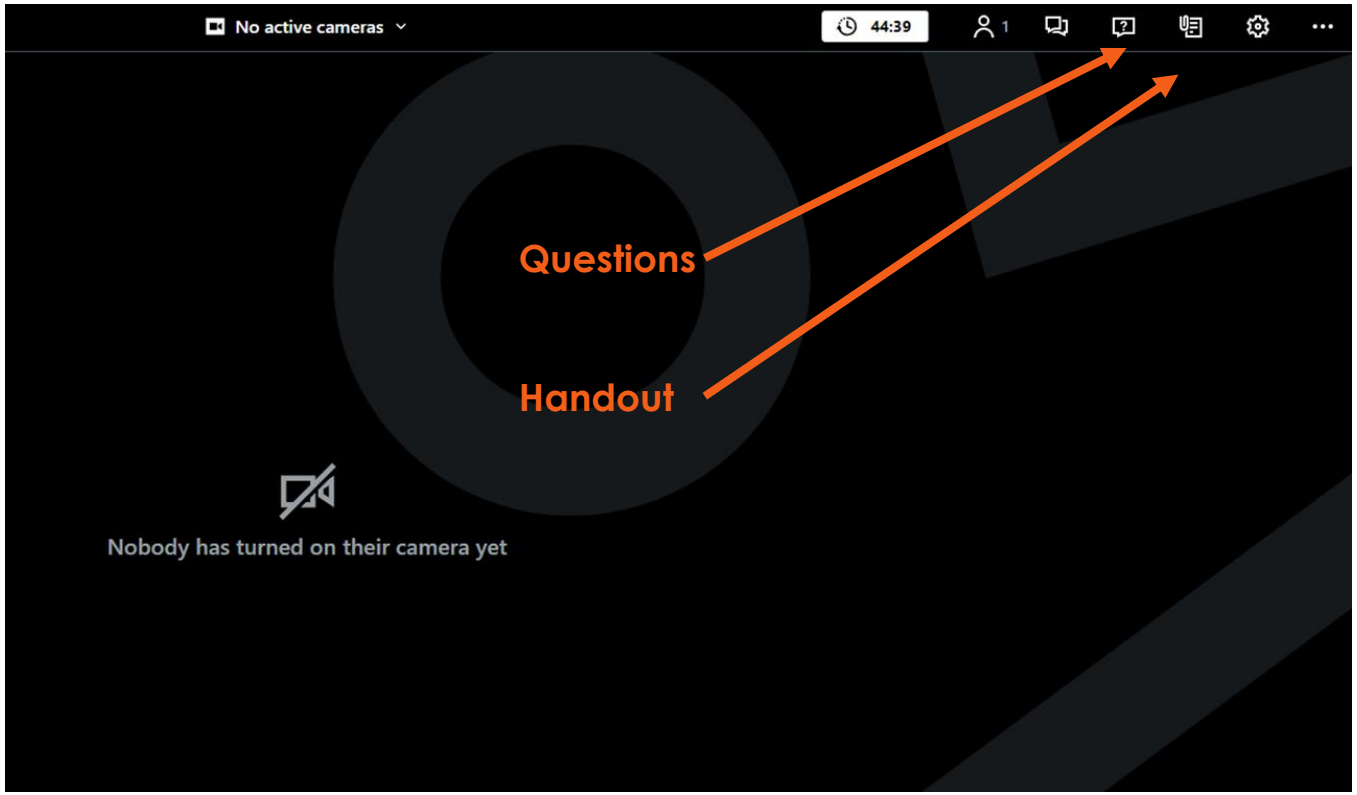
Sr. Director of Content Strategy Solutions, Contentrules

Todd Georgieff

Principal Consultant, futurpositif

Logistics for the Webinar

- **All participants will be muted for this call.**
- **For audio**: Connect to audio to listen to presentations via your computer or phone
- **To submit a question to the presenters**:
  - Type your question in the Questions panel and click Send.



Reminder: This webinar may be recorded in whole or in part.

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Ground Rules

- **We want to make this discussion helpful and answer as many of your questions as we can, so here are some quick ground rules:**
  - Participation is voluntary, as is using TransCelerate assets/tools
  - The responsibility for compliance with laws and regulations is owned by the solution adopter
  - You don't have to identify what company you work for
- **Things we would ask you <u>not to post questions on</u>:**
  - For clinical trial sponsors, what vendors/sites/CROs a company is working with or not working with
  - For tech companies, vendors, CROs, & others, what pharma companies you work with or don't work with
  - Any issues/criticisms companies have with any vendors, tech company, sites, CROs, or sponsors
  - Future and long-term development plans
  - Anything related to pricing or costs -- what you pay for the purchase off or receive for the sale of any goods or services
- **We can't answer questions about**:
  - Specific vendors or other business partners with whom member companies are working
  - Costs of using/implementing TransCelerate assets/tools
  - Which member companies are using or going to use any TransCelerate solution or any commercial product or service

TransCelerate BIOPHARMA INC.

TransCelerate is a Not-for-Profit Entity Created to Foster Collaboration

Our mission is to collaborate across the global biopharmaceutical R&D community to identify, prioritize, design, and facilitate the implementation of solutions designed to drive the efficient, effective, and high-quality delivery of new medicines.

CDISC Standards

By bringing together a global community of experts to develop and advance data standards of the highest quality, CDISC creates clarity in clinical research.

Together, we enable the accessibility, interoperability, and reusability of data for more meaningful and efficient research that has greater impact on global health.

- Consensus-based standards development
- Standards for clinical and translational research
- Standards are freely available at www.cdisc.org
- IP Policy ensures open standards
- Ongoing global research support in the Americas, Europe, Japan, China, India, Korea and other regions
- Standards downloaded in 90+ countries

About This Webinar Series

TransCelerate and CDISC are co-sponsors of this webinar series:

- TransCelerate leads the Digital Data Flow (DDF) initiative
- CDISC develops the USDM data standard for digitized protocols

Objective(s)

- Bring together DDF solution providers, sponsors, and industry stakeholders to witness innovative solutions
- Provide a platform to showcase different approaches to protocol digitalization (utilizing the USDM standard)
- Foster knowledge sharing relative to protocol digitalization

Save the Date!

"DDF In-person Event for 2025 (2 Days)"

(similar to DDF in Action Day 2024)

Dates: September 24th and 25th of 2025

Locations: New Jersey, USA and Basel, Switzerland

Registration link and further details of event to follow

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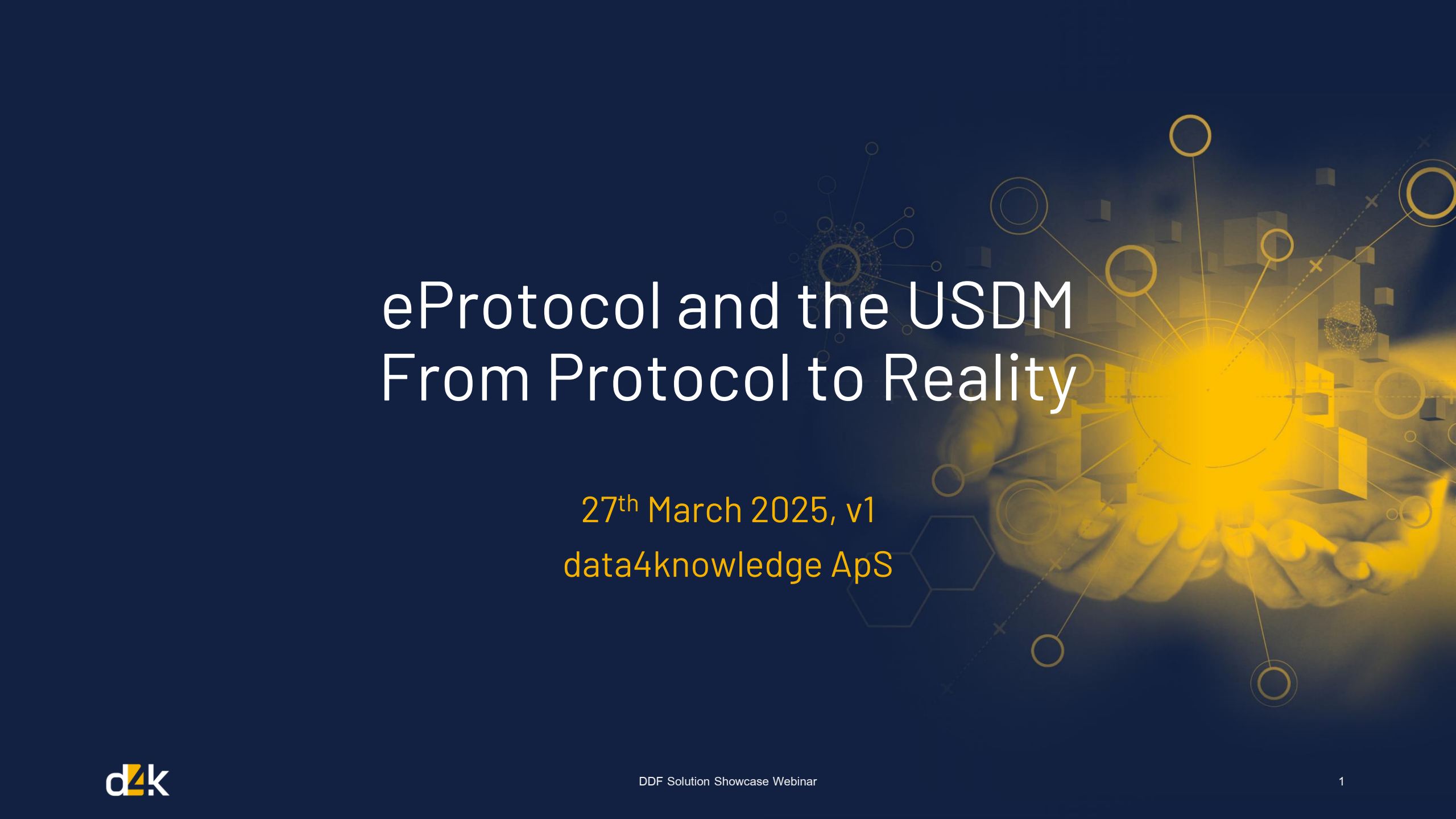
Solution Showcase Presentations

eProtocol and the USDM
From Protocol to Reality



27th March 2025, v1

data4knowledge ApS

data4knowledge

Making better use of data

Kirsten Walther Langendorf

Johannes Ulander

Dave Iberson-Hurst

Kerstin Forsberg

We help our customers make better use of their primary asset, the clinical data.

Disclosure

- Dave Iberson-Hurst is currently working on contract to CDISC as the CDISC USDM Product Owner
- The views expressed during this presentation are d4k's and **NOT** those of CDISC

Agenda as a timeline

- Introduction

- Load the protocol
  - *Timelines*
  - *Biomedical Concepts*

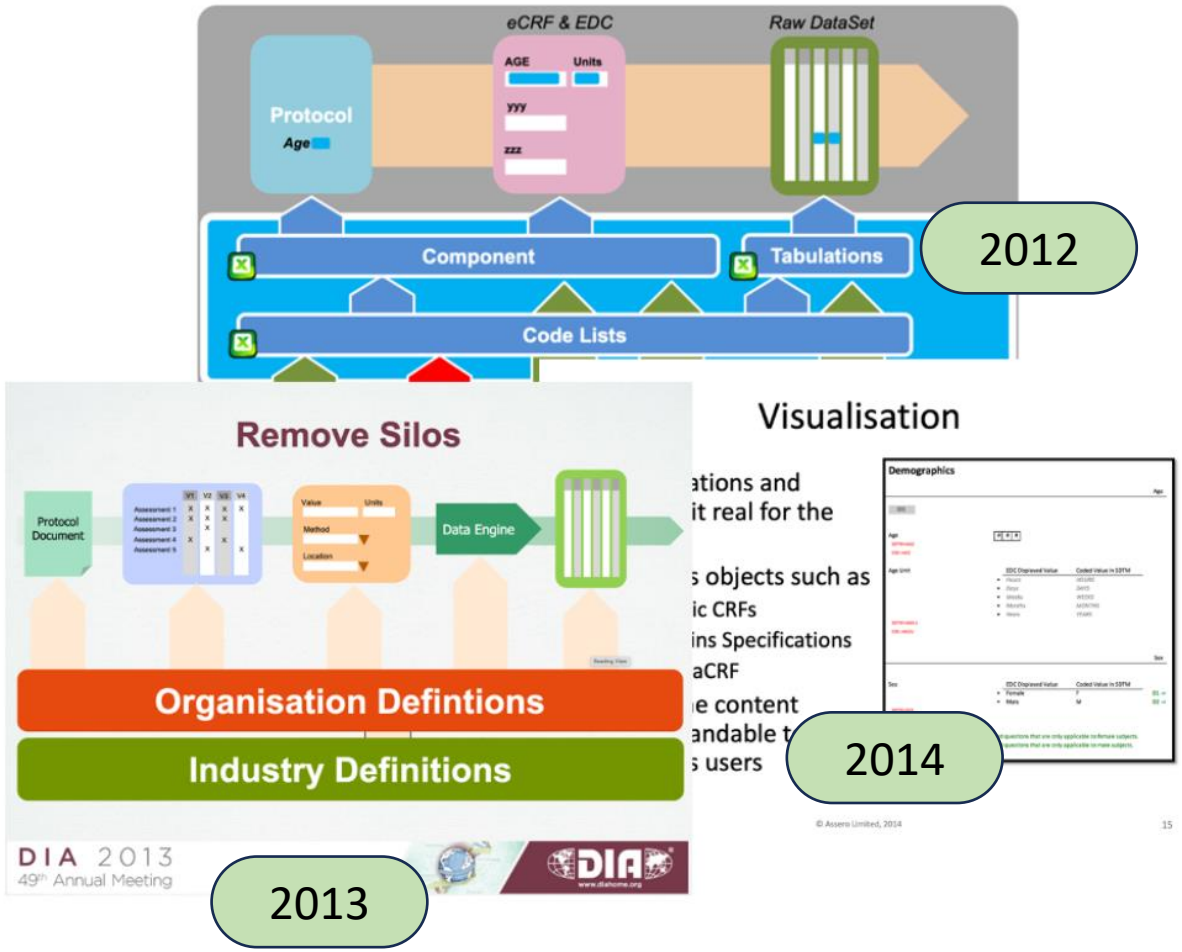
- Data Contracts
  - *Forms*
  - *Define*
  - *Trial Design Domains*

- Subjects and Data

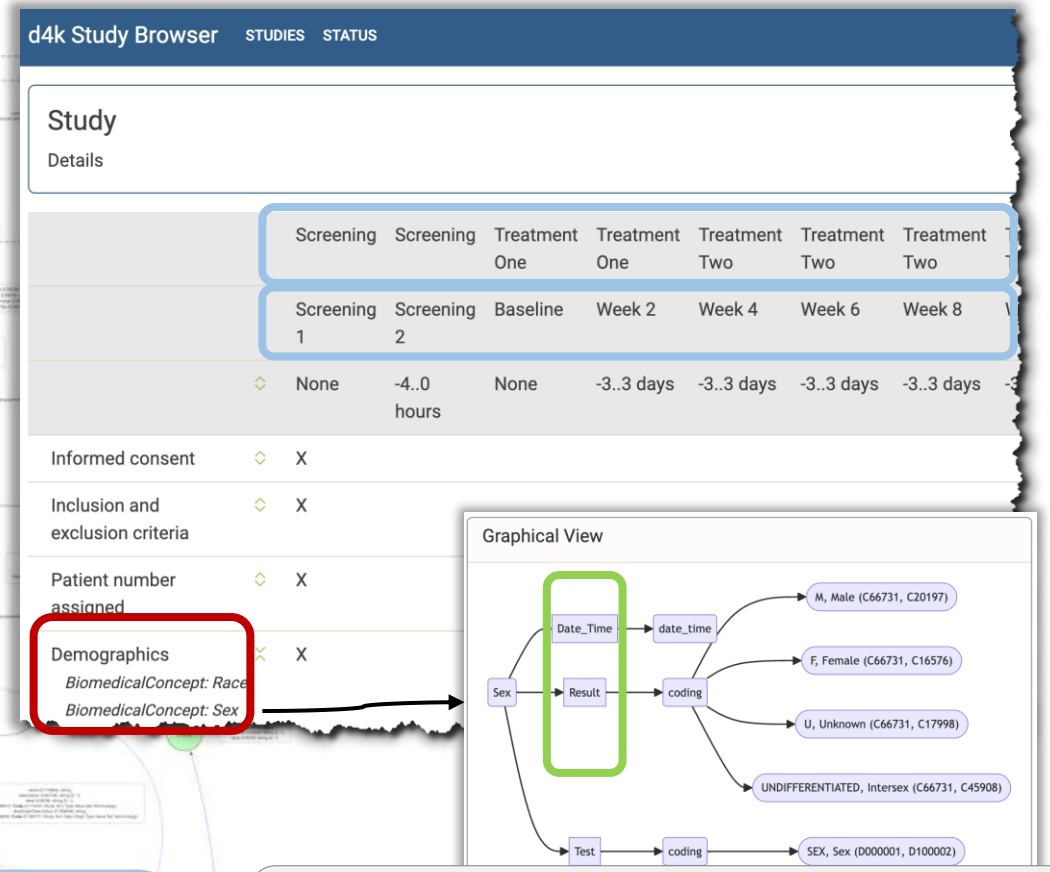
- SDTM
- Traceability

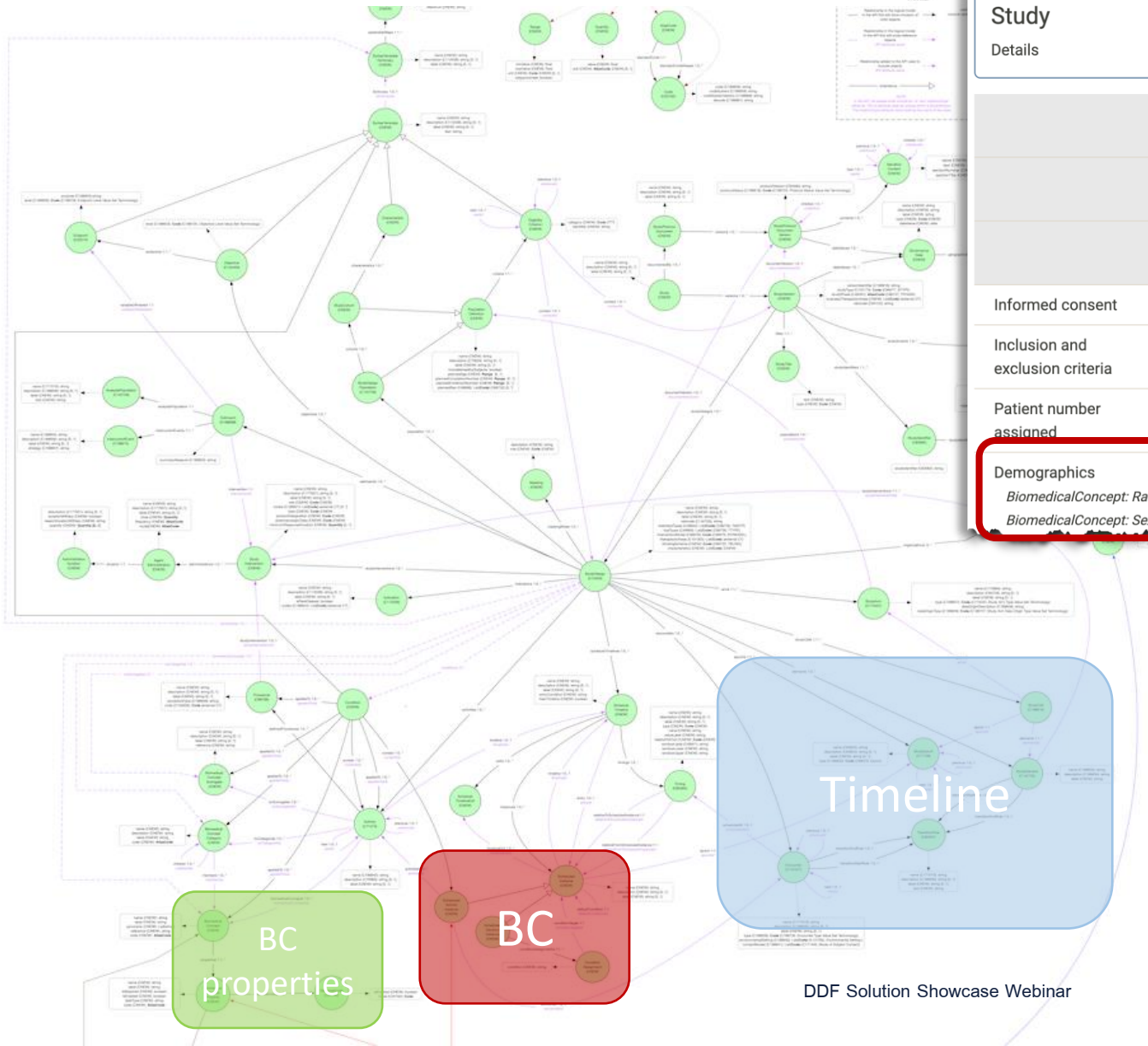
Old Ideas Whose Time Has Come

- We [industry] have been looking at removing silos for a decade or more
- We have been looking at “eProtocol” for probably two decades or more
- DDF, USDM, ICH M11, precisonFDA … all these initiatives / standards are making it a reality



USDM - SoA is key





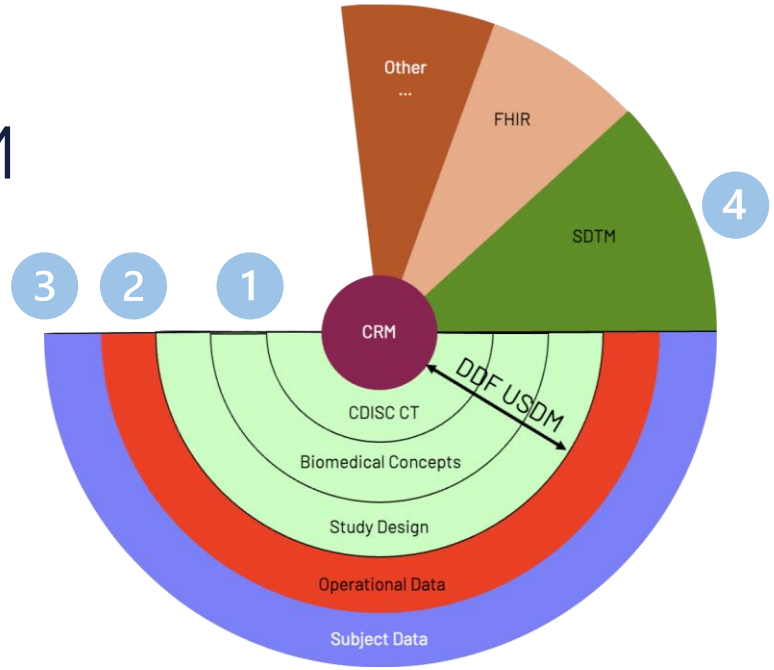
Notes

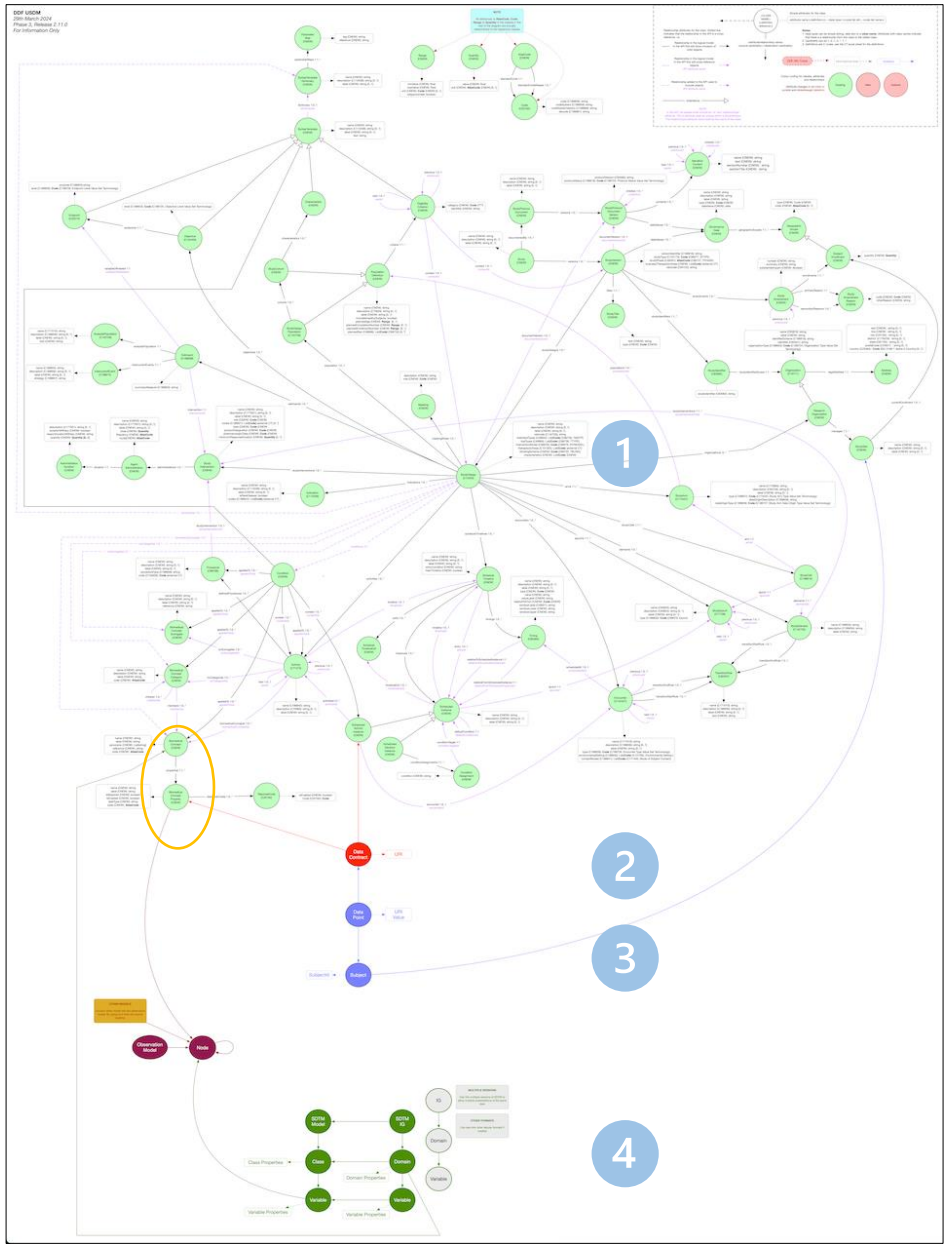
- USDM provides the solid foundation
- Provides the SoA
- Provides the SoA+ (SoA plus observations)

USDM as the Foundation

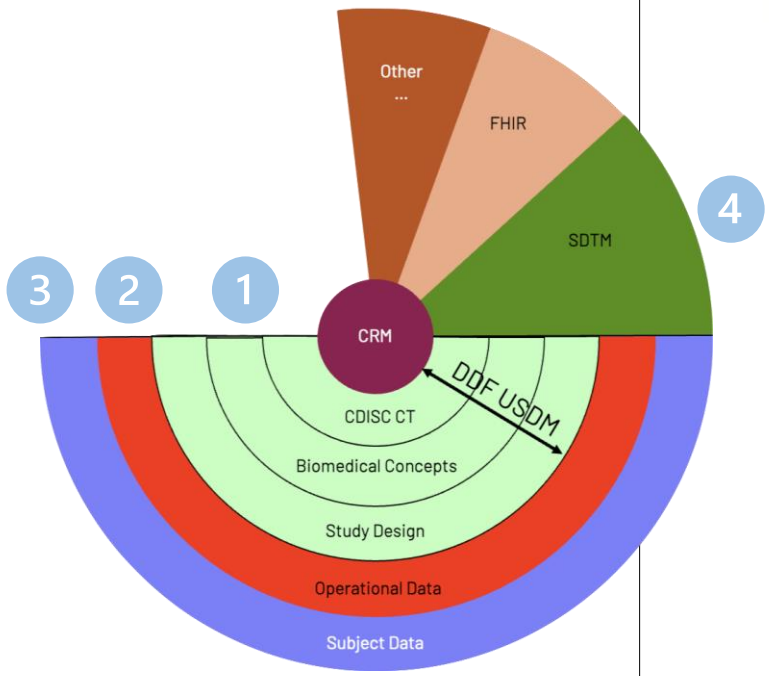
1. USDM is the foundation (includes BCs)
2. Add the “data contract”
3. Attach subjects and their data
4. Link to SDTM

… and use …





Extending USDM



BC

BC properties

Timeline

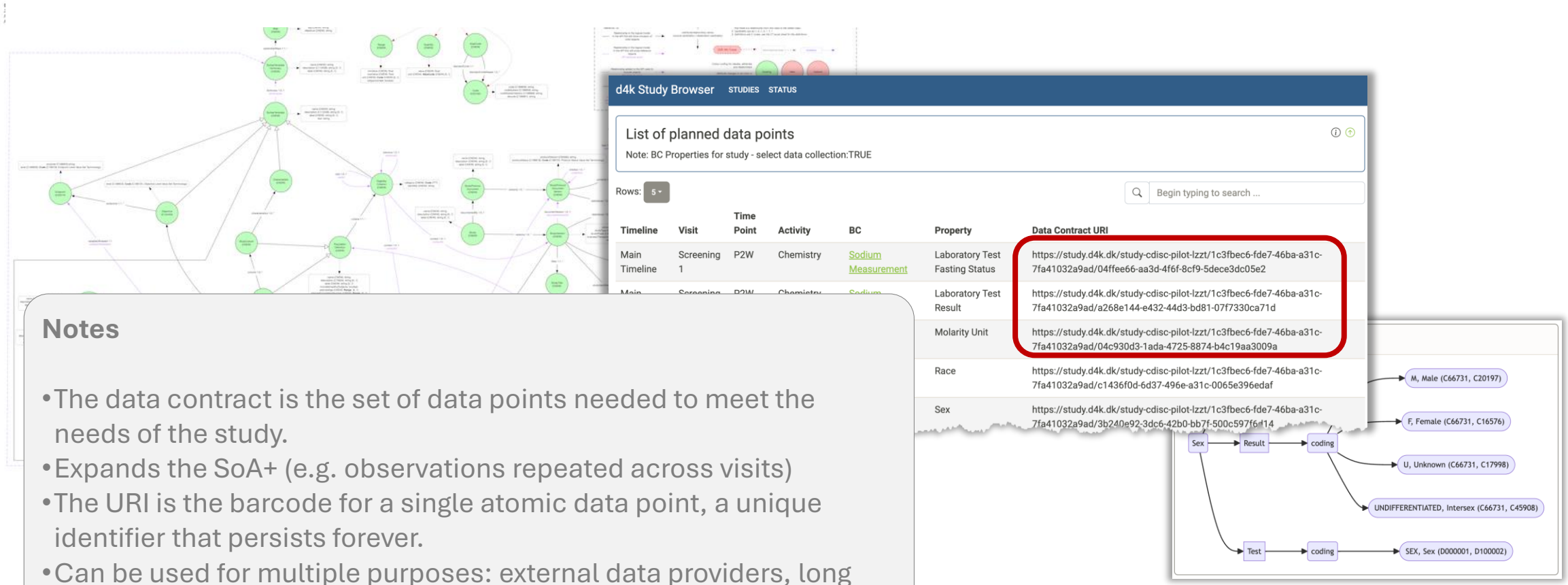
1 USDM is the foundation (includes BCs)

2 Add the “data contract”

3 Attach subjects and their data

4 Link to SDTM

The “Data Contract”



Notes

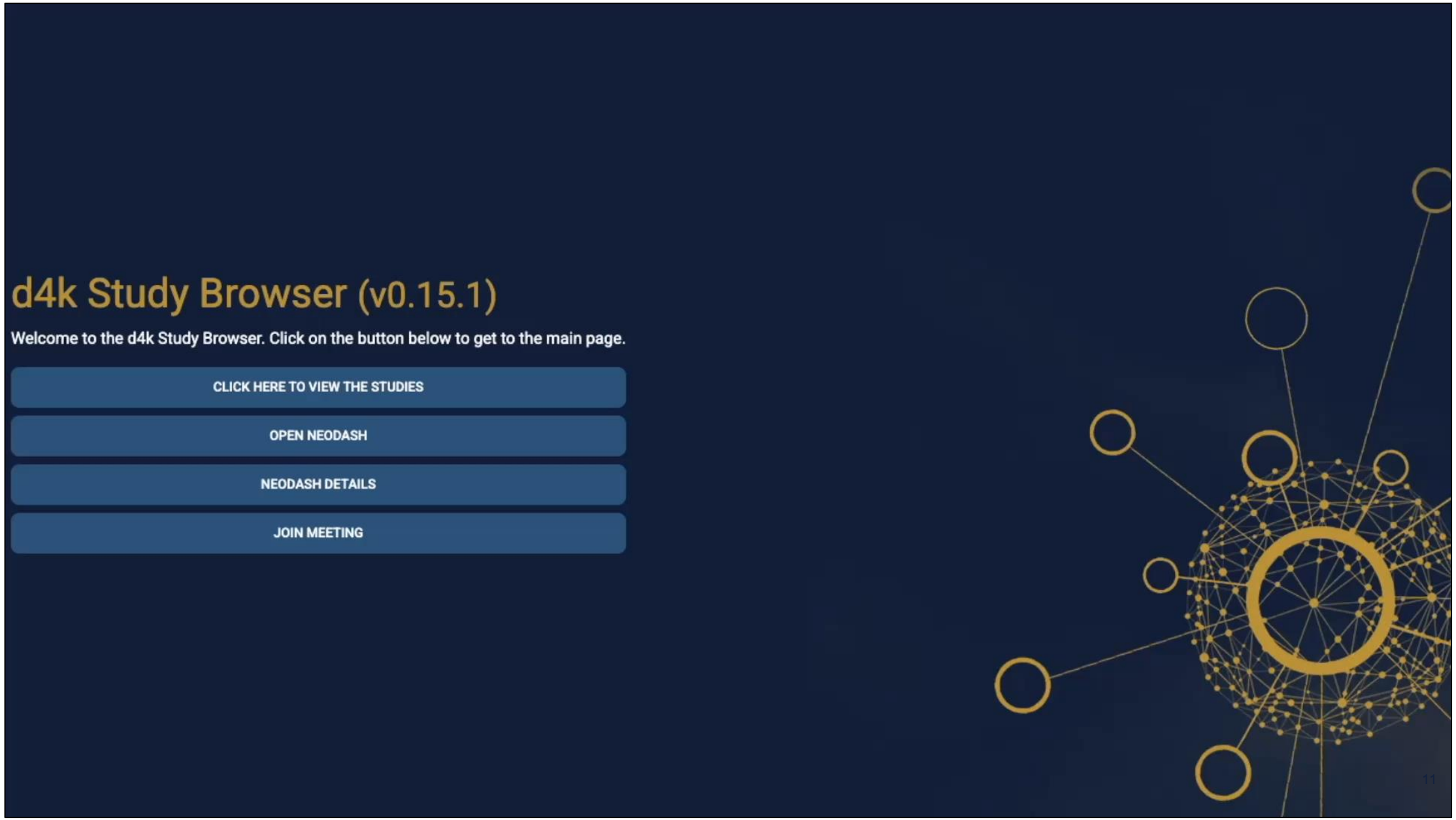
- The data contract is the set of data points needed to meet the needs of the study.
- Expands the SoA+ (e.g. observations repeated across visits)
- The URI is the barcode for a single atomic data point, a unique identifier that persists forever.
- Can be used for multiple purposes: external data providers, long term retention of data …

Technology Demonstrator

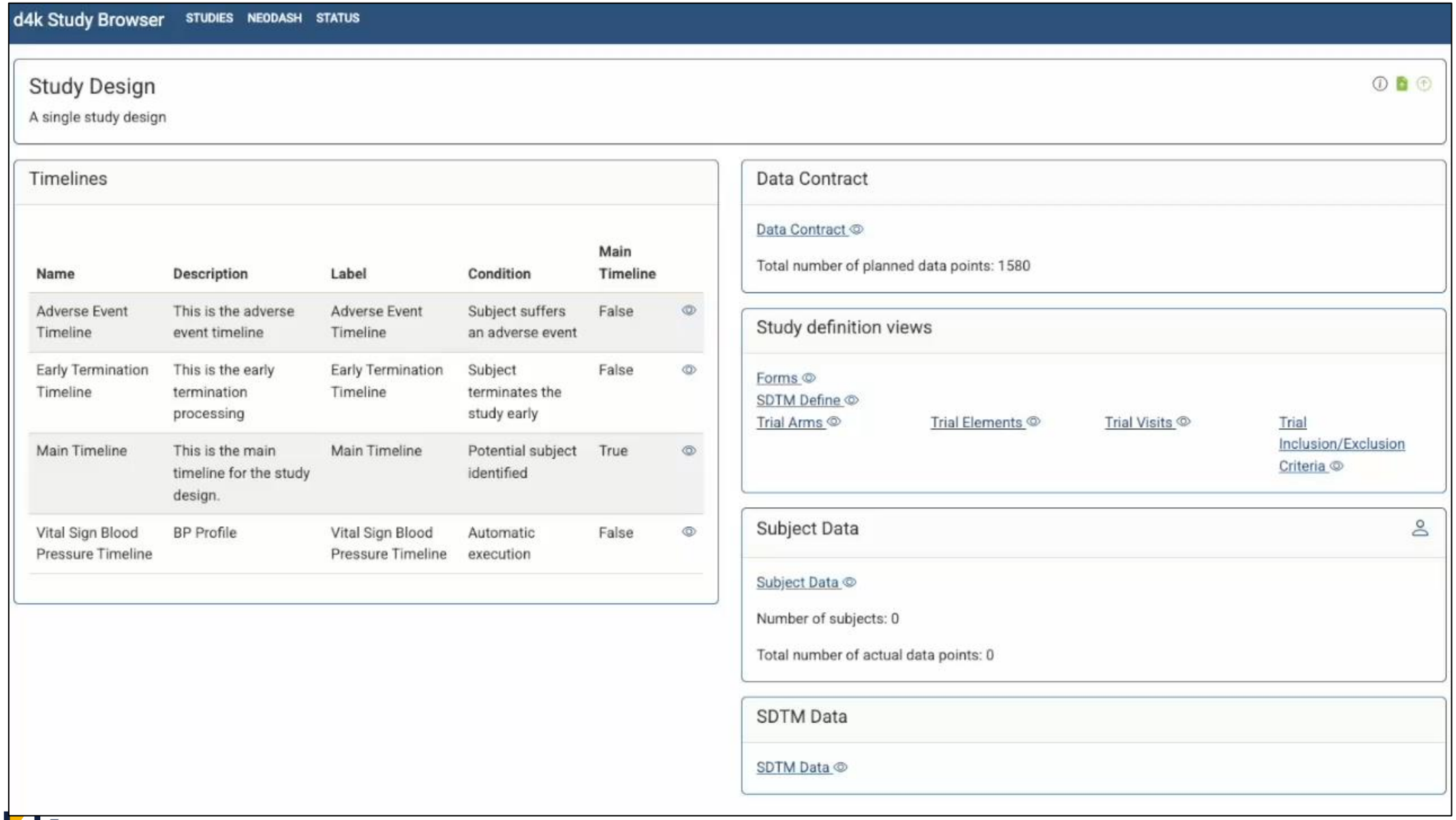
- A PowerPoint just doesn't do the job
- Need to see the ideas in action
- Can be run on a laptop using a graph database
- Has a basic User Interface (UI)
- We are continuing to work on it

Load the protocol (video)

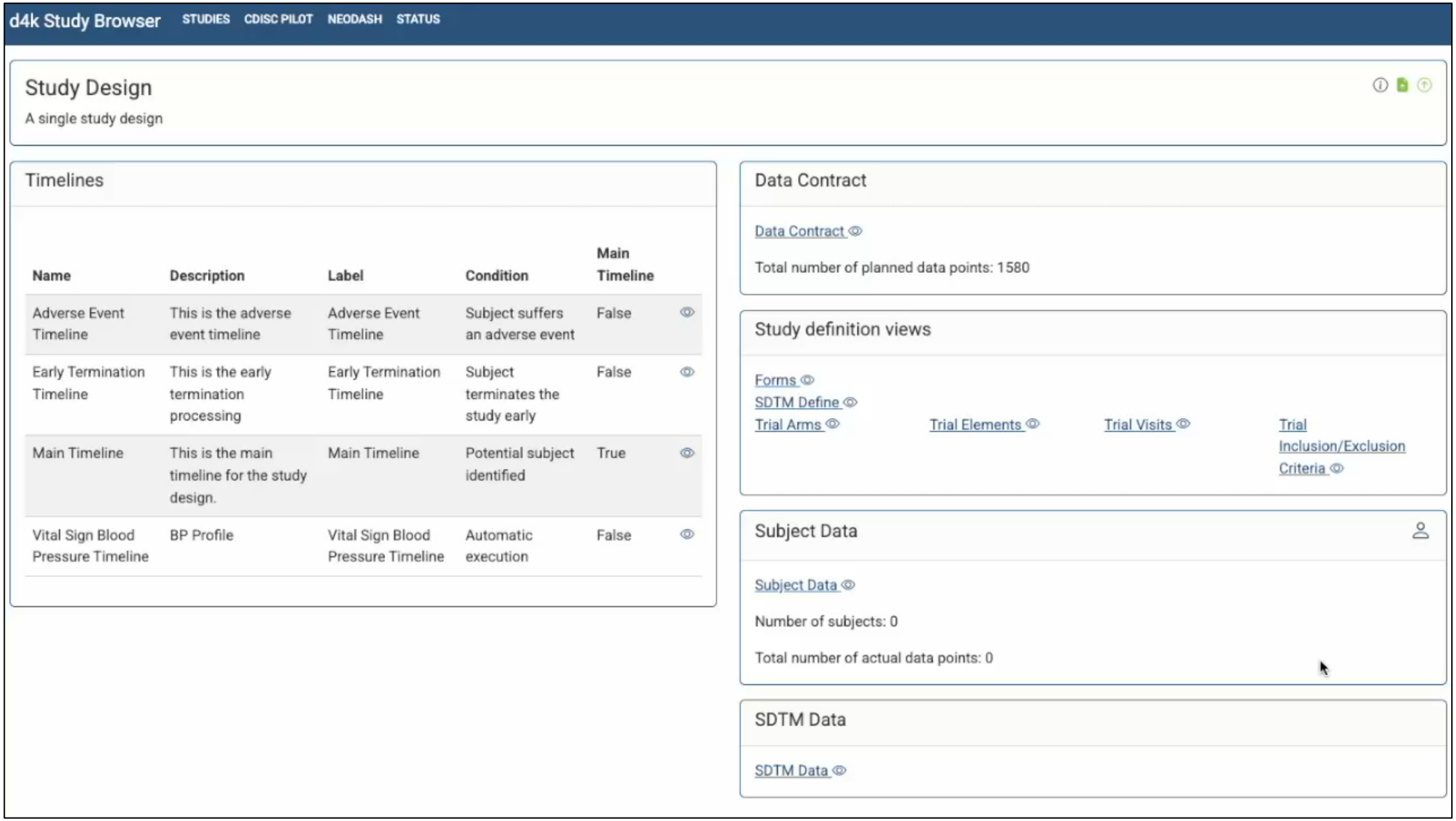
Timelines, Activities, Biomedical Concepts and SDTM
Creates data contracts



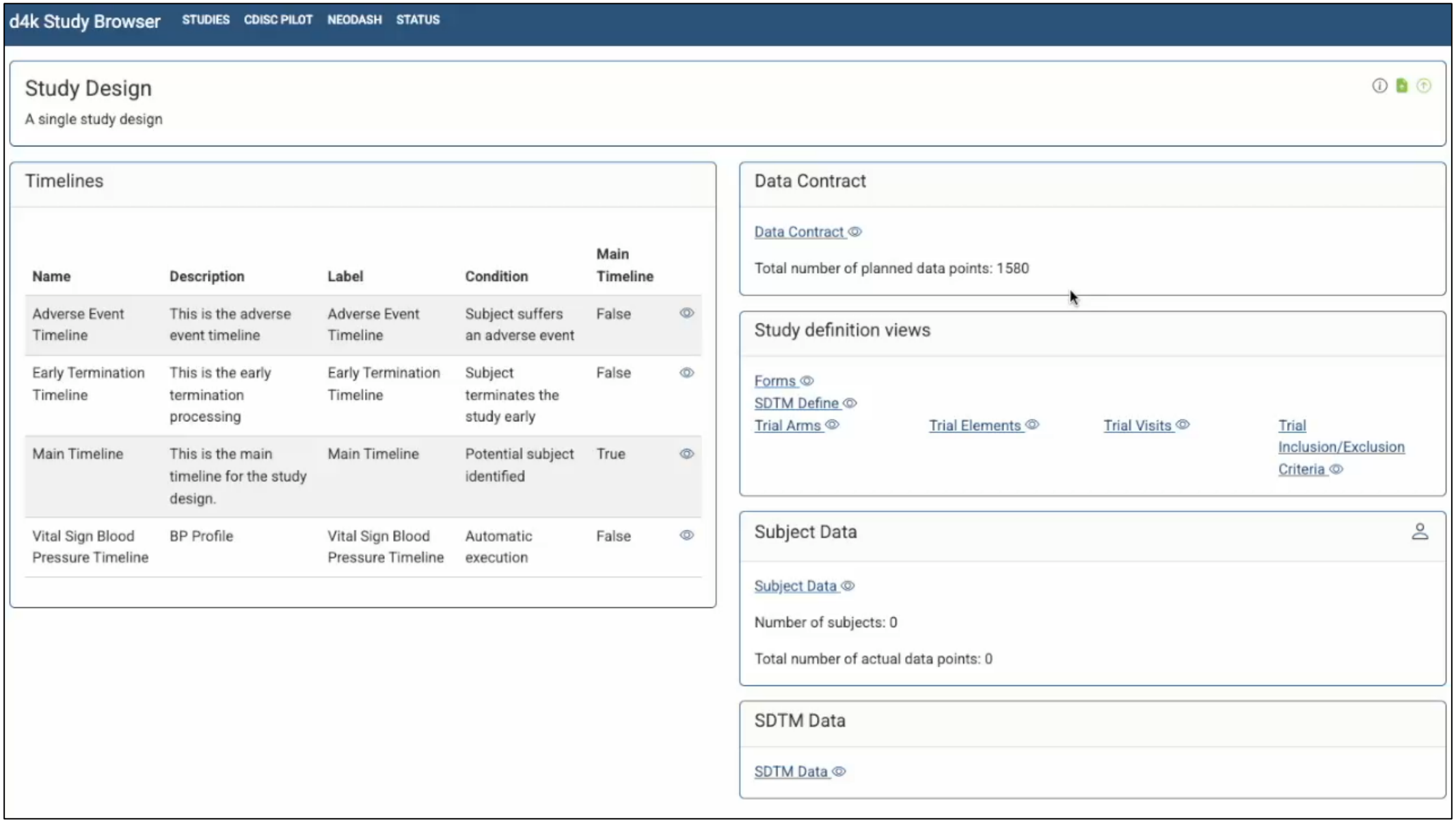
Timelines (video)



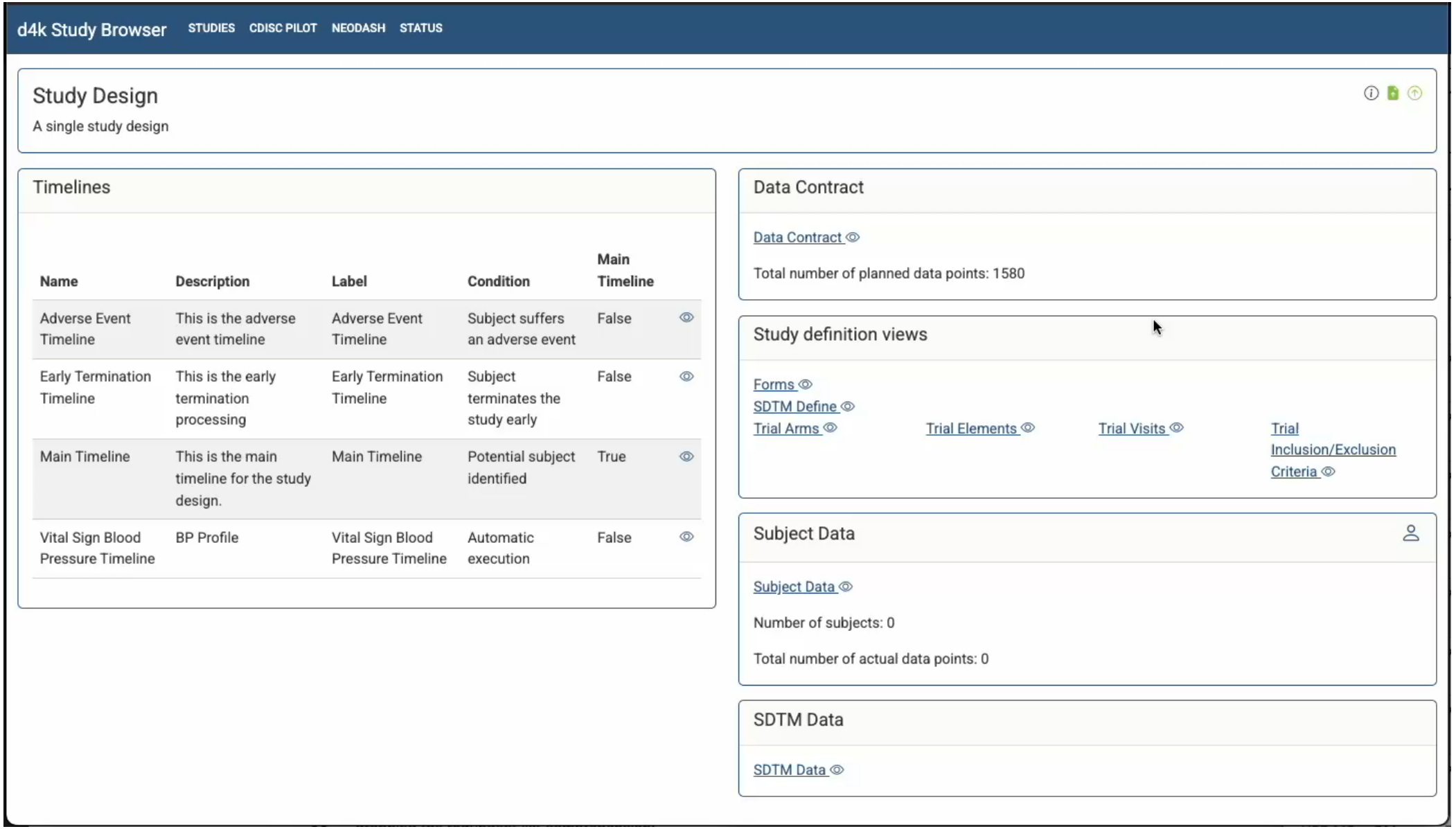
Data Contracts (video)



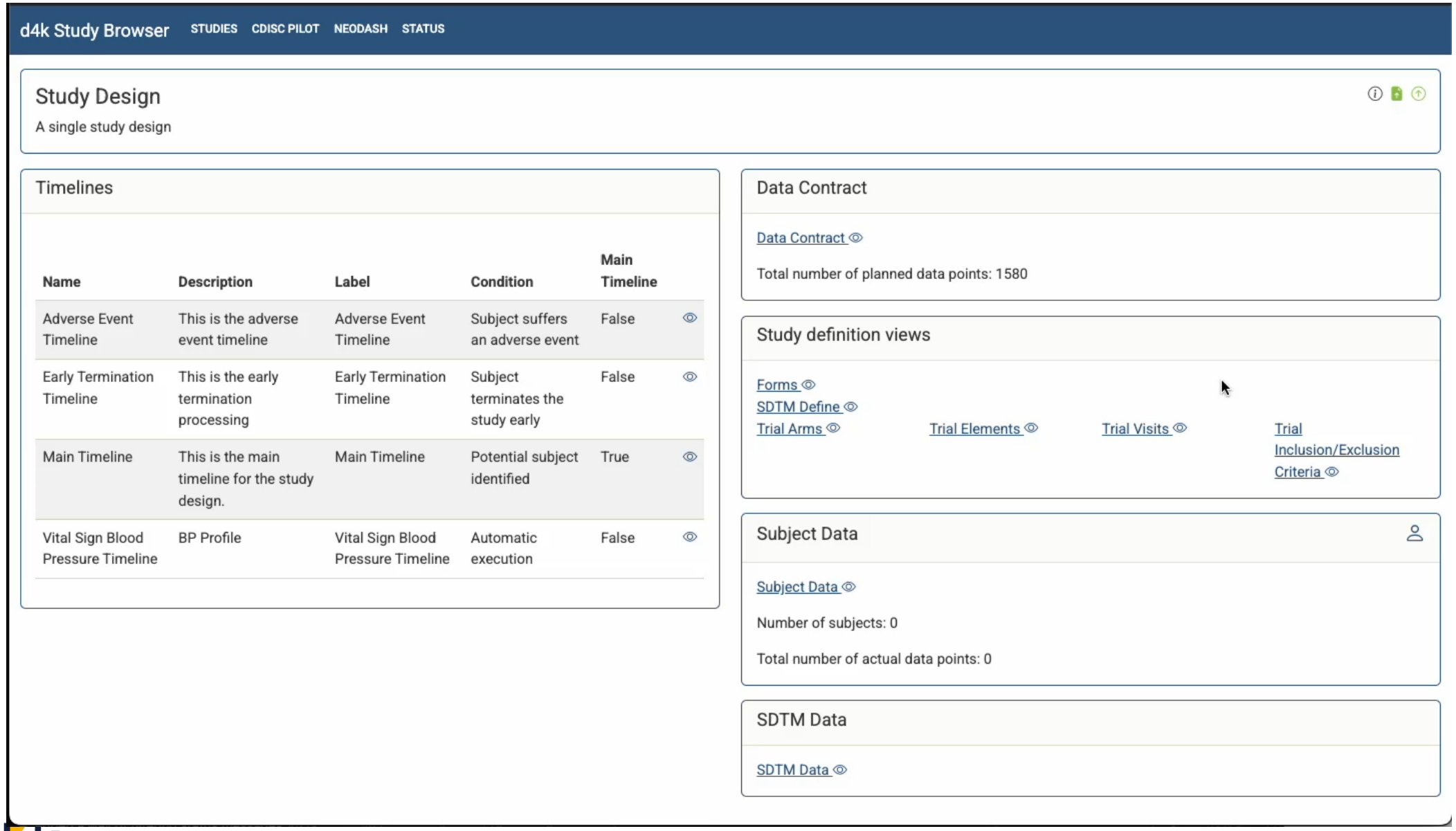
Forms, Define, Trial Design (video)



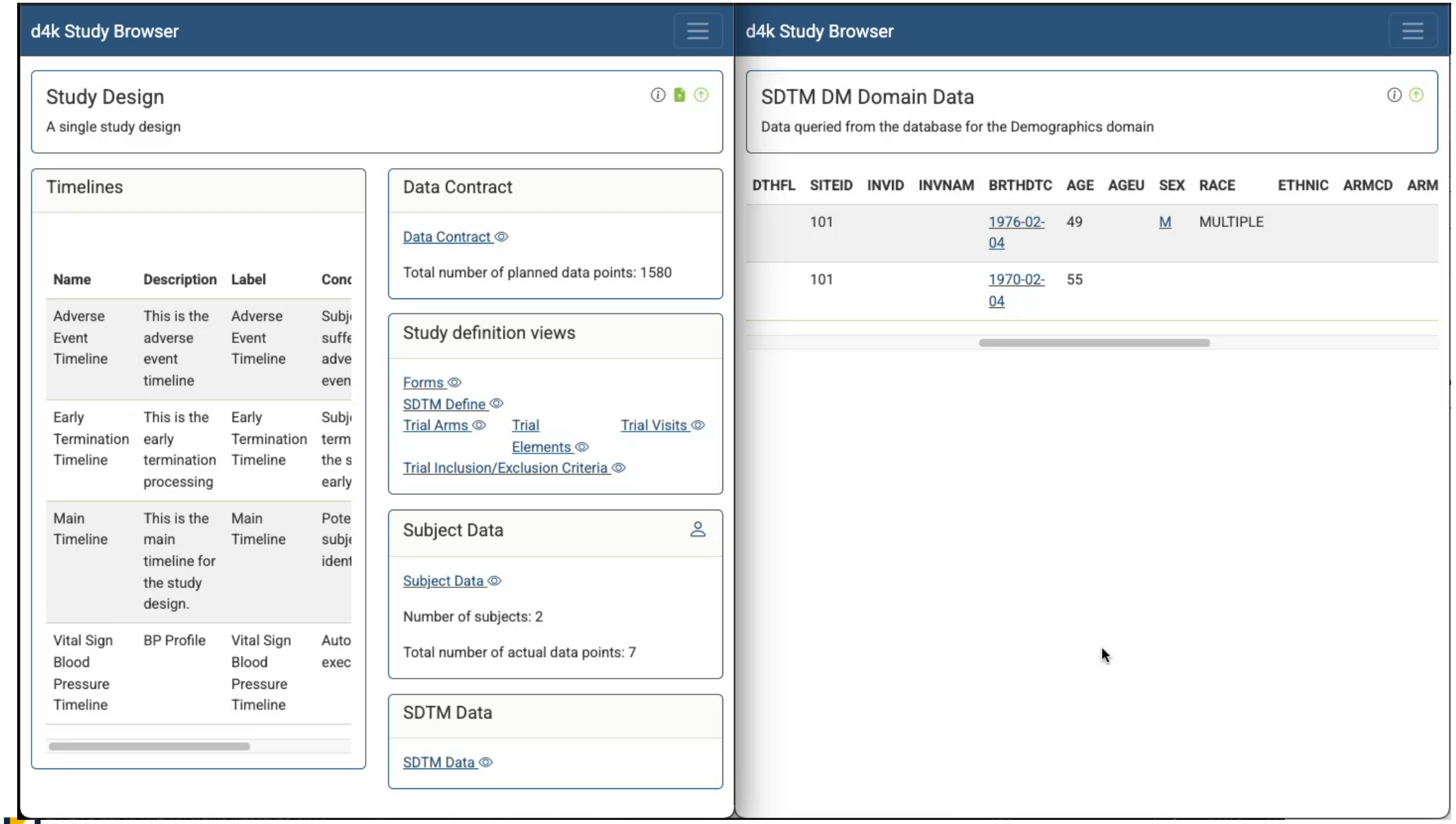
Biomedical Concepts linked to SDTM domains (video)



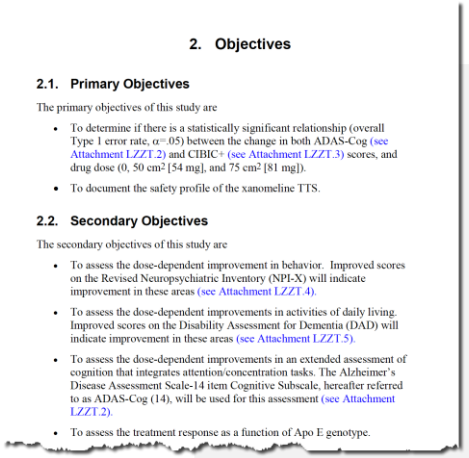
Data Entry (video)



Load data (video)



And so …



2. Objectives

2.1. Primary Objectives

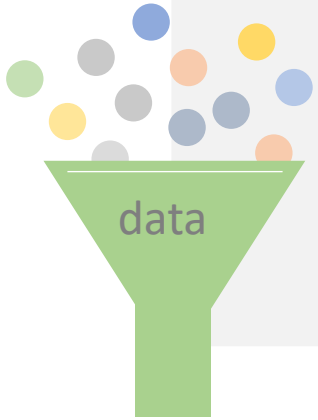
The primary objectives of this study are

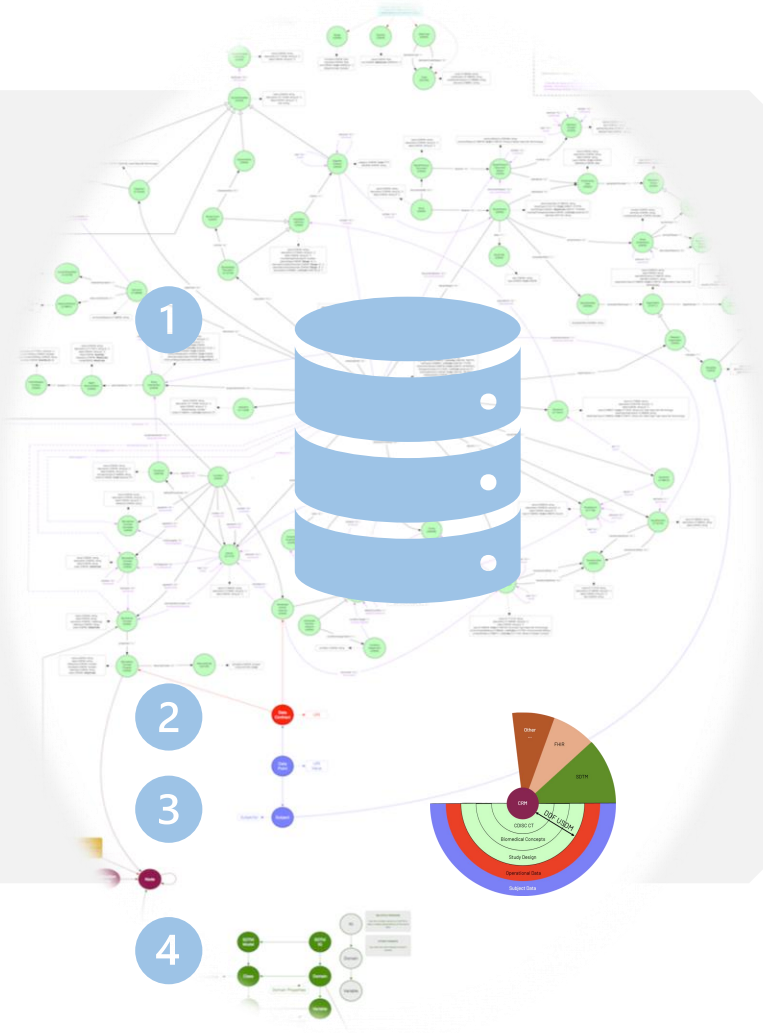
- To determine if there is a statistically significant relationship (overall Type 1 error rate, α=.05) between the change in both ADAS-Cog (see Attachment LZZT.2) and CIBIC+ (see Attachment LZZT.3) scores, and drug dose (0, 50 cm² [54 mg], and 75 cm² [81 mg]).
- To document the safety profile of the xanomeline TTS.

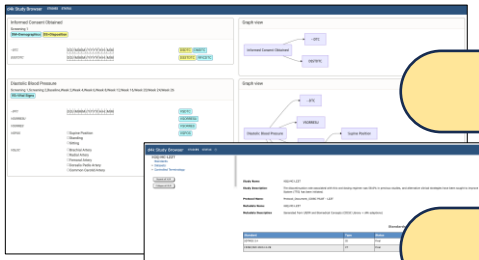
2.2. Secondary Objectives

The secondary objectives of this study are

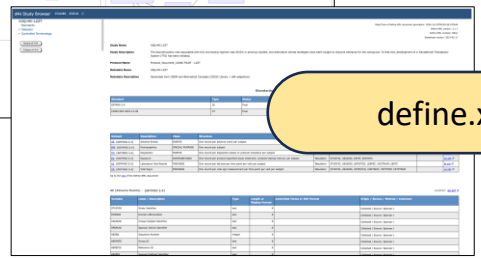
- To assess the dose-dependent improvement in behavior. Improved scores on the Revised Neuropsychiatric Inventory (NPI-X) will indicate improvement in these areas (see Attachment LZZT.4).
- To assess the dose-dependent improvements in activities of daily living. Improved scores on the Disability Assessment for Dementia (DAD) will indicate improvement in these areas (see Attachment LZZT.5).
- 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 LZZT.2).
- To assess the treatment response as a function of Apo E genotype.



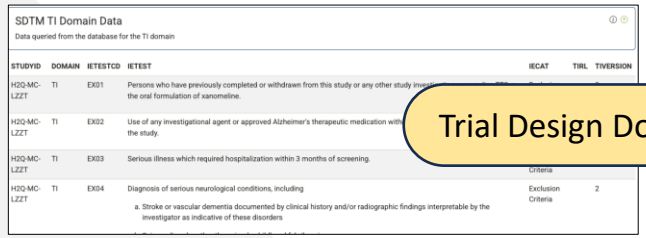




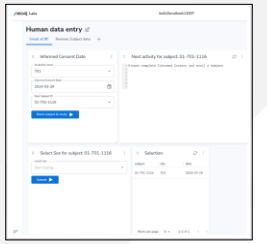
aCRF

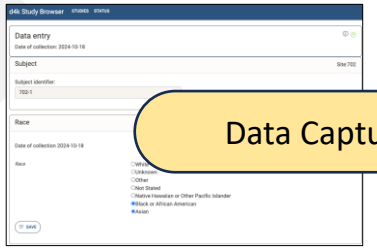


define.xml

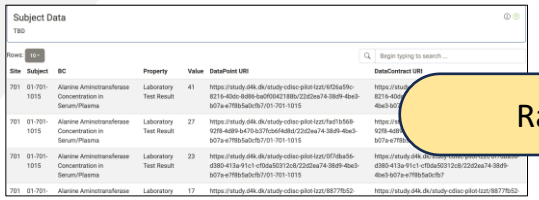


Trial Design Domains

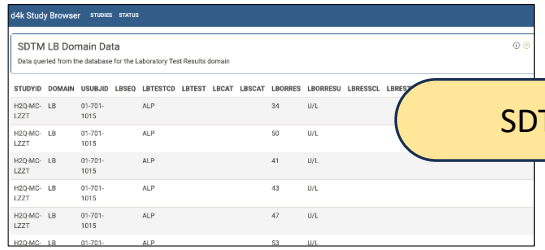




Data Capture



Raw Data



SDTM Data

Summary

- USDM provides the strong foundation
- We extended USDM …
  - Established the data contract
  - Linked in the subject data
  - Linked in SDTM
  - Allows for data capture
  - Extracted SDTM, aCRF and define.xml
- And more to come …

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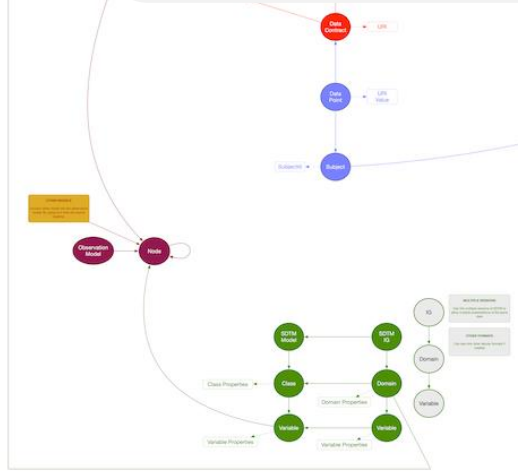
Contact Details

dih@data4knowledge.dk
kf@data4knowledge.dk
kwl@data4knowldge.dk
ju@data4knowledge.dk

Dave Iberson-Hurst
Kerstin Forsberg
Kirsten Walther Langendorf
Johannes Ulander



Supporting Protocol Content Reuse: Starting with USDM

USDM provides a critical first step to prepare Protocol content for reuse and automation

Todd Georgieff
futurpositif Digital Clinical Trials
todd@futurpositif.com

Regina Lynn Preciado
Content Rules, Inc
reginap@contentrules.com

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Contents

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Introduction

- Clinical trials require extensive information sharing across stakeholders
- That information is a combination of raw data, summarized data, and narrative text
- The Digital Data Flow (DDF) initiative makes raw and summarized data FAIR (findable, accessible, interoperable, and reusable)
- DDF principles can also apply to narrative text
- Technology-driven, FAIR-aligned workflows can reduce risks and costs in life sciences

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Problem Statement

Study protocols contain narrative content in machine-incompatible formats.

Unstructured text in traditional tools limits reuse, automation, and AI integration.

Unstructured documents are the least efficient way to create, manage, and publish content.

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The Impact

Clinicians and writers lose time on repetitive tasks, delaying documents and increasing errors. Unstructured content also limits AI potential.

01

Inefficiency and Cost

Clinicians and writers spend time on manual, repetitive tasks, often re-creating existing content.

02

Ineffective Use of Time

Development of “downstream” documents, registry entries, and other outputs takes longer than it should.

03

Risk

Copy-paste and transcription can introduce errors and inconsistencies.

04

Lost Opportunity

Unstructured documents are a poor resource to train LLMs, optimize RAG, or provide quality source content for GenAI processing and drafting content.

Objective

- Conduct a gap analysis
- Determine whether the CDISC USDM provides adequate semantic XML markup for narrative content

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Opportunity

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Opportunity

Structure and mark up narrative information with semantic XML

Based on the USDM– information can be managed like data and processed by machines

- **Reuse approved content for submission documents**
- **Extract verbatim content for registry listings**
- **Use GenAI to generate summaries, derivatives, and lay language variants**

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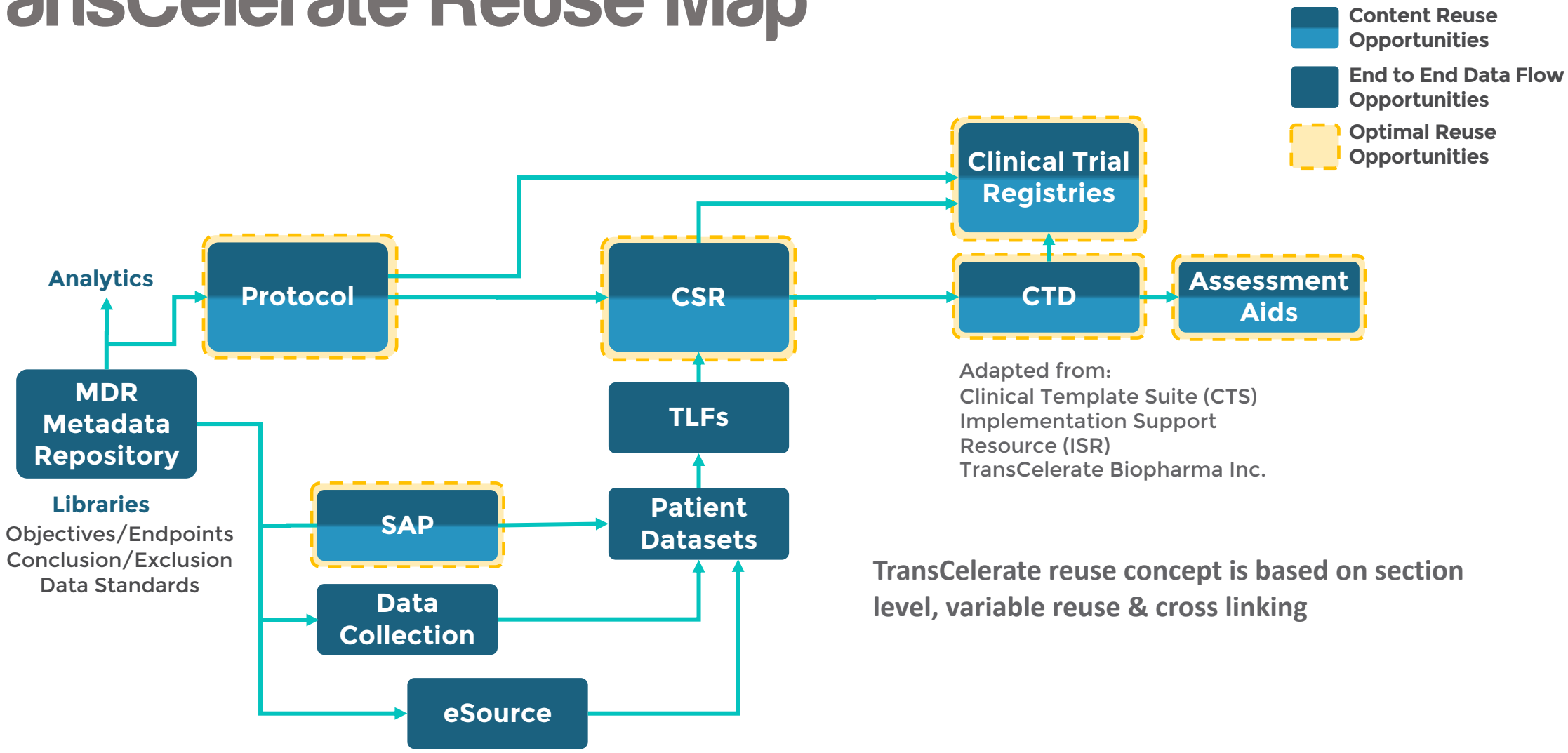
TransCelerate Reuse Map



TransCelerate reuse concept is based on section level, variable reuse & cross linking

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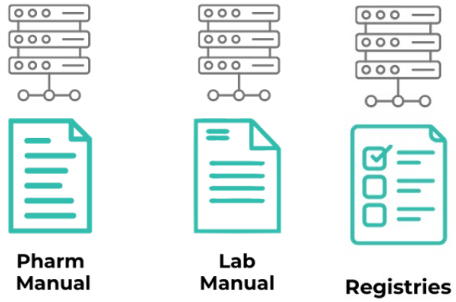
Taking Reuse a Step Further



Protocol

The Protocol contains core reusable content essential to many closely related documents and registries.

Informed Consent

The Informed Consent Form (ICF) reuses core content from the Protocol.

Clinical Study Report

The CSR reuses core content from the Protocol and provides essential reusable content to other related documents.

Plain Language Summary

The Plain Language Summary reuses core content from the Protocol, CSR and ICF.

Common Technical Document

CTD Module 2 summaries reuse core content from the Protocol and CSR.

Adapted from:
Clinical Template Suite (CTS)
Implementation Support Resource (ISR)
TransCelerate Biopharma Inc.

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Gap Analysis

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Gap Analysis

	Word Processing + Document Management System	Structured Content System Configured with USDM + XML
Apply metadata to documents	X	X
Apply metadata to granular components (“chunks”)		X
Apply clinically relevant, semantic metadata to source components		X
Provide component content management & publishing capabilities from a single source of truth		X
Provide curated, semantically tagged chunks to AI solution		X
Automatically generate content from source text	X	X
Automate content reuse		X
Authoring by humans and AI assistants	X	X

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Word Processing

- Style tags indicate formatting, not content type
- Easy for authors to apply wrong style
- Challenging for machines to retrieve the right content
- Manual copy/paste introduces errors & requires many reviews

[[Style:H2]]**STUDY RATIONALE**[[EndStyle]]
[[Style:Normal]]Hypoglycemia is a common complication in all patients with T1DM and some patients with T2DM who use insulin to reduce blood glucose levels. Use of sulfonylurea and glinide by patients with T2DM may also cause hypoglycemia. Depending on the severity, hypoglycemia causes physical symptoms ranging from weakness, dizziness, and sweating progressing to blurred vision, behavioral changes, progressing to unconsciousness, seizures, and coma, and possibly to death (American Diabetes Association 2017). When emergency services are available in a timely manner, intravenous (IV) glucose supplementation is also an effective treatment. Glucagon for injection is a globally available product currently indicated for the treatment of severe hypoglycemia, and is another important treatment option outside of a clinical setting for people who try to rescue patients with severe hypoglycemia.[[EndStyle]]

[[Style:Heading2]]**STUDY DESIGN**[[EndStyle]]
[[Style:Normal]]This is a Phase 3, multicenter, randomized, open-label, active comparator, single-dose, 2-period, 2-treatment, crossover study in Japanese patients with T1DM and T2DM. The study consists of a screening period; treatment period 1 (Period 1); washout period; treatment period 2 (Period 2); follow-up period. Figure IGBJ.1 illustrates the study design. Prior to the study drug administration on Period 1 Day 1, patients will be randomly assigned to a treatment sequence (either LY900018 in Period 1 and IMG in Period 2, or vice versa).[[EndStyle]]
[[Style:Body2]]Safety data will be reviewed after the first 6 patients (regardless of type of diabetes) are administered LY900018 in Period 2, and the remaining patients will be dosed after confirmation of the safety. The investigator and Lilly clinical research physician (CRP) or scientist will review available safety data, including AEs, SAEs, vital signs, electrocardiograms (ECGs), and safety laboratory tests, from these patients after they complete Period 2 Day 1. If no clinically significant safety findings for treatment or study procedure are noted, the remaining patients will be dosed.
[[EndStyle]]

Sample Protocol text excerpts are content based on DDF-RA (GitHub) used under the CC-BY-4.0 license. No changes were made to the text. Simplified markup is for illustrative purposes only and is not valid XML.

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USDM

- Semantic tags indicate content type
- Machines easily retrieve correct content
- GenAI creates derivatives from correct content
- Automated reuse eliminates copy/paste & associated risk

```
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<title>STUDY RATIONALE</title>
<body>
<p>Hypoglycemia is a common complication in all patients with T1DM and some patients with T2DM who use insulin to reduce blood glucose levels. Use of sulfonylurea and glinide by patients with T2DM may also cause hypoglycemia. Depending on the severity, hypoglycemia causes physical symptoms ranging from weakness, dizziness, and sweating progressing to blurred vision, behavioral changes, progressing to unconsciousness, seizures, and coma, and possibly to death (American Diabetes Association 2017). When emergency services are available in a timely manner, intravenous (IV) glucose supplementation is also an effective treatment. Glucagon for injection is a globally available product currently indicated for the treatment of severe hypoglycemia, and is another important treatment option outside of a clinical setting for people who try to rescue patients with severe hypoglycemia.</p>
<p>....</p>
</body>
</studyRationale>
<USDM:study_design>
<title>STUDY DESIGN</title>
<body>
<p>This is a Phase 3, multicenter, randomized, open-label, active comparator, single-dose, 2-period, 2-treatment, crossover study in Japanese patients with T1DM and T2DM. The study consists of a screening period; treatment period 1 (Period 1); washout period; treatment period 2 (Period 2); follow-up period. Figure IGBJ.1 illustrates the study design. Prior to the study drug administration on Period 1 Day 1, patients will be randomly assigned to a treatment sequence (either LY900018 in Period 1 and IMG in Period 2, or vice versa).</p>
<p>Safety data will be reviewed after the first 6 patients (regardless of type of diabetes) are administered LY900018 in Period 2, and the remaining patients will be dosed after confirmation of the safety. The investigator and Lilly clinical research physician (CRP) or scientist will review available safety data, including AEs, SAEs, vital signs, electrocardiograms (ECGs), and safety laboratory tests, from these patients after they complete Period 2 Day 1. If no clinically significant safety findings for treatment or study procedure are noted, the remaining patients will be dosed.</p>
<p>....</p>
</body>
</study_design>
```

Sample Protocol text excerpts are content based on DDF-RA (GitHub) used under the CC-BY-4.0 license. No changes were made to the text. Simplified markup is for illustrative purposes only and is not valid XML.

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Semantic Markup Examples

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Context for Examples

Compare format-based markup to semantic markup

Markup shown is for illustrative purposes only and is not intended to be “working XML”

Example 1: Study Rationale

Unstructured Document with Formatting

[p]Hypoglycemia is a common complication in all patients with T1DM and some patients with T2DM who use insulin to reduce blood glucose levels. Use of sulfonylurea and glinide by patients with T2DM may also cause hypoglycemia. Depending on the severity, hypoglycemia causes physical symptoms ranging from weakness, dizziness, and sweating progressing to blurred vision, behavioral changes, progressing to unconsciousness, seizures, and coma, and possibly to death (American Diabetes Association 2017). When emergency services are available in a timely manner, intravenous (IV) glucose supplementation is also an effective treatment. Glucagon for injection is a globally available product currently indicated for the treatment of severe hypoglycemia, and is another important treatment option outside of a clinical setting for people who try to rescue patients with severe hypoglycemia. However, for people without enough medical training, the multi-step reconstitution of glucagon and injection procedure would be complex and daunting with substantial risk of errors (Polonsky et al. 2016). Therefore the needle-free and easy-to-administer formulation of glucagon is desired for patients who have a risk of severe hypoglycemia related to anti-diabetes treatments. LY900018 is a powder formulation of synthetic human glucagon in a user-friendly, single-use, nasal dosing device which delivers 3 mg glucagon powder. Patients do not need to inhale, as the drug is absorbed from the nasal cavity.[/p]

DITA XML with USDM Attributes

```
<topic id="hypoglycemia_treatment">
 <title>Hypoglycemia and Its Treatment</title>
 <body>
  <p>
   <ph id="hypoglycemia_definition">Hypoglycemia is a common complication in all patients with T1DM and some patients with T2DM who use insulin to reduce blood glucose levels. Use of sulfonylurea and glinide by patients with T2DM may also cause hypoglycemia.</ph>
  </p>
  <p>
   <ph id="hypoglycemia_symptoms">Depending on the severity, hypoglycemia causes physical symptoms ranging from weakness, dizziness, and sweating progressing to blurred vision, behavioral changes, progressing to unconsciousness, seizures, and coma, and possibly to death</ph> <xref href="#ADA2017">(American Diabetes Association 2017)</xref>.
  </p>
  <p>
   <ph id="emergency_treatment">When emergency services are available in a timely manner, intravenous (IV) glucose supplementation is also an effective treatment.</ph>
  </p>
  <p>
   <ph id="glucagon_injection">Glucagon for injection is a globally available product currently indicated for the treatment of severe hypoglycemia, and is another important treatment option outside of a clinical setting for people who try to rescue patients with severe hypoglycemia.</ph>
  </p>
  <p>
   <ph id="glucagon_challenges">However, for people without enough medical training, the multi-step reconstitution of glucagon and injection procedure would be complex and daunting with substantial risk of errors</ph> <xref href="#Polonsky2016">(Polonsky et al. 2016)</xref>.
  </p>
  <p>
   <ph id="needle_free_desire">Therefore the needle-free and easy-to-administer formulation of glucagon is desired for patients who have a risk of severe hypoglycemia related to anti-diabetes treatments.</ph>
  </p>
  <p>
   <ph id="LY900018_description">LY900018 is a powder formulation of synthetic human glucagon in a user-friendly, single-use, nasal dosing device which delivers 3 mg glucagon powder. Patients do not need to inhale, as the drug is absorbed from the nasal cavity.</ph>
  </p>
 </body>
</topic>
```

Example 1: Study Rationale (Close-up)

[p] Hypoglycemia is a common complication in all patients with T1DM and some patients with T2DM who use insulin to reduce blood glucose levels. Use of sulfonylurea and glinide by patients with T2DM may also cause hypoglycemia. Depending on the severity, hypoglycemia causes physical symptoms ranging from weakness, dizziness, and sweating progressing to blurred vision, behavioral changes, progressing to unconsciousness, seizures, and coma, and possibly to death (American Diabetes Association 2017). When emergency services are available in a timely manner, intravenous (IV) glucose supplementation is also an effective treatment. Glucagon for injection is a globally available product currently indicated for the treatment of severe hypoglycemia, and is another important treatment option outside of a clinical setting for people who try to rescue patients with severe hypoglycemia. However, for people without enough medical training, the multi-step reconstitution of glucagon and injection procedure would be complex and daunting with substantial risk of errors (Polonsky et al. 2016). Therefore the needle-free and easy-to-administer formulation of glucagon is desired for patients who have a risk of severe hypoglycemia related to anti-diabetes treatments. LY900018 is a powder formulation of synthetic human glucagon in a user-friendly, single-use, nasal dosing device which delivers 3 mg glucagon powder. Patients do not need to inhale, as the drug is absorbed from the nasal cavity. [/p]

DITA XML with USDM Attributes

```
<ph
id="hypoglycemia_definition"
>
Hypoglycemia is a common complication in all patients with T1DM and some patients with T2DM who use insulin to reduce blood glucose levels. Use of sulfonylurea and glinide by patients with T2DM may also cause hypoglycemia.
</ph>
```

Example 2: Study Design

Unstructured Document with Formatting

[p] This is a Phase 3, multicenter, randomized, open-label, active comparator, single-dose, 2-period, 2-treatment, crossover study in Japanese patients with T1DM and T2DM. The study consists of a screening period; treatment period 1 (Period 1); washout period; treatment period 2 (Period 2); follow-up period. Figure IGBJ.1 illustrates the study design. Prior to the study drug administration on Period 1 Day 1, patients will be randomly assigned to a treatment sequence (either LY900018 in Period 1 and IMG in Period 2, or vice versa). [/p]

DITA XML with USDM Attributes

```
<topic id="clinical_trial_design">
 <title>Clinical Trial Design</title>
 <body>
  <p>This is a
   <ph id="study_phase">Phase 3</ph>,
   <ph id="study_characteristics">multicenter, randomized, open-label, active comparator, single-dose, 2-period, 2-treatment, crossover</ph>
   study in
   <ph id="patient_population">Japanese patients with T1DM and T2DM</ph>.
  </p>
  <p>The study consists of:
   <ul>
    <li><ph id="screening_period">a screening period</ph></li>
    <li><ph id="treatment_period_1">treatment period 1 (Period 1)</ph></li>
    <li><ph id="washout_period">washout period</ph></li>
    <li><ph id="treatment_period_2">treatment period 2 (Period 2)</ph></li>
    <li><ph id="follow_up_period">follow-up period</ph></li>
   </ul>
  </p>
  <p><ph id="study_design_reference">Figure IGBJ.1 illustrates the study design.</ph></p>
  <p>
   <ph id="randomization_process">Prior to the study drug administration on Period 1 Day 1, patients will be randomly assigned to a treatment sequence (either LY900018 in Period 1 and IMG in Period 2, or vice versa).</ph>
  </p>
 </body>
</topic>
```

Example 2: Study Design (Close-up)

Unstructured Document with Formatting

[p] This is a Phase 3, multicenter, randomized, open-label, active comparator, single-dose, 2-period, 2-treatment, crossover study in Japanese patients with T1DM and T2DM. The study consists of a screening period; treatment period 1 (Period 1); washout period; treatment period 2 (Period 2); follow-up period. Figure IGBJ.1 illustrates the study design. Prior to the study drug administration on Period 1 Day 1, patients will be randomly assigned to a treatment sequence (either LY900018 in Period 1 and IMG in Period 2, or vice versa). [/p]

DITA XML with USDM Attributes

```
<ph id="randomization_process">Prior to the study drug administration on Period 1 Day 1, patients will be randomly assigned to a treatment sequence (either LY900018 in Period 1 and IMG in Period 2, or vice versa).</ph>
```

Example 3: Eligibility Criteria

Unstructured Document with Formatting

6.1. Inclusion Criteria

Patients are eligible for inclusion in the study only if they meet all of the following criteria at screening and/or enrollment:

[1] have had a diagnosis of either:

[1a] T1DM based on the World Health Organization (WHO) diagnostic criteria, and have been on the following daily insulin therapy for at least 1 year

[A] multiple daily injection of long-acting insulin analog (either insulin glargine [U-100 or U-300] or insulin degludec [U-100]) and rapid-acting insulin analog (insulin lispro, insulin aspart, or insulin glulisine), or

[B] continuous subcutaneous insulin infusion (CSII)

Or

[1b] T2DM based on the WHO diagnostic criteria, and have received the following daily insulin therapy with or without oral anti-hyperglycemic medications (OAMs) for at least 1 year

[A] insulin: long-acting insulin analog (either insulin glargine [U-100 or U-300] or insulin degludec [U-100]) alone, or in combination with rapid-acting insulin analog (insulin lispro, insulin aspart, or insulin glulisine) or CSII

[B] OAM: up to 3 of the following OAMs in accordance with local regulations: metformin, dipeptidyl peptidase-4 inhibitor, sodium glucose cotransporter 2 inhibitor, sulfonylurea (should not be more than half of maximum approved doses), glinides, alpha-glucosidase inhibitor, or thiazolidine

DITA XML with USDM Attributes

```
<topic id="eligibility_criteria">
 <title>Eligibility Criteria</title>
 <body>
  <section id="inclusion_criteria">
   <title>Inclusion Criteria</title>
   <p>Patients are eligible for inclusion in the study only if they meet all of the following criteria at screening and/or enrollment:</p>
   <ol>
    <li>
     <ph id="diagnosis">have had a diagnosis of either:</ph>
     <ol type="a">
      <li>
       <ph id="t1dm_diagnosis">T1DM based on the World Health Organization (WHO) diagnostic criteria</ph>, and
       <ph id="t1dm_treatment_duration">have been on the following daily insulin therapy for at least 1 year</ph>
       <ol type="A">
        <li>
         <ph id="t1dm_mdi">multiple daily injection of long-acting insulin analog (either insulin glargine [U-100 or U-300] or insulin degludec [U-100]) and rapid-acting insulin analog (insulin lispro, insulin aspart, or insulin glulisine)</ph>, or
        </li>
        <li>
         <ph id="t1dm_csii">continuous subcutaneous insulin infusion (CSII)</ph>
        </li>
       </ol>
      </li>
```

Example 3: Eligibility Criteria (Close-up)

Unstructured Document with Formatting

6.1. Inclusion Criteria

Patients are eligible for inclusion in the study only if they meet all of the following criteria at screening and/or enrollment:

DITA XML with USDM Attributes

```
<topic id="eligibility_criteria">
  <title>Eligibility Criteria</title>
  <body>
    <section id="inclusion_criteria">
      <title>Inclusion Criteria</title>
      <p>Patients are eligible for inclusion in the study only if they meet all of the following criteria at screening and/or enrollment:</p>
```

Technology Requirements

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Automation Requirements

1. For effective machine processing, narrative content must have consistent, unique, and meaningful metadata.

2. To treat narrative content as data, it must be tagged more granularly than document or section levels.

3. USDM provides a common vocabulary for applying semantic markup based on meaning, not appearance.

4. The USDM metadata vocabulary helps identify narrative content, allowing systems to treat content like data for machine processing.

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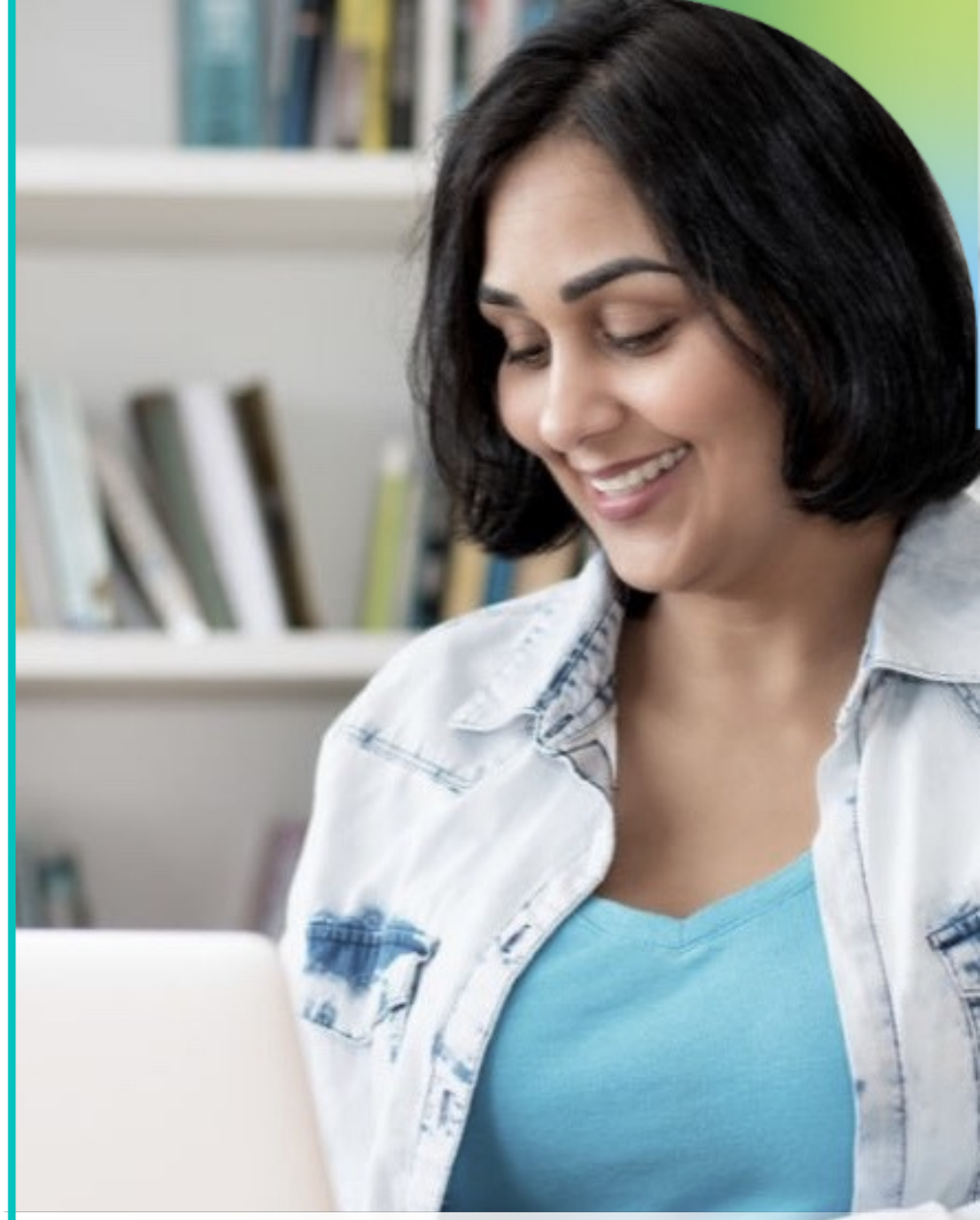
Conclusion

- Unstructured text limits machine processing and increases risk, time, and cost.
- Semantic markup helps machines identify content by type and purpose.
- Granular semantic markup enhances search, reuse, and long-term content management.
- CDISC USDM provides a semantic standard for machine-friendly, interoperable content.
- Metadata-tagged content improves LLM training and helps ensure accurate, reliable results from RAG and AI content generation.



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Questions?

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Thank You

Todd Georgieff [todd@futurpositif.com]
futurpositif Digital Clinical Trials
futurepositif.com

Regina Lynn Preciado [reginap@contentrules.com]
Content Rules, Inc.
contentrules.com

futurpositif

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Presenter Q&A

Meet Our Expert Panel

Mike Rippin
Digital Data Flow
Project Manager

Johannes Ulander

Partner, data4knowledge

Kirsten Walter Langendorf

Partner, data4knowledge

Regina Lynn Preciado

Sr. Director of Content Strategy Solutions, Contentrules

Todd Georgieff

Principal Consultant, futurpositif

Chris Decker

CEO, CDISC

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Note: depending on time, we will not be able to answer all questions

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- Costs of using/implementing TransCelerate assets/tools
- Which member companies are using the assets/tools

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