

From Criteria to Connection; Enabling Diverse Participation With USDM Through READI

John Owen and Berber Snoeijer
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Agenda

1. Introduction to the READI project
2. Introduction to USDM
3. From Criteria Digitisation to RWD patient selection: utilising USDM in the READI platform

Speakers



John Owen
Senior Director,
Standards Operations
CDISC

- >30 years of experience in pharmaceutical industry,
- dedicated to improving the quality and interoperability of clinical research data,
- guides the delivery of global standards initiatives that strengthen the foundations of connected, high-quality clinical data.

Speakers



Berber Snoeijer
USDM Trainer and
Technical Expert
CDISC

- >25 years of experience in pharmaceutical industry,
- dedicated to improving the quality and interoperability of clinical research data and real-world data,
- provides input and designs for data structures, solutions, and process optimization.



Introduction to the READI IHI Project



READI

REpresentative Clinical Research, ADvancing Inclusivity In Europe

An IHI-funded Public-Private Partnership advancing inclusive, and patient-centred clinical research in Europe

PRESENTED BY: John Owen & Berber Snoeijer – CDISC



This project is supported by the Innovative Health Initiative Joint Undertaking (IHI JU) under grant agreement No 101166227. The JU receives support from the European Union's Horizon Europe research and innovation programme and COCIR, EFPIA, Europa Bio, MedTech Europe, and Vaccines Europe and Medicines and Healthcare Products Regulatory Agency and Breakthrough T1D.

This project is also supported by UKRI (UK Research and Innovation) under grant agreement No 10152425 for National Institute for Health and Care Excellence and grant agreement No 31052024 for The University Court of the University of Aberdeen.

**How can we make
clinical studies in
Europe more
representative and
inclusive, to better
reflect the population
ultimately receiving
the therapy?**



READI

The Challenge READI wants to tackle



Europe's population presents a **rich variety** of societal and environmental influence across multiple countries and includes **heterogeneous demographic and genetic profiles**.



Clinical research in Europe often fails to be representative, as it frequently does not include patients who reflect fully the population that ultimately receives the therapy, leading to significant gaps in medical knowledge and healthcare access.¹



This gap particularly affects **underserved and underrepresented (US/UR) populations**, who face barriers to participation in clinical studies.

READI aims to transform the clinical research ecosystem and its capabilities, with patients at the centre, and key stakeholders working together for more representative and inclusive clinical studies in Europe.

¹ EHA Diversity, Equity, and Inclusion Taskforce. *A Lack of Diversity, Equity, and Inclusion in Clinical Research Has Direct Impact on Patient Care*. HemaSphere. 2023;7(3):e842.

READI participants at a glance



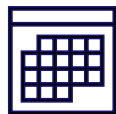
80
Organizations



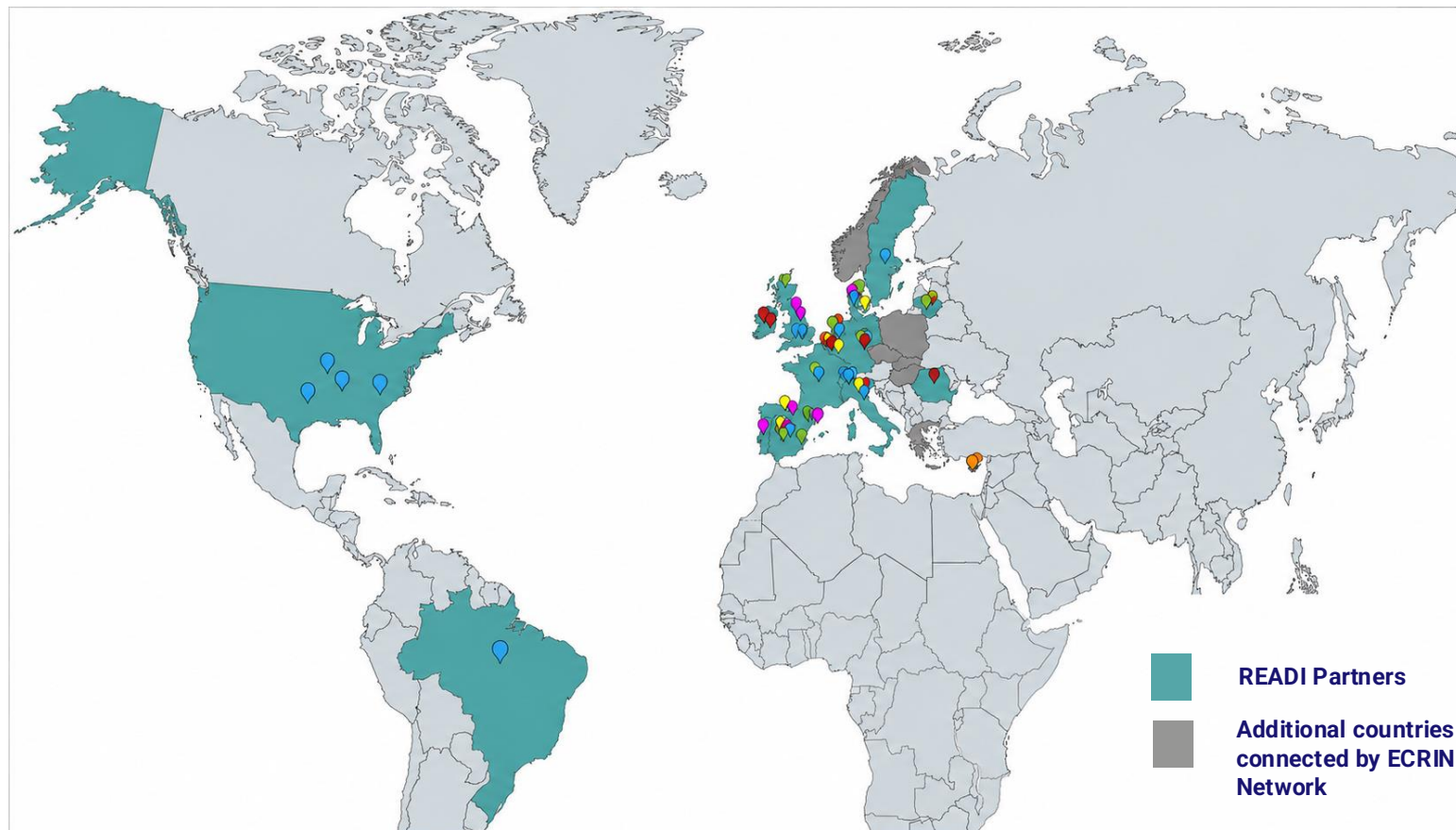
18
Countries



68.8 Million €
Budget



72
Months



Patient Advocates Groups



Academic Research



Information and Communication
Technology (ICT)



University Hospitals / Clinical Sites

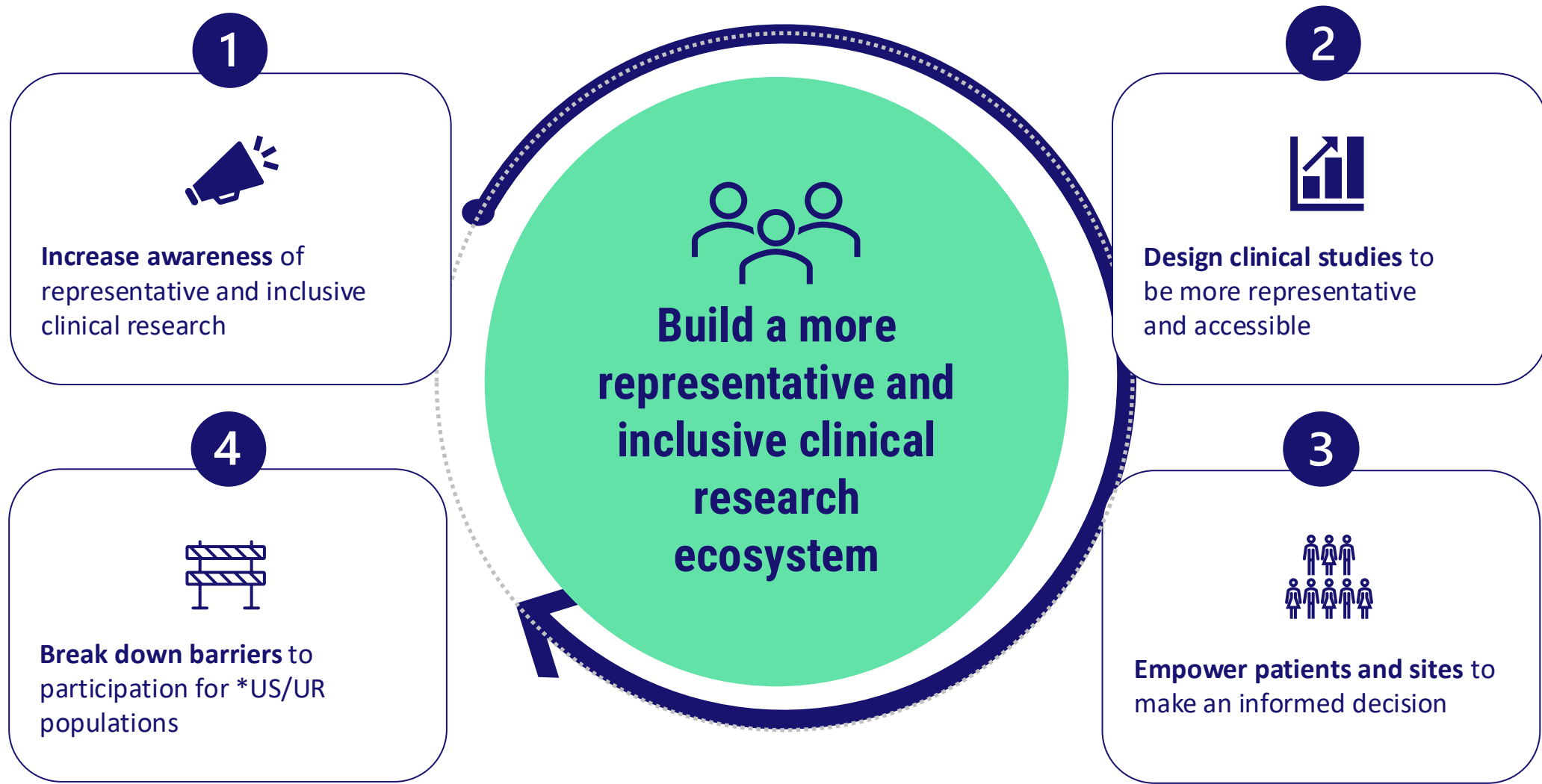


Industry



Regulatory, Health Technology
Assessment, Communication and
Management

READI Goals



** Underserved and underrepresented (US/UR) populations*

READI's intended impact across Europe



Building trust in clinical research



Integrating patient perspectives and lived experience into clinical research



Improving access and representativeness for underserved and underrepresented populations in clinical studies



Building capabilities across the clinical research ecosystem



Generating evidence that better reflects patient needs

READI WP configuration

Pillar I



Understanding and characterisation of underserved and underrepresented (US/UR) populations in clinical studies

WP1: Understanding and Characterising US/UR populations and Guidance to Enhance Inclusion in EU Clinical Studies

Pillar II



Digital platform and tools for clinical studies

WP2: Digital Platform Development
WP3: Protocol Design and Clinical Operations
WP4: Training & Virtual Learning Platform

Pillar III



Community, connectivity and capacity building

WP5: Clinical Sites Capability Building
WP6: Community Connectivity

Pillar IV



Demonstration in clinical and non-clinical use cases

WP7: Use Cases Development, Execution and Outcome

WP 8: Ethical Dimension and Responsible Research



WP 9: Communication & Dissemination



WP 11: Stakeholder Engagement and Long-Term Sustainability



WP 10: Coordination and Project Management



WP2

Digital Platform Development

OBJECTIVE

Develop the digital platform and core components that support the READI ecosystem, enabling better search, connection and interaction across clinical studies.

Core tasks

- Definition of requirements and specifications of the digital platform
- Design and implementation of the platform architecture
- Development of an AI parser and processes for the collection, validation and review of structured and enriched data
- Establishment of a resource plan including strategies for testing, validation and resource scaling

WP2 ensures that inclusive and representative participation in clinical research is not just a goal, but a technical reality, built into the data infrastructure from the ground up.



Introduction to USDM

Supporting the READI platform



Unified Study Definitions Model (USDM)

- Data Model for capturing the Study Design in a digitised format.
- Enables agnostic exchange of study design information downstream.
- Used for the READI platform.
- Enables the digitisation of eligibility criteria.
- Enables connectivity of the study design with EHR data sources.



The USDM Standard

CDISC Controlled Terminology

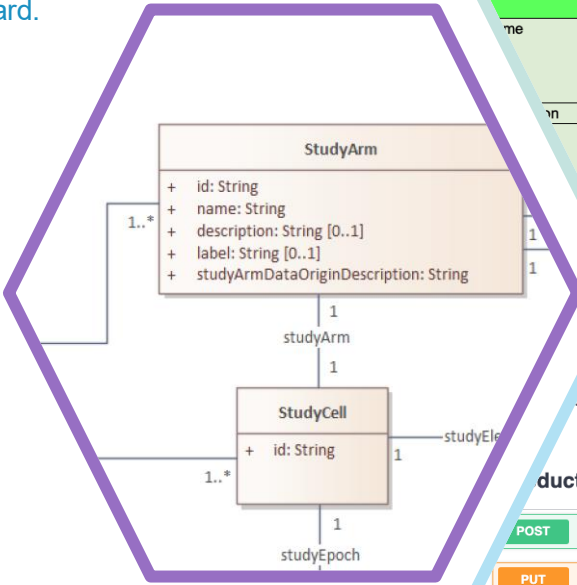
Provides further semantics, complementing the UML model.
Includes the definition of classes, attributes, and value sets

Examples

Example protocols implemented in the USDM with associated JSON files and visualisations

Logical Model

The UML logical model (a class diagram) that provides the basis for the USDM standard.



API Specification

Provides the means to exchange a single study between machines using a JSON API

	C174447	Study Arm
	C170984	Study Arm Name
	C93728	Study Arm Description
	C188827	Study Arm Type
DataOriginDescription	C188828	Study Arm Data Origin Description
originType	C188829	Study Arm Data Origin Type
Label	CNEW	Study Arm Label
StudyEpoch	C71738	Study Epoch
Name	C93825	Study Epoch Name
Description	C93824	Study Epoch Description
Type	C188830	Study Epoch Type
	CNEW	Study Epoch Label

CORE Rules

Specification of the rules that define USDM compliance

Rule	Warning/ Error	Entity/Type applies
Must conform with the USDM schema based on the API specification.	ERROR	All
Attributes (string, number, boolean) must conform with the schema based on the API specification.	ERROR	All
Required properties must be included as defined in the USDM schema based on the API specification (i.e., all required properties are present and no disallowed attributes are present).	ERROR	All
Identities must be as defined in the USDM schema based on the API specification (i.e., required properties have at least one value and single-valued properties are not lists).	ERROR	All
Within a study version, all id values must be unique.	ERROR	All
The names of all child instances of the same parent class must be unique.	ERROR	All
The same Biomedical Concept Category must not be referenced more than once from the same activity.	ERROR	Activity
Each specified biomedical concept category is expected to be referenced by an activity.	WARNING	Activity
Each specified biomedical concept surrogate is expected to be referenced by an activity.	WARNING	Activity
Each specified biomedical concept is expected to be referenced by an activity.	WARNING	Activity
Children must not refer to a timeline, procedure, concept, biomedical concept category or biomedical concept surrogate.	ERROR	Activity
A procedure is expected to be referenced by an activity.	WARNING	Activity
An activity is expected to refer to at least 1 procedure, biomedical concept category or biomedical concept.	WARNING	Activity
Activities must be ordered chronologically by their start and end dates (including the previous and next attributes) must be defined.	WARNING	Activity

```

studyArms: [
  {
    "id": "StudyArm_1",
    "name": "Placebo",
    "label": "",
    "description": "Placebo",
    "type": {
      "id": "Code_61",
      "code": "C174268",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Placebo Comparator Arm"
    }
  },
  {
    "id": "StudyArm_2",
    "name": "Xanomeline Low Dose",
    "label": "",
    "description": "Active Substance",
    "type": {
      "id": "Code_63",
      "code": "C174267",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Data Generated Within Study"
    }
  }
]

```

API for DDF 2.4 Provisional (0.39)	
Accelerate Digital Data Flow (DDF) Study Definitions Repository API.	
Introduction Routes that form the production specification.	
POST	/v3/studyDefinitions Create a study
PUT	/v3/studyDefinitions/{studyId} Update a study
GET	/v3/studyDefinitions/{studyId} Return a study
GET	/v3/studyDefinitions/{studyId}/history Returns the study history
GET	/v3/studyDesigns Study designs for a study

Implementation Guide

Guidance on using the USDM model and ensuring conformance with the standard



Unified Study Definitions Model Implementation Guide (USDM-IG)

Version 2.0 (Draft for Internal Review)

Prepared by the DDF Team

Notes to Readers

- This is the draft version 2.0 of the Unified Study Definitions Model Implementation Guide (USDM-IG v2.0). It is intended for Internal Review only and is not a final version.

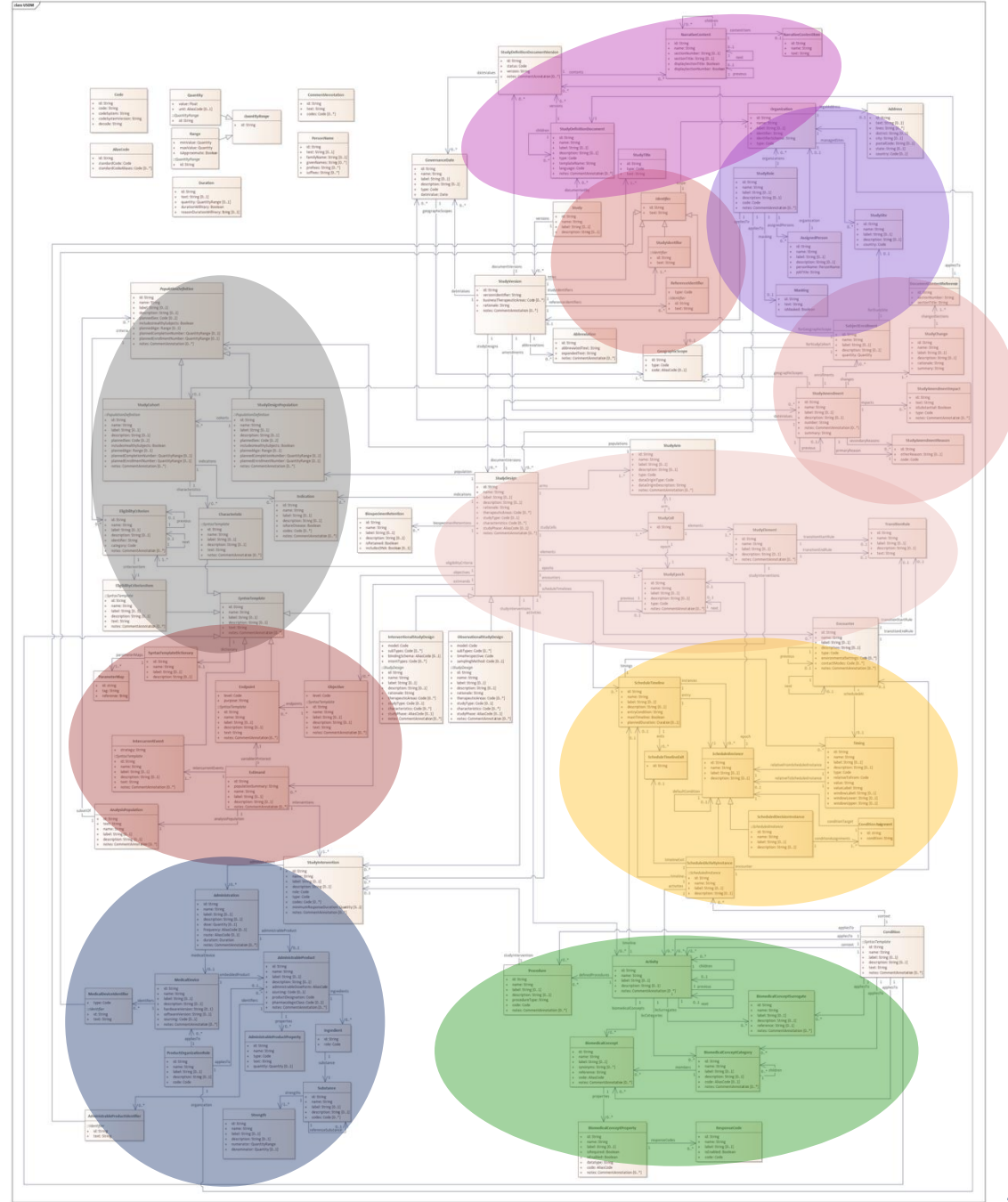
History

Version	Description
2.0 Draft for Internal Review	

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Model areas

- Study, Titles and Identifiers
- Amendments
- Roles and Responsibilities
- Study Design, Arms and Epochs
- Population and Eligibility Criteria
- Objectives/Endpoints and Estimands
- Detailed Study Logic/Timelines
- Procedures / Biomedical Concepts
- Interventions
- Unstructured Content





From Criteria Digitisation to RWD patient selection

Utilising USDM in the READI platform



Digitising Eligibility Criteria within READI

- Download study design from registries
 - CTIS / ClinicalTrials.gov
- Digitise and Map to USDM
- Digitising aspects:
 - Conditions and contra-indications
 - Assessments and expected responses
 - (Contra-)medications
 - Procedures
- Validated AI processes
- Supporting the identification of potentially eligible patients based on structured eligibility criteria.



Expected responses

- Each criterion can be digitised into 1 or more expected responses. For example:
 - Females between 18 and 55 =>
 - Gender is female
 - Age>=18
 - Age<=55
- All responses can be coded and stored in USDM according to the CDISC Biomedical Concepts
- Alias codes allow for inclusion of mapping to external code systems used in EHR records like ICD-10, SNOMED, LOINC and others.
- Corresponding timing information is digitised and stored in USDM format, like:
 - Within last 6 months
 - At screening





EHR patient matching

- Expected response information, corresponding coding, and timing information can support patient matching and help identify individuals who may meet study eligibility criteria for further assessment through appropriate clinical processes.
- Additional representativeness-related criteria are planned to support broader participation of underserved and underrepresented populations.





USDM enables many use cases

- Integration with the READI digital ecosystem can support use cases aimed at improving the representativeness of clinical study participation.
- The industry is in the phase of adoption of USDM which gives us the opportunity to directly use structured data in USDM format instead of the registry download.
- Many other digital data flow use cases can be handled by digitising a study design / protocol like EDC set-up, patient burden assessments, and more.



The expertise behind READI

Patient Organizations



Industry



The expertise behind READI

Academia



Digital



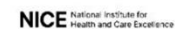
Research



Innovation & Implementation Partners

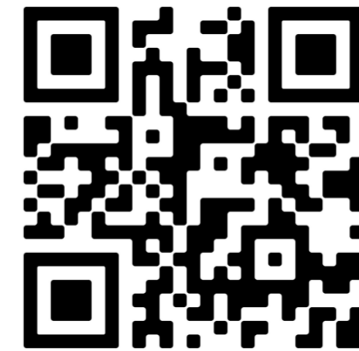


Institution





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Thank You!





Questions?

