CDISC Standards & Real-World Data

FEBRUARY 21 | 11 AM EST

Webinar Logistics

- You will remain on **mute**
- Submit questions at any time via the Questions tool on your Zoom app
- **Audio Issues?**
  - First, close and restart your Zoom App
  - Second, check your local internet connection strength
- A recording of this webinar and a PDF of the slides will be available in the Public Webinar Archive on the CDISC website.
  - Hover over the “Events” tab and find the Webinars section

Agenda

- **Welcome & CDISC's RWD Strategy** – Dave Evans, MS
- **Observational Studies – Considerations on Using SDTM for Observational Data** – Jon Neville, PSM
- **Biomedical Concepts** – Bess LeRoy, MPH
- **Electronic Health Records Demonstrations**
  - **FHIR – CDISC Mapping** – Rebecca Baker, MS, MHA
  - **Alzheimer's Disease Data Elements to SDTM** – Meredith Zozus, PhD
  - **eECG Collection and Data Management in Multicenter Trials** – Meredith Zozus, PhD
- **Digital Health Technologies** – Peter Van Reusel
  - **CDISC Activities Related to DHT, DEEP**
  - **Device Standards**
- **Exchange Formats** – Sam Hume, DSc
  - **ODM, FHIR Integration, Dataset-Json**
- **Q & A** – Rhonda Facile, MS

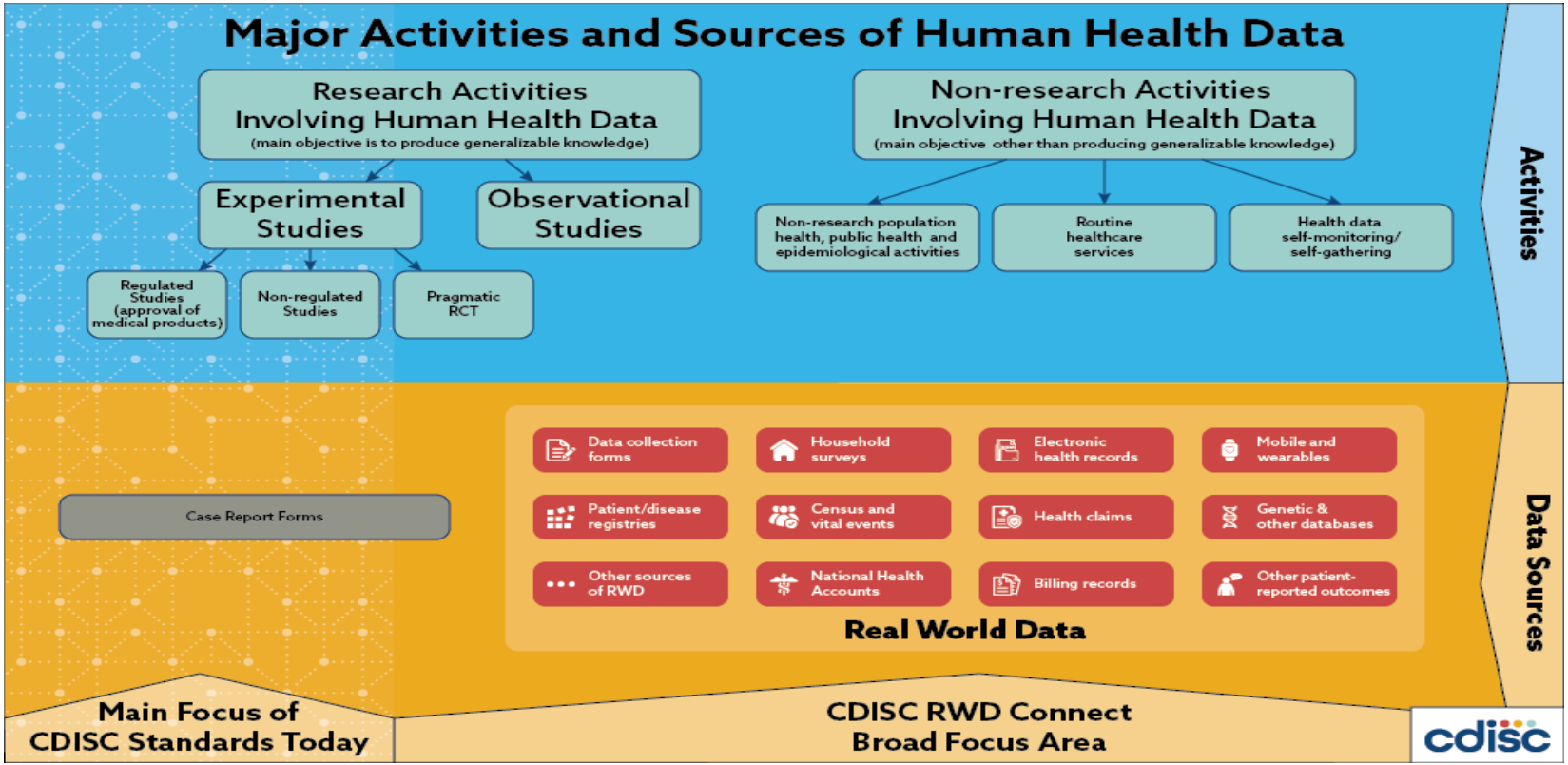
Definitions of Real-World Data and Real-World Evidence

Section 505F(b) of the FD&C Act defines RWE as “data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than traditional clinical trials” (21 U.S.C. 355g(b)).5 In developing its RWE program, FDA believes it is helpful to distinguish between the sources of RWD and the evidence derived from that data. Evaluating RWE in the context of regulatory decision-making depends not only on the evaluation of the methodologies used to generate the evidence but also on the reliability and relevance of the underlying RWD; these constructs may raise different types of considerations. For the purposes of this framework, FDA defines RWD and RWE as follows:

- Real-World Data (RWD) are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.
- Real-World Evidence (RWE) is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.

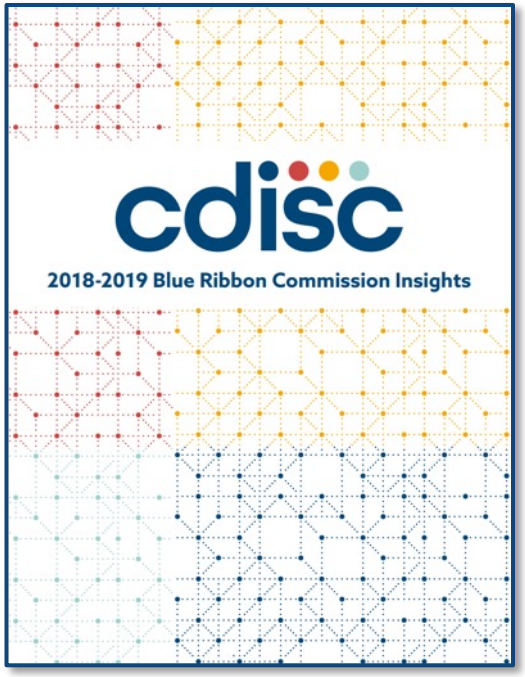
https://www.fda.gov/media/120060/download

Real World Data



Blue Ribbon Commission Recommendations

- CDISC standards are growing in use-cases beyond the original regulatory approvals use case
- The most important use case for CDISC to support is standardization of:
  - Academic research
  - Observational research
  - Patient-reported outcomes
  - EHR data – the largest source of clinical data
- Areas of Focus:
  - User specific education
  - Visual, web-based, natural-language search
  - Success stories and case studies publication
  - Accessible training
  - Expand membership to new groups
  - Leverage the data sharing movement



https://www.cdisc.org/system/files/about/brc/2018-2019_Blue_Ribbon_Commission_Insights.pdf

CDISC RWD Connect Delphi

Recommendations:

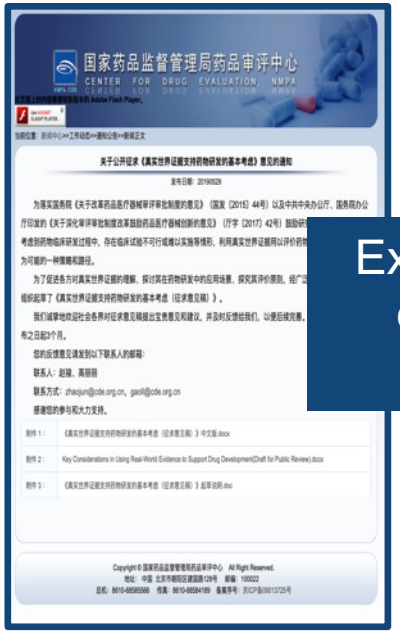
- Standardization of RWD is necessary. The primary focus should be on improving data sharing and quality.

Priorities:

- Electronic health records, such as data shared using HL7-FHIR and data stemming from observational studies, wearables and patient-reported outcomes.
- With different standardization efforts already underway in these areas a gap analysis should be performed to identify the areas where synergies and efficiencies are possible, e.g., extension of SDTM for RWD
- Collaborate with stakeholders to create or extend existing mappings between CDISC and other standards, controlled terminologies, and models to represent data originating across different sources
- JMIR Med Inform 2021;9(11):e30363) doi: 10.2196/30363

RWD and the Regulatory Environment

China's NMPA



http://www.cde.org.cn/news.do?method=largeInfo&id=23a2b4cbe0807fe2

US FDA

https://www.fda.gov/media/120060/download

EU EMA

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf

Japan's PMDA

https://www.pmda.go.jp/english/about-pmda/0004.pdf

Exploring and promoting the use of high-quality RWD in decision-making as a strategic goal

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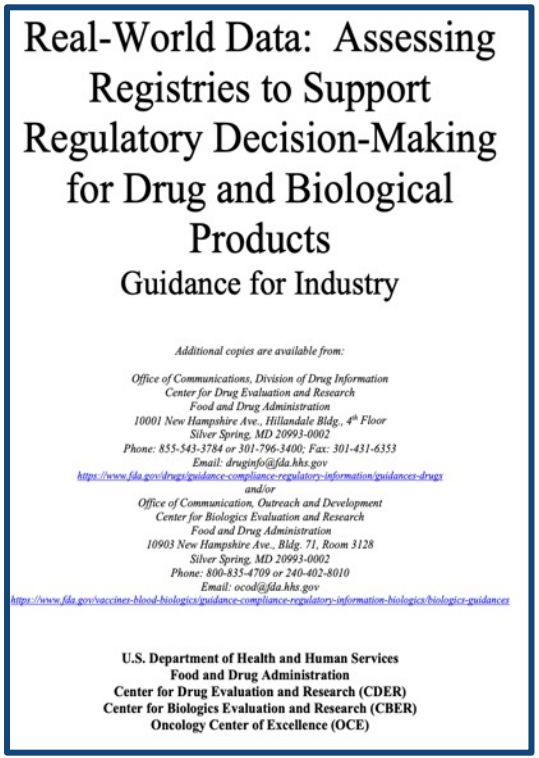
Draft FDA RWD Guidance



Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products

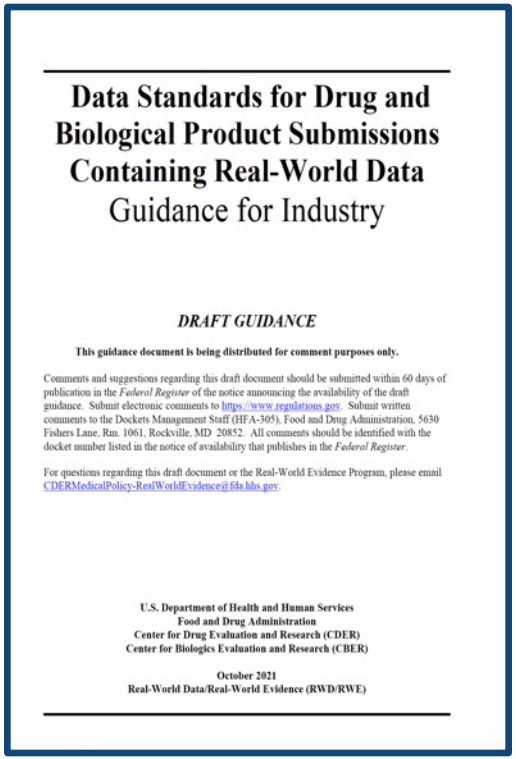
Guidance for Industry

Additional copies are available from:

Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs
and/or
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Room 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010
Email: ocod@fda.hhs.gov
https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Oncology Center of Excellence (OCE)

https://www.fda.gov/media/154449/download



Data Standards for Drug and Biological Product Submissions Containing Real-World Data

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

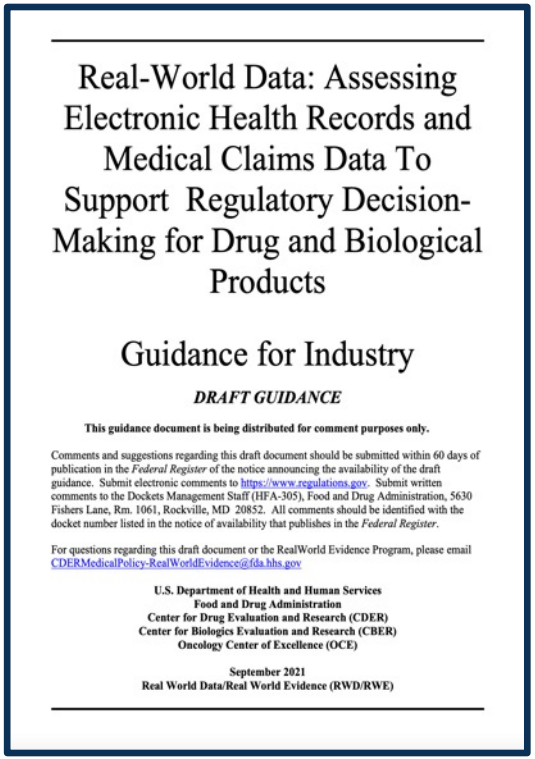
Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document or the Real-World Evidence Program, please email CDERMedicalPolicy-RealWorldEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

October 2021
Real-World Data/Real-World Evidence (RWD/RWE)

https://www.fda.gov/media/124795/download



Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products

Guidance for Industry

DRAFT GUIDANCE

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Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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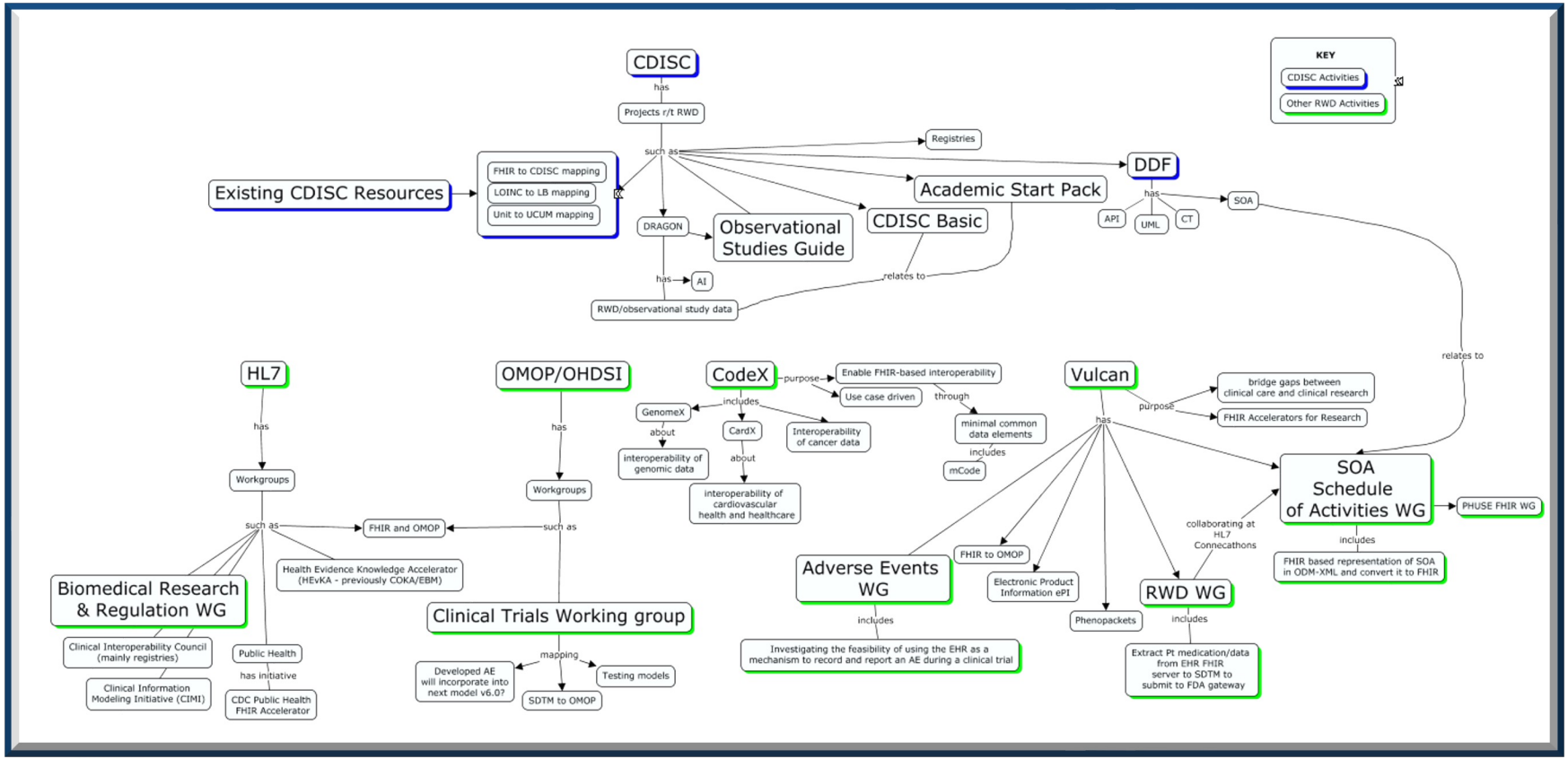
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Oncology Center of Excellence (OCE)

September 2021
Real World Data/Real World Evidence (RWD/RWE)

https://www.fda.gov/media/152503/download

CDISC RWD Activities Landscape



RWD Collaboration History (1)

Year	RWD Project
2004-2016	IHE Retrieve Form for Data Capture IHE Profile
2006	Leveraging the CDISC Standards to Facilitate the use of Electronic Source Data within Clinical Trials
2016-Present	HL7 FHIR Connectathons
2017-2018	TransCelerate Biopharma eSource Roundtables
2017-2022	HL7 Biomedical Research and Regulation (BR&R) participation
2018	CDISC Standards and Real-World Data
2018-2020	FDA/NIH/ONC/CDC Common Data Model Harmonization Project
2019-Present	Vulcan HL7 FHIR Accelerator Member
2020	Clinical trial data conventions for the OMOP Common Data Model (SDTM-to-OMOP conversion)

RWD Collaboration History (2)

Year	RWD Project
2020	Clinical trial data conventions for the OMOP Common Data Model (SDTM-to-OMOP conversion)
2016-2019	FDA eSource for Regulated Clinical Trials - Transforming research through eSource and standards FDA BAA HHSF223201510105C
2021-Present	Vulcan HL7 FHIR Real World Data: Utilizing EHR source data to directly populate clinical research data capture systems.
2021-Present	Vulcan HL7 FHIR Adverse Event: Investigate the feasibility of utilizing the EHR as mechanism for recording and reporting AEs that occur during a clinical trial.
2021-Present	DRAGON IMI project maps RWD implementation to CDISC standards. While the data originates in RWD the emphasis is on using structured data to feed the AI to elevate the response for health systems during a pandemic.

CDISC's RWD Strategy

- Expansion of CDISC Standards to address multiple modalities of data capture, exchange, processing, analysis and reporting
- Collaborate, partner and harmonize with other industry standards initiatives and standards organizations to enable an efficient pathway for RWD to be transformed for ultimate use cases, such as data sharing; regulatory submissions; exploratory analysis and incorporation into clinical research trials
- Enable the development and use of open-source solutions that utilize standards to collect, exchange, process, transform and analyze clinical data
- Partner with technology and solution providers to embed CDISC standards within the most commonly-used formats and platforms to provide machine-ready forms of the standards for use
- Develop, release and govern standards validation rules and an open-source conformance engine for verification of the integrity and completeness of data for use
- Provide the industry with training and education on the use and importance of standards in the RWD ecosystem
- Support and Facilitate the use of RWD by Regulatory Agencies and the development of the tools necessary for proper, efficient data transformations and metadata-rich data exchange

CDISC's RWD - SDTM

- CDISC is planning a project to develop an SDTM Implementation Guide for Real World Data
- Projected Project Start: Q3 2023

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RWD Initiatives

Jon Neville, PSM
CDISC, Senior Director, Standards Development

Considerations for Using CDISC Standards for Observational Studies

Goal

- To publish a CDISC-endorsed approach to working with observational research data
- Provide a “stake in the ground” for future expansion

Scope of Use Cases

- **Observational Research Studies**
  - Cross-sectional studies
  - Cohort studies
- **Clinical trials:** external control arm using RWD

Development Scope

- SDTM for now
- CDASH, ADaM could come in subsequent version

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Funding is provided by the IMI DRAGON project

imi innovative medicines initiative DRAGON

Considerations for Using CDISC Standards for Observational Studies - Overview

Discussion on common issues encountered when implementing SDTM for observational studies / RWD for External Control Arm studies

Implementation strategies or guidance to address these issues.

Examples illustrating these strategies (where applicable)

- Reuse existing standards; create new domains and variables only if necessary

Examples illustrating any new concepts/strategies that may be identified

Discussion on adjusting conformance rules to better fit these data

- New conformance rules as needed
- Note irrelevant conformance rules for validation checks of observational studies.

Resulting document will be CDISC-endorsed by having gone through our development process.

SDTM comes with conformance rules

Adhering to some of them is not always feasible in observational research/RWD

- **Many SDTM required domains and variables may not be available nor relevant to observational studies**
  - Observational studies may not have EX domain
  - The concept of VISIT may not be as rigid as we think of in SDTM
  - Multiple other variables and domains that are “required” may not be present
- **Perfectly appropriate observational data may result in validation errors**

Conformance rules were originally written for regulatory submissions of RCT data and cannot all be met in all of these use cases

Examples of required/expected variables that may not be relevant

Variable(s)	Domain	Core	Challenge Presented
RFSTDTC / RFENDTC	DM	Expected	Defining these dates can be challenging. Sometimes dates will be missing altogether.
RFICDTC	DM	Expected	**May not be available to sponsors using RWD**
RFXTSDTC / RFXENDTC	DM	Expected	Studies may not include regimented exposure to a protocol-defined drug. External control arm studies and post-marketing surveillance could possibly provide these
SITEID	DM	Required	Observational research includes observations from across healthcare and clinical settings. These will likely vary and not be available in the data anyway
ARM / ARMCD ACTARM / ACTARMCD	DM	Required	There are no arms to describe in observational research. **However, we're proposing using them to represent cohorts in a cohort study**
VISITNUM	Multiple	Sometimes Required	The concept of "visit" may not be relevant in observational research
EPOCH	Multiple	Sometimes Required	Use cases for observational research have not been explored. Existing controlled terminology is specific to clinical trials

What the guide will *not* address…

- **SDTM implementation basics**
  - The document will supplement SDTMIG knowledge
  - Researchers/newcomers will be able to refer to the Basic Implementation guide when it becomes available
- **How to handle dirty or missing data, such as imputing missing values**
- **Source-to-target mapping guidance**
  - Legacy/RWD are too highly variable
- **How to improve a "validation score" on third-party validation software like P21**
  - We focus on impact of CDISC conformance rules
  - Any changes proposed *may* eventually be incorporated into such vendor software

Where are we now?

Example use cases identified

- Demography, Medications, Trial (or *Study*) Design Model, Some specific variables (e.g., timing variables, VISITNUM)

Examples Drafted

- They look like normal SDTM examples
- Drafting discussions on considerations (e.g., how to populate specific variables, how to define how domains/variables were used) as these are more informative.

Addressing conformance rules

- There are hundreds; focusing v1.0 on those rules affected by example use cases above
- Proposing solutions (coping strategies; relaxing rules for the scoped use cases, etc)

Lessons learned so far…

There aren't many truly show-stopping conformance rules

Existing SDTM domains cover what we need for the use cases we've examined.

- Trial Summary could work for observational research if we re-label TS domain as "Trial *or Study* Summary"

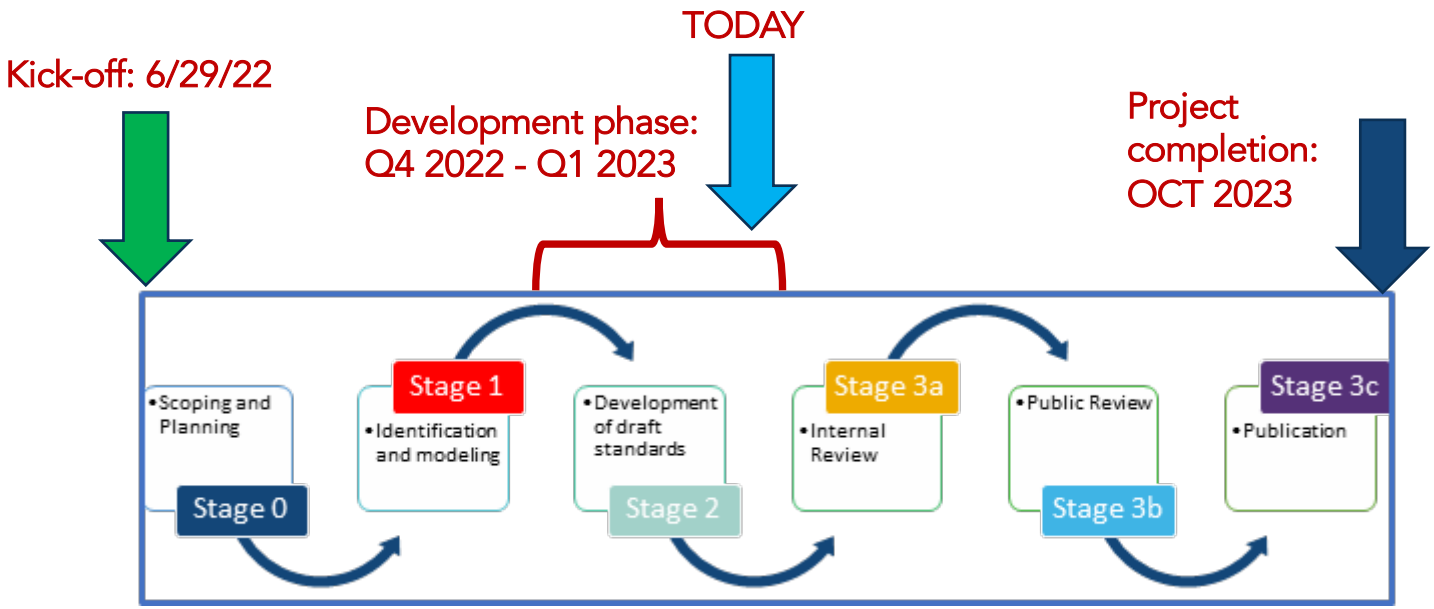
Existing variables can also be used as-is or repurposed

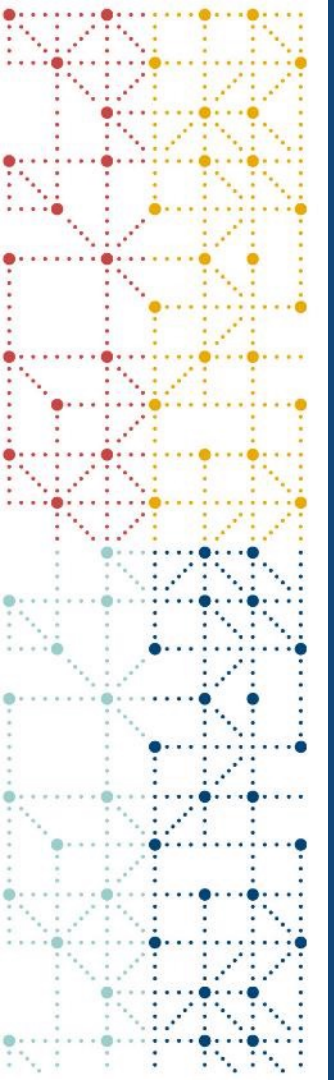
- Would require "palatable" adjustments to variable definitions/ labels
- Could add words to labels to accommodate use (e.g., ARM could be used to represent cohorts by adding "*or cohort*" to the definition)

SDTM Examples are less informative than discussions of considerations

- Examples look like normal SDTM examples
- Discussing how we arrived at the modeling, and how to explain that to reviewers is more impactful

Timeline


Kick-off: 6/29/22
TODAY
Development phase:
Q4 2022 - Q1 2023
Project
completion:
OCT 2023
•Scoping and Planning
Stage 0
Stage 1
•Identification and modeling
•Development of draft standards
Stage 2
Stage 3a
•Internal Review
•Public Review
Stage 3b
Stage 3c
•Publication



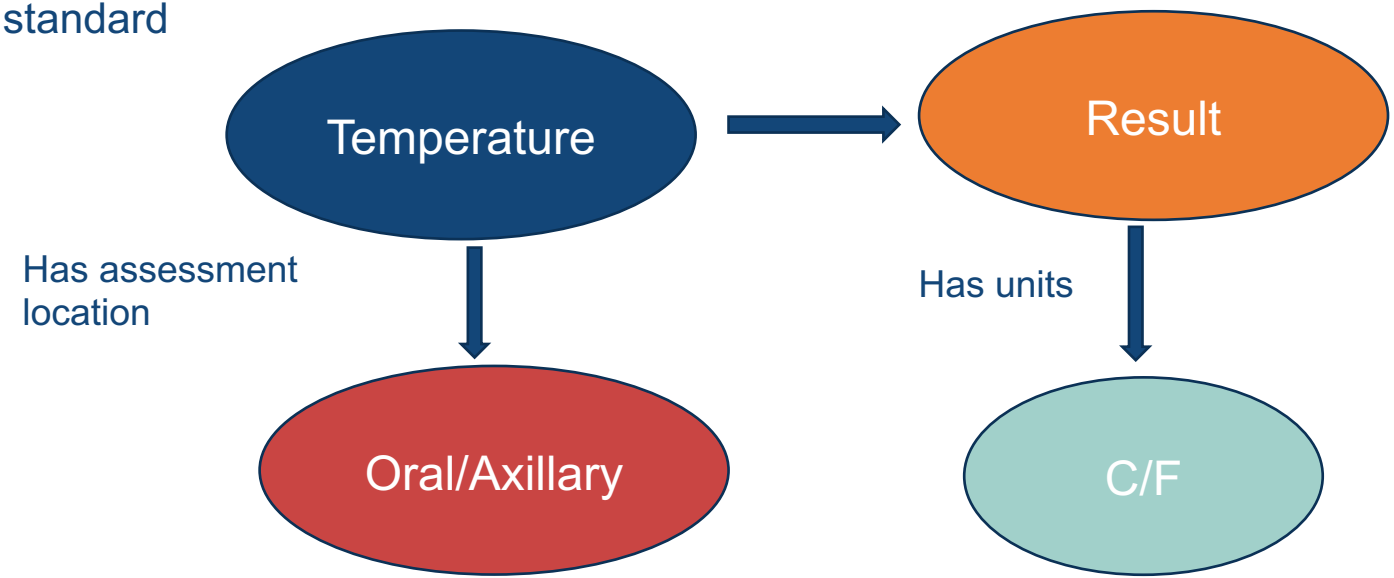
Biomedical Concepts

Bess LeRoy, MPH
CDISC, Head of Standards Innovation

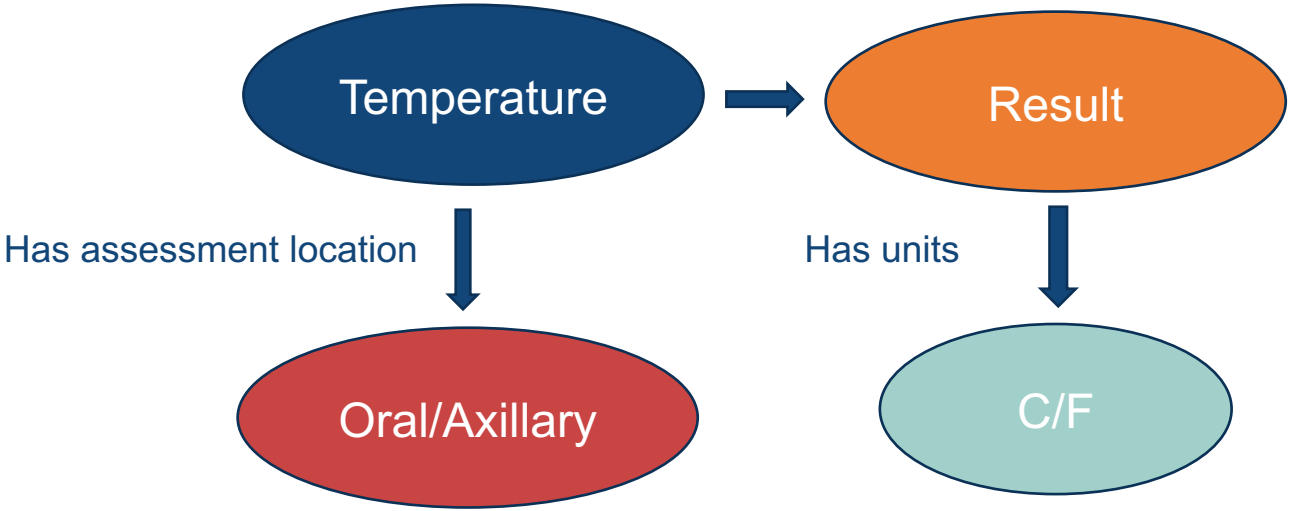
What Is a Biomedical Concept (BC)?

ISO 11179 Definition: *A unit of knowledge created by a unique combination of characteristics*

- Independent of study
- Independent of a representation in any standard, but can be tethered to a standard



What Is a Biomedical Concept (BC)?



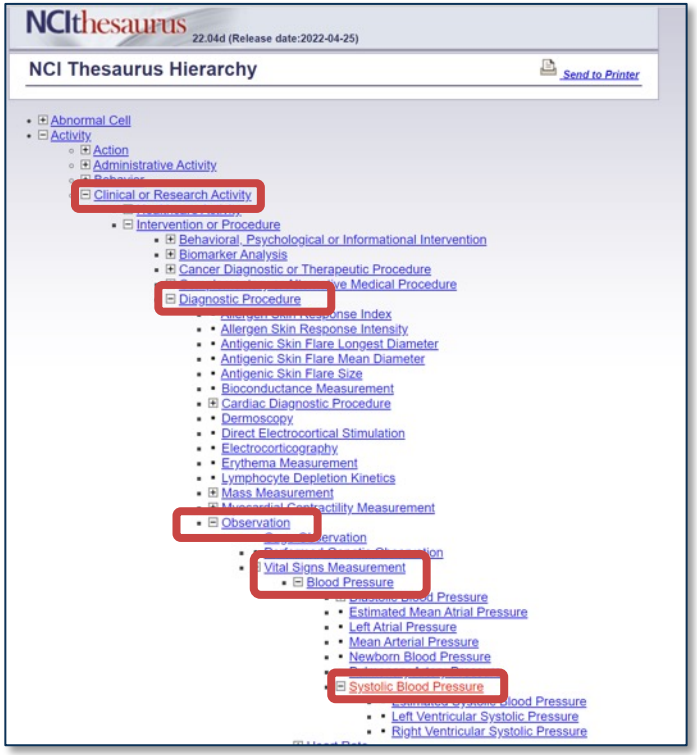
Conceptual Layer

VSTEST	VSTESTCD	VSORRES	VSUNIT	VSLOC
Temperature	TEMP	101.3	F	ORAL

Implementation Layer

Conceptual Layer

- Consistent reference definitions provide consistent meaning across studies, all phases of development
- Data standard agnostic
- Rooted in NCI Hierarchy
- All indexed by C-Codes
- Provides for consistency in standards implementation

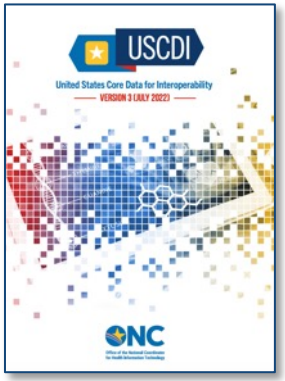


Implementation Layer

- Representation of a BC in a specific standard with implementation details such as value level metadata, formats, terminology

Connecting to Real-World Data

- FDA assessing the use of RWD to support regulatory decisions
- Office of the National Coordinator for Health IT (ONC) promotes the use of standards in health care
- The United States Core Data for Interoperability (USCDI) is a standardized set of data elements for nationwide, interoperable health information exchange
- Electronic health care record (EHR) systems will be required support the USCDI



Vital Signs

- Systolic Blood Pressure
- Diastolic Blood Pressure
- Heart Rate
- Respiratory Rate
- Body Temperature
- Body Height
- Body Weight
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 24 Months)
- Head Occipital-frontal Circumference Percentile (Birth- 36 Months)

Representation of USCDI in HL7 FHIR and CDISC SDTM

USCDI Data Element: Ethnicity			
US Core v5.0.1 based on HL7 FHIR 4.0.1 Value Set: OMB Ethnicity Categories		**CDISC STDMIG v3.2 Value Set: Ethnic Group**	
Display	**Code**	**Submission Value**	**Code**
Hispanic or Latino	2135-2	HISPANIC OR LATINO	C17459
Not Hispanic or Latino	2186-5	NOT HISPANIC OR LATINO	C41222
Asked but Unknown	ASKU	NOT REPORTED	C43234
Unknown	UNK	UNKNOWN	C17998

Benefits of Creating Biomedical Concepts

- BCs provide consistent meaning around collected concepts
  - Helps address the challenge of semantic interoperability
- BCs provide consistent implementation of standards
- BCs have the power to significantly lower barriers to implementation of standards
  - Start with the concepts, the standards implementation details come along with them
  - Sponsors no longer need to spend as much effort poring over documentation to match their data with implementation details

EHR Demonstrations

HL7 FHIR to CDISC Joint Mapping IG Application

Rebecca Baker, MS, MHA
CDISC, Standards Developer

HL7 FHIR to CDISC Joint Mapping IG

WHAT IS IT

HOW TO USE IT

CONSIDERATIONS

https://www.cdisc.org/standards

90%

Getting Started | CDISC Standards in th... | Quick WIKI Links - Reb... | SDTMIG v3.3 | CDISC | NCI Thesaurus | HL7 Fundamentals Co... | CDE Browser 5.3.5 | Principles for concept ... | Construction of Datas...

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Foundational
- BRIDG
- PRM
- SEND
- CDASH
- SDTM
- SDTMIG
- ADaM
- QRS
- Medical Devices
- Genomics

Data Exchange
- CTR-XML
- Dataset-XML
- Define-XML
- LAB
- ODM-XML
- RDF
- SDM-XML

Terminology
- Glossary
- Controlled Terminology

Therapeutic Areas
- Alphabetical
- By Disease Area
- Published User Guides

Standards
- Publications

In Development
- Public Reviews
- Standards in Development
- CDISC 360
- CORE
- COSMoS
- Digital Data Flow

CDISC Library
- CDISC Library

Real World Data
- FHIR-CDISC
- Vaccine Administration

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Non-clinical

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CDASH | SDTM | ADaM

https://www.cdisc.org/standards/real-world-data/fhir-cdisc-joint-mapping-implementation-guide-v1-0

Home / Standards / Real World Data / FHIR to CDISC Joint Mapping Implementation Guide v1.0

FHIR to CDISC Joint Mapping Implementation Guide v1.0

View | Edit | Delete | Clone

Release Date: 01 September 2021

Version 1.0 of the FHIR to CDISC Joint Mapping Implementation Guide defines mappings between **FHIR release 4.0**, HL7's standard for exchanging healthcare information electronically and three CDISC Standards: **CDASHIG v2.1**, **SDTMIG v3.2**, and **LAB v1.0.1** to streamline the flow of data from electronic health records (EHRs) to CDISC submission-ready datasets.

- **FHIR to CDISC Mapping Implementation Guide** - A spreadsheet of the FHIR to CDISC mappings with domain tabs and details from FHIR to CDASH to SDTM.
- **FHIR to CDISC Mapping Implementation Guide Public Review Comments***
- **FHIR to CDISC Mapping Implementation Guide in XML Format**

Additional RWD Resources

- **LOINC to LB Mapping File** is an additional resource for capturing real-world data. **Logical Observation Identifiers Names and Codes (LOINC®)** terminology includes laboratory and clinical observations used in healthcare systems around the globe.
- **Unit-UCUM Codetable** provides mapping to toggle between UCUM and CDISC Units. Unified Code for Units of Measure (UCUM) contains a blueprint for the creation of compliant units of measure from more than 300 terminal unit symbols. UCUM is used in healthcare to populate electronic health records, such as laboratory records in LOINC, and in the **ISO IDMP** standard.

By making it easier to convert data between HL7 FHIR (commonly used in clinical systems to collect and share healthcare data) and CDISC standards, both organizations aim to reduce the barriers to using clinical information to support research.

HL7 FHIR Resources

In FHIR, implementation guides are a set of rules of how a particular interoperability or standards problem is solved through the use of FHIR resources. The **FHIR to CDISC Joint Mapping Implementation Guide (IG) v1.0** is also posted to the **HL7 website** and provides the same content in a format similar to other FHIR implementation guides.

* CDISC posts Public Review comments and resolutions to ensure transparency and show implementers how comments were addressed in the standard development process.

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https://www.cdisc.org/standards/real-world-data/fhir-cdisc-joint-mapping-implementation-guide-v1-0

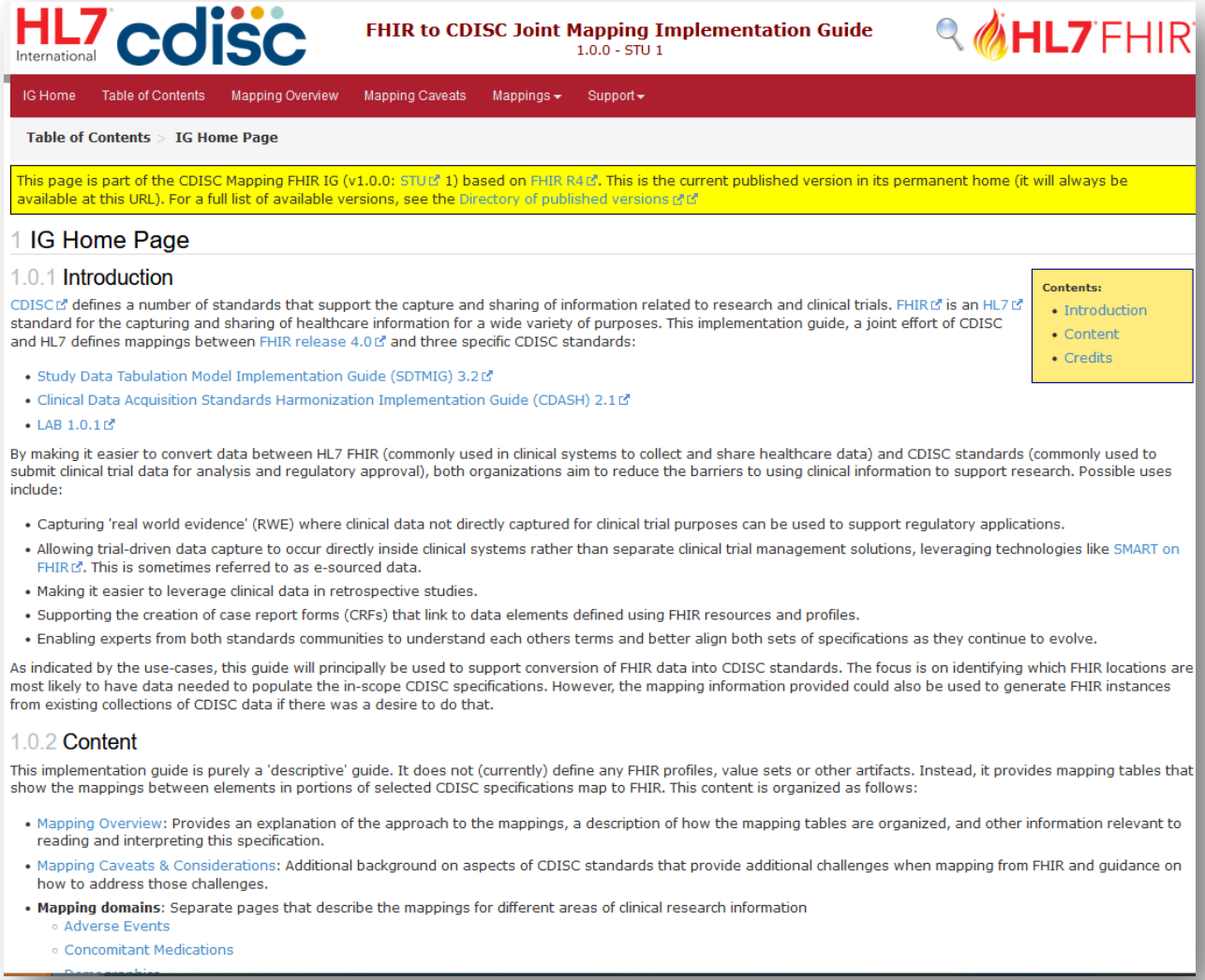
Advantages by site

HL7 site

- Toggle view for quick look up
- Interactive
  - View from FHIR to CDASH variable
  - View from CDASH variable to FHIR
- Content linked to FHIR resources
- Machine readable version
- Provide tips and tricks

CDISC site

- Spreadsheet for deep mapping
- Set up similar to the CDASHIG tables
- Walks across from FHIR to CDASH to SDTM
- Tabular format
- Machine readable version
- Provide tips and tricks



HL7 International cdisc

FHIR to CDISC Joint Mapping Implementation Guide
1.0.0 - STU 1

HL7 FHIR

IG Home | Table of Contents | Mapping Overview | Mapping Caveats | Mappings | Support

Table of Contents > IG Home Page

This page is part of the CDISC Mapping FHIR IG (v1.0.0: STU 1) based on FHIR R4. This is the current published version in its permanent home (it will always be available at this URL). For a full list of available versions, see the Directory of published versions

1 IG Home Page

1.0.1 Introduction

Contents:
- Introduction
- Content
- Credits

CDISC defines a number of standards that support the capture and sharing of information related to research and clinical trials. FHIR is an HL7 standard for the capturing and sharing of healthcare information for a wide variety of purposes. This implementation guide, a joint effort of CDISC and HL7 defines mappings between FHIR release 4.0 and three specific CDISC standards:

- Study Data Tabulation Model Implementation Guide (SDTMIG) 3.2
- Clinical Data Acquisition Standards Harmonization Implementation Guide (CDASH) 2.1
- LAB 1.0.1

By making it easier to convert data between HL7 FHIR (commonly used in clinical systems to collect and share healthcare data) and CDISC standards (commonly used to submit clinical trial data for analysis and regulatory approval), both organizations aim to reduce the barriers to using clinical information to support research. Possible uses include:

- Capturing 'real world evidence' (RWE) where clinical data not directly captured for clinical trial purposes can be used to support regulatory applications.
- Allowing trial-driven data capture to occur directly inside clinical systems rather than separate clinical trial management solutions, leveraging technologies like SMART on FHIR. This is sometimes referred to as e-sourced data.
- Making it easier to leverage clinical data in retrospective studies.
- Supporting the creation of case report forms (CRFs) that link to data elements defined using FHIR resources and profiles.
- Enabling experts from both standards communities to understand each others terms and better align both sets of specifications as they continue to evolve.

As indicated by the use-cases, this guide will principally be used to support conversion of FHIR data into CDISC standards. The focus is on identifying which FHIR locations are most likely to have data needed to populate the in-scope CDISC specifications. However, the mapping information provided could also be used to generate FHIR instances from existing collections of CDISC data if there was a desire to do that.

1.0.2 Content

This implementation guide is purely a 'descriptive' guide. It does not (currently) define any FHIR profiles, value sets or other artifacts. Instead, it provides mapping tables that show the mappings between elements in portions of selected CDISC specifications map to FHIR. This content is organized as follows:

- Mapping Overview: Provides an explanation of the approach to the mappings, a description of how the mapping tables are organized, and other information relevant to reading and interpreting this specification.
- Mapping Caveats & Considerations: Additional background on aspects of CDISC standards that provide additional challenges when mapping from FHIR and guidance on how to address those challenges.
- **Mapping domains**: Separate pages that describe the mappings for different areas of clinical research information
  - Adverse Events
  - Concomitant Medications

cdisc

1.5 Demographics

Demographic information in FHIR is captured using the Patient resource. Even if an individual isn't directly receiving care, if they're a potential subject of care, they're represented using Patient. The ResearchSubject resource is used to tie patients to specific research studies and to capture metadata about the patient's involvement with that study. In theory the same patient could be involved in many studies, some even at the same time.

1.5.1 DM Mappings

Guidance on interpreting the tables can be found here.

CDISC Lookup view | FHIR mapping view

CDISC			FHIR map (or gap)		
Label	**CDASH**	**SDTM**	**Element**	**FHIRPath**	**Comment**
Study Identifier	**STUDYID** Core: HR Type: Char	**STUDYID** Core: Req Type: Char	**ResearchStudy.identifier** 0..* Identifier	ResearchSubject.where(subject=Patient).study.resolve().partOf.resolve().identifier	
Study Site Identifier	**SITEID** Core: HR Type: Char	**DM.SITEID** Core: Req Type: Char	**ResearchStudy.identifier** 0..* Identifier	ResearchSubject.where(subject=Patient).study.resolve().identifier	
Subject Identifier for the Study	**SUBJID** Core: HR Type: Char	**DM.SUBJID** Core: Req Type: Char	**ResearchSubject.identifier** 0..* Identifier	ResearchSubject.where(individual=Patient).identifier.identifier	
Birth Date	**BRTHDAT** Core: R/C Type: Char	**BRTHDTC** Core: Perm Type: Char values: ISO 8601	**Patient.birthDate** 0..1 date	Patient.birthDate	There is potential where the birth date can not be collected due to country regulations. In those cases an estimated age may be entered. Birth time is captured as a standard extension

FHIR to CDISC Joint Mapping Implementation Guide

1.0.0 - STU 1

The mapping in this spreadsheet has been published by CDISC and HL7 International - BR&R Workgroup. It represents all SDTM controlled terminology developed and in production to date. This version is based on HL7 FHIR release 4.0 and three specific CDISC standards

- **Study Data Tabulation Model Implementation Guide (SDTMIG) v3.2**
- **Clinical Data Acquisition Standards Harmonization Implementation Guide (CDASHIG) v2.1**
- **Laboratory Data Model (LAB) v1.0.1**

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Tab	Description
Background	General information about the mapping document*.
LAB FHIR Mapping	Mapping from FHIR to the LAB Data Model v1.0.1
LB FHIR Mapping	Mapping from FHIR to Laboratory Test Results (LB) Domain (Findings General Observation Class)
VS FHIR Mapping	Mapping from FHIR to Vital Signs (VS) Domain (Findings General Observation Class)
AE FHIR Mapping	Mapping from FHIR to Adverse Event (AE) Domain (Events General Observation Class)
MH FHIR Mapping	Mapping from FHIR to Medical History (MH) Domain (Events General Observation Class)
CM FHIR Mapping	Mapping from FHIR to Concommitant Medication (CM) Domain (Interventions General Observation Class)
PR FHIR Mapping	Mapping from FHIR to Procedures (PR) Domain (Interventions General Observation Class)
DM FHIR Mapping	Mapping from FHIR to Demographics (DM) Domain (Special Purpose Domains)
MedDRA for MH, CE, and AE	Mapping Caveats for Conditions to MedDRA for Medical History, Clinical Events and Adverse Events
RELREC, PRESP OCCUR, MHEVDTYP	Mapping Caveats for RELREC, PRESP, OCCUR, MHEVDTYP
PROC and MEDS Caveats	Mapping Caveats for Procedures and Medications
VS Caveats	Mapping Caveats for Vital Signs
ALL CDISC Maps	All domain specifications included in one table

READ ME | Background | LAB FHIR Mapping | LB FHIR Mapping | VS FHIR Mapping | AE FHIR Mapping | MH FHIR Mapping | CM FHIR Mapping ...

Domain	CDASH/Lab Element	FHIR Resource	FHIR Element	FHIR Path	FHIR Min	FHIR Max	FHIR Type	FHIR Binding Name	FHIR Binding Strength	FHIR Binding Valueset	FHIR Condition	FHIR Definition	FHIR Comment	FHIR Gap	Comment	CDASH/Lab Element	CDASH Core	CDASH Type	CDASH Definition
														Sex and gender are multi-faceted.concepts. Both FHIR and CDISC standards have a large degree of ambiguity in their definitions for their primary data elements describing a subjectâ€™s sex or gender (DM.SEX and Patient.gender). This ambiguity often exists in original source systems. Depending on the use case, the Various facets of sex and gender may be utilized or captured within clinical data.. - physiologic, social, chromosomal, etc. As such, it's not advisable to indicate a mapping where all the facets of sex and gender are ambiguous in both the source and study data standards. Study sponsors and regulators will need to establish policies and look into the quality and nature of the source data as well as the analysis that needs to be performed to determine appropriate mappings. Extensions such as US core "birth sex"		SEX	R/C	Char	Sex of the subject as determ the investigator.

FHIR Gap

Sex and gender are multi-faceted.concepts. Both FHIR and CDISC standards have a large degree of ambiguity in their definitions for their primary data elements describing a subjectâ€™s sex or gender (DM.SEX and Patient.gender). This ambiguity often exists in original source systems. Depending on the use case, the Various facets of sex and gender may be utilized or captured within clinical data.. - physiologic, social, chromosomal, etc. As such, it's not advisable to indicate a mapping where all the facets of sex and gender are ambiguous in both the source and study data standards. Study sponsors and regulators will need to establish policies and look into the quality and nature of the source data as well as the analysis that needs to be performed to determine appropriate mappings.

Extensions such as US core "birth sex" and FHIR core "gender identity" may give more semanticly consistent values, but may not be widely populated Some gender concepts such as physiologic and genetic characteristics may be captured as Observation values rather than as demographics elements on Patient

Key point: Check the FHIR Gap column and the Comments for content.

The mapping may have been discussed and deemed “too fuzzy”, so for a better picture review the FHIR Gap or Comment columns.
Teams did not always agree of the certainty of the mappings.

CM domain – Concomitant/Prior Medications

Concomitant Medication_1_Sample aCRF

Created by Joe Ben Clark, last modified by Dana Booth on May 09, 2021

Title: Concomitant Medications

	Concomitant Medication Category CMCAT *Hidden/pre-populated*	GENERAL
Indicate if the subject took any concomitant medications/treatments. If Yes, include the appropriate details where indicated on the CRF.	Were any concomitant medications taken? CMYN Not Submitted	(•) Yes ( ) No *<NY codelist>*
If collected on the CRF, sponsor may insert instructions to ensure each record has a unique identifier.	CM Number CMSPID	1
Record only one treatment per line. Provide the full trade or proprietary name of the medication/treatment; otherwise, record the generic name .	What was the medication? CMTRT	CAPTOPRIL
Record the reason the medication was taken based on clinical investigator's evaluation. If taken to treat a condition, and a diagnosis was made, the indication should be the diagnosis. If taken to treat a condition, and no diagnosis was made, the indication should be the signs and symptoms. If taken as prophylaxis, report as "Prophylaxis for " and include a description of the condition(s).	For what indication was the medication taken? CMINDC	HYPERTENSION
Record the dose of medication/treatment per administration (e.g., 200).	Dose CMDSTXT CMDOSTXT/ CMDOSE	25
Record the dose unit of the dose of concomitant medication/treatment taken (e.g., mg).	Unit CMDOSU	mg *<UNIT codelist>*
Record the pharmaceutical dosage form (e.g., TABLET CAPSULE, SYRUP) of delivery for the concomitant [medication/treatment/therapy] taken.	Dose Form CMDOSFRM	TABLET *<FRM codelist>*
Record how often the medication was taken (e.g., BID, PRN).	Frequency CMDOSFRQ	BID *<FREQ codelist>*
Provide the route of administration for the medication.	Route CMROUTE	ORAL *<ROUTE codelist>*
Record the date the concomitant medication/treatment was first taken using this format (DD-MON-YYYY). If the subject has been taking the concomitant medication/treatment for a considerable amount of time prior to the start of the study, it is acceptable to have an incomplete date. Concomitant medications taken during the study are expected to have a complete start date. Prior concomitant medications that are exclusionary should have both a start date and an end date.	Start Date CMSTDAT CMSTDTC	20-MAR-2020
Record the concomitant medication/treatment as ongoing if the subject has not stopped taking the concomitant medication/treatment at the time of data collection and the end date should be left blank.	Is the medication ongoing? CMONGO CMENRF or CMENRTPT	[x] Yes *<NY codelist>*
Record the date the concomitant medication/treatment was stopped using this format (DD-MON-YYYY). If the subject has not stopped taking the concomitant medication/treatment leave this field blank.	End Date CMENDAT CMENDTC	

Title: Concomitant Medications

	Concomitant Medication Category CMCAT *Hidden/pre-populated*	GENERAL
Indicate if the subject took any concomitant medications/treatments. If Yes, include the appropriate details where indicated on the CRF.	Were any concomitant medications taken? CMYN Not Submitted	(•) Yes ( ) No *<NY codelist>*
If collected on the CRF, sponsor may insert instructions to ensure each record has a unique identifier.	CM Number CMSPID	1
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Record the dose of medication/treatment per administration (e.g., 200).	Dose CMDSTXT CMDOSTXT/ CMDOSE	25
Record the dose unit of the dose of concomitant medication/treatment taken (e.g., mg).	Unit CMDOSU	mg *<UNIT codelist>*
Record the pharmaceutical dosage form (e.g., TABLET CAPSULE, SYRUP) of delivery for the concomitant [medication/treatment/therapy] taken.	Dose Form CMDOSFRM	TABLET *<FRM codelist>*
Record how often the medication was taken (e.g., BID, PRN).	Frequency CMDOSFRQ	BID *<FREQ codelist>*
Provide the route of administration for the medication.	Route CMROUTE	

MedicationStatement.category

Not submitted - What constitutes a 'concomitant' drug is study-specific and would need to be evaluated on a study level. FHIR would not normally store that information.

MedicationStatement.identifier

MedicationStatement.medicationCodeableConcept

SNOMED-CT =318821008

MedicationStatement.reasonCode

SNOMED-CT =59621000 OR ICD-10=I10

MedicationStatement.medicationReference.resolve().form

MedicationStatement.dosage.doseAndRate.doseQuantity

Record how often the medication was taken (e.g., BID, PRN).	Frequency CMDOSFRQ	
Provide the route of administration for the medication.	Route CMROUTE	*<ROUTE codelist>*
Record the date the concomitant medication/treatment was first taken using this format (DD-MON-YYYY). If the subject has been taking the concomitant medication/treatment for a considerable amount of time prior to the start of the study, it is acceptable to have an incomplete date. Concomitant medications taken during the study are expected to have a complete start date. Prior concomitant medications that are exclusionary should have both a start date and an end date.	Start Date CMSTDAT CMSTDTC	20-MAR-2020
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Record the date the concomitant medication/treatment was stopped using this format (DD-MON-YYYY). If the subject has not stopped taking the concomitant medication/treatment leave this field blank.	End Date CMENDAT CMENDTC	

MedicationStatement.dosage.doseAndRate.doseQuantity

MedicationStatement.dosage.route

MedicationStatement.effectiveDateTime

This would need to be an extension added to the study extension on the medication resource - normally it is not captured except in the context of a study (and would be a study-specific assertion)

MedicationStatement.effectiveDateTi

CMENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the medication relative to the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR", "ONGOING, or "CONTINUING" was collected, this information may be translated into CMENRF. Not all values of the codelist are allowable for this variable. See Section 4.4.7, Use of Relative Timing Variables.	Perm

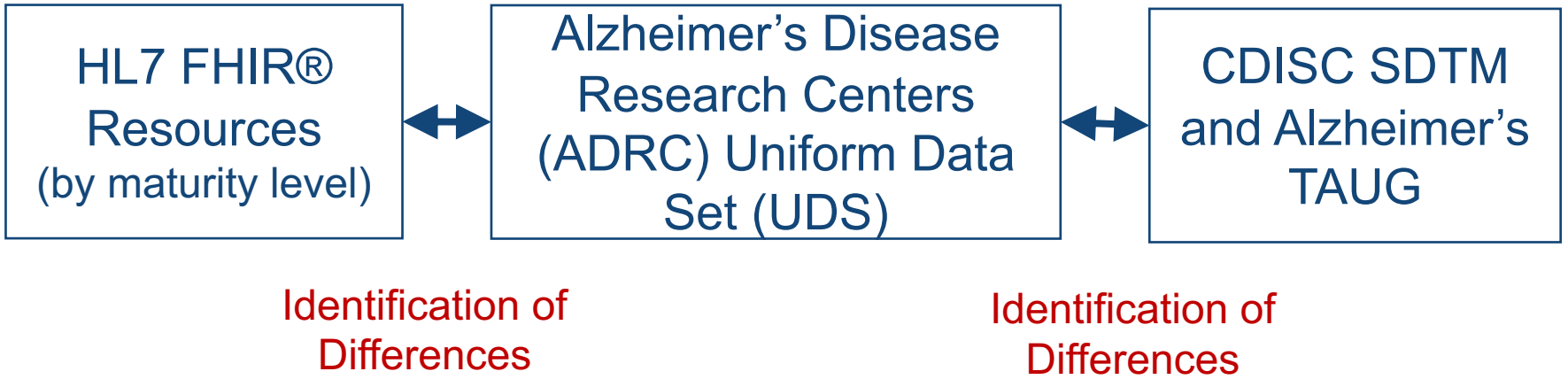
CL.C66728.STENRF	Relation to Reference Period (STENRF)	text Extensible: No	C66728	Relation to Reference Period
	AFTER		C38008	
	BEFORE		C25629	
	BEFORE/DURING		C184710	
	COINCIDENT		C25456	
	DURING		C25490	
	DURING/AFTER		C49640	
	ONGOING		C53279	Continuous
	UNKNOWN		C17998	U;UNK;Unknown

EHR Demonstrations

Registry RWD: Mapping FHIR, SDTM, and the Alzheimer's Disease Research Data Center (ADRC) Longitudinal Uniform Data Set

Meredith Zozus, PhD
UT Health San Antonio, Division Chief, Clinical Research Informatics

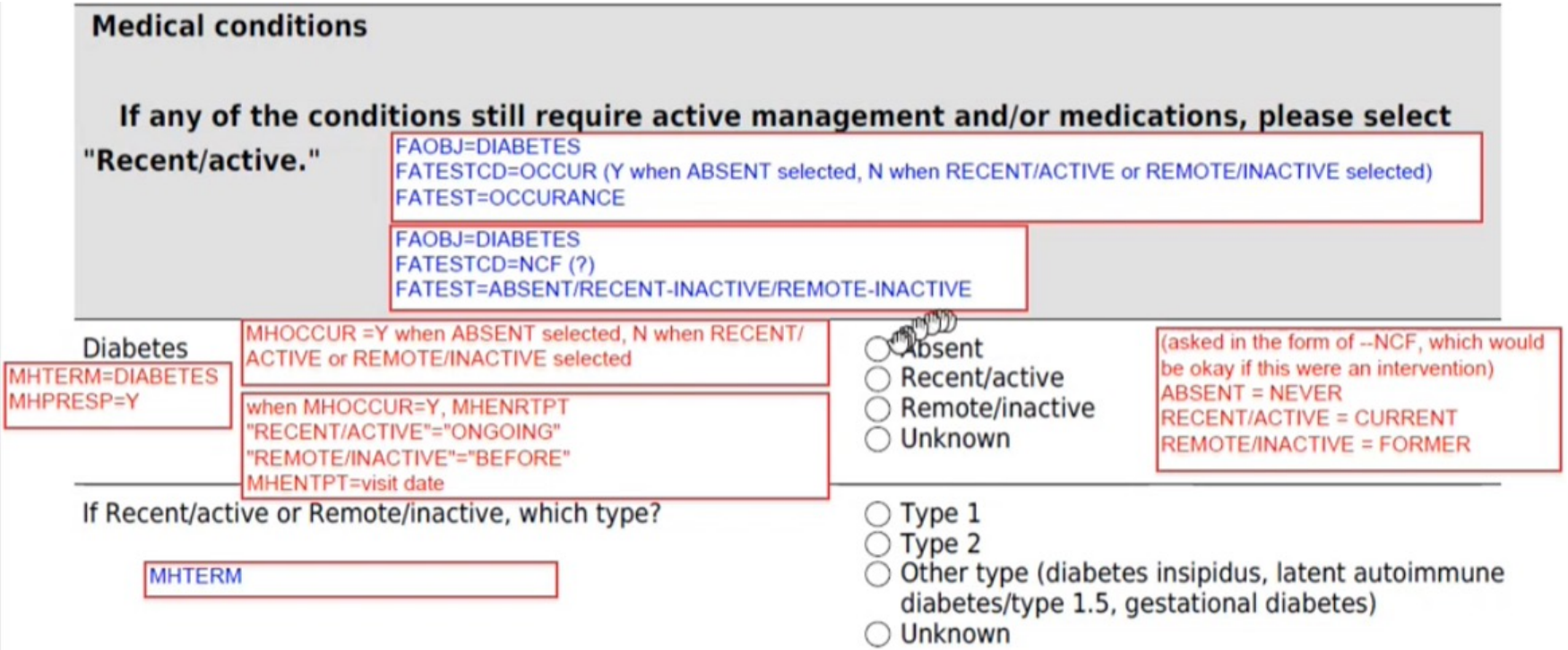
The Project


HL7 FHIR® Resources (by maturity level)
Alzheimer's Disease Research Centers (ADRC) Uniform Data Set (UDS)
CDISC SDTM and Alzheimer's TAUG
Identification of Differences
Identification of Differences

FHIR and CDISC Adjudicated Mapping Results

ADRC UDS Form Packet	Number of Data Elements	FHIR® Mapping IRR n (%)	FHIR® Mapping Rate n (%)	CDASH Domain Mapping IRR (%)	CDASH Domain Mapping rate n (%)	CDASH Data Element Mapping IRR (%)	CDASH Data Element Mapping rate n (%)
UDS IVP	963	87%	407 (42%)	98%	934(97%)	96%	934(97%)
UDS FVP	893	83%	403 (45%)	98%	859(96%)	97%	859(96%)
UDS TIP	994	85%	437 (44%)	99%	936(94%)	98%	936(94%)
UDS FIP	850	82%	350 (41%)	97%	790(93%)	97%	790(93%)
UDS 4	883	86%	361 (41%)	98%	837(95%)	97%	837(95%)
FTLD TVP	342	57%	75 (22%)	100%	342 (100%)	100%	342 (100%)
FTLD TFP	346	57%	75 (22%)	100%	346(100%)	100%	346(100%)
LBD IVP	285	53%	116 (38%)	100%	285(100%)	100%	285(100%)
LBD FVP	286	58%	129 (42%)	100%	286(100%)	100%	286(100%)
CLD	31	45%	4 (13%)	100%	31(100%)	100%	31(100%)
AD	11	100%	3 (27%)	64%	10(91%)	64%	10(91%)
COVID-19	70	94%	55 (79%)	100%	64(91%)	100%	64(91%)
Total	5,954	79%	2,399 (40%)	98%	5,776 (**96%**)	98%	5,776 (**96%**)

SDTM UDS Mapping Example



Major Depressive Disorder (MDD) and Post Traumatic Stress Disorder (PTSD)

TAUG	# of SDTM Variables:	Maturity Level >=3 n (%)	Maturity Level < 3 n (%)
MDD	Mapped	9 (47%)	16 (84%)
(N=19)	Gap	10 (53%)	3 (16%)
PTSD	Mapped	17 (77%)	21 (95%)
(N=22)	Gap	5 (23%)	1 (5%)
Both	Mapped	26 (63%)	37 (90%)
(N=41)	Gap	15 (37%)	4 (10%)

Table 2. Gap analysis of HL7 FHIR R4 successful mappings to TAUG specific SDTM variables for MDD and PTSD.

Nash, 2019 CDISC Interchange.

Things to Consider

1. Questionnaires may “map” but they won't be available unless they are actually in the EHR
2. FHIR® Mapping results reflect presence of a structured field in the standard with which EHR data may be associated
   → An EHR vendor may not map anything to it
   →Facilities, specialties and providers may not use the field that maps to the FHIR® resource; we observed a ~10% variability among three sites where we mapped three studies.
   →THUS - mapping should be repeated at sites
3. Data may not be complete or of acceptable quality
   →These should be measures at sites
4. Sites may differ with respect to participants actually being patients at the facility. The care relationship with a participant impacts the type and extent of data available from the EHR unless sites choose to document research visits in the EHR .

Big Thank You To Those Who Worked on This!

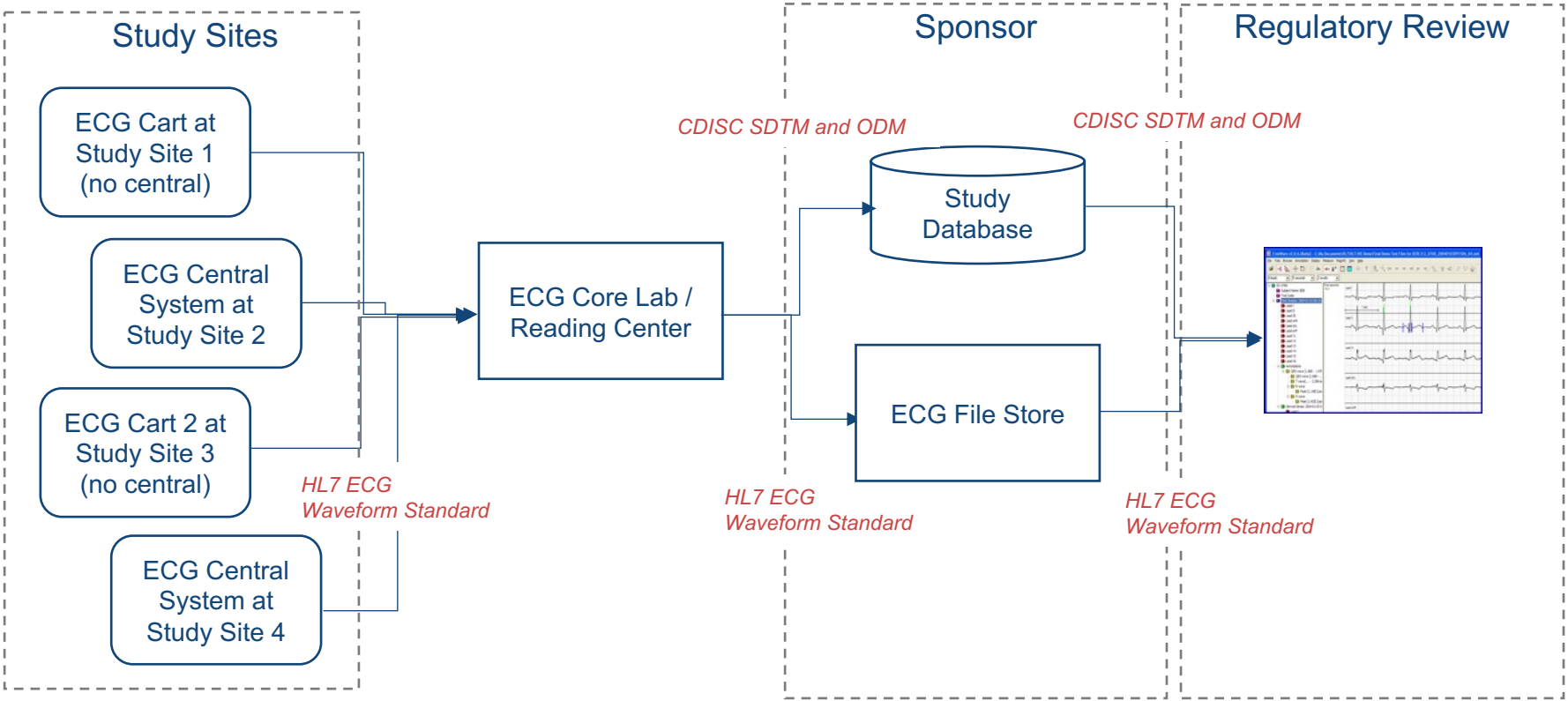
- Zhan Wang, PhD University of Texas Health Science Center at San Antonio
- Helen Foster, MSN, University of Texas Health Science Center at San Antonio
- Kayla Torres, University of Texas Health Science Center at San Antonio
- Gary Walker, CDISC
- Bess LeRoy, CDISC
- Rhonda Facile, CDISC
- Amy Palmer, CDISC
- Maryam Garza, PhD, University of Arkansas for Medical Sciences

EHR Demonstrations

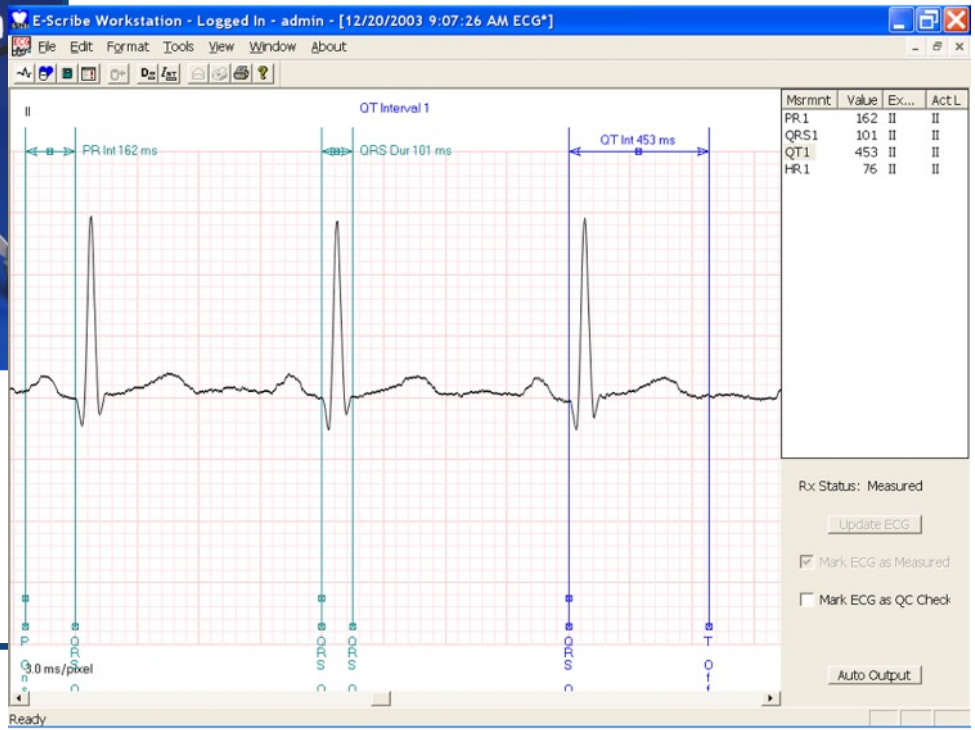
eECG Collection and Data Management in Multicenter Trials

Meredith Zozus, PhD
UT Health San Antonio, Division Chief, Clinical Research Informatics

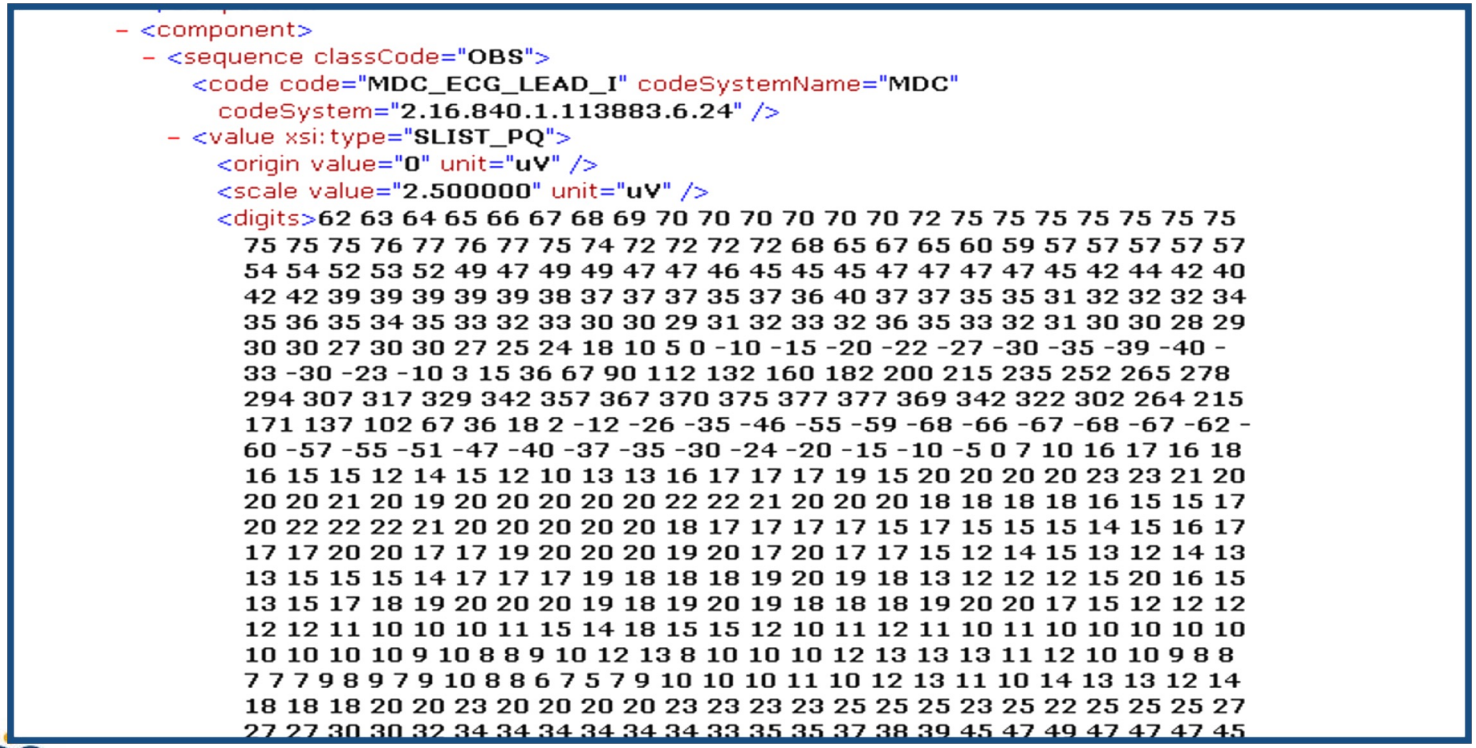
An Example of Device RWD in CDISC SDTM



ECG Data Origination at Study Sites



Raw ECG Waveform File as Received from the ECG Cart or Healthcare Facility Central ECG Management System



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- <component>
  - <sequence classCode="OBS">
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        codeSystem="2.16.840.1.113883.6.24" />
    - <value xsi:type="SLIST_PQ">
        <origin value="0" unit="uV" />
        <scale value="2.500000" unit="uV" />
        <digits>62 63 64 65 66 67 68 69 70 70 70 70 70 70 72 75 75 75 75 75 75 75
          75 75 75 76 77 76 77 75 74 72 72 72 72 68 65 67 65 60 59 57 57 57 57 57
          54 54 52 53 52 49 47 49 49 47 47 46 45 45 45 47 47 47 47 45 42 44 42 40
          42 42 39 39 39 39 39 38 37 37 37 35 37 36 40 37 37 35 35 31 32 32 32 34
          35 36 35 34 35 33 32 33 30 30 29 31 32 33 32 36 35 33 32 31 30 30 28 29
          30 30 27 30 30 27 25 24 18 10 5 0 -10 -15 -20 -22 -27 -30 -35 -39 -40 -
          33 -30 -23 -10 3 15 36 67 90 112 132 160 182 200 215 235 252 265 278
          294 307 317 329 342 357 367 370 375 377 377 369 342 322 302 264 215
          171 137 102 67 36 18 2 -12 -26 -35 -46 -55 -59 -68 -66 -67 -68 -67 -62 -
          60 -57 -55 -51 -47 -40 -37 -35 -30 -24 -20 -15 -10 -5 0 7 10 16 17 16 18
          16 15 15 12 14 15 12 10 13 13 16 17 17 17 19 15 20 20 20 20 23 23 21 20
          20 20 21 20 19 20 20 20 20 20 22 22 21 20 20 20 18 18 18 18 16 15 15 17
          20 22 22 22 21 20 20 20 20 20 18 17 17 17 17 15 17 15 15 15 14 15 16 17
          17 17 20 20 17 17 19 20 20 20 19 20 17 20 17 17 15 12 14 15 13 12 14 13
          13 15 15 15 14 17 17 17 19 18 18 18 19 20 19 18 13 12 12 12 15 20 16 15
          13 15 17 18 19 20 20 20 19 18 19 20 19 18 18 18 19 20 20 17 15 12 12 12
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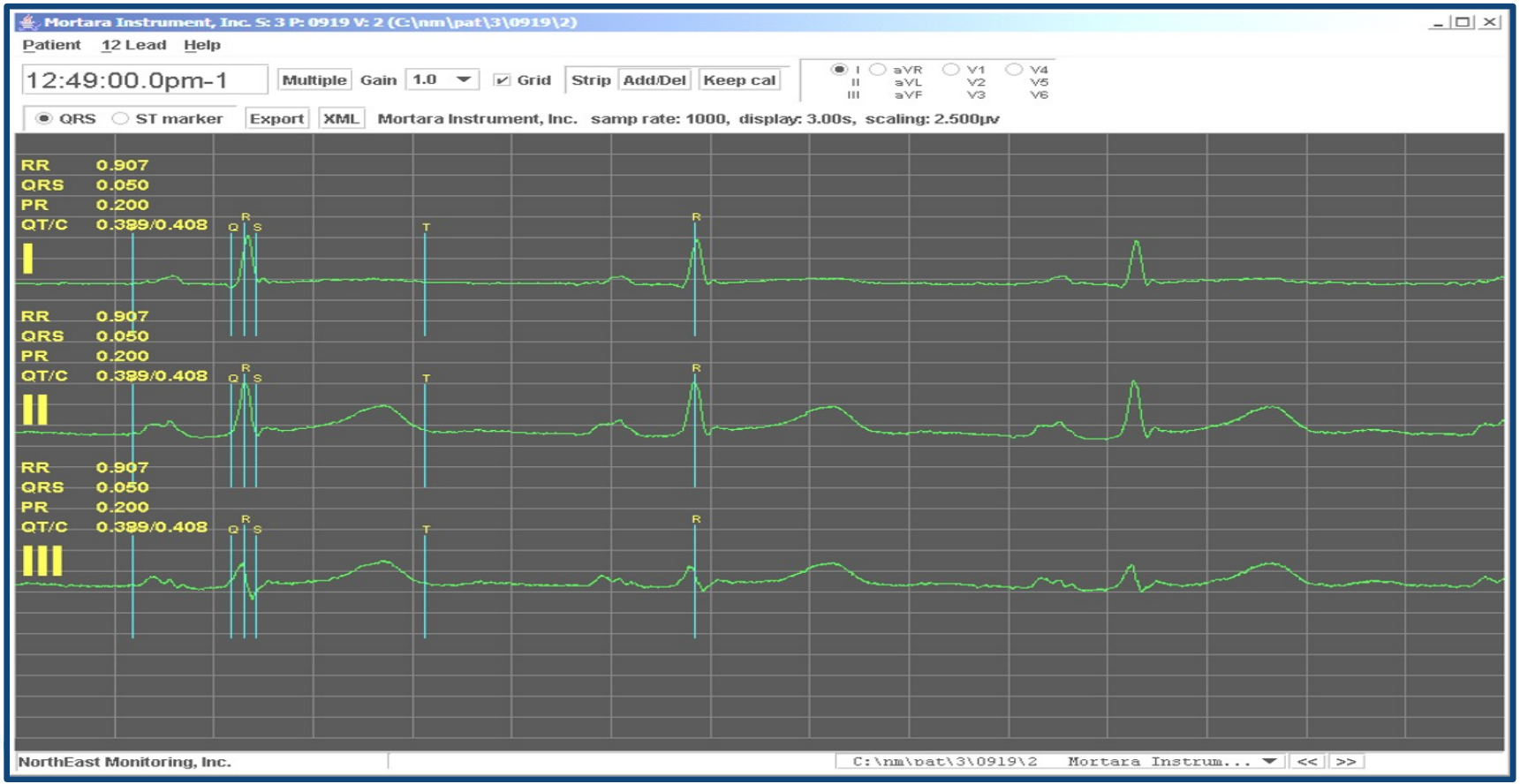
          10 10 10 10 9 10 8 8 9 10 12 13 8 10 10 10 12 13 13 13 11 12 10 10 9 8 8
          7 7 7 9 8 9 7 9 10 8 8 6 7 5 7 9 10 10 10 11 10 12 13 11 10 14 13 13 12 14
          18 18 18 20 20 23 20 20 20 20 23 23 23 23 25 25 25 23 25 22 25 25 25 27
          27 27 30 30 32 34 34 34 34 34 34 33 35 35 37 38 39 45 47 49 47 47 47 45
```

ECG Waveform Displayed in the ECG Annotation Tool at the Core Lab



Interval Data displayed in the Study Database

select studyid, usubjid, visit, egrectm, eglead, eghrmn, egqrsmn, egqtmn, egpqmn, egqtcbmn from himss.ecg_update order by us

Studyid	Usubjid	Visit	Egrectm	Eglead	Eghrmn	Egqrsmn	Egqtmn	Egpqmn	Egqtcbmn
555	0010241	1	12/16/2003 12:16:00	L1	72	0	0	0	
555	0010241	2	12/30/2003 12:44:00	L1	78	0	0	0	
555	0010241	3	1/10/2004 19:45:22	L1	83	0	0	0	
555	0010241	4	1/11/2004 17:18:20	L1	82	0	0	0	
555	0010241	4	1/11/2004 17:18:20	L1	82	0	0	0	
555	0010241	3	1/10/2004 19:45:22	L1	83	0	0	0	
555	0010241	2	12/30/2003 12:44:00	L1	78	0	0	0	
555	0010241	1	12/16/2003 12:16:00	L1	72	0	0	0	
555	0010241	2	12/30/2003 12:44:00	L2	78	49	349	200	
555	0010241	2	12/30/2003 12:44:00	L2	78	49	349	200	
555	0010241	4	1/11/2004 17:18:20	L2	82	79	360	189	
555	0010241	3	1/10/2004 19:45:22	L2	83	49	349	200	
555	0010241	1	12/16/2003 12:16:00	L2	72	47	347	200	
555	0010241	3	1/10/2004 19:45:22	L2	83	49	349	200	
555	0010241	1	12/16/2003 12:16:00	L2	72	47	347	200	
555	0010241	4	1/11/2004 17:18:20	L2	82	79	360	189	
555	0010241	1	12/16/2003 12:16:00	L3	72	0	0	0	
555	0010241	4	1/11/2004 17:18:20	L3	82	0	0	0	
555	0010241	3	1/10/2004 19:45:22	L3	83	0	0	0	
555	0010241	2	12/30/2003 12:44:00	L3	78	0	0	0	

ECG Interval Data for Analysis in CDISC SDTM and ODM for Transfer to the Sponsor

```
        <ItemData ItemOID="egdy" Value="10" />
      </ItemGroupData>
    - <ItemGroupData ItemGroupOID="EG" ItemGroupRepeatKey="296">
        <ItemData ItemOID="studyid" Value="555" />
        <ItemData ItemOID="usubjid" Value="5550020432" />
        <ItemData ItemOID="visitnum" Value="4" />
        <ItemData ItemOID="visit" Value="Day 4" />
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        <ItemData ItemOID="egtest" Value="QT" />
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Annotated ECG File in the FDA Viewer

2004 HIMSS Connect-a-thon Participants:

- Phillips
- GE
- Mortara
- NorthEast Monitoring Digital Infuzion
- Duke Clinical Research Institute

Formal Association Between ECG Files and SDTM

6.3.3 ECG Test Results (EG)

EG – Description/Overview

A findings domain that contains ECG data, including position of the subject, method of evaluation, all cycle measurements and all findings from the ECG including an overall interpretation if collected or derived.

EG – Specification

eg.xpt, ECG Test Results — Findings. One record per ECG observation per replicate per time point or one record per ECG observation per beat per visit per subject, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	EG	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SPDEVID	Sponsor Device Identifier	Char		Identifier	Sponsor-defined identifier for a device.	Perm
EGSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
EGGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
EGREFID	ECG Reference ID	Char		Identifier	Internal or external ECG identifier. Example: "334PT89".	Perm

Challenges and Lessons Learned

Challenge: Waveform is standard, the carts are not

- Carts use different sampling rates, 500Hz, 1000Hz, etc.
- Carts take samples for different periods of time, e.g., 3 seconds - 12 seconds
- To display waveforms from different carts, we had to adjust for these differences, e.g., Fast Fourier, Nearest neighbor, Interpolation, etc.
- Cart manufactures generate the Waveform Standard file at different points in the clinical workflow and from different systems such as a central ECG management system, or the actual ECG cart.
- Different carts have different “fields” enterable versus preprogrammed or system generated where a research subject or site identifier can be input.
- Some transformation and mapping were needed.
- Take advantage of near real-time data: check and reconcile files when received.
- This work was done in 2004 with RWD (equipment representing multiple sites), SDTM and ODM.

SDTM and RWD

Most Common Data Models

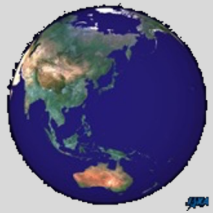
Including those for RWD

1. Designed to fit the data.
2. Built for particular use/s
3. Use a “least common denominator” approach so data from multiple sites fit

CDISC SDTM

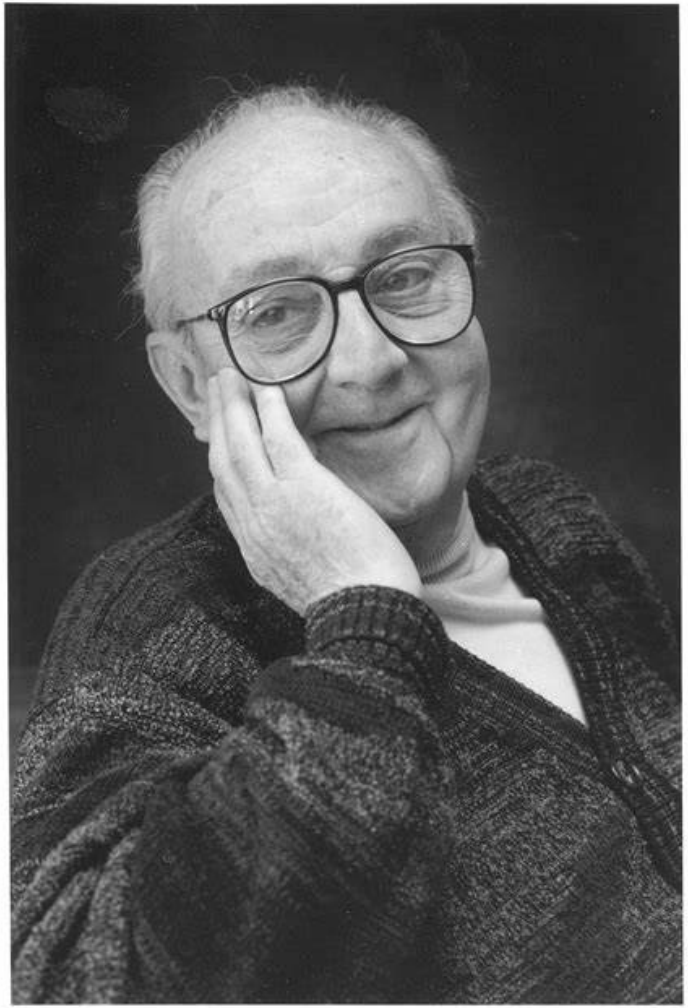
Built for *exact representation* of clinical study data.

RWD requires high-fidelity representation of the world.



When used in a traditional clinical trial, also requires representing the RWD in a traditional study structure

→ **sounds like SDTM**



"Essentially, all models are wrong, but some are useful."

-

George Box

We don't have to be perfect to be useful. But there are a few unanswered questions:

- In what ways would SDTM need to be extended to faithfully represent RWD?
- How quickly can we make and rigorously evaluate the practical extensions to identify gaps. Fix gaps !
- How future-proof can we get it? We may need to monitor the performance as new RWD sources are used in studies.

Extending SDTM to carry RWD we will benefit from 20 years of work and existing tools.

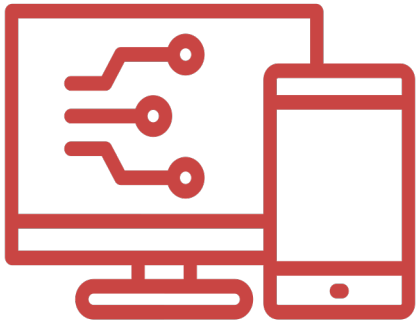
Digital Health Technologies

Peter Van Reusel
CDISC, Chief Standards Officer

Digital Health Technologies (DHT)

- An electronic method, system, product, or process that generates, stores, displays, processes and/or uses data within a healthcare setting.

- Examples include mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine.



Regulators are increasing their focus on DHTs

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INDUSTRY NEWS

FDA to Host Digital Health Technologies for Drugs Public Workshop

The U.S. Food and Drug Administration is hosting the virtual public workshop "Understanding Priorities for the Development of Digital Health Technologies to Support Clinical Trials for Drug Development and Review" on March 28th and 29th, 2023. The workshop will focus on understanding the priorities and challenges of developing Digital Health Technologies (DHTs) to support clinical drug trials.

The workshop will be convened by the Robert J. Margolis, MD, Center for Health Policy at Duke University under a cooperative agreement with FDA.

For more information on the Digital Health Technologies virtual public workshop and to register, please visit FDA's Meeting's, Conferences & Workshops (Drugs).

Data standards landscape

Data standards for DHT data are currently lacking across the clinical trial data lifecycle

Data Generation	Data Exchange	Data Tabulation	Data Analysis	Regulatory Submission
Raw sensor data often millisecond (e.g., touch event from device screen, accelerometers from sensors, etc.) & **metadata** (e.g., device data)	Data transferred to the Cloud, **feature data** calculated (summarizing information in **raw sensor data**) in lower resolution	**Feature data** and associated **metadata** are tabulated.	**Feature data** analyzed (alone or in combination with other clinical trial data) and **digital endpoints** derived	**DHT data package** (tabulated & analysis-ready) submitted to health authorities.

Clinical Trial Data Lifecycle

CDISC Standards Are Robust Enough to Represent DHT Data

ECG Test Results Domain

Identifier Variable Connects Device Information with Results

Device Domains

Example

Device SDTM Domains

Intended to support most or all types of devices

Device Identifiers (DI)	• Consistent unique sponsor-defined identifier that links data across domains.
Device Properties (DO)	• Important unvarying device characteristics that are not identifiers
Device-In-Use (DU)	• Measurements and settings intentionally set that may vary between uses of a device
Device Exposure (DX)	• Subject's exposure to a medical device under study
Device Events (DE)	• Reportable device-related occurrences such as malfunctions and calibrations
Tracking and Disposition (DT)	• Physical locations of device, either at each movement or just final status
Device-Subject Relationship (DR)	• Look-up table providing single consistent link between each device and subject

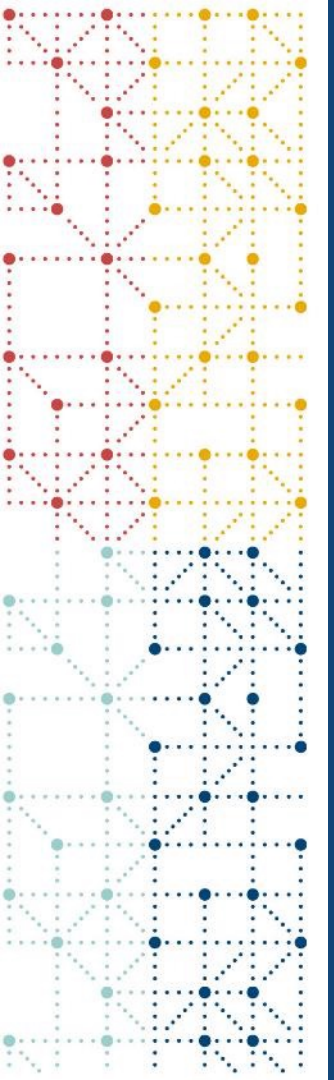
DHT Proposed Scope

- Identify domains for the most commonly generated measurements from passive monitoring and active tests
- Define Controlled Terminologies and Codetable Mapping Files for the most commonly used digital endpoints
- Adoption of SDTMIG for Medical Device to accommodate DHT needs
- Release the first draft for Public Review

Industry Collaboration

- Collaborate, partner and harmonize with other industry standards initiatives, standards organizations and stakeholders

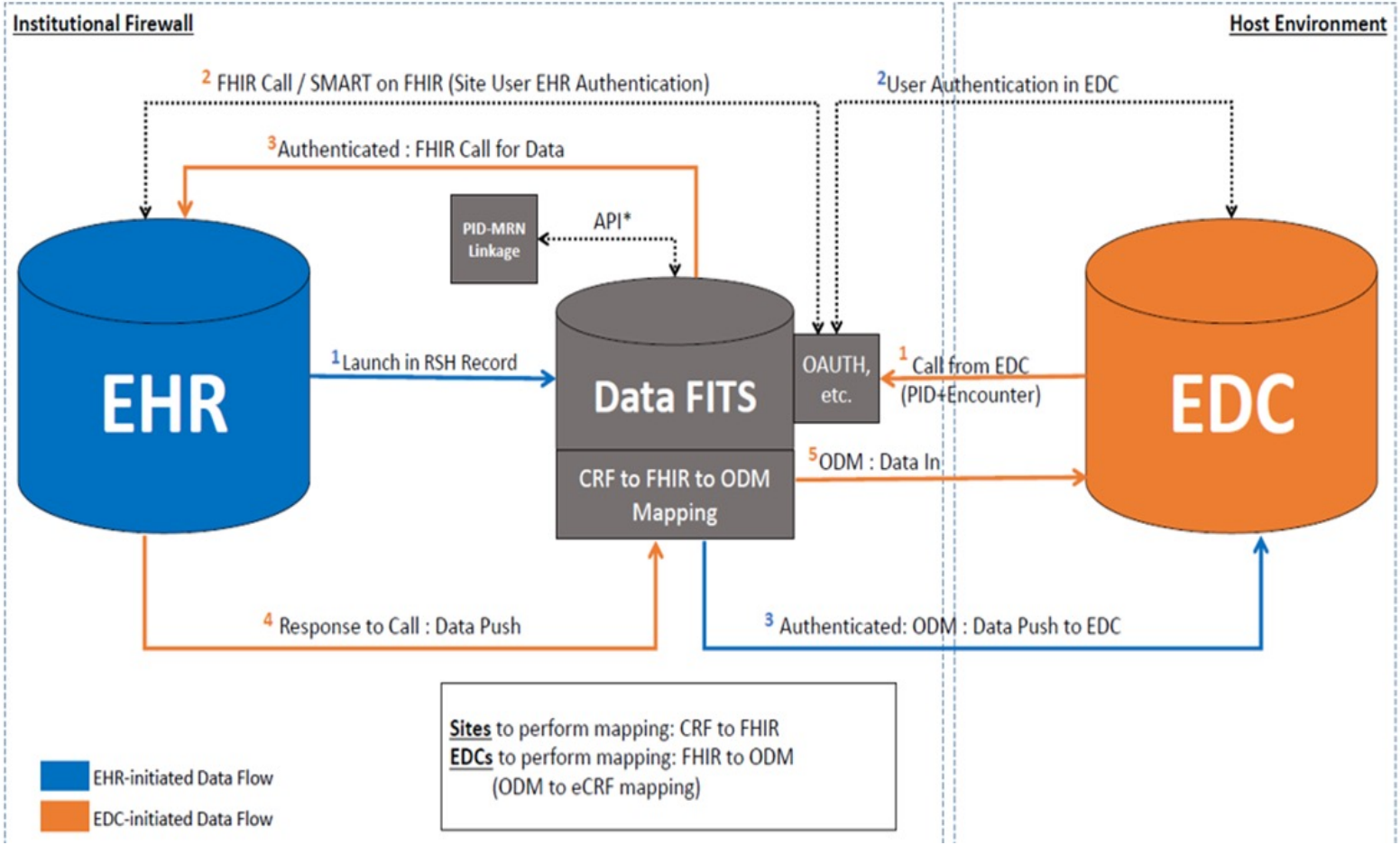
- Building on existing and new collaborations
  - DEEP – Digital Evidence Ecosystem & Protocols
    - Harmonize the definition of patient-centric digital measure
  - Droice Labs
    - Transforming RWD into CDISC formats without using a Common Model
  - DiMe
    - Crowdsourced Library of Digital Endpoints
  - C-Path, Regulatory agencies



Data Exchange Standards

Sam Hume, DSc.
CDISC, VP, Data Science

ODM Widely Used for eSource: FDA eSource Initiative



ODM v2.0 and HL7 FHIR Interoperability

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FHIR Resource

LOINC Code

https://wiki.cdisc.org/display/ODM2/Origin

ODM v2.0 JSON Serialization - Dataset-JSON Example


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            {
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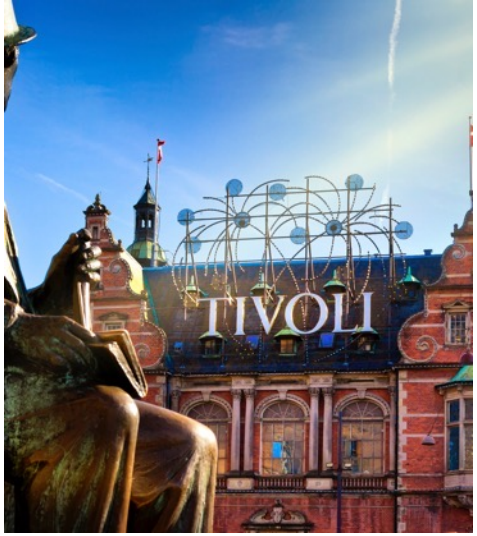
Question and Answer Session

Rhonda Facile, MSc.
CDISC, VP Business Development

Starting Question:

What other types of RWD do you want to see?

Enter your answer in the chat.



2023 CDISC Europe Interchange

Copenhagen, Denmark
26-27 April 2023

https://www.cdisc.org/events/interchange/2023-europe-interchange

CDISC Interchanges 2023

2023 Europe
Interchange
26 – 27 April
Copenhagen
Denmark

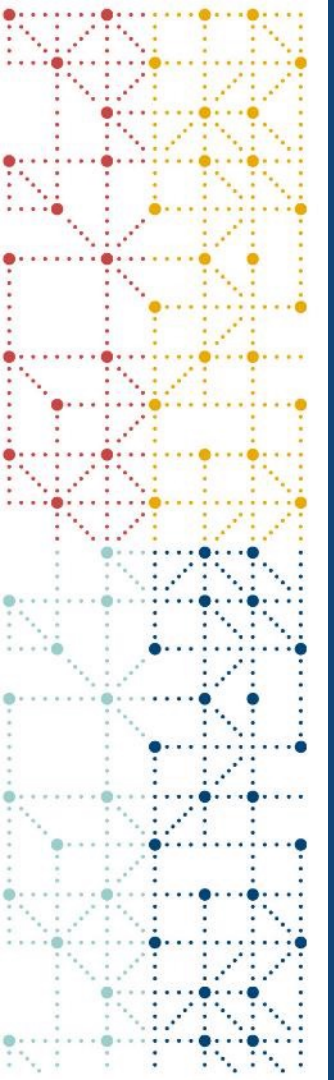
2023 Japan
Interchange
10 – 11 July
Tokyo
Japan

2023 China
Interchange
25 – 26 August
Beijing
China

2023 US
Interchange
18 – 19 October
Washington, DC
USA

2023 Korea
Interchange
11 – 14 December
Seoul
Korea

#ClearDataClearImpact



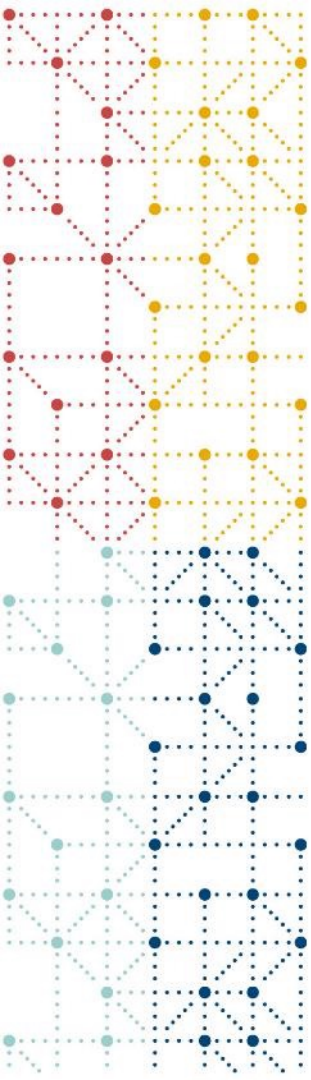
Clear data. Clear impact.

Thank you!

Questions or comments?

Contact any of the presenters today or at info@cdisc.org

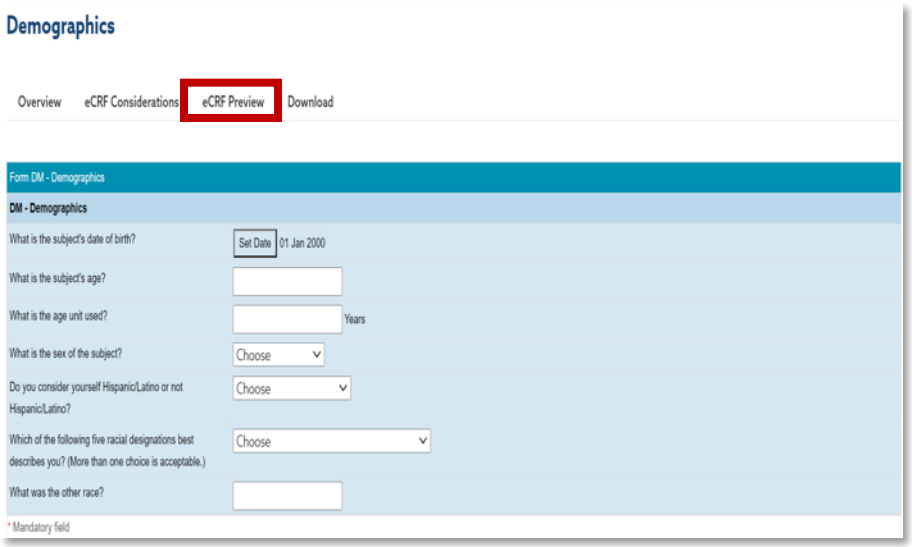
Extra Slides – time permitting

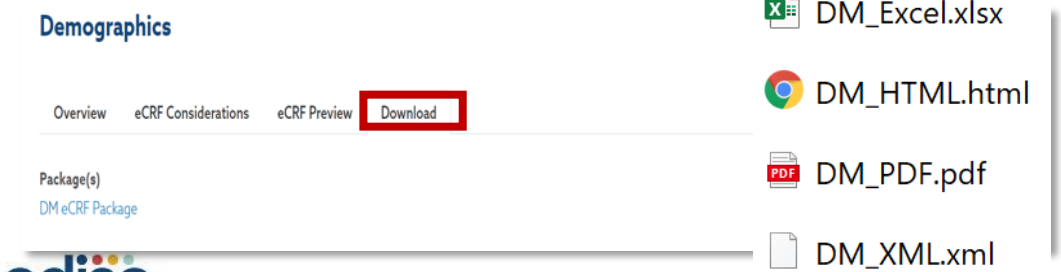


Resources Available Now

Rhonda Facile

CDASH eCRFs





- ✓ 65 CDASH eCRFs available
- ✓ Can be used as is or customized from the OpenClinica and REDCap libraries
- ✓ All needed metadata included

Downloadable from:

cdisc eCRF Portal

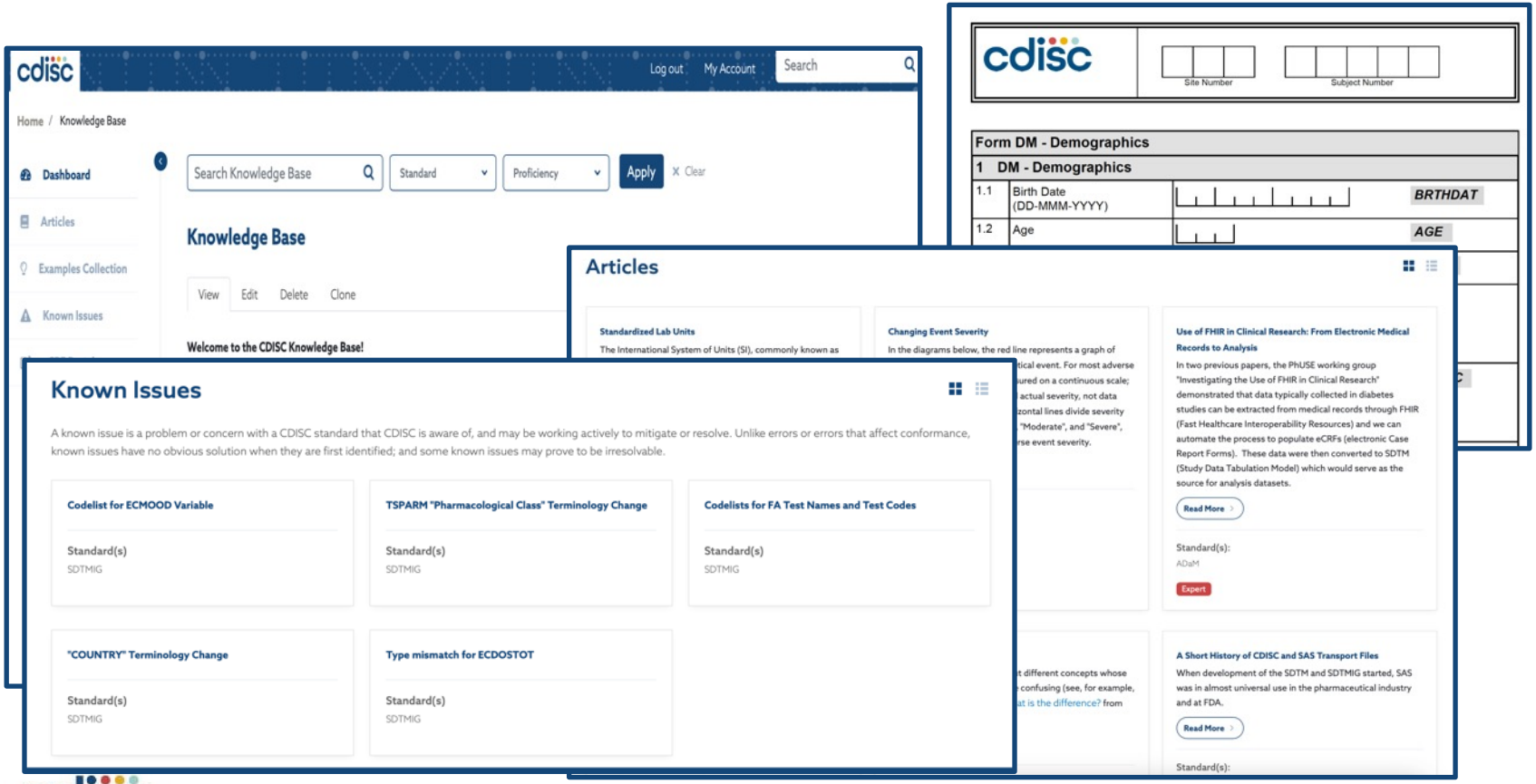
OpenClinica

REDCap
Research Electronic Data Capture

cdisc

CDISC Knowledge Base

eCRF Portal – 65 eCRFs available



Journal of the Society for Clinical Data Management

- Papers focused on CDISC implementation use cases (all data sources)
- 8 articles published as of 21 Feb 2023
- 9 articles near completion
- Target completion: End of Q1 2023

https://www.jscdm.org/issue/9/info/

Standardizing Paediatric Clinical Data: The Development of the conect4children (c4c) Cross Cutting Paediatric Data Dictionary

Anando Sen , Victoria Hedley , John Owen , Ronald Cornet , Dipak Kalra , Corinna Engel , Avril Palmeri , Joanne Lee , Jean-Christophe Roze , Joseph F Standing , Adilia Warris , Claudia Pansieri , Rebecca Leary , Mark Turner and Volker Straub

2023-02-13 Volume 2 • Issue 3 • 2022 • Fall 2022 - Innovative Implementation of CDISC Standards

Electronic Submission and Utilization of CDISC Standardized Clinical Study Data in Japan

Yuki Ando

2023-01-13 Volume 2 • Issue 3 • 2022 • Fall 2022 - Innovative Implementation of CDISC Standards

Implementation of COVID-19 Pandemic Impact Standards

Miho Hashio , Sarah Huggett , Stephen Hamburg , Robyn Eichenbaum and Nadeem Gul

2023-01-05 Volume 2 • Issue 3 • 2022 • Fall 2022 - Innovative Implementation of CDISC Standards

Developing Technical Specifications for Submitting Clinical Trial Data Sets for Treatment of Noncirrhotic Nonalcoholic Steatohepatitis (NASH) Liver Fibrosis

Y. Veronica Pei , Vaishali Popat , Aaron Belowich and Chenoa Conley

2023-01-05 Volume 2 • Issue 3 • 2022 • Fall 2022 - Innovative Implementation of CDISC Standards