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2023
KOREA
INTERCHANGE
SEOUL | 11-14 DECEMBER

RWD Activities Update

Rhonda Facile MS
VP, Partnerships and Development

Meet the Speaker

Rhonda Facile, MS

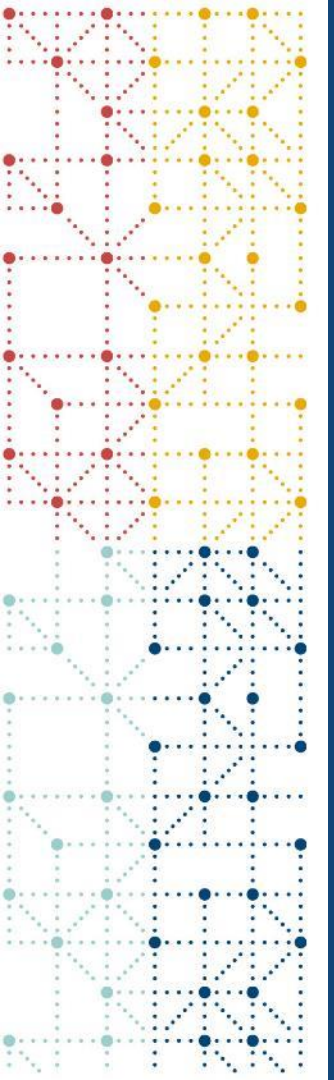
Title: VP, Partnerships and Development

Organization: CDISC

Rhonda Facile is Vice President, Partnerships and Development at CDISC where she oversees business development and new project development. She brings together, key and diverse stakeholder communities to establish effective collaboration structures to ensure project success. At CDISC Rhonda has led numerous standards development projects and initiatives including CDASH, therapeutic area guides and more recently CDISC RWD Connect. Prior to joining CDISC, Rhonda worked in clinical operations and regulatory affairs in Pharmaceutical, Biotechnology, and Contract Research Organizations in the US and Europe.

Agenda

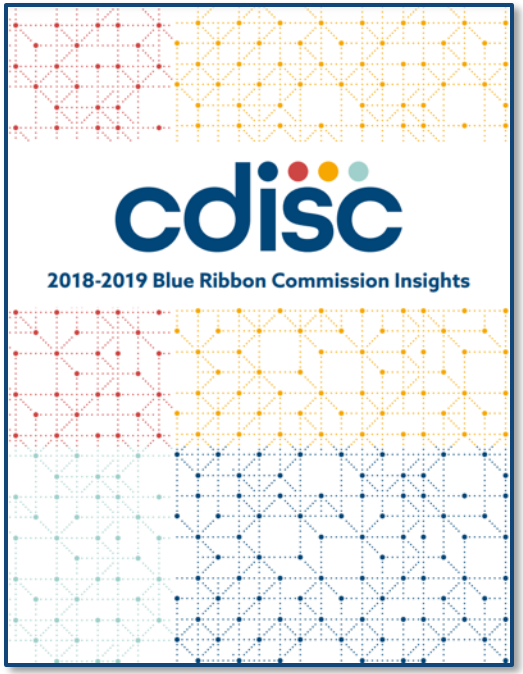
1. CDISC RWD Background
2. CDISC RWD Strategy
3. CDISC RWD Activities and Resources



CDISC RWD Background

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:

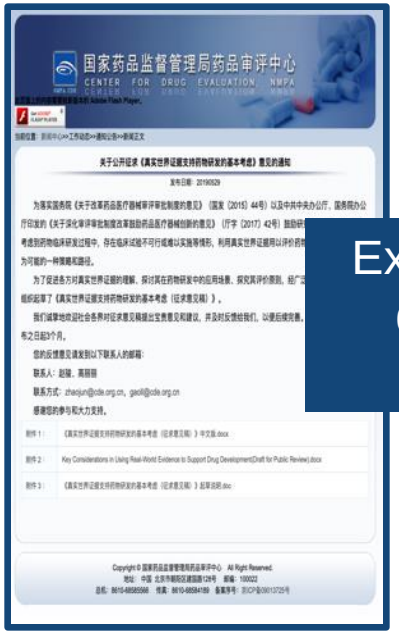
- Standardization of RWD is **necessary**. The primary focus should be on **improving data sharing and quality**.

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 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 PMDA

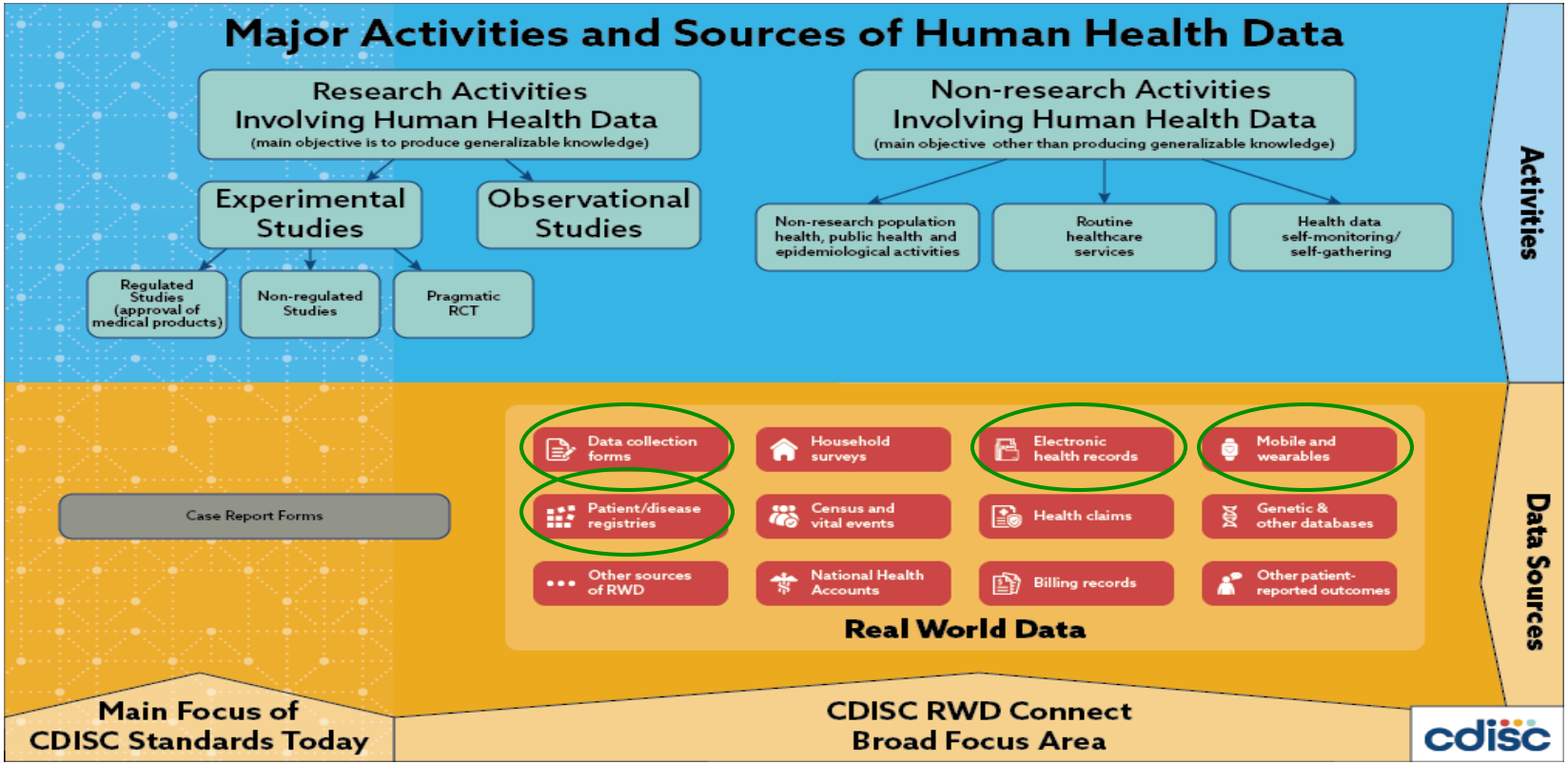
https://www.pmda.go.jp/english/about-pmda/0004.pdf

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

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** 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 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

Real World Data



Note!

- CDISC Standards **Do Not** specify what data should be collected or how to conduct clinical trial protocols, assessments or endpoints.
- CDISC Standards specify **how** to structure data to support efficient data sharing for regulated clinical trials
- **You can't standardize everything**
  - Focus on commonalities, cross-cutting concepts, data collected repeatedly

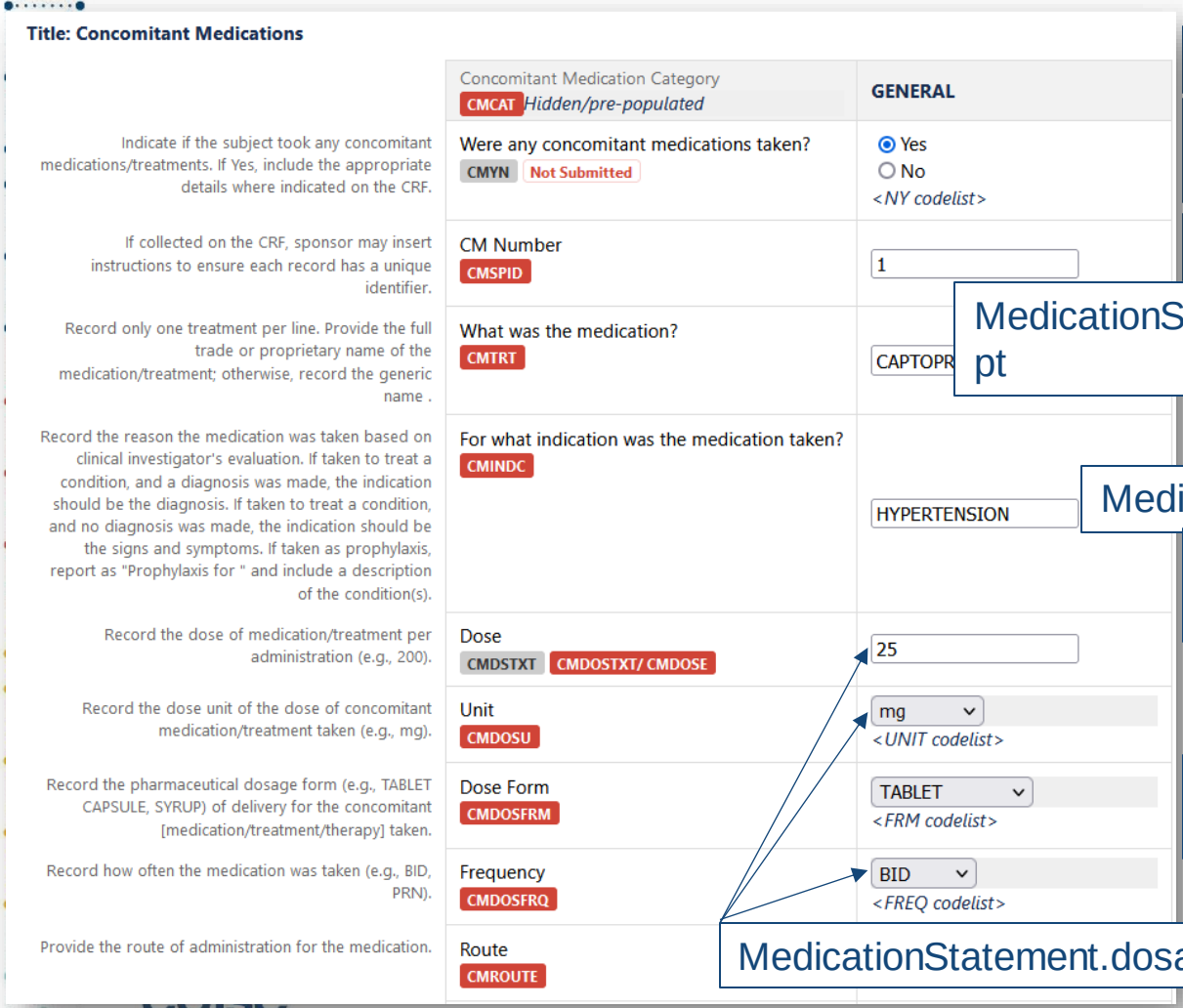
RWD Activities and Resources

CDISC Real World Data Resources

- HL7-FHIR to CDISC Mapping – Extracting eHR data to SDTM
- Considerations - Using SDTM for Observational Studies
- CDISC eCRF Portal, REDCap & OpenClinica - CDASH eCRFs
- Digital Health Technologies
- Knowledge Base
- eCRFs
- Peer-reviewed Articles

HL7–FHIR to CDISC Mapping

- Aim: provide a pathway for going from extracted EHR data to SDTM format
- Joint effort between CDISC and HL7
  - Balloted by both SDOs
- Domains mapped:
  - Events: AE, MH
  - Interventions: PR, CM
  - Findings: LB, VS, Lab Model
  - Special Purpose: DM
- Published 1 Sep 2021



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

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.

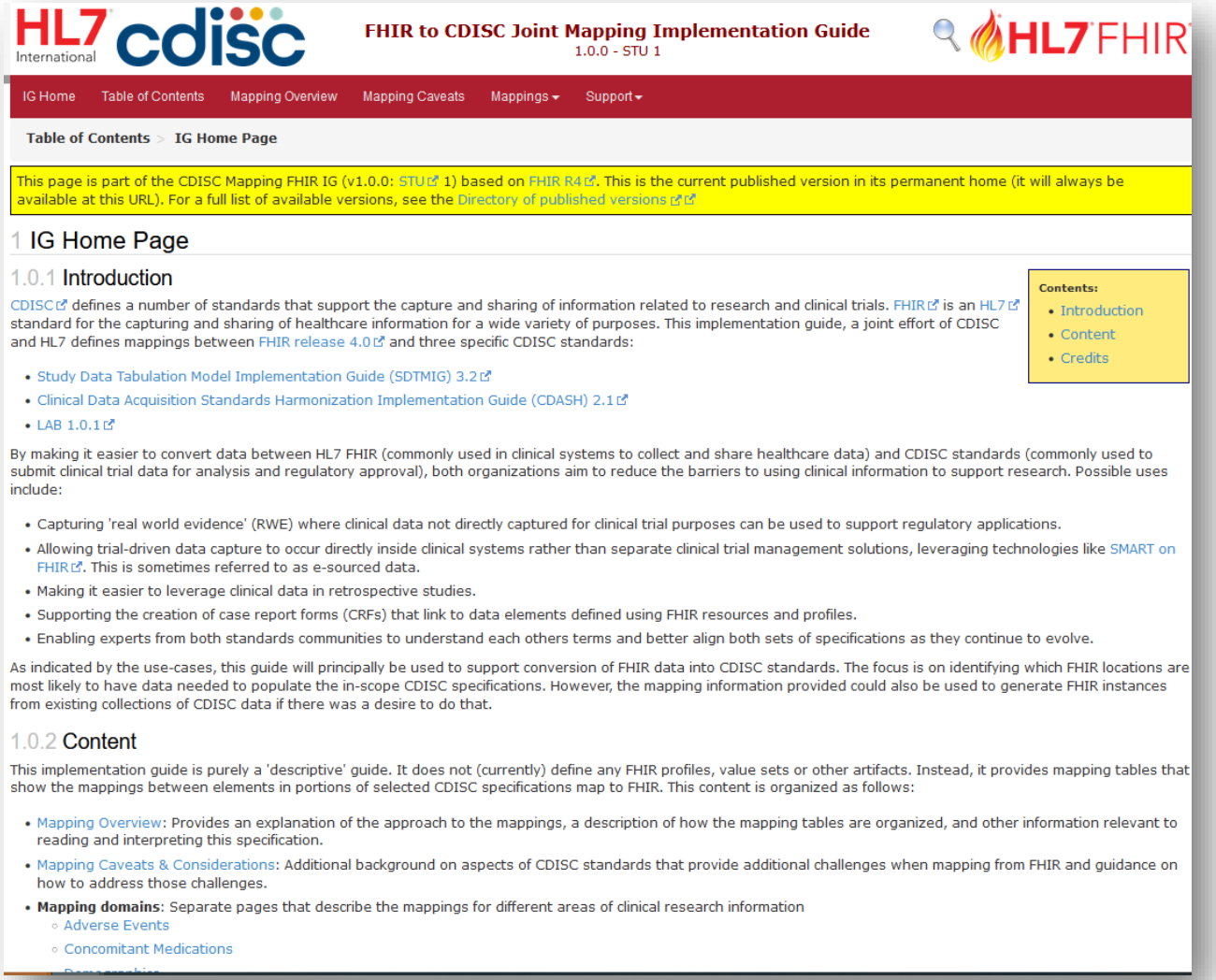
By making it easier to convert data between HL7 FHIR (commonly used in clinical systems to collect and share healthcare data) and CDISC standards, both organizations aim to reduce the barriers to using clinical information to support research.

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.

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



FHIR to CDISC Joint Mapping Implementation Guide
1.0.0 - STU 1

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

Considerations for Using CDISC Standards for Observational Studies

Goal

- 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
- 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)

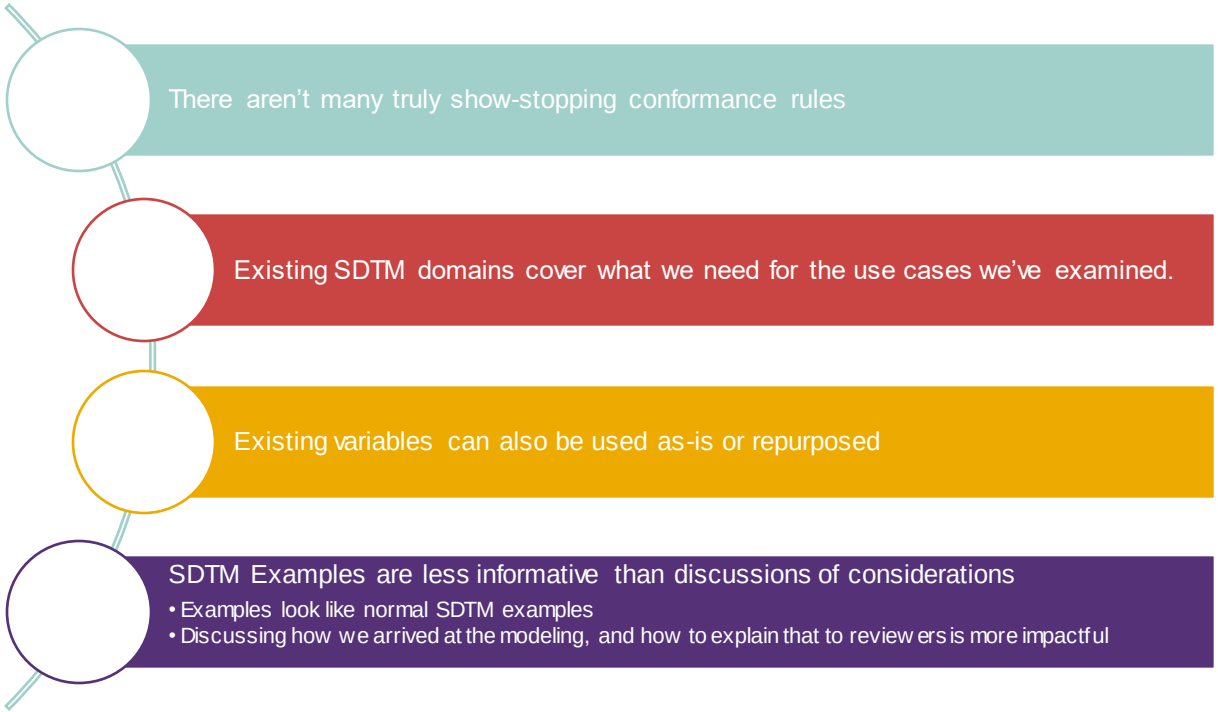
- Reuse existing standards; create new domains and variables only if necessary

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.

Lessons learned so far…



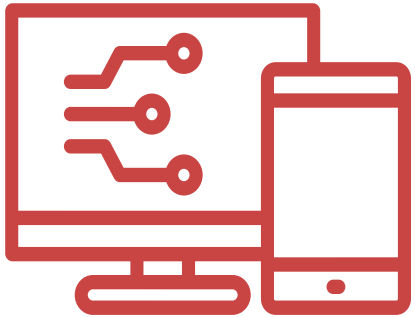
Now Available in the CDISC Knowledge Base

https://www.cdisc.org/kb/articles/considerations-using-cdisc-standards-observational-studies

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.



CDISC Digital Health Technologies (DHT) Team

The purpose of this team is to explore and enhance standardization of digital health technologies data.

Our aims are to:

- Increase our collective knowledge of digital health technologies and related data;
- In collaboration with a diverse group of stakeholders;
- To determine how CDISC standards can further support use of DHTs; and to
- Develop and publish new supporting standards.

CDISC Standards Are Robust Enough to Represent DHT Data

ECG Test Results Domain

Identifier Variable Connects Device Information with Results

Device Domains

Example

Deliverables

Initial areas of focus include standards for data:

- Collected using DHTs which contribute to endpoints
- About attributes of devices used

Under consideration are:

- Enhancements to the SDTM and other foundational standards
- Controlled Terminologies and Codetable Mapping Files for digital endpoints
- TBD

CDISC Digital Health Technologies (DHT) Team

- **Team** of ~ thirty members with diverse experience with DHTs (DEEP, Droice Labs, DiME, C-Path and regulatory agencies

- **Research areas** include cardiovascular, central nervous system, dermatology, infectious diseases, respiratory, oncology

Scoping

Team Complete

Development

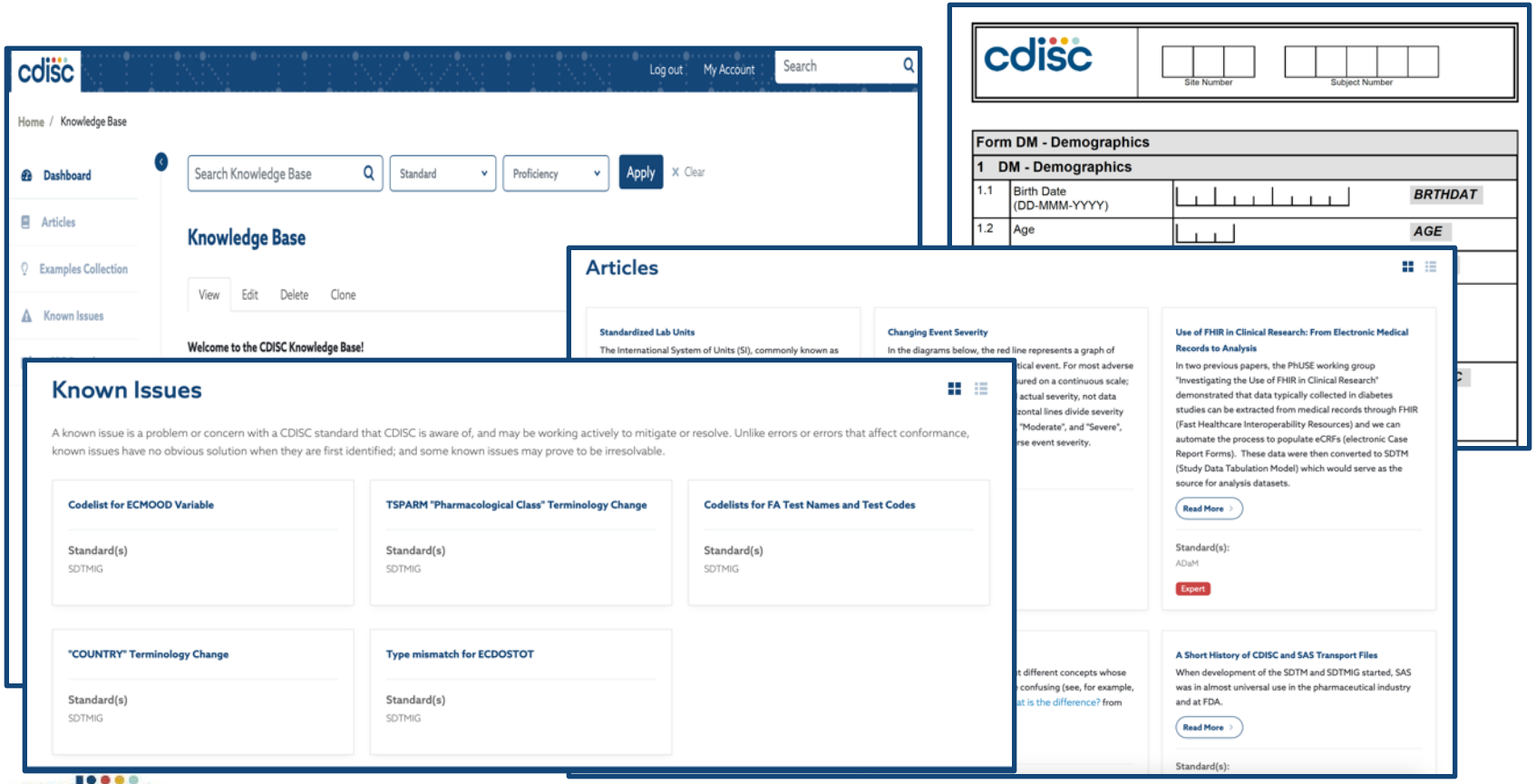
Standards development began in September

Deliverables

Planned completed Q4 2024

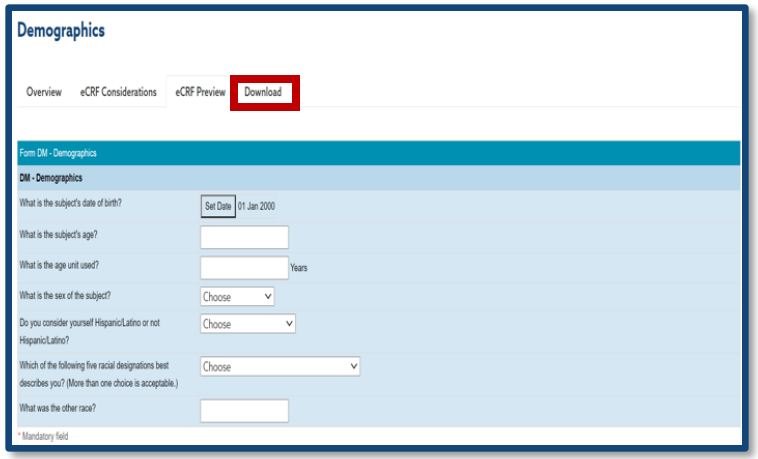
CDISC Knowledge Base

eCRF Portal – 65 eCRFs available



CDISC eCRFs

- The eCRF Portal contains machine readable eCRFs
  - Visual representation of CRF layout with CDASH annotations
  - Machine-readable in ODM format
- Includes CRFs from:
  - CDASH Implementation Guide v2.1
  - Crohn's Disease Therapeutic Area UG
  - COVID-19 Therapeutic Area UG
  - 65 customizable eCRFs are available
  - Freely downloadable from:



cdisc eCRF Portal | REDCap Research Electronic Data Capture | OpenClinica | formedix

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Funding provided by THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST

Journal of the Society for Clinical Data Management

- Papers focused on CDISC implementation use cases (all data sources)
- 8 articles published
- 9 articles near completion

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

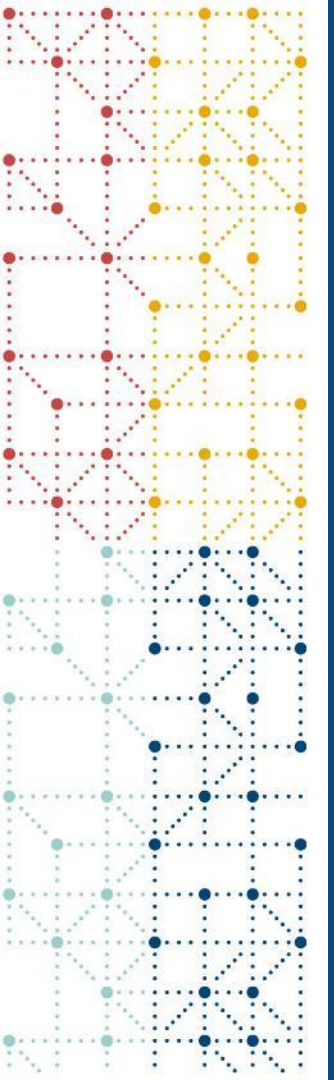
Miho Hashio , Sarah Huggett , Stephen Hamburg , Robyn Eichenbaum and Nadeem Gul

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



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Clear data. Clear impact.

Thank you!