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The Common Data Model Harmonization Project

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FDA U.S. FOOD & DRUG ADMINISTRATION

Agenda

- Overview to the Common Data Model Harmonization (CDMH)
  - Phase I Accomplishments
  - Phase II Deliverables
- Leveraging CDMH in COVID-19 activities
- I-SPY COVID-19 Trial

Overview:
PCORTF CDM Harmonization Project

Goal:

Build a data infrastructure for conducting research using Real World Data (RWD) derived from the delivery of health care in routine clinical settings.

Objective:

Develop the method to harmonize the Common Data Models of various networks, allowing researchers to simply ask research questions on much larger amounts of RWD than currently possible, leveraging open standards and controlled terminologies to advance PCOR.

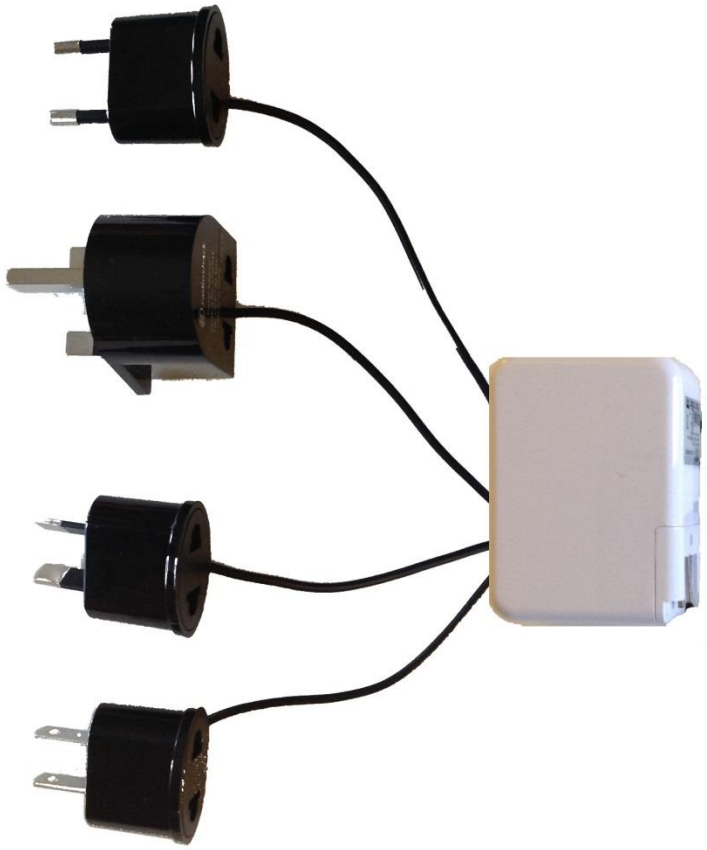
The solution, using the Adapter Analogy

Sentinel

i2b2/ACT

PCORNET

OMOP



- Different countries use different “outlets”.
- There is a need for travel adapters.

The Solution:

- Use a converter between various adapters.
- Allow researchers to ask a question once and receive results from many different sources using a common agreed-upon standard structure, or a Common Data Model.

Phase I Accomplishments

1. Harmonized 5 Common Data Models (i.e. Sentinel, PCORnet versions 3.1 and 4.0, OMOP and i2b2/ACT) with an intermediary model (BRIDG).
2. Developed the infrastructure (in collaboration with NIH/NCATS) to build a query, view and store the results leveraging open, consensus-based standards.
3. Collaborated with Yale/Mayo Clinic as well as Elligo Health Research on the execution of the query focusing on the oncology use case.

Phase II Deliverables

1. Collaborate with new data partners leveraging the CDMH architecture as well as direct query from Electronic Health Records and Clinical Data Repositories.
2. Enhance the existing infrastructure to leverage Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) standard as the exchange data standard.
3. Submit RWD leveraging Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) via the FDA Gateway.

COVID-19 ACTIVITIES

National COVID-19 Cohort Collaborative (N3C)

- A **centralized**, secure portal for hosting row-level COVID-19 clinical data and deploying and evaluating methods and tools for clinicians, researchers, and healthcare

- A **partnership** among several HHS agencies, the CTSA network, distributed clinical data networks (e.g. PCORnet, OHDSI, ACT/i2b2, and TriNetX), and other clinical partners

National COVID Cohort Collaborative

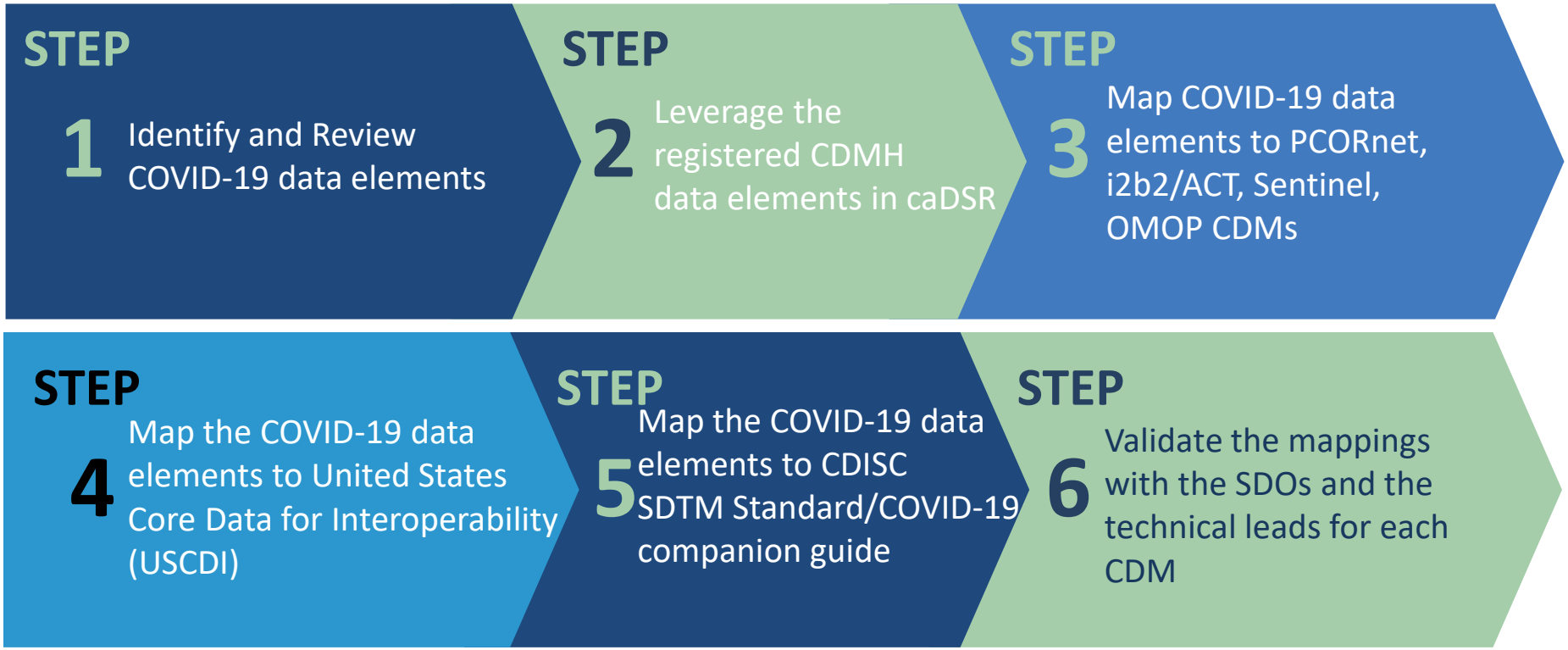
Four community workstreams:

- Data Partnership & Governance
- Phenotype & Data Acquisition
- Data Ingestion & Harmonization
- Collaborative Analytics

COVID-19 Evidence Accelerator Collaborative

- An initiative launched by the Reagan-Udall Foundation (RUF) for the FDA in collaboration with Friends of Cancer Research (*Friends*) to provide a unique venue for major data organizations, government and academic researchers, and health systems to gather and design quick-turn-around queries and share their results
- Two work steams:
  1. Accelerator Parallel Analyses: Developing key research questions that multiple organizations and teams can address simultaneously.
  2. Accelerator Lab Meetings: Share findings from interested data partners on critical questions

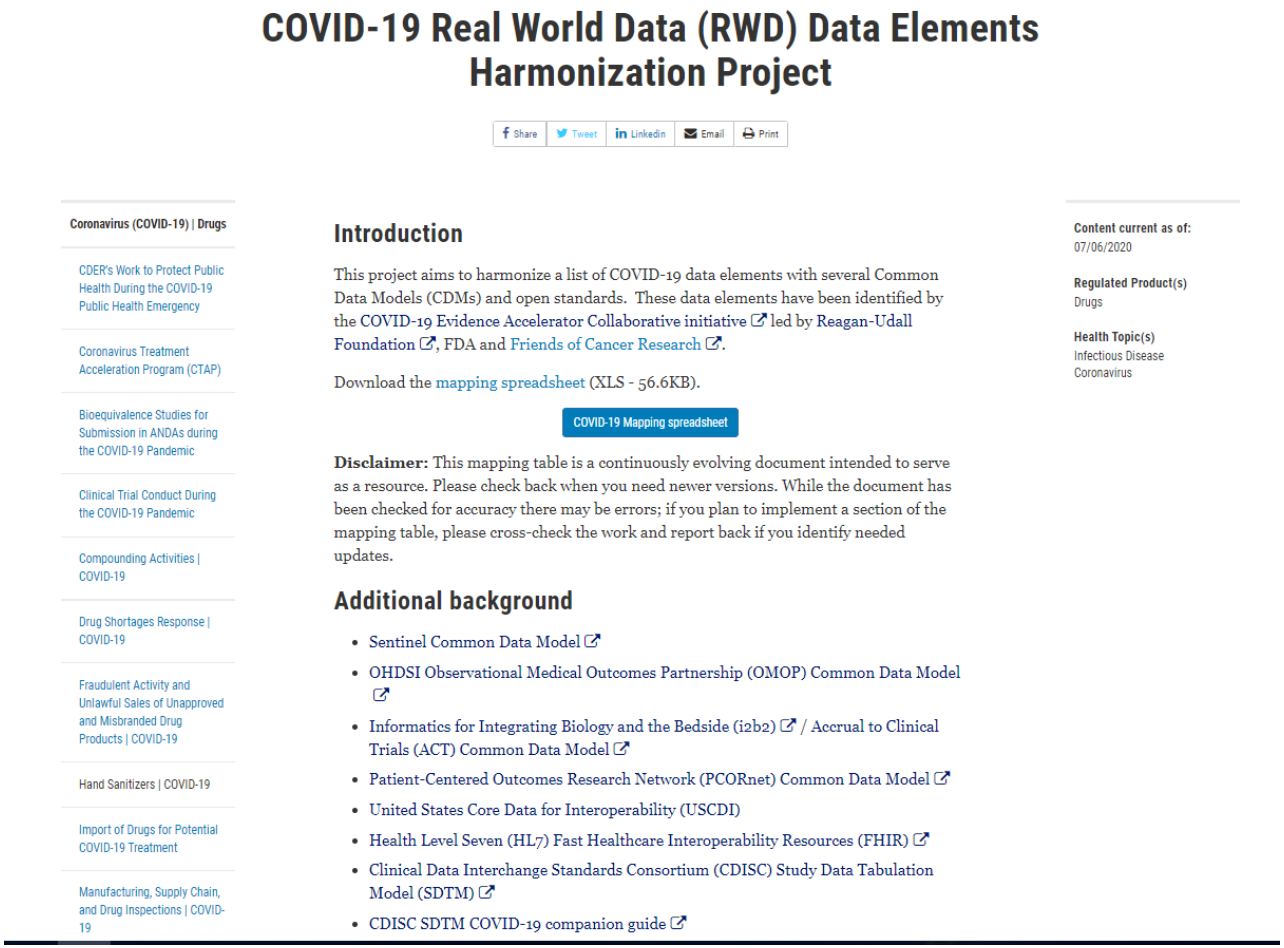
COVID-19 Common Data Elements Mapping Process



A Mapping Example

COVID-19 Data Element	Sentinel CDM	PCORnet CDM	I2b2/ACT CDM	OMOP	CDISC SDTM + COVID-19 Companion Guide	USCDI + HL7 FHIR R4	VA EHR-S
Treatment setting (e.g., hospital, clinic, inpatient, outpatient)	ENCOUNTER.EncType **(6333690)**	ENCOUNTER.Enc_Type **(6421520)**	VISIT.Visit_type **(6333697)**	VISIT_OCCURRENCE.visit_concept_id **(6381648)** VISIT_OCCURENCE.visit_type_concept_id **(6422451)**	HOTERM	FHIR R4: Organization.id FHIR R4: Organization.type OR Location.type	Outpat and Inpat records has VISN and StationID Then, cross walk with dimension table to figure out facility info
On ventilation (Yes/No)	PROCEDURE.PX **(6385457)**	PROCEDURES.PX **(6369924)**	PROCEDURE.Procedure_code **(6400757)**	PROCEDURE_OCCURRENCE.procedure_concept_id **(6381632)**	PRPRESP PROCCUR PRTRT=Ventilation	USCDI Profile: us-core-procedure FHIR R4: Procedure.category and Procedure.code	CPRSORder.CPRSORder & orderable item
COVID 19 Medication dosing regimen	INPATIENTPHARMACY.RxDose **(6385427)** INPATIENTPHARMACY.RxUOM **(6385429)**	MED_ADMIN.MEDADMIN_DOSE_ADMIN **(6369879)** MED_ADMIN.MEDADMIN_DOSE_ADMIN_UNIT **(6379539)**	Medication.MEDICATION_CODE **(6333698)** Medication.MEDICATION_CODING_SYSTEM **(6400752)** Medication.MEDICATION_CLASSIFICATION_SYSTEM_VERSION (6400753)	DRUG_EXPOSURE.drug_concept_id **(6381591)** DRUG_EXPOSURE.quantity **(6381599)** DRUG_EXPOSURE.sig **(6381600)**	EXDOSE, EXDOSTXT, EXDOSU, EXDOSFRM, EXDOSFRQ, EXDOSRGM	USCDI Profile: us-core-medication FHIR R4: MedicationStatement.medication.amount	Inpatient - BCMA, Outpt-Outpatient Fill

FDA Website for the COVID-19 Mapping Spreadsheet



COVID-19 Real World Data (RWD) Data Elements Harmonization Project

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Coronavirus (COVID-19) | Drugs

- CDER's Work to Protect Public Health During the COVID-19 Public Health Emergency
- Coronavirus Treatment Acceleration Program (CTAP)
- Bioequivalence Studies for Submission in ANDAs during the COVID-19 Pandemic
- Clinical Trial Conduct During the COVID-19 Pandemic
- Compounding Activities | COVID-19
- Drug Shortages Response | COVID-19
- Fraudulent Activity and Unlawful Sales of Unapproved and Misbranded Drug Products | COVID-19
- Hand Sanitizers | COVID-19
- Import of Drugs for Potential COVID-19 Treatment
- Manufacturing, Supply Chain, and Drug Inspections | COVID-19

Introduction

This project aims to harmonize a list of COVID-19 data elements with several Common Data Models (CDMs) and open standards. These data elements have been identified by the COVID-19 Evidence Accelerator Collaborative initiative led by Reagan-Udall Foundation, FDA and Friends of Cancer Research.

Download the mapping spreadsheet (XLS - 56.6KB).

COVID-19 Mapping spreadsheet

Disclaimer: This mapping table is a continuously evolving document intended to serve as a resource. Please check back when you need newer versions. While the document has been checked for accuracy there may be errors; if you plan to implement a section of the mapping table, please cross-check the work and report back if you identify needed updates.

Additional background

- Sentinel Common Data Model
- OHDSI Observational Medical Outcomes Partnership (OMOP) Common Data Model
- Informatics for Integrating Biology and the Bedside (i2b2) / Accrual to Clinical Trials (ACT) Common Data Model
- Patient-Centered Outcomes Research Network (PCORnet) Common Data Model
- United States Core Data for Interoperability (USCDI)
- Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR)
- Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM)
- CDISC SDTM COVID-19 companion guide

Content current as of:
07/06/2020

Regulated Product(s)
Drugs

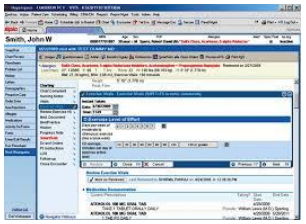
Health Topic(s)
Infectious Disease
Coronavirus

https://www.fda.gov/drugs/coronavirus-covid-19-drugs/covid-19-real-world-data-rwd-data-elements-harmonization-project

I-SPY COVID TRIAL
Investigation of Serial studies to Predict Your Therapeutic Response with biomarker Integration and Adaptive Learning

- Create an adaptive platform trial to efficiently and effectively find agents with the most potential to reduce mortality/morbidity
- Harness the **OneSource** infrastructure built for the I-SPY 2 TRIAL
- Augment the existing mappings with data elements required for I-SPY COVID TRIAL project

Streamlining Study Management through EHR integration



EHR systems

Integrated Referrals

Study reports sent back

I-SPY COVID Study System

Receive alerts for eligibility or outcome confirmation

Minimal data entry
Focus is on clinical care!

- **Automated patient referral and study registration**
  - Triggered by O2 order
  - Pull in demographic info from EHR system
- **Alerts to clinician and signoff using handheld devices**
  - Patient newly enrolled
  - Confirmation of patient outcome
- **Automated Study Report documented in EHR system**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