FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION & RESEARCH

FDA and Patient-Centered Outcomes Research Trust Fund (PCORTF)

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FDA-Funded PCORTF Projects

1. Utilizing Data from Various Data Partners in a Distributed Manner
2. Cross-Network Directory Service
3. Collection of Patient-Provided Information through a Mobile Device Application for Use in Comparative Effectiveness and Drug Safety Research
4. Development of a Natural Language Processing (NLP) Web Service for Public Health Use
5. Source Data Capture from Electronic Health Records (EHRs): Using Standardized Clinical Research Data

FDA-Funded PCORTF Projects

6. Standardization and Querying of Data Quality Metrics and Characteristics for Electronic Health Data
7. Developing a Strategically Coordinated Registry Network (CRN) for Women's Health Technologies
8. Common Data Model Harmonization (CDMH) and Open Standards for Evidence Generation
9. Enhancing Data Resources for Studying Patterns and Correlates of Mortality in Patient-Centered Outcomes Research: Linking National Death Index (NDI) and Commercial Claims

FDA-Funded PCORTF Projects

10. SHIELD - Standardization of Lab Data to Enhance Patient-Centered Outcomes and Value-Based Care
11. WHT-CRN Project: Bridging the PCOR Infrastructure and Innovation through Coordinated Registry Network (CRN) Community of Practice
12. CURE ID: Aggregating and Analyzing COVID-19 Treatments from EHRs & Registries Globally
13. Making Medicaid Data More Accessible Through Common Data Models and FHIR APIs

Research and Data Collaborations Evolvement to meet PCOR Research

- Need for a new infrastructure for research.
- Adopt Finable, Accessible, Interoperable, Reusable (FAIR) principles as a goal and use metrics to measure the progress.
- Figure out ways of sharing analyses done with software. Rather than transferring data, we need to transfer the software (a container) to the data partner and run the analysis on the systems where the data are.
- Build Trust and validation engineered into the system.
- Develop open-source tools to support sharing, discovering and reusing research data.
- Convene workshops with internal and external stakeholders around particular problems.
- Improve the quality and completeness of EHR data.

Barriers and potential solutions to the access and use of linked public data

- A strategy and set of standards at the HHS level that addresses the identifier issue (lack of an Enterprise Master Patient Index (EMPI)).
- A national standard to link relevant data sources while protecting reidentification.
- Conduct a systematic review of the HHS data sources with an eye towards transparency.
- Develop informed consent guidelines for data sharing.

Barriers and potential solutions to the access and use of linked public data

- Develop an ontology at the HHS level to find the data.
- Establish a metadata registry and repository at the HHS level for data elements and controlled terminologies.
- Need for interoperability.
- Lack of data consistency and quality, and missing values at the point of data collection.
- Healthcare data and infrastructure heterogeneity.
- Lack of data standardization at the point of care.
- Data Sharing Challenges.
- Integration of health care and clinical research will require a change in culture that begins at the point of care, where data are generated.

Feasibility and Utility of Developing a phased-in approach to building the interoperable data capacity for PCOR

- Link existing databases within HHS and other Federal Government agencies and the private sector.
- Need for a universal data use agreement.
- Apply PCORTF developed tools, standards and services to other types of HHS data.
- Encourage the development of common architectures and integration frameworks to enable interoperability than delving into single solutions.
- Focus the PCORTF investments in cutting edge solutions that may result in technical leaps.

Thank you

Back Up

Overview:
PCORTF CDM Harmonization Project

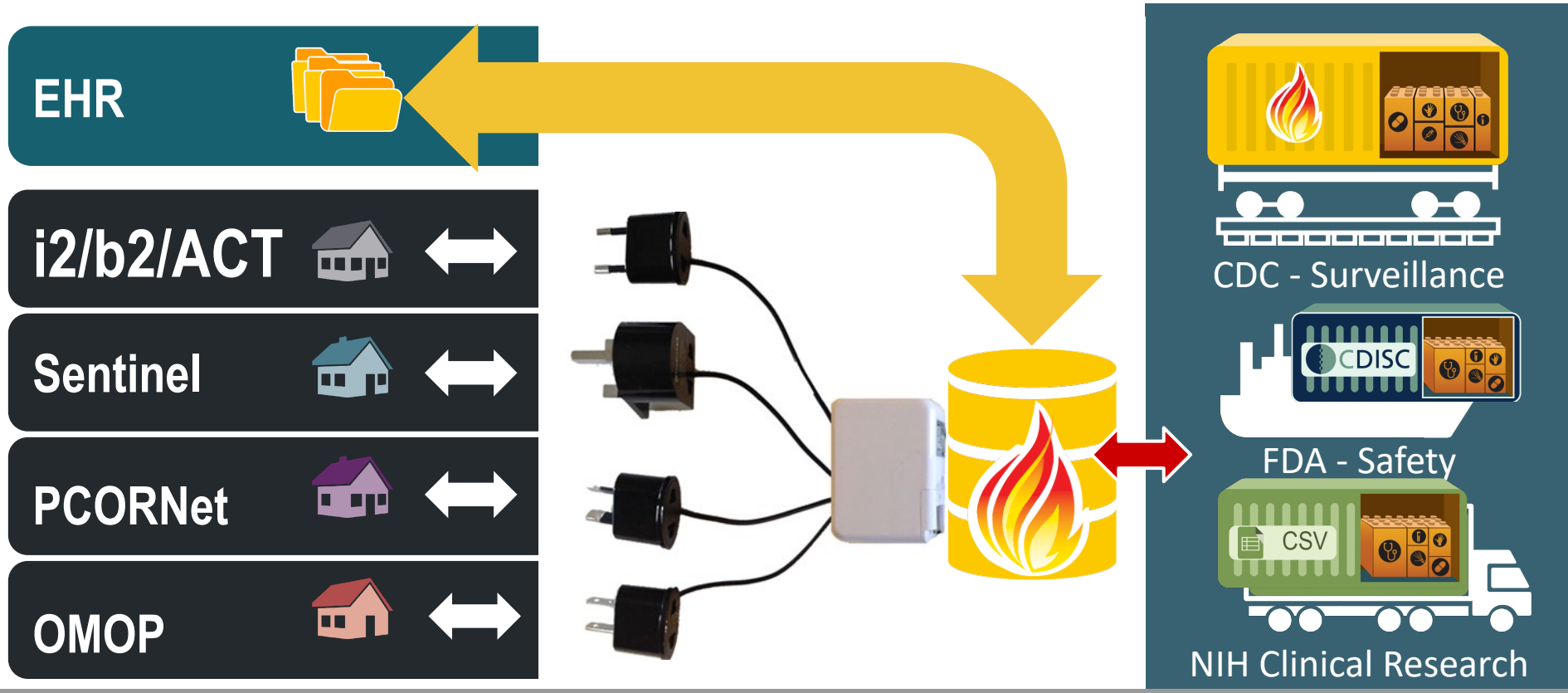
Goal:

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.

Common Data Model Harmonization

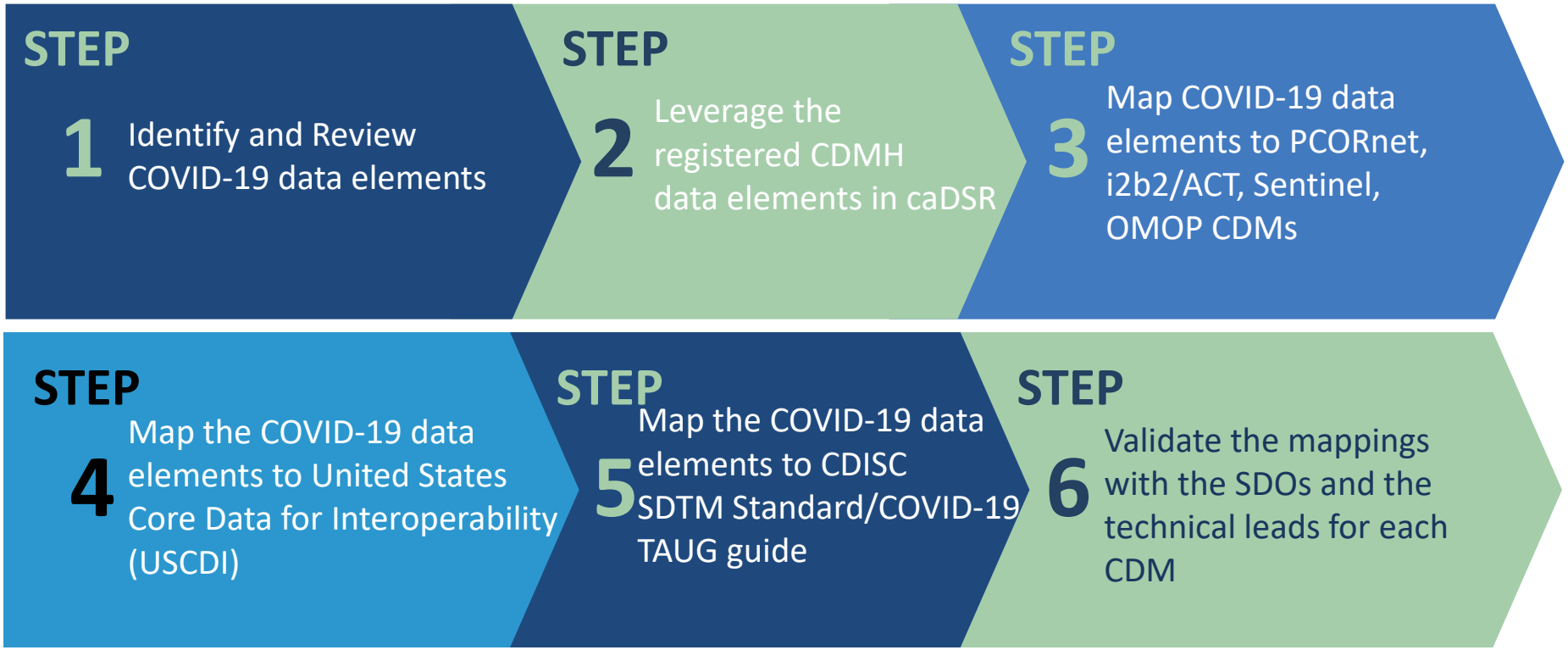


COVID-19 EVIDENCE ACCELERATOR COLLABORATIVE

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

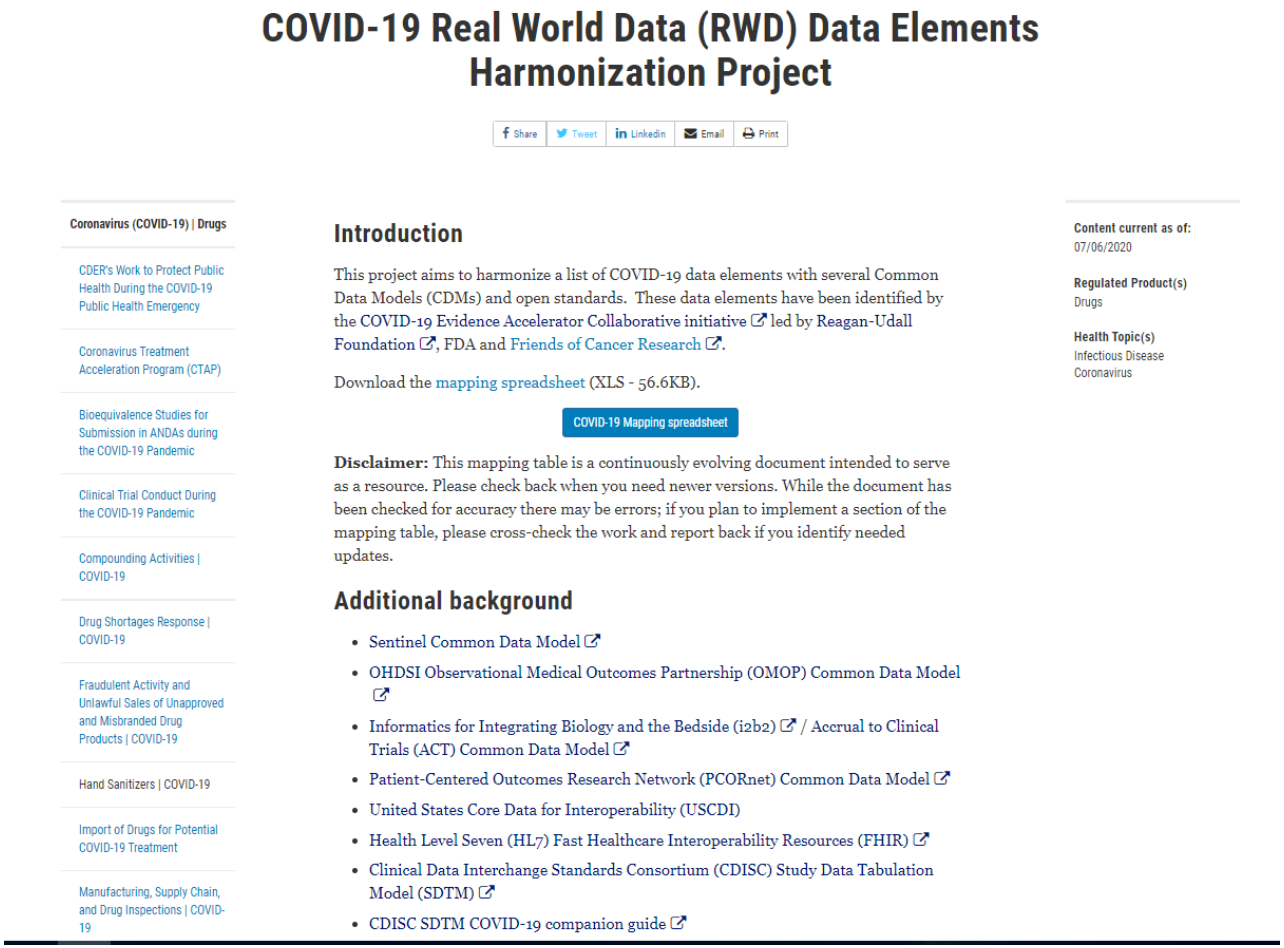
COVID-19 Common Data Elements Mapping Process



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

NATIONAL COVID COHORT COLLABORATIVE (N3C)

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

Five community workstreams:

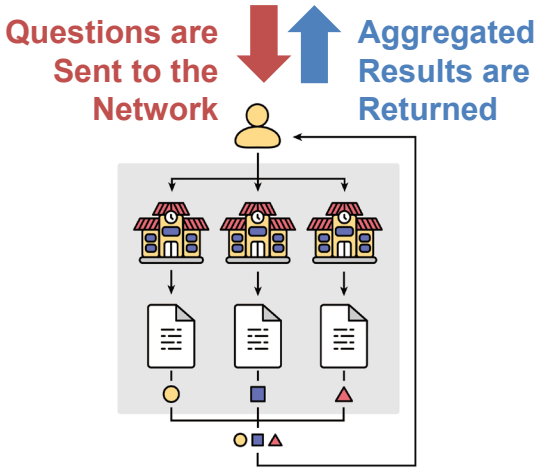
- Data Partnership & Governance
- Phenotype & Data Acquisition
- Data Ingestion & Harmonization
- Collaborative Analytics
- Synthetic Data

Centralized Repository

National COVID Cohort Collaborative

FDA

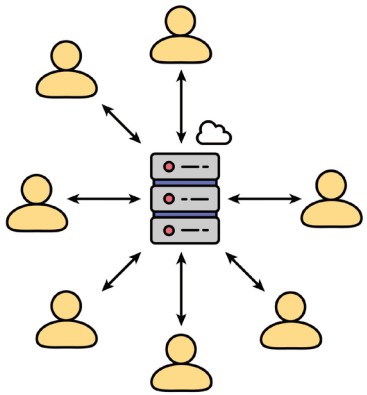
Federated Query



Is **drug X** beneficial to COVID-19 patients?
Does **disease Y** impair course?

Centralized Analytics

Data Resides Centrally in a Secure enclave



What **drugs** help or hinder COVID patients?
What **factors** predict being placed on a ventilator?
What comorbid **diagnosis** are risk factors

OneSource COVID Trial:
Source Data Capture from Electronic Health Records using Standardized Clinical Research Data in the COVID-19 Critical Care Environment

Project Goals

- Leverage the architecture and data standards form the OneSource platform and use the SMART on FHIR App to auto populate WHO COVID Clinical Assessment Scale data.
- Add the capability of collecting COVID scale data on a smart phone on rounds with the capacity for write back to a daily note to the UCSF EHR.
- Demonstrate backwards compatibility to prior WHO COVID scales as the scale may evolve.
- Assess scalability to broader EHR platforms beyond EPIC such as Cerner.

COVID I-SPY Proposed Solution

- Deploy a technology to reduce clinician documentation burden and make data collection easier with enhanced software systems (Electronic Data Capture (EDC) System and SMART on Fast Healthcare Interoperability Resources (FHIR), optimized for use at point of care)
- Virtual support for care and clinical research at non-research institutions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