ASTP Assistant Secretary for Technology Policy

USCDI+ for Respiratory Illness

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11/18/2024

Agenda

- Opening Remarks
- Background on USCDI/USCDI+
- Why do we need USCDI+ for ARDS?
- Project and Data Element Overview
- Questions
- Commenting and Next Steps

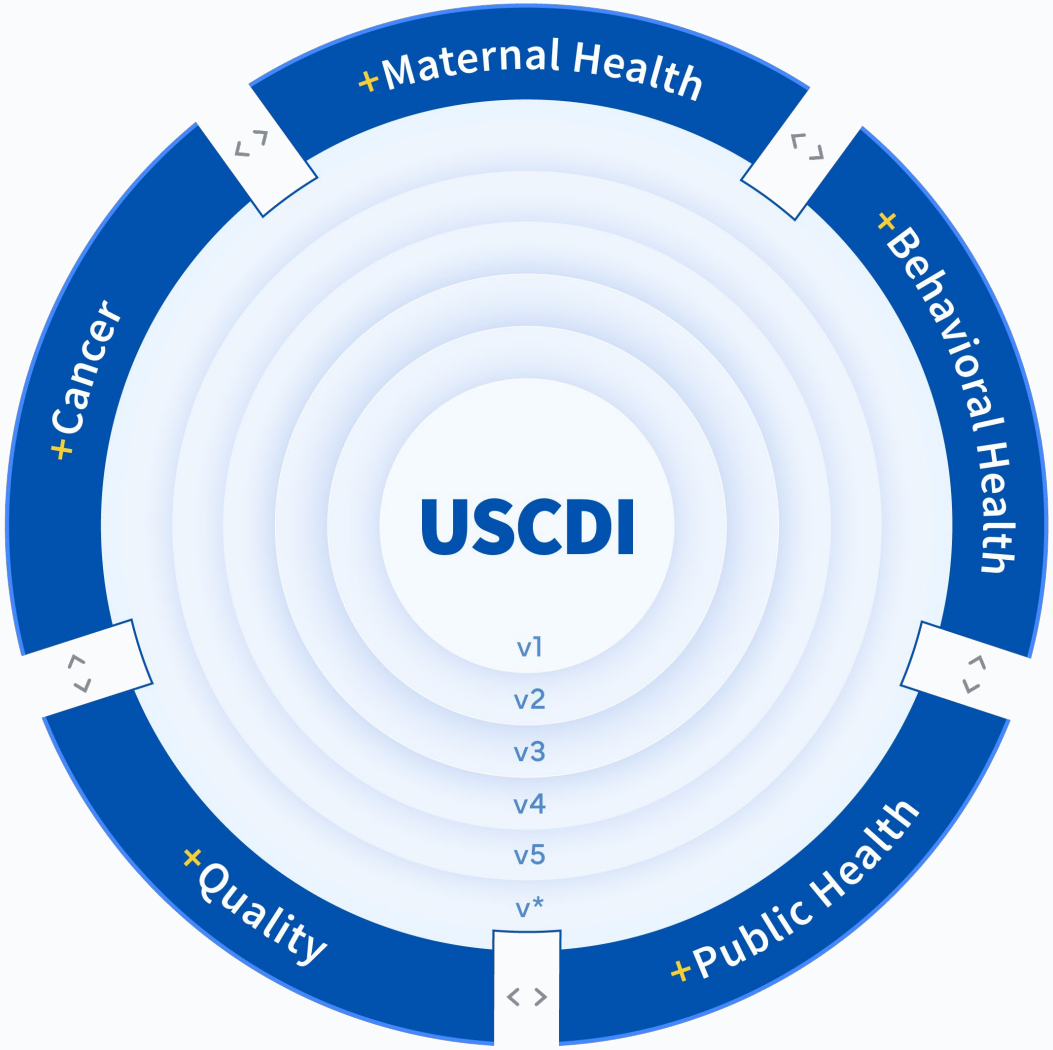
United States Core Data for Interoperability: USCDI Essentials

Comprises a core set of data needed to support patient care and facilitate patient access using health IT.

Establishes a consistent baseline of harmonized data elements that can be broadly reused across use cases, including those outside of patient care and patient access.

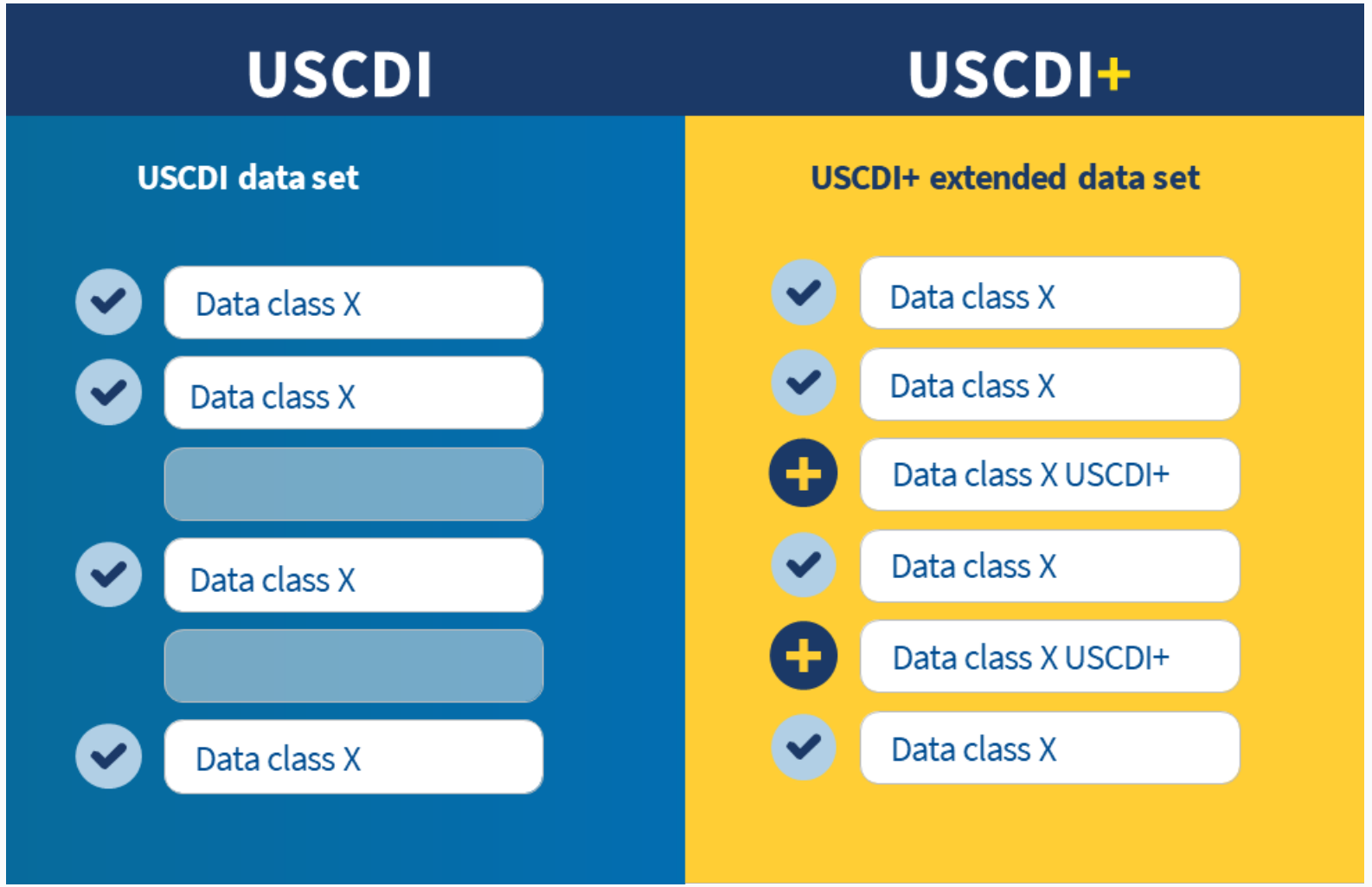
Expands incrementally over time via a transparent, established, and collaborative process, weighing both anticipated benefits and industry-wide impacts.

USCDI+: Extending Beyond the USCDI

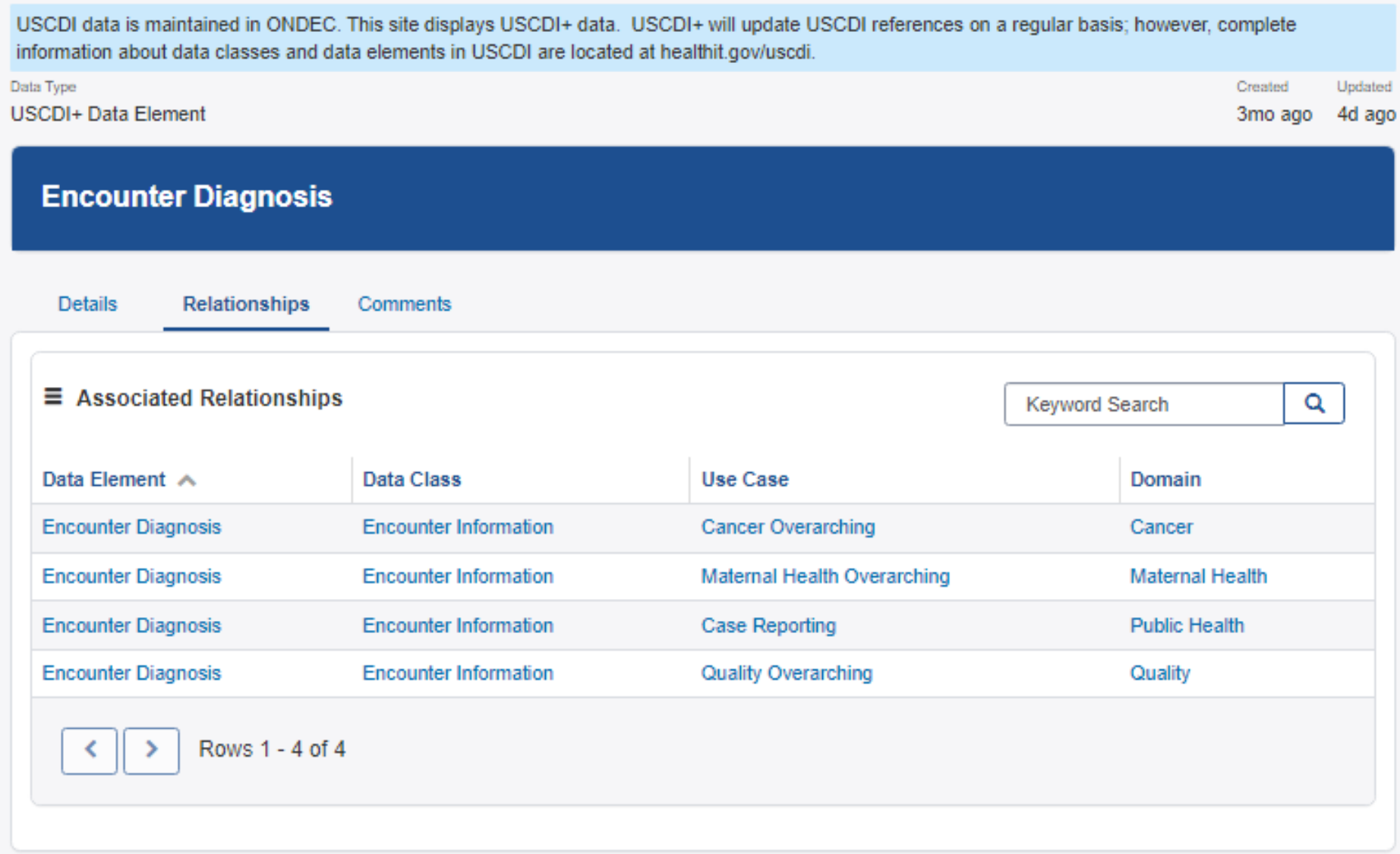


- Unique program and use case-specific data needs are sometimes not fully met by USCDI.
- ASTP's USCDI+ initiative helps government and industry partners build on USCDI to support specific program needs.
- Applies USCDI processes for submission and harmonization while focusing on programmatic priorities.
- Seeks to leverage programs and authorities across HHS to drive adoption.

USCDI and USCDI+



USCDI+ Relationships and Alignment



USCDI data is maintained in ONDEC. This site displays USCDI+ data. USCDI+ will update USCDI references on a regular basis; however, complete information about data classes and data elements in USCDI are located at healthit.gov/uscdi.

Data Type: USCDI+ Data Element

Created: 3mo ago

Updated: 4d ago

Encounter Diagnosis

Details | Relationships | Comments

Associated Relationships

Keyword Search

Data Element	Data Class	Use Case	Domain
Encounter Diagnosis	Encounter Information	Cancer Overarching	Cancer
Encounter Diagnosis	Encounter Information	Maternal Health Overarching	Maternal Health
Encounter Diagnosis	Encounter Information	Case Reporting	Public Health
Encounter Diagnosis	Encounter Information	Quality Overarching	Quality

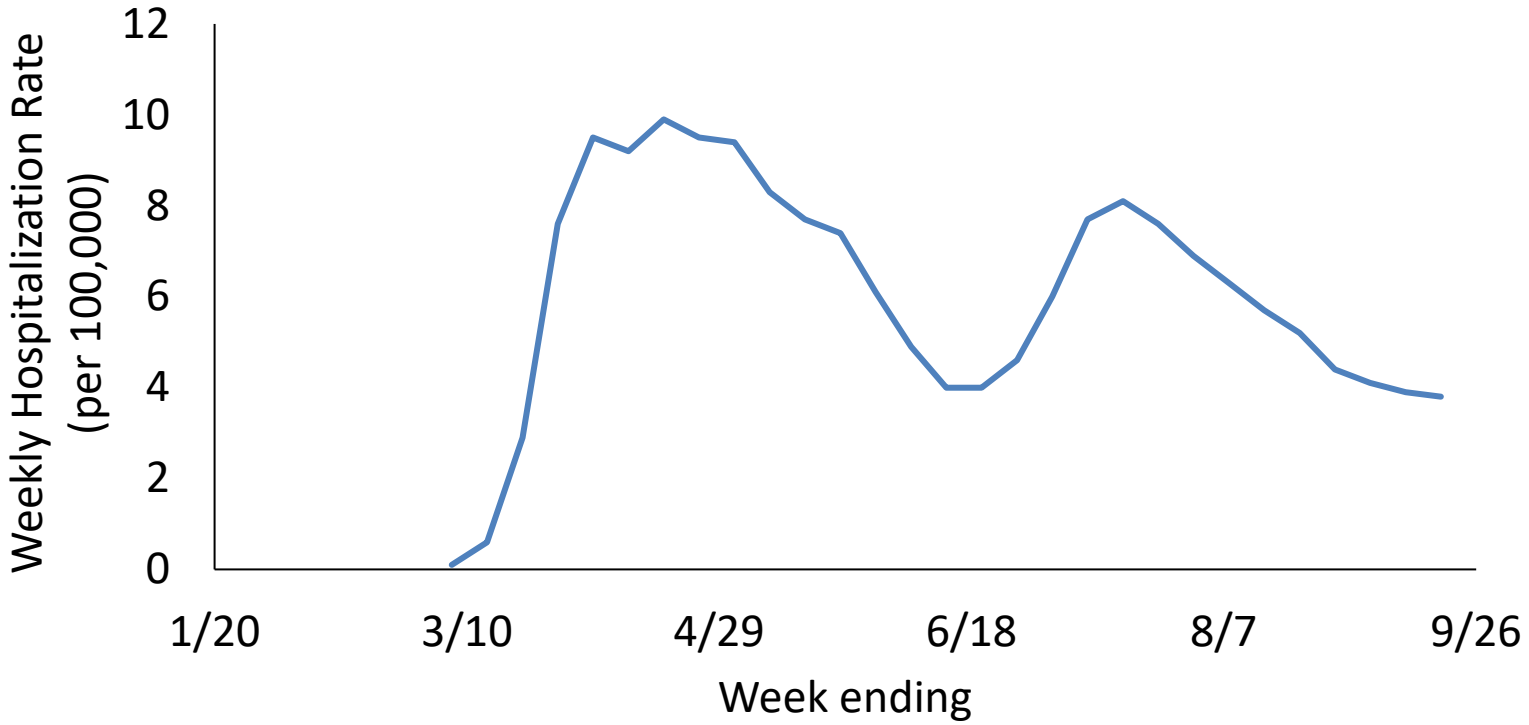
Rows 1 - 4 of 4

Why we need USCDI+ for ARDS?

Hilary D. Marston, MD, MPH
Chief Medical Officer
U.S. Food and Drug Administration

The COVID-19 pandemic highlighted the need for efficient evidence generation

COVID-19 Hospitalizations in 2020



Data Source: CDC COVID-19 NET

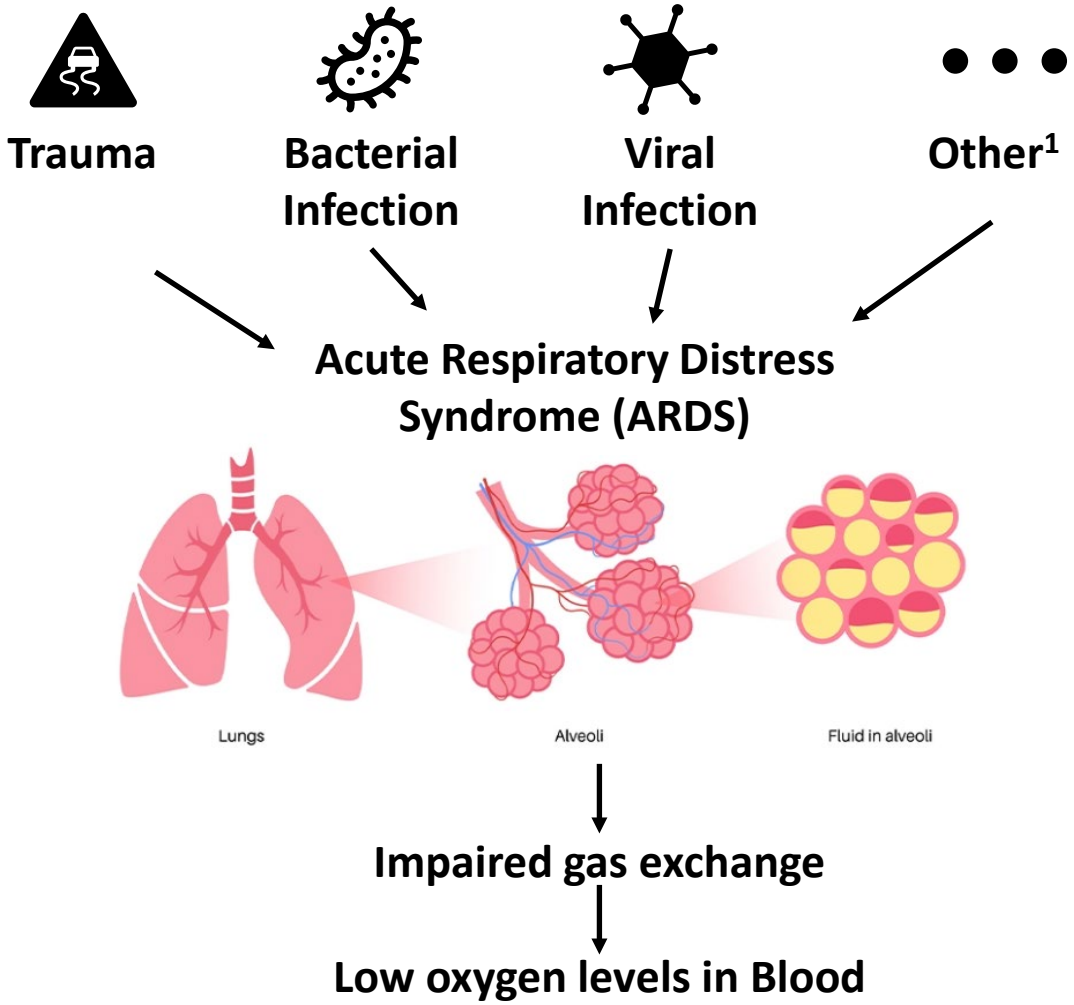
Data infrastructure is essential for evidence generation

B.2 *Create foundational infrastructure*

Establish consistent data and system standards across preparedness categories (i.e. minimal data necessary, minimum standards for EHRs, USCDI+). Identify mechanisms to formalize and implement the standards.

HHS Data Strategy 2023-2028 available at: www.cdo.hhs.gov/s/hhs-data-strategy

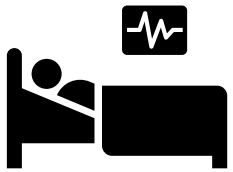
Severe COVID causes Acute Respiratory Distress Syndrome (ARDS)

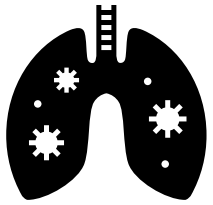


1 Other causes include transfusion, aspiration, or shock, but the ARDS definition excludes pulmonary edema is primarily from cardiogenic edema or fluid overload.
Consensus definition according to: Matthay MA, et al., A New Global Definition of Acute Respiratory Distress Syndrome. Am J Respir Crit Care Med. 2024

ARDS is one of the most common diseases faced in critical illness

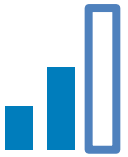
Global incidence[1]

10.4%  **of ICU Admissions**

23.4%  **of patients on a ventilator**

Hospital Mortality[1]

34.9%  **Mild ARDS**

40.3%  **Moderate ARDS**

46.1%  **Severe ARDS**

1 Bellani G, Laffey JG, Pham T, et al. Epidemiology, Patterns of Care, and Mortality for Patients With Acute Respiratory Distress Syndrome in Intensive Care Units in 50 Countries. *JAMA.* 2016

FDA recognizes the potential of Real-World Data to accelerate evidence generation

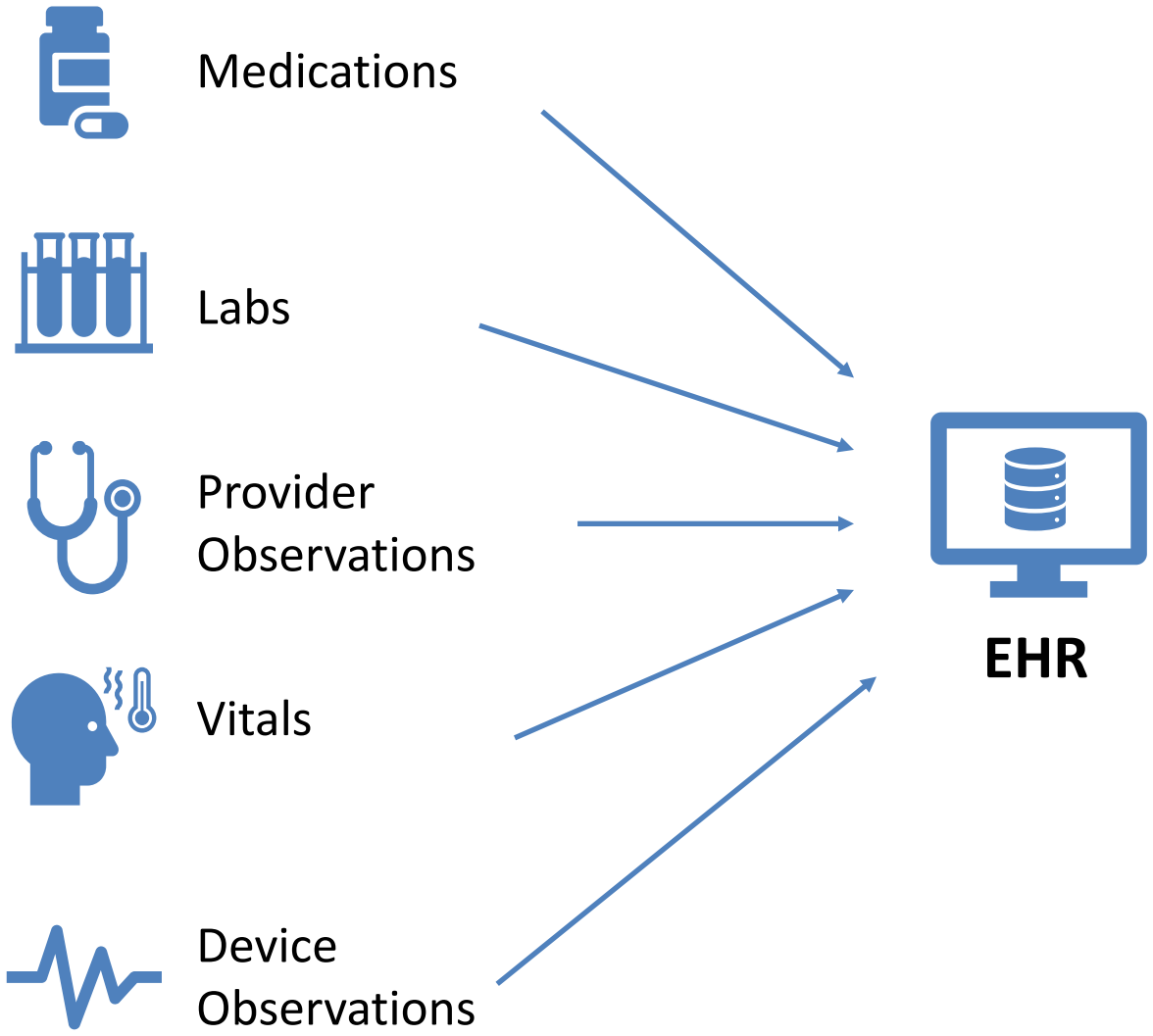
Real-world data[1] *are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.*

Real-world evidence *is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.*

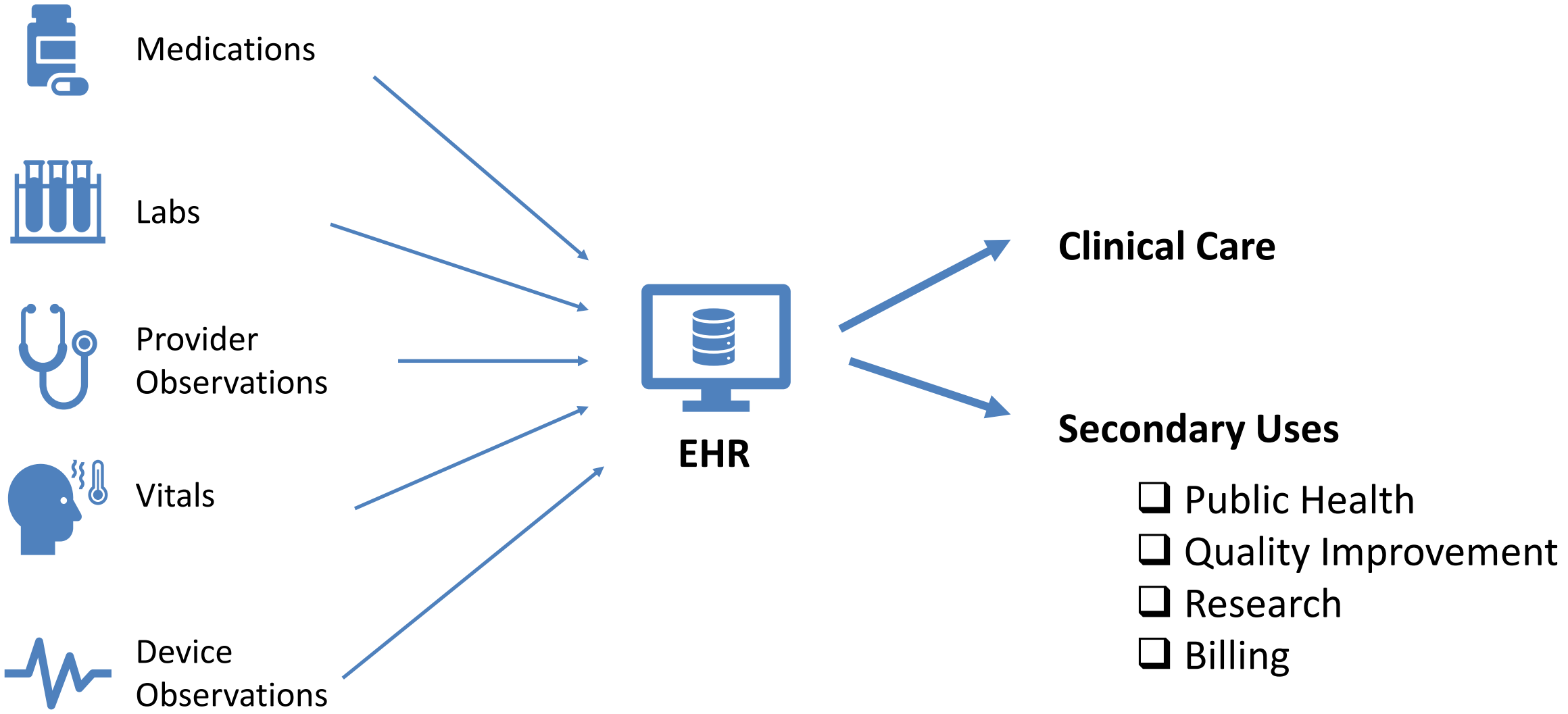
Real-world data, including Electronic Health Record (EHR) data, can be used to streamline clinical investigations, when deployed in fit-for-purpose study designs.

1 Definitions from FDA 2018 Real-world evidence framework available at https://www.fda.gov/media/120060/download?attachment

The EHR serves as the hub for data used to care for patients with critical illness



EHR data can support clinical care and secondary data uses



FHIR and USCDI+ can streamline uses of EHR data

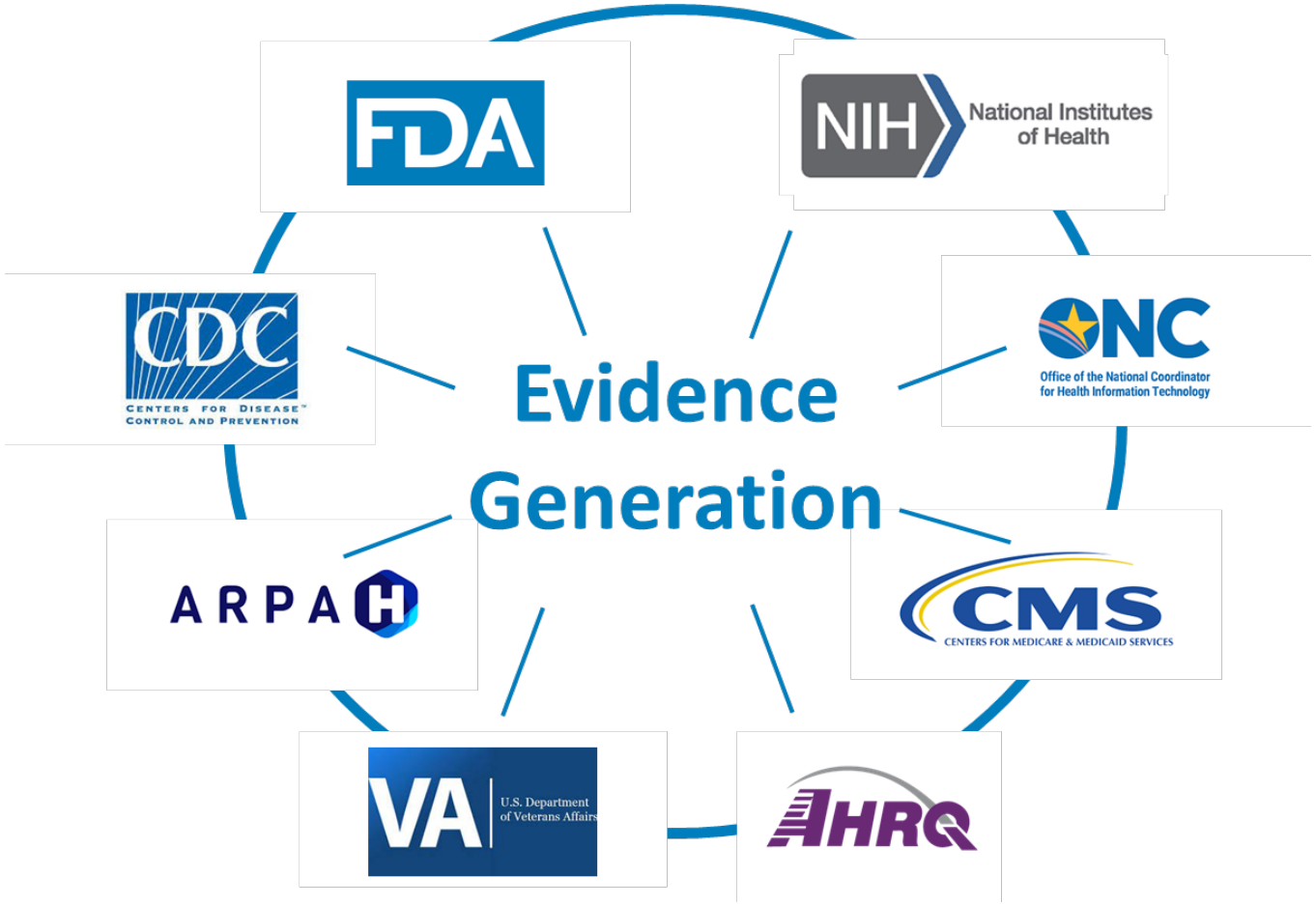
Current State

- Labor intensive
- Slow
- Error prone

Future State

+ Automated
+ Real-Time
+ Accurate

Solving these challenges requires multi-agency engagement



USCDI+ ARDS: Project Overview

USCDI+ for Respiratory Illness: ARDS

Purpose: To create USCDI+ data element list and FHIR implementations for trials of interventions to treat ARDS

Scope:
- Data standards needed to evaluate the efficacy and safety of interventions for ARDS
- Clinical trials of therapeutic interventions, irrespective of the type of intervention, that take place in the ICU
- Data generated should be able to support regulatory applications to FDA, if the study design is fit-for-purpose

Exclusions:
- Trials for preventative measures, such as vaccines
- Care settings outside the ICU
- Data not collected in the EHR
- Prospective/interventional adverse event reporting

Pilot use case:
- Data extraction from the EHR, to an electronic data capture system (EDC) or registry focused on an intervention to treat severe acute respiratory failure

High Level Timeline

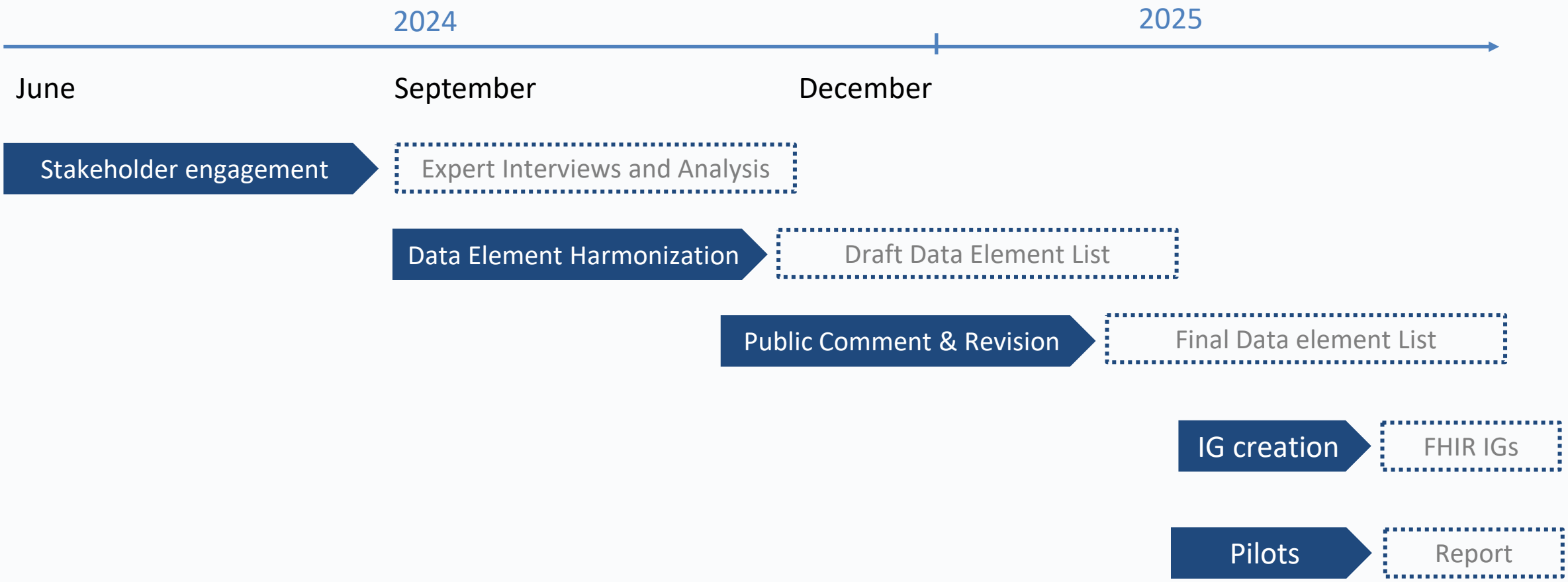


Figure Legend

Process

Product

Federal Partners and relevant programs

- USCDI+ for public health case reporting
- CDC Resp net

- CDER OneSource program: eSource capture used in I-SPY COVID-19 trial
- Cure ID EHR data extraction for SCCM Virus Registry
- RWD Standardization Project

- Common Data Element Repository
- Data COUNTS
- ARDS pneumonia and sepsis phenotyping consortium
- Data Element Repositories at individual ICs

Outside Stakeholders

Discussions held with

- ✓ Professional Societies
- ✓ Clinical Trial Investigators
- ✓ Clinicians Caring for patients with ARDS
- ✓ Health IT experts in trial data capture
- ✓ Registries

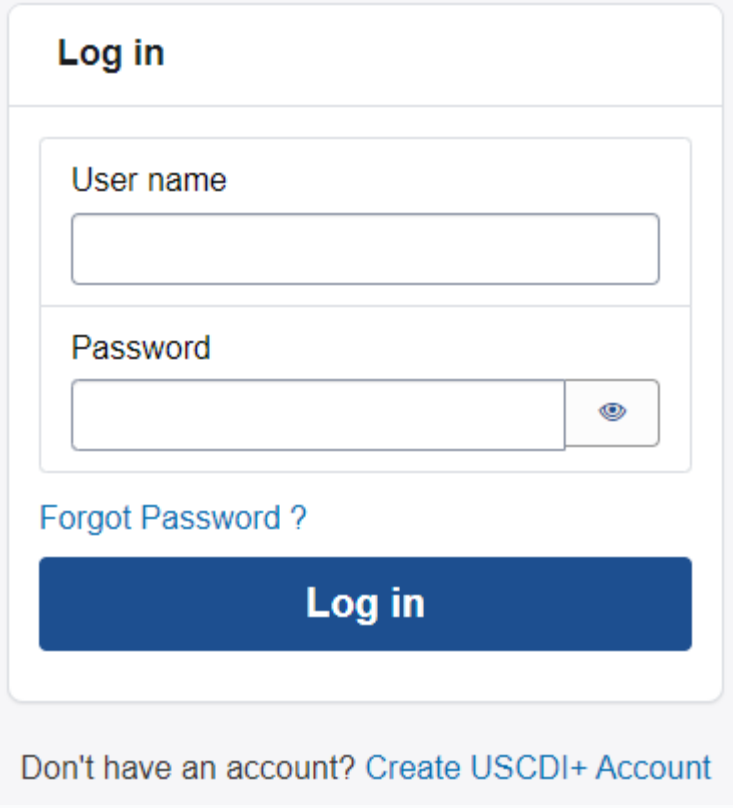
Emerging Themes

- ICU trials require a high volume of data
- EHR is the source of most trial data, but electronic source data capture remains challenging
- Low penetration of FHIR resources for research
- Ventilator settings are a huge gap for critical care trials, even though they are captured in EHR
  - Institution specific workarounds exist
- Medication administration
  - Can be difficult to define/observe
- Need for structured capture of major clinical events
  - Not part of the usual workflow

USCDI+ ARDS: Data Set

Navigating USCDI+

https://uscdiplus.healthit.gov/



USCDI+ Domains: Respiratory Illness

Other Use Cases

Use Cases | Details | Comments

Use Cases in Domain

Keyword Search

Name	Description
Respiratory Illness	This data element list aims to enhance our national capacity to conduct efficient trials for therapeutic interventions in patients with Acute Respiratory Distress Syndrome (ARDS) by providing data standards that allow for easier and seamless research on the treatment of ARDS.

Respiratory Illness Data Elements

Respiratory Illness

This data element list aims to enhance our national capacity to conduct efficient trials for therapeutic interventions in patients with Acute Respiratory Distress Syndrome (ARDS) by providing data standards that allow for easier and seamless research on the treatment of ARDS.

Details | Comments

Details

Keyword Search

Data Element	Description	Data Class	Domain
Admission Date/Time	Date and time the patient was admitted to a treatment facility; e.g., hospital	Enrollment/Treatment/Outcome	Other Use Cases
Adverse Event	Harm to a patient resulting from medical care rather than the underlying disease that requires additional monitoring, treatment or hospitalization, or that results in death.	Adverse Events	Other Use Cases
Adverse Event Onset Date	The date on which the adverse event was first evident.	Adverse Events	Other Use Cases
Adverse Event Resolution Date	The date on which the adverse event was resolved.	Adverse Events	Other Use Cases
Bicarbonate (blood gas)	Bicarbonate concentration in blood gas specimen	Laboratory	Other Use Cases
Blood Gas Specimen type	Type of specimen used to determine blood gas values. Options should include arterial and venous	Laboratory	Other Use Cases
Body position	This variable denotes the patient position (proned, supine) at the time of recording	Respiratory Support	Other Use Cases
Body Temperature	Temperature is a measure of the patient's ability to generate and get rid of heat.	Vital Signs	Other Use Cases
Cardiac Arrest	Whether the patient experienced a cardiac arrest	Adverse Events	Other Use Cases

Data Element – Details

Admission Date/Time

Details | Relationships | Comments

Click on the Relationships tab for the Domain, Use Case, and Data Class values.

Admission Date/Time

Data Element Name:

Admission Date/Time

Submission Status:

Published

USCDI+ Level:

Description:

Date and time the patient was admitted to a treatment facility; e.g., hospital

Additional Information:

USCDI Information

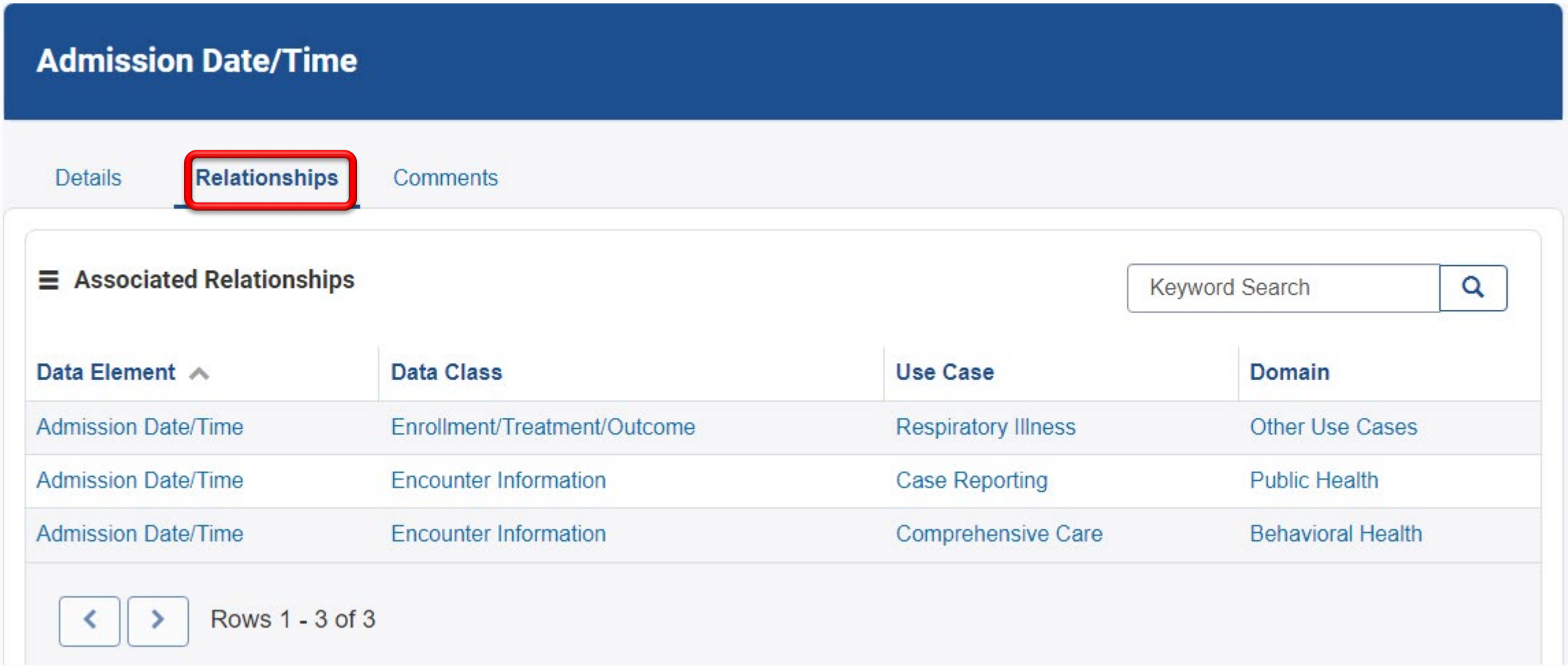
In USCDI:

Yes

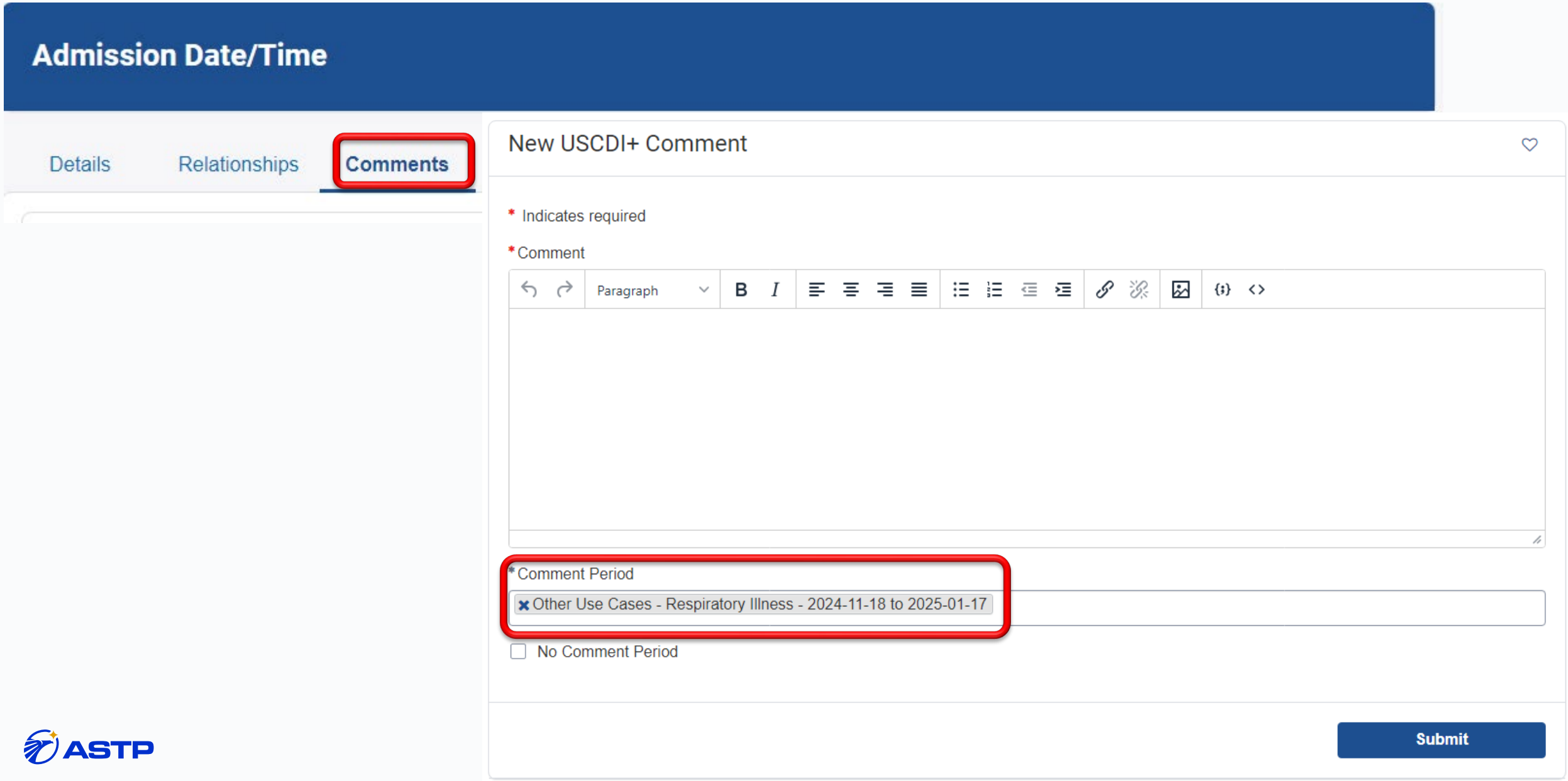
Current USCDI Level:

Level 0

Data Element - Relationships



USCDI+ Respiratory Illness: Comments



Overview of USCDI+ Respiratory Illness Data Element List

7 Data Classes including **4 New Data Classes** (not included in USCDI V5)
61 Data Elements

7 Data Classes

1. Vital Signs
2. Respiratory Support **(new)**
3. Enrollment/Treatment/Outcome **(new)**
4. Adverse Events **(new)**
5. Medications
6. Laboratory
7. Intake and Output **(new)**

Questions on USCDI+ Respiratory Illness Data Element List

ASTP is seeking public comment on the USCDI+ Respiratory Illness Data Element List and requests specific attention to the following as a part of the review:

- Does the draft USCDI+ Respiratory Illness dataset include all the core data elements necessary to conduct clinical trials for ARDS? Are there any data elements that are not relevant to ARDS trials and should be removed?
- Are the data classes and elements detailed enough to support the accurate collection of ARDS data from EHR systems?
- Are the data elements and descriptions clear? What clarifications or updates are needed?
- Are there data elements in the USCDI+ Respiratory Illness dataset that might be too difficult to capture or share using current health IT systems?
- What are the potential barriers to collecting these data elements?
- How can we refine the data elements to reduce the documentation burden and better align with EHR workflows?

Questions and Discussion

How to Stay Involved

- REMINDER: Comments are due on the data element list on the USCDI+ Platform on **January 17, 2025**, by 11:59PM ET.
- ASTP will review public comments received and expects to publish a final version of the USCDI+ Respiratory Illness v1 in mid 2025.
- Questions? Contact USCDI.Plus@hhs.gov.