

# Close Encounters with Real World Data (RE01)

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# Introduction

- Defining RWD & RWE
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# Defining Real World Data (RWD) & Real World Evidence (RWE)

- 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)).
  - **Real-World Data (RWD)**: Data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources; and
  - **Real-World Evidence (RWE)**: The clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.
- For the purposes of this paper, we will use the working definition of RWD as data relating to patient health status and/or the delivery of health care that is not collected under a protocol, and RWE as the data derived from the RWD to be submitted to the FDA.
- We are also defining **RWD studies** as those done retrospectively, where data was collected prior to the development of a protocol and are excluding studies using RWD that are conducted prospectively under a protocol.

# Previous Papers

Challenges for submitting RWD is presented in our previous six papers:

1. Abolafia J, Ferko S, Holt I (2024). “Future Clinical Data Submission Standards: CDISC, FHIR, OMOP, or Hybrid Model.” Pharmaceutical Users Software Exchange (PHUSE) US, Bethesda, MD. Feb 25-28, 2024.  
[https://www.lexjansen.com/phuse-us/2024/re/PAP\\_RE03.pdf](https://www.lexjansen.com/phuse-us/2024/re/PAP_RE03.pdf)
2. Abolafia, J, Ferko, S, & Holt, I. (2023). “Submission Standards for Real World Data: Gaps, Limitations and Recommendations”. Paper presented at the PHUSE Annual Conference 2023, Birmingham, United Kingdom.  
[https://phuse.s3.eu-central-1.amazonaws.com/Archive/2023/Connect/EU/Birmingham/PAP\\_RE03.pdf](https://phuse.s3.eu-central-1.amazonaws.com/Archive/2023/Connect/EU/Birmingham/PAP_RE03.pdf)
3. Ferko, S., Holt, I., & Abolafia, J., (2023). “Challenges and Considerations for Submitting Real World Data”. Paper presented at the PHUSE US Annual Conference 2023, Orlando, FL.  
[https://phuse.s3.eu-central-1.amazonaws.com/Archive/2023/Connect/US/Florida/PRE\\_RE05.pdf](https://phuse.s3.eu-central-1.amazonaws.com/Archive/2023/Connect/US/Florida/PRE_RE05.pdf)
4. Abolafia, J, Ferko, S, & Holt, I. (2022). “Submission Standards for RWD: The Good, the Bad and the Ugly”. Paper presented at the PHUSE Annual Conference 2022, Belfast, United Kingdom.  
[https://phuse.s3.eu-central-1.amazonaws.com/Archive/2022/Connect/EU/Belfast/PRE\\_RE09.pdf](https://phuse.s3.eu-central-1.amazonaws.com/Archive/2022/Connect/EU/Belfast/PRE_RE09.pdf)
5. Abolafia, J, Ferko, S, & Holt, I. (2024). “Considerations for the Submission of RWD using CDISC with Insights from HL7 FHIR and OMOP”. Paper presented at the PHUSE Annual Conference 2024, Strasbourg, France.  
[https://phuse.s3.eu-central-1.amazonaws.com/Archive/2024/Connect/EU/Strasbourg/PAP\\_RE03.pdf](https://phuse.s3.eu-central-1.amazonaws.com/Archive/2024/Connect/EU/Strasbourg/PAP_RE03.pdf)
6. Abolafia, J, Ferko, S, & Holt, I. (2025). “AE, CE, & MH Considerations for the Submission of RWD using CDISC, with Insights from HL7 FHIR and OMOP”. Paper presented at the PHUSE Annual Conference 2025, Orlando, FL.  
[https://phuse.s3.eu-central-1.amazonaws.com/Archive/2025/Connect/US/Orlando/PAP\\_RE02.pdf](https://phuse.s3.eu-central-1.amazonaws.com/Archive/2025/Connect/US/Orlando/PAP_RE02.pdf)

# RWD Background

- Increase in RWD and RWE submitted as part of NDAs/BLAs.
- RWD has variable quality and is usually collected at inconsistent intervals based on patient need.
- CDISC is the current submission standard required for all study data submitted to CDER and CBER.
  - Designed for representing high quality, protocol-specified randomized controlled trial (RCT) data.
  - CDISC does not contain all the necessary domains or data elements for RWD
  - Challenging for both FDA and sponsors.
- Data standards for RWD exist, including OMOP, HL7 FHIR, and PCORnet.
  - Designed for specific uses with RWD.
  - Can help inform on the data needed for RWD to meet regulatory review needs.

# Current State

- CDISC SV & DM Domains
- BIMO Data
- Subject Visits: RCTs vs. RWD
- Gaps in Subject Visits

# Subject Visits Background

CDISC SDTM Subject Visits (SV) Domain designed for RCTs:

- Visits are driven by the protocol's Schedule of Activities (SoA)
- Provider and Care site are not expected to change
- Relevant data is documented clearly in a CRF

## CDISC SDTM SDTMIGv3.4

### SV – Specification

sv.xpt, Subject Visits — Special Purpose. One record per actual or planned visit per subject, Tabulation.

| Variable Name | Variable Label            | Type | Controlled Terms, Codelist or Format <sup>1</sup> | Role               | CDISC Notes                                                                                                                                                                               | Core |
|---------------|---------------------------|------|---------------------------------------------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| STUDYID       | Study Identifier          | Char |                                                   | Identifier         | Unique identifier for a study.                                                                                                                                                            | Req  |
| DOMAIN        | Domain Abbreviation       | Char | <a href="#">SV</a>                                | Identifier         | Two-character abbreviation for the domain most relevant to the observation. The domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged. | 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  |
| VISITNUM      | Visit Number              | Num  |                                                   | Topic              | Clinical encounter number. Numeric version of VISIT, used for sorting.                                                                                                                    | Req  |
| VISIT         | Visit Name                | Char |                                                   | Synonym Qualifier  | Protocol-defined description of a clinical encounter.                                                                                                                                     | Perm |
| SVPRESP       | Pre-specified             | Char | <a href="#">(NY)</a>                              | Variable Qualifier | Used to indicate whether the visit was planned (i.e., visits specified in the TV domain). Value is "Y" for planned visits, null for unplanned visits.                                     | Exp  |
| SVOCCUR       | Occurrence                | Char | <a href="#">(NY)</a>                              | Record Qualifier   | Used to record whether a planned visit occurred. The value is null for unplanned visits.                                                                                                  | Exp  |
| SVREASOC      | Reason for Occur Value    | Char |                                                   | Record Qualifier   | The reason for the value in SVOCCUR. If SVOCCUR="N", SVREASOC is the reason the visit did not occur.                                                                                      | Perm |

| Variable Name | Variable Label                        | Type | Controlled Terms, Codelist or Format <sup>1</sup> | Role             | CDISC Notes                                                                                                                 | Core |
|---------------|---------------------------------------|------|---------------------------------------------------|------------------|-----------------------------------------------------------------------------------------------------------------------------|------|
| SVCNTMOD      | Contact Mode                          | Char | <a href="#">(CNTMODE)</a>                         | Record Qualifier | The way in which the visit was conducted. Examples: "IN PERSON", "TELEPHONE CALL", "IVRS".                                  | Perm |
| SVEPCHGI      | Epi/Pandemic Related Change Indicator | Char | <a href="#">(NY)</a>                              | Record Qualifier | Indicates whether the visit was changed due to an epidemic or pandemic.                                                     | Perm |
| VISITDY       | Planned Study Day of Visit            | Num  |                                                   | Timing           | Planned study day of VISIT. Should be an integer.                                                                           | Perm |
| SVSTDTC       | Start Date/Time of Observation        | Char | ISO 8601 datetime or interval                     | Timing           | Start date/time of an observation represented in ISO 8601 character format.                                                 | Exp  |
| SVENDTC       | End Date/Time of Observation          | Char | ISO 8601 datetime or interval                     | Timing           | End date/time of the observation represented in ISO 8601 character format.                                                  | Exp  |
| SVSTDY        | Study Day of Start of Observation     | Num  |                                                   | Timing           | Actual study day of start of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics. | Perm |
| SVENDY        | Study Day of End of Observation       | Num  |                                                   | Timing           | Actual study day of end of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.   | Perm |
| SVUPDES       | Description of Unplanned Visit        | Char |                                                   | Record Qualifier | Description of what happened to the subject during an unplanned visit. Only populated for unplanned visits.                 | Perm |

## Example SoA

|                                                                            | STUDY PERIOD    |                  |                 |         |         |                  |                  |                 |
|----------------------------------------------------------------------------|-----------------|------------------|-----------------|---------|---------|------------------|------------------|-----------------|
|                                                                            | Enrolment       | Allocation       | Post-allocation |         |         |                  |                  | Close-out       |
|                                                                            | Enrolment visit | Allocation visit | Visit 1         | Visit 2 | Visit 3 | Visit 4          | Visit 5          | Close-out visit |
| TIMEPOINT, days                                                            | -14 to 0        | 0                | 14 ± 2          | 30 ± 2  | 60 ± 2  | 90 ± 2           | 120 ± 2          | 30 POST         |
| Enrolment                                                                  |                 |                  |                 |         |         |                  |                  |                 |
| Eligibility screening                                                      | X               |                  |                 |         |         |                  |                  |                 |
| Informed consent                                                           | X               |                  |                 |         |         |                  |                  |                 |
| Allocation                                                                 |                 | X                |                 |         |         |                  |                  |                 |
| Interventions                                                              |                 |                  |                 |         |         |                  |                  |                 |
| Treatment with 3-mont HR (Control arm)                                     |                 |                  | ←————→          |         |         |                  |                  | X               |
| Treatment with 3-month HP (experimental-1 arm)                             |                 |                  | ←————→          |         |         |                  |                  | X               |
| Treatment with 4-month R (experimental-2 arm)                              |                 |                  | ←————→          |         |         |                  |                  | X               |
| Assessments                                                                |                 |                  |                 |         |         |                  |                  |                 |
| Demographics, medical history, physical exam, & chest X-ray <sup>(1)</sup> | X               |                  |                 |         |         |                  |                  |                 |
| Blood test                                                                 | X               |                  | X               | X       | X       | X <sup>(2)</sup> | X                |                 |
| Concomitant medication                                                     |                 |                  | X               | X       | X       | X                | X <sup>(3)</sup> |                 |
| Adherence                                                                  |                 |                  | X               | X       | X       | X                | X <sup>(3)</sup> |                 |
| Adverse events                                                             |                 |                  | X               | X       | X       | X                | X <sup>(3)</sup> | X               |
| Treatment conclusion                                                       |                 |                  |                 |         |         |                  |                  | X               |

# CDISC's Demographics (DM) Specification and Assumptions

| Variable Name | Variable Label                     | Type | Controlled Terms, Codelist or Format <sup>1</sup> | Role              | CDISC Notes                                                                                                                                                                                                                                                                                                                  | Core |
|---------------|------------------------------------|------|---------------------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| STUDYID       | Study Identifier                   | Char |                                                   | Identifier        | Unique identifier for a study.                                                                                                                                                                                                                                                                                               | Req  |
| DOMAIN        | Domain Abbreviation                | Char | DM                                                | 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. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.                                                                                 | Req  |
| SUBJID        | Subject Identifier for the Study   | Char |                                                   | Topic             | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.                                                                                                                                                                                                                 | Req  |
| RFSTDTC       | Subject Reference Start Date/Time  | Char | ISO 8601                                          | Record Qualifier  | Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. See Assumption 9 for additional detail on when RFSTDTC may be null.                                                                                               | Exp  |
| RFENDTC       | Subject Reference End Date/Time    | Char | ISO 8601                                          | Record Qualifier  | Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the trial, and often equivalent to date/time of last exposure to study treatment. Required for all randomized subjects; null for screen failures or unassigned subjects. | Exp  |
| RFXSTDTC      | Date/Time of First Study Treatment | Char | ISO 8601                                          | Record Qualifier  | First date/time of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC.                                                                                                                                                                                                          | Exp  |
| RFXENDTC      | Date/Time of Last Study Treatment  | Char | ISO 8601                                          | Record Qualifier  | Last date/time of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing).                                                                                                                                 | Exp  |
| RFICDTC       | Date/Time of Informed Consent      | Char | ISO 8601                                          | Record Qualifier  | Date/time of informed consent in ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be null only in studies not collecting the date of informed consent.                                                            | Exp  |
| RFPENDTC      | Date/Time of End of Participation  | Char | ISO 8601                                          | Record Qualifier  | Date/time when subject ended participation or follow-up in a trial, as defined in the protocol, in ISO 8601 character format. Should correspond to the last known date of contact. Examples include completion date, withdrawal date, last follow-up, date recorded for lost to follow up, or death date.                    | Exp  |
| DTHDTC        | Date/Time of Death                 | Char | ISO 8601                                          | Record Qualifier  | Date/time of death for any subject who died, in ISO 8601 format. Should represent the date/time that is captured in the clinical-trial database.                                                                                                                                                                             | Exp  |
| DTHFL         | Subject Death Flag                 | Char | (NY)                                              | Record Qualifier  | Indicates the subject died. Should be "Y" or null. Should be populated even when the death date is unknown.                                                                                                                                                                                                                  | Exp  |
| SITEID        | Study Site Identifier              | Char | *                                                 | Record Qualifier  | Unique identifier for a site within a study.                                                                                                                                                                                                                                                                                 | Req  |
| INVID         | Investigator Identifier            | Char |                                                   | Record Qualifier  | An identifier to describe the Investigator for the study. May be used in addition to SITEID. Not needed if SITEID is equivalent to INVID.                                                                                                                                                                                    | Perm |
| INVNAM        | Investigator Name                  | Char |                                                   | Synonym Qualifier | Name of the investigator for a site.                                                                                                                                                                                                                                                                                         | Perm |

## DM Specification

- SITEID: Unique identifier for a site within a study
- INVID: Unique identifier for the site investigator.

## DM Assumptions

- The subject will be seen at a single, consistent site
- The subject will be seen by one physician (investigator) associated with that site
- Site and investigator information will be submitted in the BIMO data package
  - BIMO SITEID matches DM SITEID

# Bioresearch Monitoring (BIMO) Program and Data

- Monitors all aspects of the conduct and reporting of FDA regulated research
- Facilitates the analysis of site-specific efficacy results, to ensuring that one site is not unduly influencing the study results
- Data is submitted for each study that is part of a New Drug Application (NDA) or Biologics License Application (BLA) and must adhere to the eCTD<sup>1</sup> format
- Bioresearch Monitoring Technical Conformance Guide<sup>2</sup> contains non-binding recommendations for data submission
  - The format for Clinical Site Lists contains a unique Site Identifier, the investigator name, and site address

| Protocol Number: Protocol Title                                                                     |                                                    |                                                                                                  |                                                                                                                                    |
|-----------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| Site Identifier                                                                                     | Investigator Name (Prior Clinical Investigator(s)) | Site Address at Time of Clinical Study (Updated Site Address when exists and available)          | Site Contact Information at Time of Clinical Study (Updated Contact Information when exists and available)                         |
| SITEID                                                                                              | LASTNAME, FRSTNAME, MINITIAL                       | FACILITY NAME<br>STREET<br>CITY, STATE, POSTAL COUNTRY                                           | PHONE<br>FAX<br>EMAIL                                                                                                              |
| 0001*                                                                                               | Doe, John M.                                       | Doe University Department of Medicine<br>1 Main St., Suite 100<br>Silver Spring, MD 20850<br>USA | Phone: 1-555-555-5555<br>Fax: 1-555-555-5555<br>Email: john.doe@mail.com                                                           |
| 0002                                                                                                | Doe, Jean (Smith, John)                            | Doe University Department of Medicine<br>1 Main St., Suite 100<br>Silver Spring, MD 20850<br>USA | Phone: 1-555-555-5555<br>Fax: 1-555-555-5555<br>Email: john.smith@mail.com<br>(Phone: 1-555-555-5554<br>Email: jean.doe@mail.com ) |
| 003                                                                                                 | Dietric-Fischer, Inge                              | Hartmannstrasse 7<br>5300 Bonn 1<br>Germany                                                      | Phone:49-555-555-5555<br>Fax: 49-555-555-5555<br>Email: Dietric.Fischer@web.de                                                     |
| * Site terminated, or clinical investigator changed, at request of sponsor before study completion. |                                                    |                                                                                                  |                                                                                                                                    |

<sup>1</sup>[Electronic Common Technical Document \(eCTD\) | FDA](#)

<sup>2</sup>[Bioresearch Monitoring Technical Conformance Guide | FDA](#)

# Subject Visits: RCTs vs RWD

| Topic                                                          | Randomized Controlled Trial                                                                                        | Real World Data                                                                                                                                   |
|----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Scheduled Patient Provider Interaction / Healthcare Delivery   | <b>Protocol-defined</b> visit                                                                                      | Encounter (patient-initiated)                                                                                                                     |
| Randomization                                                  | Patients are randomized to treatment or control using a randomization schedule                                     | Patients are usually matched or selected using a non-randomized method                                                                            |
| Unscheduled Patient Provider Interaction / Healthcare Delivery | Unscheduled visit (not protocol-defined)                                                                           | Encounter (patient-initiated)                                                                                                                     |
| Treatment Facility and Provider                                | Subject assigned to <b>one site and one investigator</b>                                                           | Site and care provider may vary widely                                                                                                            |
| Schedule Cadence                                               | Pre-specified and <b>protocol driven</b>                                                                           | Driven by <b>patient need</b> , standard of care, reimbursement                                                                                   |
| Care Structure                                                 | <b>Driven by a protocol</b> , upon which all investigators are trained                                             | Heterogenous and <b>can vary by site, system, payer, etc.</b>                                                                                     |
| Recording Structure                                            | Highly-standardized <b>Case Report Form (CRF)</b> , upon which study site staff have been trained                  | Source dependent, often a <b>non-standardized electronic system</b> that is customized by the individual provider site                            |
| Timing                                                         | Nominal VISIT/VISITNUM, actual dates, study days based on reference dates and a protocol defined <b>index date</b> | Calendar dates when an encounter took place, <b>encounters may span multiple dates</b> , or <b>multiple encounters may occur on the same date</b> |
| Outcomes and Safety                                            | <b>Prospectively defined endpoints; solicited adverse events</b> (AEs)                                             | <b>Opportunistic outcomes, AEs not systemically solicited</b> and rely on patient and/or physician to initiate the report                         |
| Visit Content / Actions Taken                                  | <b>Protocol-mandated</b> assessments (e.g., labs with specified panels, PROs, imaging)                             | Varies per patient <b>based on the provider judgement</b> and may be influenced by payer decisions                                                |

# Gaps in Subject Visit Domain

Assumptions are made based on the way RCTs are commonly run, including:

- SV domain primarily contains timing variables without many other visit details to provide context.
  - Site and investigator information is in the study protocol, BIMO and related study documents, not CDISC.
- Only one provider (investigator) can be specified in DM, and provider specialty not specified.
- Only one location/facility can be specified in DM.
  - The Healthcare Encounters (HO) domain contains data for inpatient and outpatient healthcare events.
  - Provider and facility location are not in HO but could be provided in a supplemental domain.
- DM.SITEID and DM.INVID identifiers assigned by the sponsor and are not standardized but do specify Type.
- SITEID can be used as a unique key in BIMO and in DM, but currently not enforced by the standard.
  - This enables a site to have more than one investigator and an investigator to work at more than one site, but a different SITEID is required for each investigator.
  - To identify the visit healthcare provider, SITEID and INVID both need to be in the SV dataset.
- No stated rule that the BIMO SITEID and investigator information match DM.SITEID and DM.INVNAM, although it is assumed this is required.
  - SITEID matches could be electronically implemented, but INVNAM would be harder to do electronically given the field formatting differences in BIMO and CDISC DM.
    - This may be remedied by the work FDA is currently doing to standardize the BIMO file.

# RWD Models

- HL7 FHIR
- PCORnet
- OMOP
- Sentinel

# Subject Encounter Entities in HL7 FHIR R4

| Entities #1                                                                                                                                                        | Entities #2                                                                                                                              | Workflow                                                                                                                                                                  | Management                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>Organization 3</li><li>OrganizationAffiliation 0</li><li>HealthcareService 2</li><li>Endpoint 2</li><li>Location 3</li></ul> | <ul style="list-style-type: none"><li>Substance 2</li><li>BiologicallyDerivedProduct 0</li><li>Device 2</li><li>DeviceMetric 1</li></ul> | <ul style="list-style-type: none"><li>Task 2</li><li>Appointment 3</li><li>AppointmentResponse 3</li><li>Schedule 3</li><li>Slot 3</li><li>VerificationResult 0</li></ul> | <ul style="list-style-type: none"><li>Encounter 2</li><li>EpisodeOfCare 2</li><li>Flag 1</li><li>List 1</li><li>Library 2</li></ul> |

Source: <https://hl7.org/fhir/R4/clinicalsummary-module.html>

# Subject Encounter Resource in HL7 FHIR R4

**Encounter Resource:** Designed to represent interactions between a patient and healthcare provider(s) for the purpose of providing healthcare service(s) or assessing the health status of a patient (Maturity Level 2)

Structure

| Name          | Flags | Card. | Type                                                       | Description & Constraints                                                                                                                                                           |
|---------------|-------|-------|------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Encounter     | TU    |       | DomainResource                                             | An interaction during which services are provided to the patient<br>Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension |
| identifier    | Σ     | 0..*  | Identifier                                                 | Identifier(s) by which this encounter is known                                                                                                                                      |
| status        | ?! Σ  | 1..1  | code                                                       | planned   arrived   triaged   in-progress   onleave   finished   cancelled +<br>EncounterStatus (Required)                                                                          |
| statusHistory |       | 0..*  | BackboneElement                                            | List of past encounter statuses                                                                                                                                                     |
| status        |       | 1..1  | code                                                       | planned   arrived   triaged   in-progress   onleave   finished   cancelled +<br>EncounterStatus (Required)                                                                          |
| period        |       | 1..1  | Period                                                     | The time that the episode was in the specified status                                                                                                                               |
| class         | Σ     | 1..1  | Coding                                                     | Classification of patient encounter<br>V3 Value SetActEncounterCode (Extensible)                                                                                                    |
| classHistory  |       | 0..*  | BackboneElement                                            | List of past encounter classes                                                                                                                                                      |
| class         |       | 1..1  | Coding                                                     | inpatient   outpatient   ambulatory   emergency +<br>V3 Value SetActEncounterCode (Extensible)                                                                                      |
| period        |       | 1..1  | Period                                                     | The time that the episode was in the specified class                                                                                                                                |
| type          | Σ     | 0..*  | CodeableConcept                                            | Specific type of encounter<br>Encounter type (Example)                                                                                                                              |
| serviceType   | Σ     | 0..1  | CodeableConcept                                            | Specific type of service<br>Service type (Example)                                                                                                                                  |
| priority      |       | 0..1  | CodeableConcept                                            | Indicates the urgency of the encounter<br>v3 Code System ActPriority (Example)                                                                                                      |
| subject       | Σ     | 0..1  | Reference(Patient   Group)                                 | The patient or group present at the encounter                                                                                                                                       |
| episodeOfCare | Σ     | 0..*  | Reference(EpisodeOfCare)                                   | Episode(s) of care that this encounter should be recorded against                                                                                                                   |
| basedOn       |       | 0..*  | Reference(ServiceRequest)                                  | The ServiceRequest that initiated this encounter                                                                                                                                    |
| participant   | Σ     | 0..*  | BackboneElement                                            | List of participants involved in the encounter                                                                                                                                      |
| type          | Σ     | 0..*  | CodeableConcept                                            | Role of participant in encounter<br>Participant type (Extensible)                                                                                                                   |
| period        |       | 0..1  | Period                                                     | Period of time during the encounter that the participant participated                                                                                                               |
| individual    | Σ     | 0..1  | Reference(Practitioner   PractitionerRole   RelatedPerson) | Persons involved in the encounter other than the patient                                                                                                                            |

|                        |   |      |                                                                             |                                                                                                                                                                           |
|------------------------|---|------|-----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| appointment            | Σ | 0..* | Reference(Appointment)                                                      | The appointment that scheduled this encounter                                                                                                                             |
| period                 |   | 0..1 | Period                                                                      | The start and end time of the encounter                                                                                                                                   |
| length                 |   | 0..1 | Duration                                                                    | Quantity of time the encounter lasted (less time absent)                                                                                                                  |
| reasonCode             | Σ | 0..* | CodeableConcept                                                             | Coded reason the encounter takes place<br>Encounter Reason Codes (Preferred)                                                                                              |
| reasonReference        | Σ | 0..* | Reference(Condition   Procedure   Observation   ImmunizationRecommendation) | Reason the encounter takes place (reference)                                                                                                                              |
| diagnosis              | Σ | 0..* | BackboneElement                                                             | The list of diagnosis relevant to this encounter                                                                                                                          |
| condition              | Σ | 1..1 | Reference(Condition   Procedure)                                            | The diagnosis or procedure relevant to the encounter                                                                                                                      |
| use                    |   | 0..1 | CodeableConcept                                                             | Role that this diagnosis has within the encounter (e.g. admission, billing, discharge ...)<br>DiagnosisRole (Preferred)                                                   |
| rank                   |   | 0..1 | positiveInt                                                                 | Ranking of the diagnosis (for each role type)                                                                                                                             |
| account                |   | 0..* | Reference(Account)                                                          | The set of accounts that may be used for billing for this Encounter                                                                                                       |
| hospitalization        |   | 0..1 | BackboneElement                                                             | Details about the admission to a healthcare service                                                                                                                       |
| preAdmissionIdentifier |   | 0..1 | Identifier                                                                  | Pre-admission identifier                                                                                                                                                  |
| origin                 |   | 0..1 | Reference(Location   Organization)                                          | The location/organization from which the patient came before admission                                                                                                    |
| admitSource            |   | 0..1 | CodeableConcept                                                             | From where patient was admitted (physician referral, transfer)<br>Admit source (Preferred)                                                                                |
| reAdmission            |   | 0..1 | CodeableConcept                                                             | The type of hospital re-admission that has occurred (if any). If the value is absent, then this is not identified as a readmission<br>v2 RE-ADMISSION INDICATOR (Example) |
| dietPreference         |   | 0..* | CodeableConcept                                                             | Diet preferences reported by the patient<br>Diet (Example)                                                                                                                |
| specialCourtesy        |   | 0..* | CodeableConcept                                                             | Special courtesies (VIP, board member)<br>Special courtesy (Preferred)                                                                                                    |
| specialArrangement     |   | 0..* | CodeableConcept                                                             | Wheelchair, translator, stretcher, etc.<br>Special arrangements (Preferred)                                                                                               |
| destination            |   | 0..1 | Reference(Location   Organization)                                          | Location/organization to which the patient is discharged                                                                                                                  |
| dischargeDisposition   |   | 0..1 | CodeableConcept                                                             | Category or kind of location after discharge<br>Discharge disposition (Example)                                                                                           |
| location               |   | 0..* | BackboneElement                                                             | List of locations where the patient has been                                                                                                                              |
| location               |   | 1..1 | Reference(Location)                                                         | Location the encounter takes place                                                                                                                                        |
| status                 |   | 0..1 | code                                                                        | planned   active   reserved   completed<br>EncounterLocationStatus (Required)                                                                                             |
| physicalType           |   | 0..1 | CodeableConcept                                                             | The physical type of the location (usually the level in the location hierarchy - bed room ward etc.)<br>Location type (Example)                                           |
| period                 |   | 0..1 | Period                                                                      | Time period during which the patient was present at the location                                                                                                          |
| serviceProvider        |   | 0..1 | Reference(Organization)                                                     | The organization (facility) responsible for this encounter                                                                                                                |
| partOf                 |   | 0..1 | Reference(Encounter)                                                        | Another Encounter this encounter is part of                                                                                                                               |

Source: <https://build.fhir.org/index.html>

# Organization and Location Resources in HL7 FHIR R4

- **Organization Resource:** Contains information about healthcare providers(s)
- **Location Resource:** Contains Details and position information for a physical place where services are provided and resources and participants may be stored, found, contained, or accommodated
- **Practitioner:** A person with a formal responsibility in the provisioning of healthcare or related services

## ORGANIZATION

### Structure

| Name         | Flags | Card. | Type                    | Description & Constraints                                                     |
|--------------|-------|-------|-------------------------|-------------------------------------------------------------------------------|
| Organization | I TU  |       | DomainResource          | A grouping of people or organizations with a common purpose<br>+ Rule: The or |
| identifier   | Σ I   | 0..*  | Identifier              | Identifies this                                                               |
| active       | ?! Σ  | 0..1  | boolean                 | Whether the o                                                                 |
| type         | Σ     | 0..*  | CodeableConcept         | Kind of organiz                                                               |
| name         | Σ I   | 0..1  | string                  | Name used for                                                                 |
| alias        |       | 0..*  | string                  | A list of altern                                                              |
| telecom      | I     | 0..*  | ContactPoint            | A contact deta                                                                |
| address      | I     | 0..*  | Address                 | An address for                                                                |
| partOf       | Σ     | 0..1  | Reference(Organization) | The organizati                                                                |
| contact      |       | 0..*  | BackboneElement         | Contact for the                                                               |
| purpose      |       | 0..1  | CodeableConcept         | The type of co                                                                |
| name         |       | 0..1  | HumanName               | A name associ                                                                 |
| telecom      |       | 0..*  | ContactPoint            | Contact details                                                               |
| address      |       | 0..1  | Address                 | Visiting or pos                                                               |
| endpoint     |       | 0..*  | Reference(Endpoint)     | Technical endp                                                                |

## LOCATION

| Name                   | Flags | Card. | Type                    | Description & Constraints                                                                                                                                                |
|------------------------|-------|-------|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Location               | I TU  |       | DomainResource          | Details and position information for a physical place<br>Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension |
| identifier             | Σ     | 0..*  | Identifier              |                                                                                                                                                                          |
| status                 | ?! Σ  | 0..1  | code                    |                                                                                                                                                                          |
| operationalStatus      | Σ     | 0..1  | Coding                  |                                                                                                                                                                          |
| name                   | Σ     | 0..1  | string                  |                                                                                                                                                                          |
| alias                  |       | 0..*  | string                  |                                                                                                                                                                          |
| description            | Σ     | 0..1  | string                  |                                                                                                                                                                          |
| mode                   | Σ     | 0..1  | code                    |                                                                                                                                                                          |
| type                   | Σ     | 0..*  | CodeableConcept         |                                                                                                                                                                          |
| telecom                |       | 0..*  | ContactPoint            |                                                                                                                                                                          |
| address                |       | 0..1  | Address                 |                                                                                                                                                                          |
| physicalType           | Σ     | 0..1  | CodeableConcept         |                                                                                                                                                                          |
| position               |       | 0..1  | BackboneElement         |                                                                                                                                                                          |
| longitude              |       | 1..1  | decimal                 |                                                                                                                                                                          |
| latitude               |       | 1..1  | decimal                 |                                                                                                                                                                          |
| altitude               |       | 0..1  | decimal                 |                                                                                                                                                                          |
| managingOrganization   | Σ     | 0..1  | Reference(Organization) |                                                                                                                                                                          |
| partOf                 |       | 0..1  | Reference(Location)     |                                                                                                                                                                          |
| hoursOfOperation       |       | 0..*  | BackboneElement         |                                                                                                                                                                          |
| daysOfWeek             |       | 0..*  | code                    |                                                                                                                                                                          |
| allDay                 |       | 0..1  | boolean                 |                                                                                                                                                                          |
| openingTime            |       | 0..1  | time                    |                                                                                                                                                                          |
| closingTime            |       | 0..1  | time                    |                                                                                                                                                                          |
| availabilityExceptions |       | 0..1  | string                  |                                                                                                                                                                          |
| endpoint               |       | 0..*  | Reference(Endpoint)     |                                                                                                                                                                          |

## PRACTITIONER

| Name          | Flags | Card. | Type                    | Description & Constraints                                                                                                                                                                                      |
|---------------|-------|-------|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Practitioner  | I TU  |       | DomainResource          | A person with a formal responsibility in the provisioning of healthcare or related services<br>Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension |
| identifier    | Σ     | 0..*  | Identifier              | An identifier for the person as this agent                                                                                                                                                                     |
| active        | Σ     | 0..1  | boolean                 | Whether this practitioner's record is in active use                                                                                                                                                            |
| name          | Σ     | 0..*  | HumanName               | The name(s) associated with the practitioner                                                                                                                                                                   |
| telecom       | Σ     | 0..*  | ContactPoint            | A contact detail for the practitioner (that apply to all roles)                                                                                                                                                |
| address       | Σ     | 0..*  | Address                 | Address(es) of the practitioner that are not role specific (typically home address)                                                                                                                            |
| gender        | Σ     | 0..1  | code                    | male   female   other   unknown<br>AdministrativeGender (Required)                                                                                                                                             |
| birthDate     | Σ     | 0..1  | date                    | The date on which the practitioner was born                                                                                                                                                                    |
| photo         |       | 0..*  | Attachment              | Image of the person                                                                                                                                                                                            |
| qualification |       | 0..*  | BackboneElement         | Certification, licenses, or training pertaining to the provision of care                                                                                                                                       |
| identifier    |       | 0..*  | Identifier              | An identifier for this qualification for the practitioner                                                                                                                                                      |
| code          |       | 1..1  | CodeableConcept         | Coded representation of the qualification<br>v2 table 0360, Version 2.7 (Example)                                                                                                                              |
| period        |       | 0..1  | Period                  | Period during which the qualification is valid                                                                                                                                                                 |
| issuer        |       | 0..1  | Reference(Organization) | Organization that regulates and issues the qualification                                                                                                                                                       |
| communication |       | 0..*  | CodeableConcept         | A language the practitioner can use in patient communication<br>Common Languages (Preferred but limited to AllLanguages)                                                                                       |

Source: <https://build.fhir.org/index.html>

# Subject Encounters Data in PCORnet v7.0

**ENCOUNTER Domain Description:**  
Encounters are interactions between patients and providers within the context of healthcare delivery.

**Relational Integrity:**  
The ENCOUNTER table contains one record per unique encounter.

**Primary Key:** ENCOUNTERID

**Foreign Key:**  
ENCOUNTER.PATID is a foreign key to DEMOGRAPHIC.PATID (many-to-one relationship)  
ENCOUNTER.PROVIDERID is a foreign key to PROVIDER.PROVIDERID (many-to-one relationship)

**Constraints:**  
ENCOUNTERID (unique; required, not null)  
PATID (required, not null)  
ADMIT\_DATE (required, not null)  
ENC\_TYPE (required, not null)

|                   |                  |             |   |                                                                                                                                                                                                                                                                            |
|-------------------|------------------|-------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| FACILITYID        | RDBMS<br>Text(x) | SAS Char(x) | . | Arbitrary local facility code that identifies the hospital or clinic. Used for chart abstraction and validation.<br><br>FACILITYID can be a true identifier, or a pseudoidentifier with a consistent crosswalk to the true identifier retained by the source data partner. |
| FACILITY_LOCATION | RDBMS<br>Text(5) | SAS Char(5) | . | Geographic location (5-digit zip code).                                                                                                                                                                                                                                    |

**PROVIDER Domain Description:**  
Data about the providers who are involved in the care processes documented in the PCORnet<sup>®</sup> CDM.

**Relational Integrity:**  
The PROVIDER table contains one record per PROVIDERID.

**Primary Key:** PROVIDERID

**Foreign Keys:**  
PROVIDER.PROVIDERID is a foreign key to ENCOUNTER.PROVIDERID (one-to-many relationship)  
PROVIDER.PROVIDERID is a foreign key to DIAGNOSIS.PROVIDERID (one-to-many relationship)  
PROVIDER.PROVIDERID is a foreign key to PROCEDURES.PROVIDERID (one-to-many relationship)  
PROVIDER.PROVIDERID is a foreign key to PRESCRIBING.RX\_PROVIDERID (one-to-many relationship)  
PROVIDER.PROVIDERID is a foreign key to MEDADMIN.MEDADMIN\_PROVIDERID (one-to-many relationship)

**Constraints:**  
PROVIDERID (unique; required, not null)

| PROVIDER Table Implementation Guidance                                                                                                                                                                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Guidance</i>                                                                                                                                                                                              |
| <ul style="list-style-type: none"><li>• Include one record per provider.</li><li>• When populating provider specialty, if multiple values are available, use the specialty believed to be primary.</li></ul> |

Source: <https://pcornet.org/data/common-data-model/>

# Subject Encounter Data in OMOP v5.4

visit\_occurrence

## Table Description

This table contains Events where Persons engage with the healthcare system for a duration of time. They are often also called “Encounters”. Visits are defined by a configuration of circumstances under which they occur, such as (i) whether the patient comes to a healthcare institution, the other way around, or the interaction is remote, (ii) whether and what kind of trained medical staff is delivering the service during the Visit, and (iii) whether the Visit is transient or for a longer period involving a stay in bed.

location

## Table Description

The LOCATION table represents a generic way to capture physical location or address information of Persons and Care Sites.

provider

## Table Description

The PROVIDER table contains a list of uniquely identified healthcare providers; duplication is not allowed. These are individuals providing hands-on healthcare to patients, such as physicians, nurses, midwives, physical therapists etc.

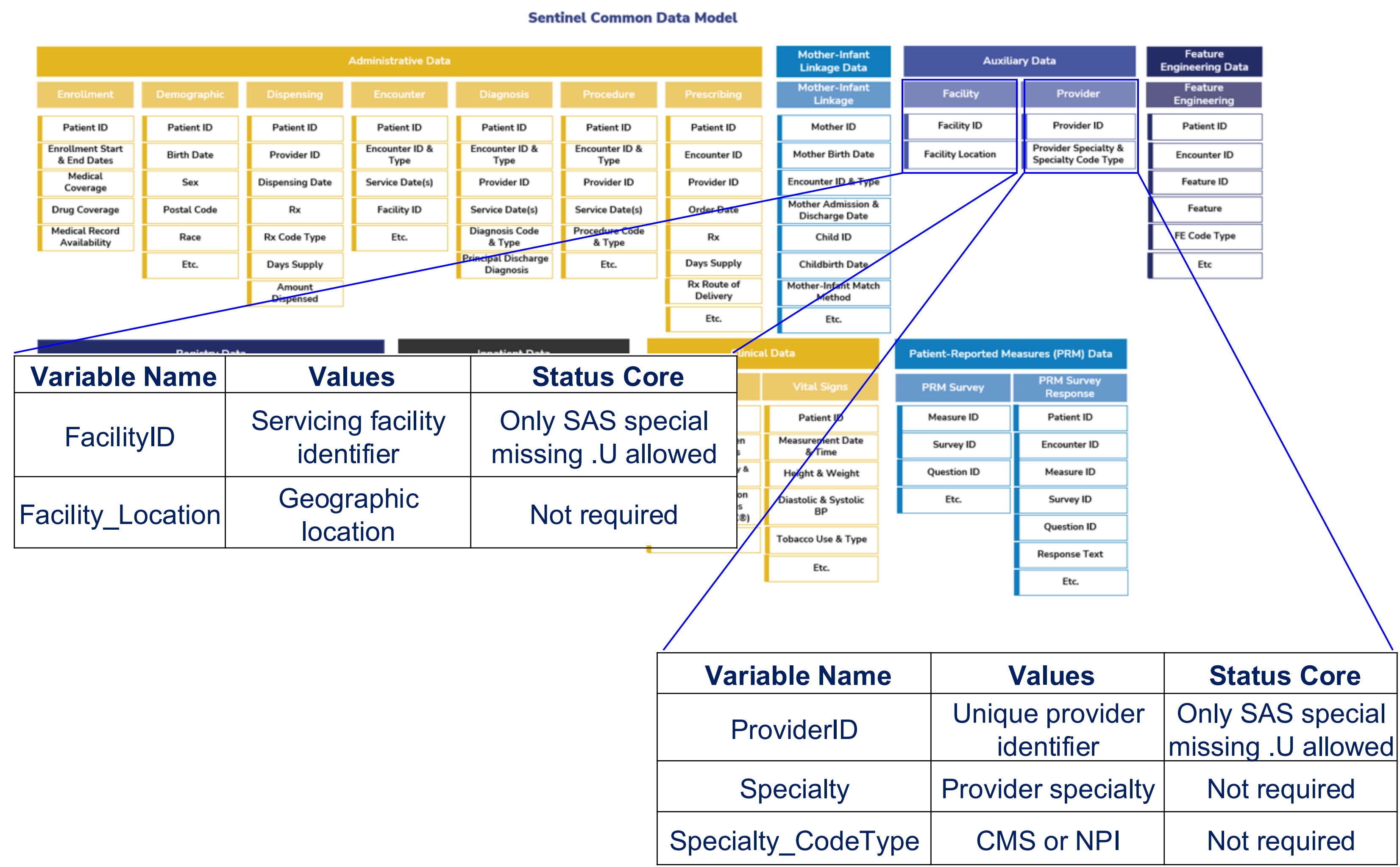
care\_site

## Table Description

The CARE\_SITE table contains a list of uniquely identified institutional (physical or organizational) units where healthcare delivery is practiced (offices, wards, hospitals, clinics, etc.).

# Sentinel Common Data Model, Facility & Provider

- Facility and Provider tables each have unique identifiers.
- **Facility ID** is a foreign key in the Encounter table, identifying treatment facility of the encounter.
- The tables **Diagnosis**, **Procedure**, **Prescription**, and **Dispensing** is linked to the healthcare provider table, identifying the provider who handled that part of the patient's care. Diagnosis, Procedure, and Prescription table also include an encounter ID, which links the visit / encounter during which the activity took place.



# Sentinel: Encounter



| Sentinel Common Data Model   |             |                  |                     |                               |                       |                      |                       |                                                    |                                |
|------------------------------|-------------|------------------|---------------------|-------------------------------|-----------------------|----------------------|-----------------------|----------------------------------------------------|--------------------------------|
| Administrative Data          |             |                  |                     |                               |                       |                      | Encounter             |                                                    |                                |
| Enrollment                   | Demographic | Dispensing       | Encounter           | Diagnosis                     | Procedure             | Prescribing          | Variable Name         | Values                                             | Status / Core                  |
| Patient ID                   | Patient ID  | Patient ID       | Patient ID          | Patient ID                    | Patient ID            | Patient ID           | PatID                 | Unique patient identifier                          | Required                       |
| Enrollment Start & End Dates | Birth Date  | Provider ID      | Encounter ID & Type | Encounter ID & Type           | Encounter ID & Type   | Encounter ID         | EncounterID           | Unique encounter identifier                        | Required                       |
| Medical Coverage             | Sex         | Dispensing Date  | Service Date(s)     | Provider ID                   | Provider ID           | Provider ID          | ADate                 | Encounter or admission date                        | Required                       |
| Drug Coverage                | Postal Code | Rx               | Facility ID         | Service Date(s)               | Service Date(s)       | Order Date           | DDate                 | Discharge date                                     | Conditional on `EncType` value |
| Medical Record Availability  | Race        | Rx Code Type     | Etc.                | Diagnosis Code & Type         | Procedure Code & Type | Rx                   | EncType               | Encounter Type                                     | Required                       |
|                              | Etc.        | Days Supply      |                     | Principal Discharge Diagnosis | Etc.                  | Days Supply          | FacilityID            | Servicing provider identifier                      | Required                       |
|                              |             | Amount Dispensed |                     |                               |                       | Rx Route of Delivery | Discharge_Disposition | Discharge Disposition Code                         | Conditional on `EncType` value |
|                              |             |                  |                     |                               |                       | Etc.                 | Discharge_Status      | Discharge Location or Type Information             | Conditional on `EncType` value |
|                              |             |                  |                     |                               |                       |                      | DRG                   | Diagnosis Related Group                            | Conditional on `EncType` value |
|                              |             |                  |                     |                               |                       |                      | DRG_Type              | DRG Version                                        | Conditional on `EncType` value |
|                              |             |                  |                     |                               |                       |                      | Admitting_Source      | Admitting Facility or Healthcare Professional Type | Conditional on `EncType` value |

| Registry Data     |                |                     | Inpatient Data                |                                        | Clinical Data                                            |                         |
|-------------------|----------------|---------------------|-------------------------------|----------------------------------------|----------------------------------------------------------|-------------------------|
| Death             | Cause of Death | State Vaccine*      | Inpatient Pharmacy            | Inpatient Transfusion                  | Lab Result                                               | Vital Signs             |
| Patient ID        | Patient ID     | Patient ID          | Patient ID                    | Patient ID                             | Patient ID                                               | Patient ID              |
| Death Date        | Cause of Death | Vaccination Date    | Encounter ID                  | Encounter ID                           | Result & Specimen Collection Dates                       | Measurement & Time      |
| Date Imputed Flag | Source         | Admission Date      | Rx Administration Date & Time | Transfusion Administration ID          | Test Type, Immediacy & Location                          | Height & Weight         |
| Source            | Confidence     | Vaccine Code & Type | National Drug Code (NDC)      | Administration Start & End Date & Time | Logical Observation Identifiers Names and Codes (LOINC®) | Diastolic & Systolic BP |
| Confidence        | Etc.           | Provider            | Rx ID                         | Transfusion Product Code               | Etc.                                                     | Tobacco Use             |
| Etc.              |                | Etc.                | Route                         | Blood Type                             |                                                          | Etc.                    |
|                   |                |                     | Dose                          | Etc.                                   |                                                          |                         |
|                   |                |                     | Etc.                          |                                        |                                                          |                         |

- Facility and provider IDs allows a patient to have encounters performed by multiple providers at a variety of sites.
- Additional variables provide useful context for the encounter.

# Challenges & Recommendations

- Recommendations for Additional Variables
- Concepts to Address Gaps
- Recommendations for CDISC & FDA BIMO
- Long-Term Recommendations

# Recommendation for Additional CDISC Variables

- The four RWD standards reviewed were assessed for both commonalities and areas of uniqueness in RWD representation
- Focus on the benefits seen in the RWD standards, primarily the ability to facilitate the analysis of potential bias
- Consider the models' commonalities and but align with reviewer needs as documented in FDA guidance
- Recommendations: Add variables and/or domains to standardize
  - Identifying the provider(s) for the Encounter/Subject Visit
  - Identify the facility and location where the Encounter/Subject Visit took place
  - Representing a patient encounter with more than one provider and/or at more than one site
  - Representing the encounter disposition (or discharge reason/status for the visit)

# Concepts to address gaps in CDISC SDTM to handle RWD

| Concept                 | Definition                                                                                                          | CDISC<br>SDTMIG v3.4 | HL7 FHIR<br>R4 | OMOP v5.4 | PCORnet<br>v7.0 | Sentinel<br>v8.2.1 |
|-------------------------|---------------------------------------------------------------------------------------------------------------------|----------------------|----------------|-----------|-----------------|--------------------|
| Encounter ID            | Source encounter identifier to identify unique interactions between an individual patient and the healthcare system | o                    | o              | o         | o               | o                  |
| Provider ID             | Unique identifier for provider                                                                                      |                      | o              | o         | o               | o                  |
| Facility ID             | Unique identifier for facility (care site)                                                                          |                      | o              | o         | o               | o                  |
| Appointment             | Link to appointment that scheduled this encounter                                                                   |                      | o              |           |                 |                    |
| Part of care plan       | Link to another care plan encounter this encounter is part of                                                       |                      | o              |           |                 |                    |
| Urgency                 | Indicates the urgency of the encounter                                                                              |                      | o              |           |                 | o                  |
| Part of                 | Link to another Encounter this encounter is part of                                                                 |                      | o              |           |                 | o                  |
| Based on                | Request that initiated this encounter                                                                               |                      | o              |           |                 | o                  |
| Status                  | Current state of the encounter (e.g., completed, in-progress)                                                       |                      | o              |           |                 | o                  |
| Service                 | Broad categorization of the service that is to be provided (e.g. cardiology)                                        |                      | o              |           |                 | o                  |
| Reason for visit        | List of medical reasons that are expected to be addressed during the episode of care                                |                      | o              |           |                 |                    |
| Reason for missed visit | Reason for missed encounter                                                                                         | o                    | o              |           |                 |                    |
| Class                   | Classification of patient encounter (e.g., ambulatory (outpatient), inpatient, emergency, home health)              |                      | o              |           |                 | o                  |
| Discharge status        | Category or location after discharge (e.g., home, long-term care)                                                   |                      | o              | o         | o               | o                  |

# Concepts to Model Provider & Healthcare Facility Information

## Provider Information

| Concept     | Definition                                                                                      | CDISC<br>SDTMIG v3.4 | HL7 FHIR R4 | OMOP v5.4 | PCORnet<br>v7.0 | Sentinel<br>v8.2.1 |
|-------------|-------------------------------------------------------------------------------------------------|----------------------|-------------|-----------|-----------------|--------------------|
| Provider ID | Unique Provider Identifier for the practitioner responsible for a given encounter, could be NPI | o                    | o           | o         | o               | o                  |
| Specialty   | The specific type of healthcare provider or field of expertise                                  |                      | o           | o         | o               | o                  |

## Healthcare Facility Information

| Concept       | Definition                                                             | CDISC<br>SDTMIG v3.4 | HL7 FHIR R4 | OMOP v5.4 | PCORnet<br>v7.0 | Sentinel<br>v8.2.1 |
|---------------|------------------------------------------------------------------------|----------------------|-------------|-----------|-----------------|--------------------|
| Facility ID   | Identifier for the care site                                           | o                    | o           | o         | o               | o                  |
| Facility Name | Name of the facility responsible for the encounter                     |                      | o           | o         |                 | o                  |
| Facility Type | The type of facility, e.g. hospital, ER, Urgent Care, ambulatory visit |                      | o           |           | o               | o                  |
| Location      | Geographic location or address of site where healthcare received       |                      | o           | o         | o               | o                  |

# Summary of Concepts to Address Gaps in CDISC SDTM to Handle RWD

| Concept                                 | BIMO | CDISC SDTMIG v3.4                                 | HL7 FHIR R4 | OMOP v5.4 | PCORnet v7.0 | Sentinel v8.2.1 |
|-----------------------------------------|------|---------------------------------------------------|-------------|-----------|--------------|-----------------|
| Unique Provider Identification          | Y*   | Y*                                                | Y           | Y         | Y            | Y               |
| Provider Specialty                      | N    | N                                                 | Y           | Y         | Y            | Y               |
| Unique Facility ID                      | Y*   | Y*                                                | Y           | Y         | Y            | Y               |
| Facility Location                       | Y    | N                                                 | Y           | Y         | Y            | Y               |
| Facility Type                           | Y    | N                                                 | Y           | N         | Y            | Y**             |
| Unique Encounter/Subject Visit ID       | N/A  | Y                                                 | Y           | Y         | Y            | Y               |
| Provider of the Encounter/Subject Visit | N/A  | Assumed                                           | Y           | Y         | Y            | Y               |
| Facility of the Encounter/Subject Visit | N/A  | Assumed                                           | Y           | Y         | Y            | Y               |
| Encounter Discharge Status              | N/A  | If AE, yes<br>DS Domain not linked to SV directly | Y           | Y         | Y            | Y               |

\* Currently only one per patient  
 \*\* Derivable from Encounter Type

# Recommendations for CDISC and FDA BIMO

- Add domains to represent unique providers and facilities which link to Subject Visits (SV)
  - The implemented solution should support multiple providers and sites for a patient's care
  - This is needed for identifying potential bias in a RWD study where treatment is not protocol driven
    - Care needs to be traced to the facility location and physician specialty at a minimum
- SV should include the identifiers for provider and facility where the diagnosis was made, where labs were done, etc.
- Evaluate SITEID, INVAM and INVID in BIMO and DM for RWD to determine optimally placed
  - BIMO specifies “providing the most relevant site for investigational purposes”
  - Updates may include identifying which SITE and INVID to represent in DM (e.g., Primary Care Physician or first visit or the group that is reusing the data)
  - Clarify use of BIMO file and DM domain for RWE submissions vs an RCT
- Expand SV to include additional qualifying information for the encounter
- Recommended variables to add
  - Unique Provider Identifier
  - Provider Specialty
  - Unique Facility Identifier
  - Facility Location
  - Facility Type
  - Discharge status

# Long Term Recommendations

- The assumption that a subject seen at one site by one physician is unrealistic for RWD
- Option 1:
  - Redefine SITEID and INVID as the primary site identifier and primary care physician
  - Secondary sites and care providers can be specified as supplemental or non-standard variables
- Option 2: Long-term Option
  - In HL7 FHIR, all data elements contain a **cardinality** attribute
  - Introduce cardinality to DM, SV and other SDTM domains as done in HL7 FHIR
    - This would allow for multiple providers (or investigators) and facilities for a given subject or encounter without the need for non-standard variables
  - This is currently not an option given the limitations by SAS Transport format
  - JSON also being considered by FDA as a submission format
    - Would require a non-tabular specification for JSON as a submission format

# Summary and Conclusion

# Summary

- Gaps for representing RWD exist in current CDISC SDTM:
  - Only one provider and care site can be represented.
  - No standard way to represent healthcare provider or facility information for a specific visit.
  - No standard way to provide important contextual information in Subject Visits (SV).
  - Adequate for RCTs where captured data is planned and known. Study protocol provides contextual information.
- RWD has unique requirements for representation in submitted data.
  - More robust capture of provider and care facility needed for real-world encounters/subject visits.
  - Need ability to identify any bias present in a non-randomized RWD study where care is not protocol driven.
  - Need context which can help the evaluator understand the level of data accuracy and quality in RWD.
- Addressing gaps:
  - Enhancements to CDISC to represent providers and facilities (link this information to SV domain).
  - FDA's BIMO standards may provide a way to capture site and provider information.
    - Ensure that this will not obscure information needed to facilitate BIMO investigations.
  - CDISC may consider expanding relevant domain specifications to incorporate use of RWD for regulatory review.
  - CDISC is designed for RCTs; using an existing RWD standard may be more straightforward than updating.

# Conclusion

Use for RWD is evolving

Guidance for submitting RWD is evolving

Standards for representing RWD is also evolving

Current submission standards have gaps for representing RWD and require supplemental domains and variables to represent RWD

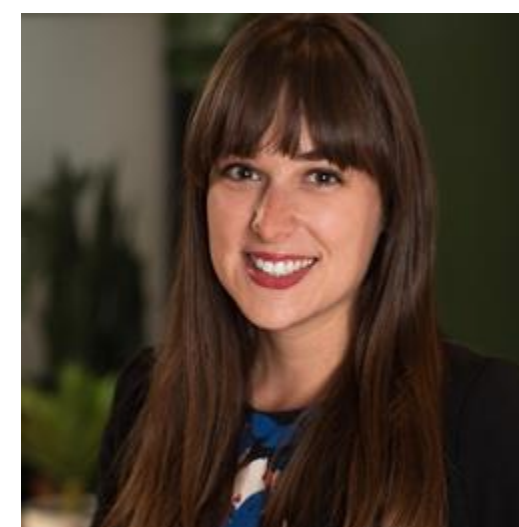
There is much that we can learn and incorporate from CDMs designed for RWD, including HL7 FHIR, OMOP, PCORnet, and Sentinel

In the interim, early communication with regulatory authorities is key to meet review needs and should be done before you begin formatting data

# Thank you!



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# Questions?