# CDISC 2019 Europe Interchange

## Amsterdam, Netherlands | 6-10 May

# Real-world data
# From observational research to clinical trials

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09.05.2019

**2019 Europe Interchange**

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Clinical Trials

Observational Research

# Regulatory Input


## FDA's Real World Evidence Program

*"…FDA uses RWD and RWE to monitor post market safety and adverse events and to make regulatory decisions…"*

*from FDA's RWE webpage*

*see also: Framework outline for RWE Program implementation, Dec 2018*

# Regulatory Input


## HMA-EMA Joint Big Data Taskforce

*"…much may be gained from the rational use of Big Data in a regulatory context for approval and monitoring of efficacy / effectiveness and safety of medicines, medical devices and combinations thereof…"*

*from Summary Report, Feb 2019*

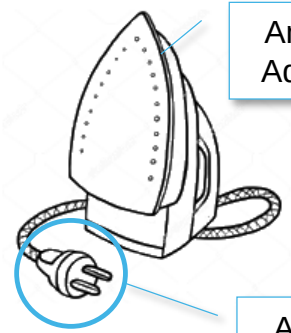
# What is OMOP?

Common Data Model that standardizes longitudinal patient data for the purpose of observational research

- Includes its own vocabulary
  - Links to SNOMED, ICD and RxNorm
- In the public domain / open-source
- Managed by OHDSI
  - Research collaborative
  - Multiple stakeholders & geographies
  - Access to 700M patients

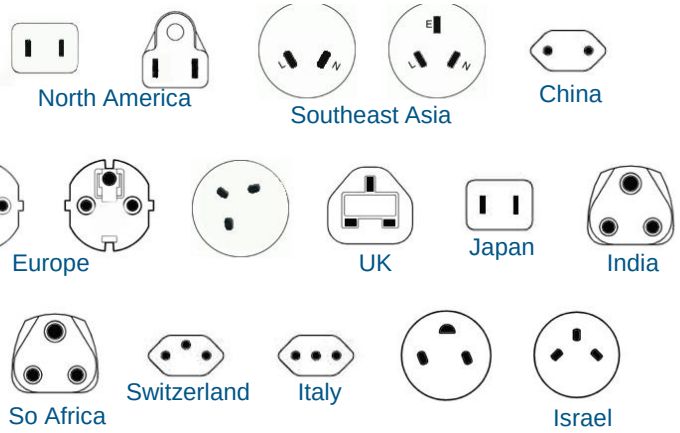
# From Multiple Study Coding...

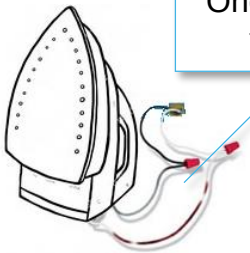
***"What's the adherence to my drug in the data assets of interest?"***



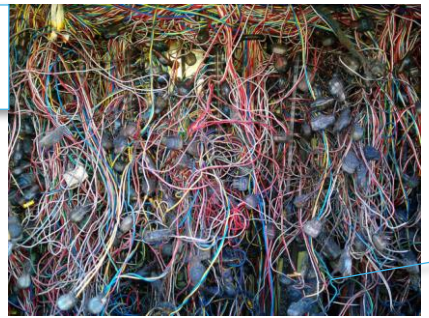
Analytical method: Adherence to Drug

Application to data



One SAS or R script for each study



- Reliant on partner capabilities
- Not scalable
- Not transparent
- Expensive
- Slow
- Prohibitive to non-expert routine use

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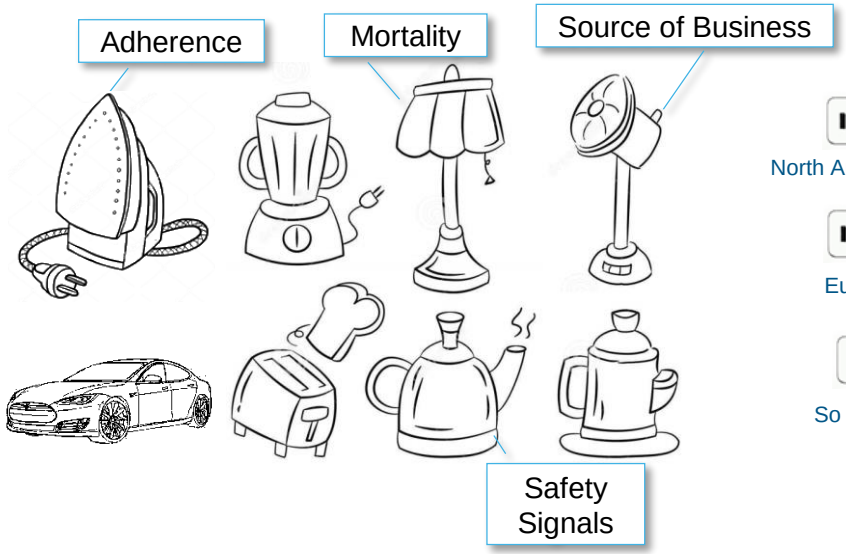
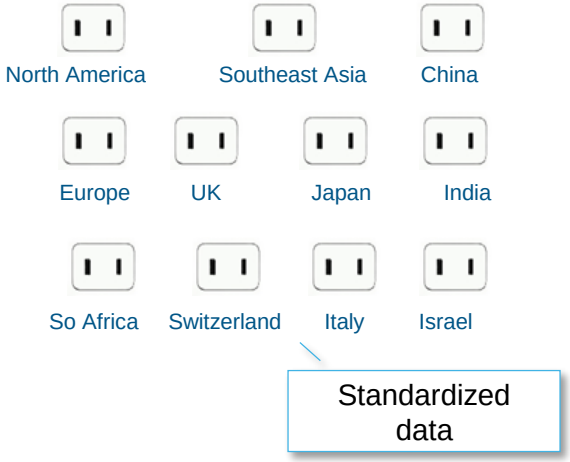
# ... To Data Standardization & Systematic Research

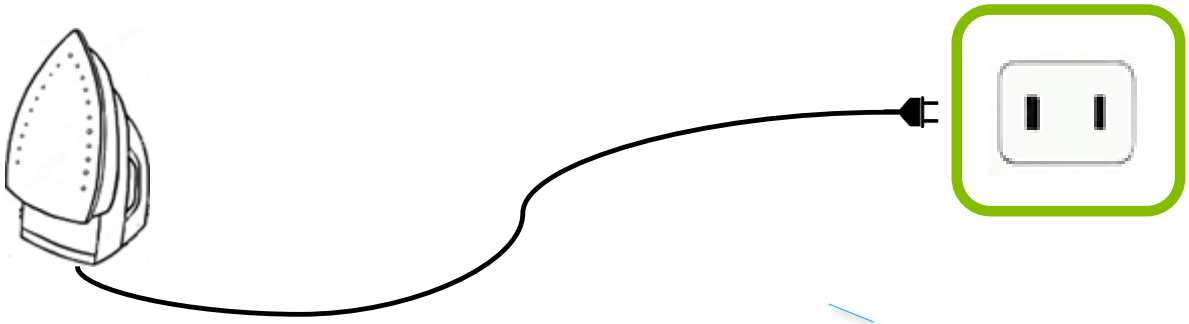



**OHDSI Tools**

**OMOP CDM**

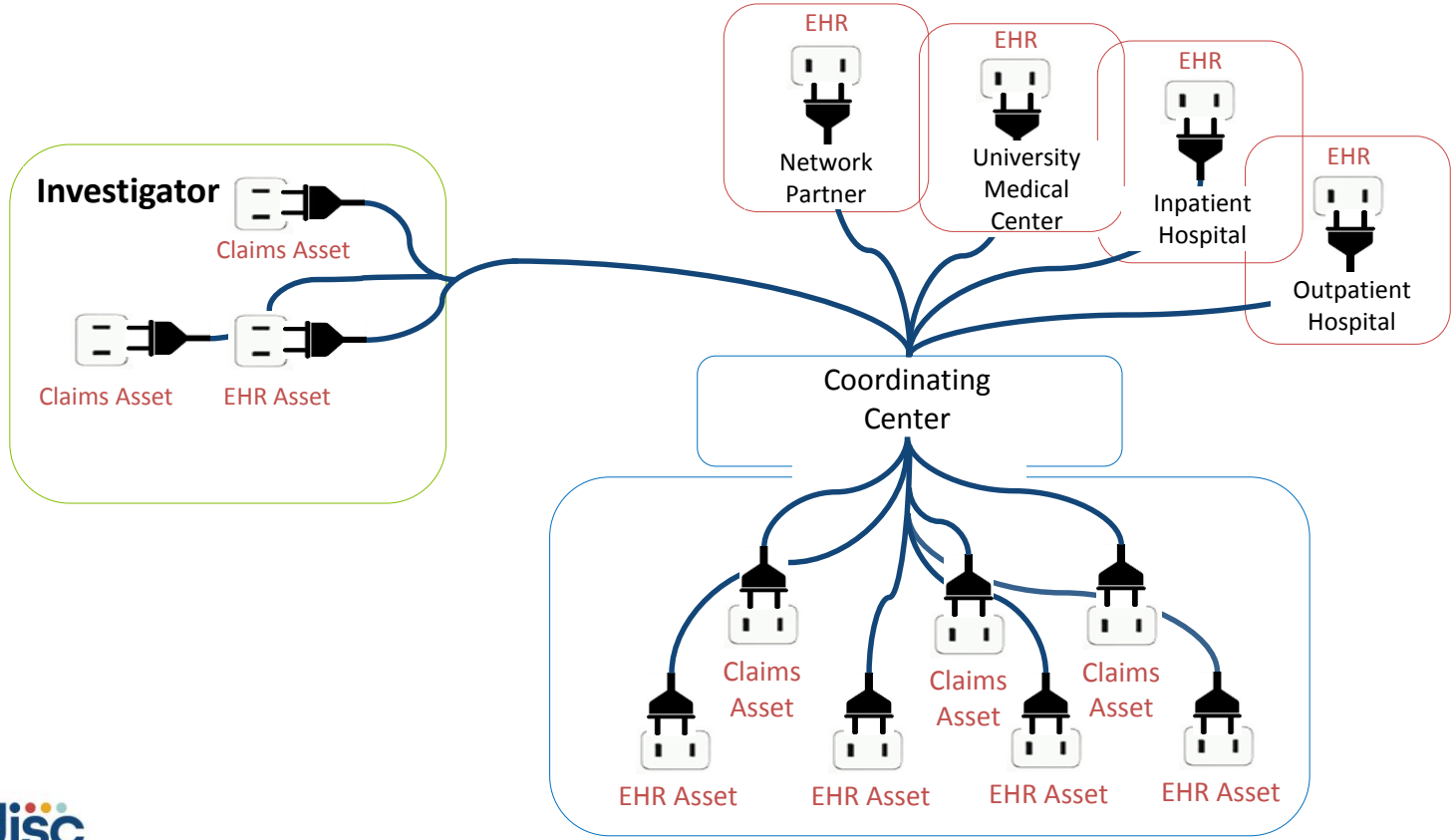
# …To Flexible Analytics



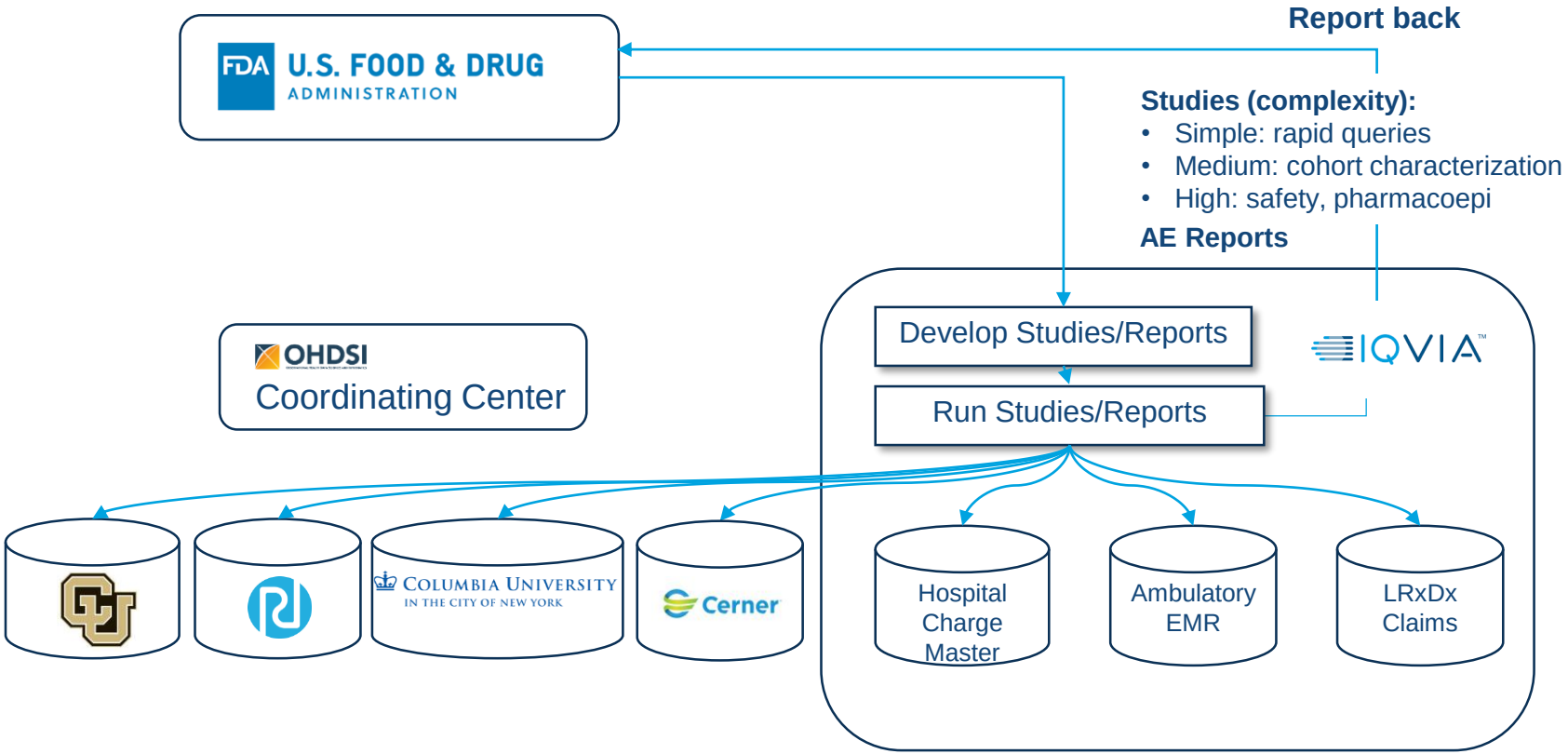
Analytics can be remote

Analytics can run behind firewall

# Network Studies / Networks of Networks



# Example of Remote Study Network: FDA BEST

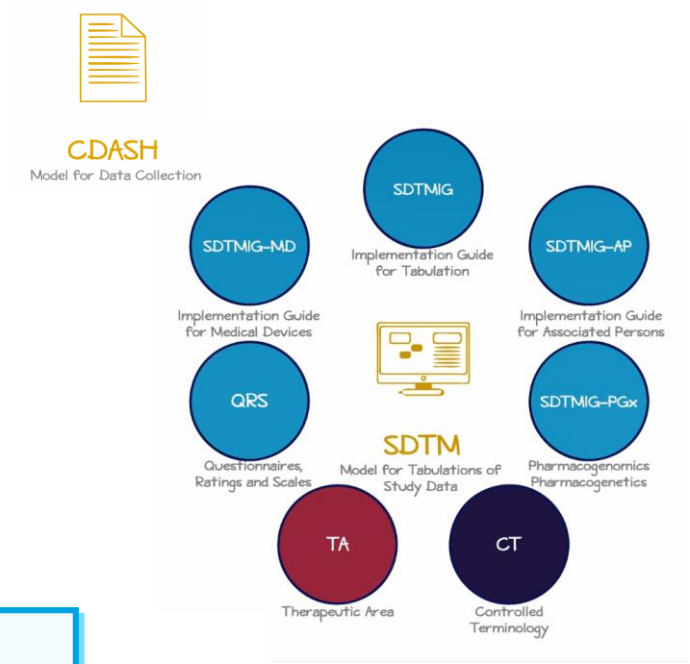


# Other Use Cases

- Drug safety
- Drug efficacy
- Pharmacoepi or epidemiology
- Population characterization
- Patient-level prediction
- Health economics research
- Clinical trial feasibility

# CDISC Standards

- **CDASH**
  - standard way to collect data at source across studies and sponsors
- **SDTM**
  - data submission standard for the FDA and the PMDA



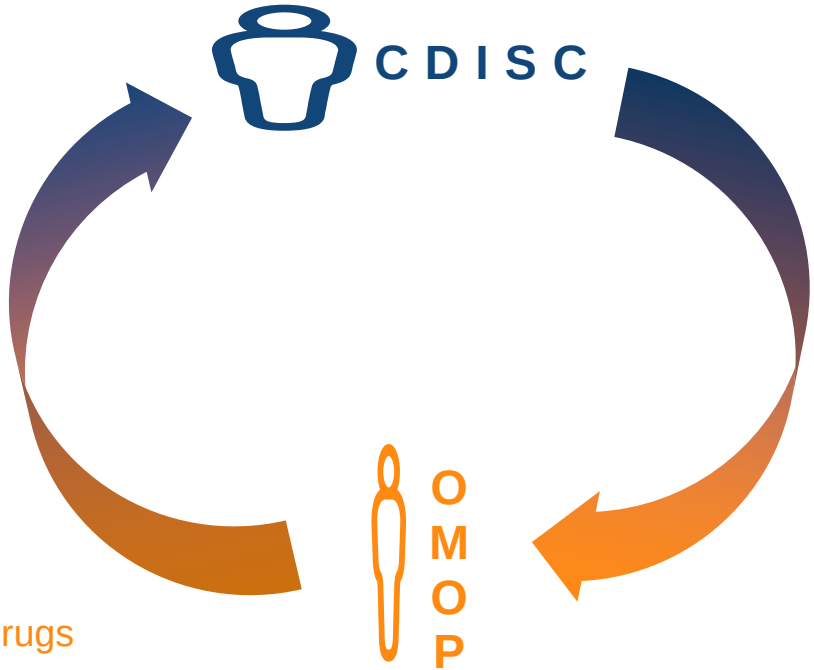

**OMOP ↔ CDASH ↔ SDTM =**



| Clinical trial data | Observational data |
|---|---|
| Clean data | “Dirty” data |
| Reflect an experiment | Collected in real-world settings |
| Small (megabytes) | Gigantic (terabytes) |
| Owned/controlled by sponsor | Owned / controlled by primary data owner |
| Collected for the purpose of running a clinical trial | Secondary use |

# Opportunities for Collaboration

- ascertain trial feasibility
- recruit trial participants, investigators and sites
- supply real data from clinical trial subjects, or “like patients”
- identify potential extra indications for marketed drugs

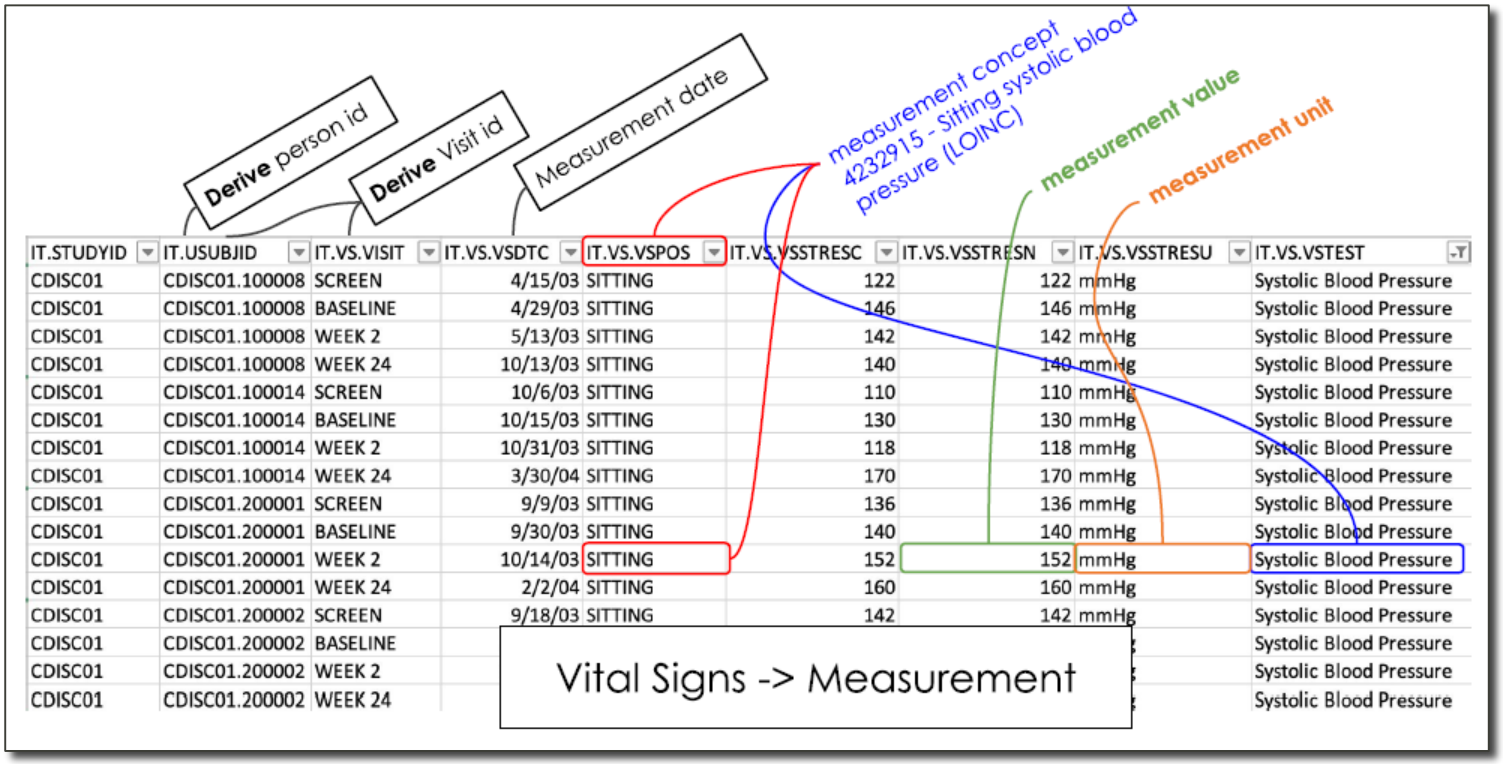



- combine multiple clinical trials’ data into a synthetic trial
- share data for extra analysis on outcomes
- use clinical trial data as another real-world data source

# OHDSI Clinical Trials WorkGroup

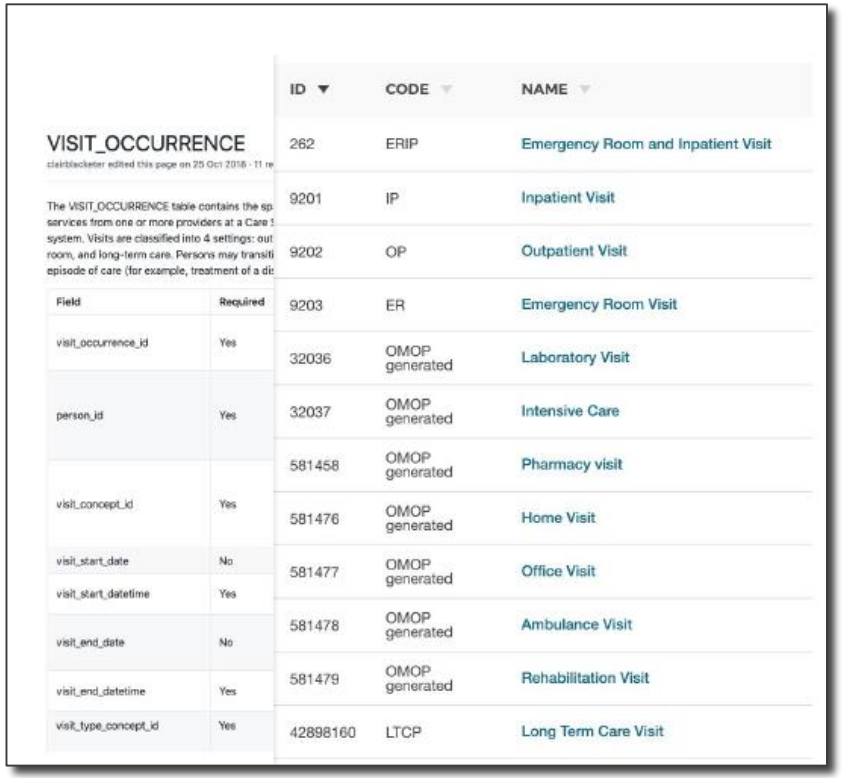
| Use cases | Objectives |
|---|---|
| Convert (multiple) clinical trials' data to OMOP *(eg, SDTM-OMOP)* | Enable aggregate / population-level analytics, create synthetic trial |
| Convert real-world data for use in clinical trials *(eg, OMOP-CDASH)* | Augment type and amount of data in an RCT *("pragmatic / enriched" studies)* |
| Run retrospective observational studies | Identify / analyse insights from clinical data *(eg, whether RCT results are generalizable, potential extra indications)* |
| Run retrospective observational studies | Help future clinical trial feasibility assessment / design |

# SDTM to OMOP Example




| IT.STUDYID | IT.USUBJID | IT.VS.VISIT | IT.VS.VSDTC | IT.VS.VSPOS | IT.VS.VSSTRESC | IT.VS.VSSTRESN | IT.VS.VSSTRESU | IT.VS.VSTEST |
|---|---|---|---|---|---|---|---|---|
| CDISC01 | CDISC01.100008 | SCREEN | 4/15/03 | SITTING | 122 | 122 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.100008 | BASELINE | 4/29/03 | SITTING | 146 | 146 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.100008 | WEEK 2 | 5/13/03 | SITTING | 142 | 142 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.100008 | WEEK 24 | 10/13/03 | SITTING | 140 | 140 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.100014 | SCREEN | 10/6/03 | SITTING | 110 | 110 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.100014 | BASELINE | 10/15/03 | SITTING | 130 | 130 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.100014 | WEEK 2 | 10/31/03 | SITTING | 118 | 118 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.100014 | WEEK 24 | 3/30/04 | SITTING | 170 | 170 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.200001 | SCREEN | 9/9/03 | SITTING | 136 | 136 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.200001 | BASELINE | 9/30/03 | SITTING | 140 | 140 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.200001 | WEEK 2 | 10/14/03 | SITTING | 152 | 152 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.200001 | WEEK 24 | 2/2/04 | SITTING | 160 | 160 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.200002 | SCREEN | 9/18/03 | SITTING | 142 | 142 | mmHg | Systolic Blood Pressure |
| CDISC01 | CDISC01.200002 | BASELINE | | | | | | Systolic Blood Pressure |
| CDISC01 | CDISC01.200002 | WEEK 2 | | | | | | Systolic Blood Pressure |
| CDISC01 | CDISC01.200002 | WEEK 24 | | | | | | Systolic Blood Pressure |

# SDTM to OMOP Example



VISIT_OCCURRENCE

clairblacketer edited this page on 25 Oct 2018 · 11 re

The VISIT_OCCURRENCE table contains the sp
services from one or more providers at a Care
system. Visits are classified into 4 settings: out
room, and long-term care. Persons may transiti
episode of care (for example, treatment of a di

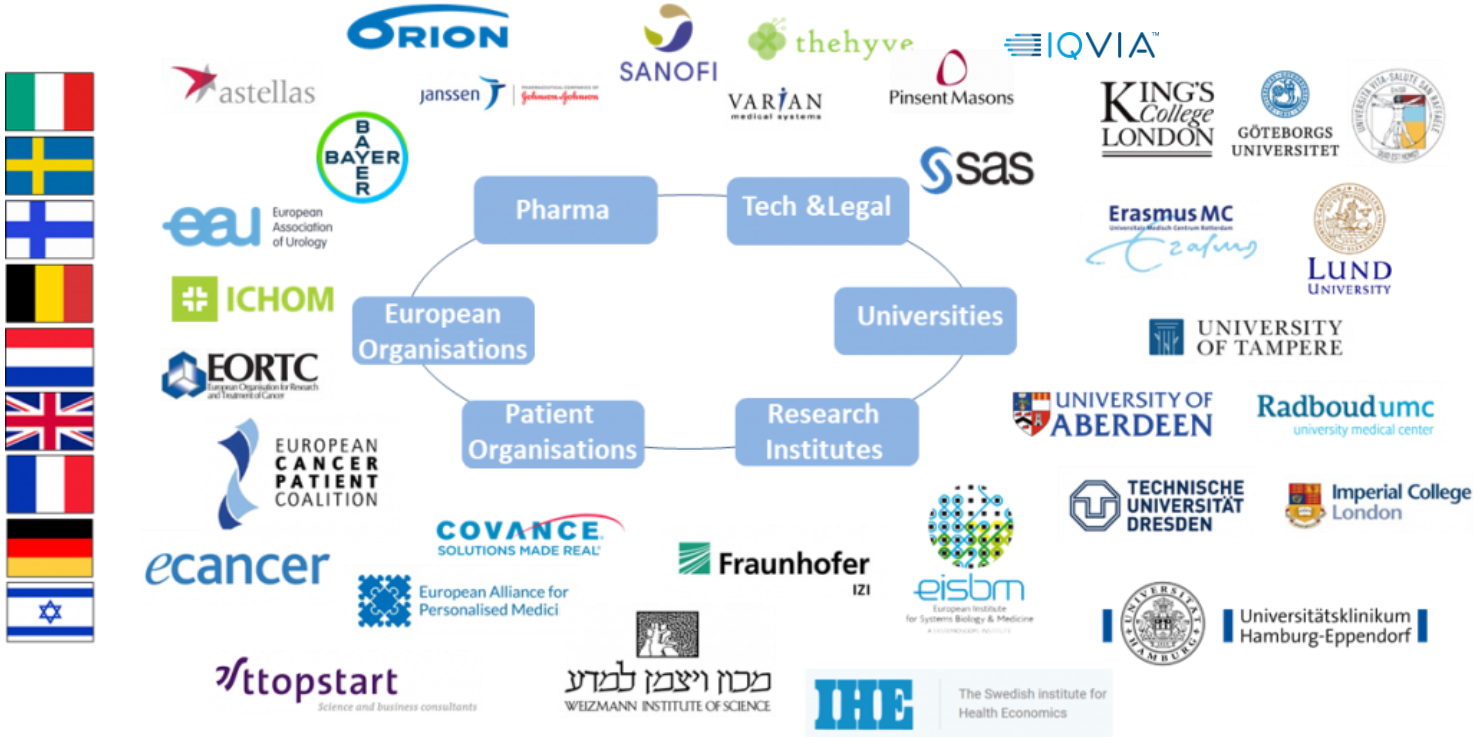
| Field | Required |
|---|---|
| visit_occurrence_id | Yes |
| person_id | Yes |
| visit_concept_id | Yes |
| visit_start_date | No |
| visit_start_datetime | Yes |
| visit_end_date | No |
| visit_end_datetime | Yes |
| visit_type_concept_id | Yes |

| ID | CODE | NAME |
|---|---|---|
| 262 | ERIP | Emergency Room and Inpatient Visit |
| 9201 | IP | Inpatient Visit |
| 9202 | OP | Outpatient Visit |
| 9203 | ER | Emergency Room Visit |
| 32036 | OMOP generated | Laboratory Visit |
| 32037 | OMOP generated | Intensive Care |
| 581458 | OMOP generated | Pharmacy visit |
| 581476 | OMOP generated | Home Visit |
| 581477 | OMOP generated | Office Visit |
| 581478 | OMOP generated | Ambulance Visit |
| 581479 | OMOP generated | Rehabilitation Visit |
| 42898160 | LTCP | Long Term Care Visit |

## OMOP CDM is extendable

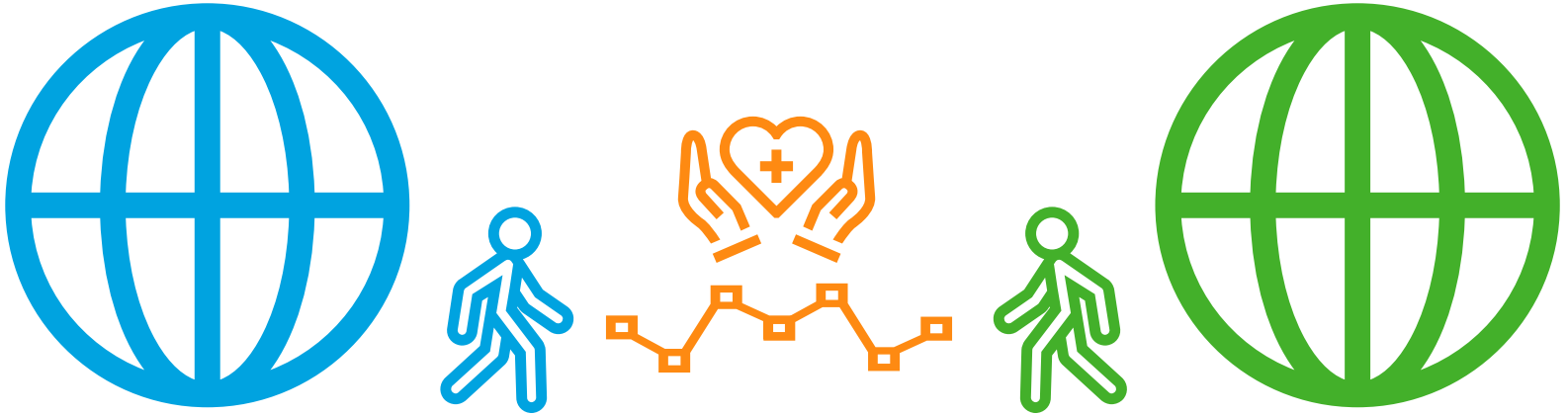
- Add new visit concepts, or custom Trial Visit domain
- Add fields to capture cycle and visit day combinations
  *(eg, Visit 1 = Screening visit + 1 week)*

# PIONEER EU Project (prostate cancer)



Clinical Trials

Observational Research



Clinical Trials

Observational Research

# Thank You!

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