



# Clinical Trials in OMOP CDM

OHDSI - Clinical Trials WG

April 2019

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# The Hyve



# The Hyve

The Hyve is a fast growing company with ~45 data scientists and software developers.  
We provide IT service to scientists and researchers around open source software.

## Our Values

Share



Reuse



Specialize



## Our Mission

“We advance biology and medical sciences,  
by creating and serving thriving open source communities.”





## Interdisciplinary team

software engineers, data scientists, project managers & staff; expertise in bioinformatics, medical informatics, software engineering, biostatistics etc.



# 4 areas of focus

- Real World Data
  - *Real World Evidence*
  - *Wearable Sensors*
- Translational Data Warehousing
- Cancer Genomics
- FAIR Data Management



# The Year 2017 at the hyve

58 Projects

13 life sciences companies

10 hospitals

11 consortia/biobanks/ patient organisations



# Context



# Background

Multiple requests for harmonizing CT data to OMOP CDM

- Consortia
  - Pioneer
  - BigData@Heart
- Several industry customers



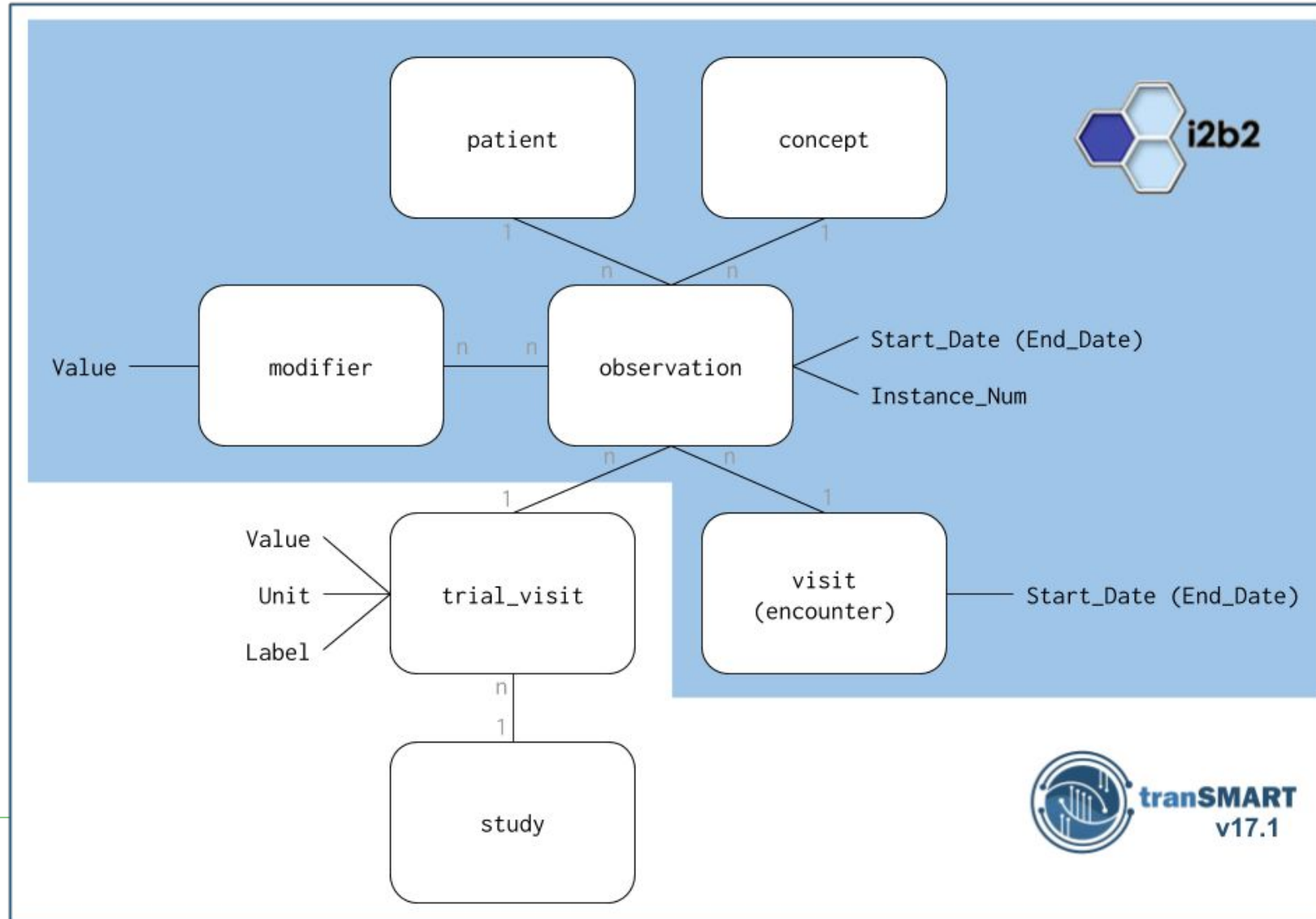


# Use case

- ▶ Conformance model
- ▶ Run same analysis on all registries within consortium/organisation.
- ▶ Easily execute analysis across RCT and observational data assets.



# tranSMART/i2b2 data model



# Common Data Models Comparison

Increased standardization



## OMOP

- ▶ Scope: Observational Data
- ▶ Standardized Vocabularies
- ▶ Person Centric Model
- ▶ Pre-defined domains:  
Condition, Drug, Procedure,  
Measurement, Observation...

## I2b2/tranSMART

- ▶ Scope: Translational Data
- ▶ Flexible Concept Trees
- ▶ Observation Centric Model
- ▶ Pre-defined dimensions:  
Patient, Study, Visit,  
Concept, Modifier etc.

## RDF

- ▶ Scope: Not Limited
- ▶ 'Knowledge' Graph
- ▶ Flexible Model
- ▶ Building on Linked  
Open Data standards

Increased flexibility



# Findings



Derive person id

Derive Visit id

Measurement date

measurement concept  
4232915 - Sitting systolic blood  
pressure (LOINC)

measurement value

measurement unit

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

Vital Signs -> Measurement



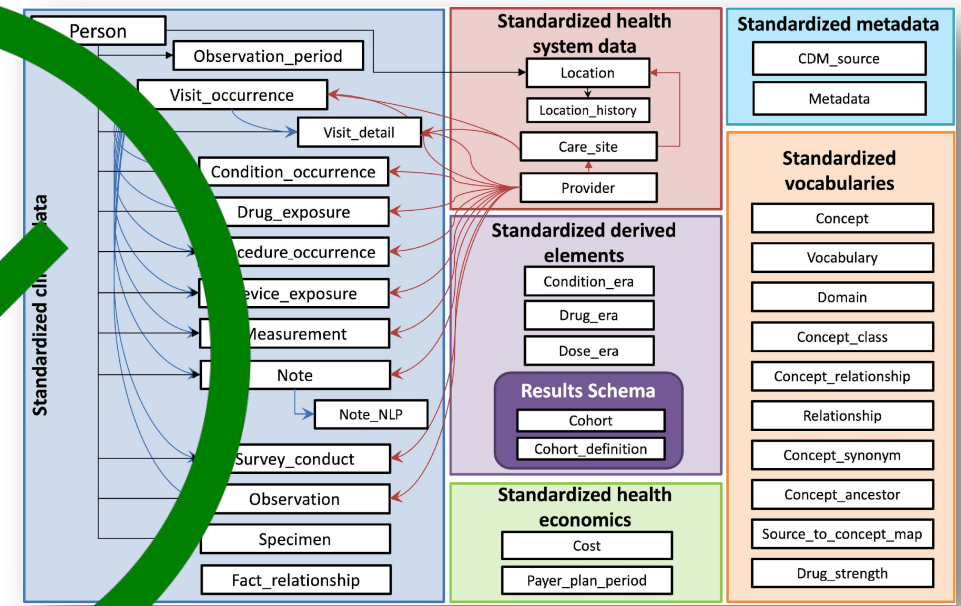
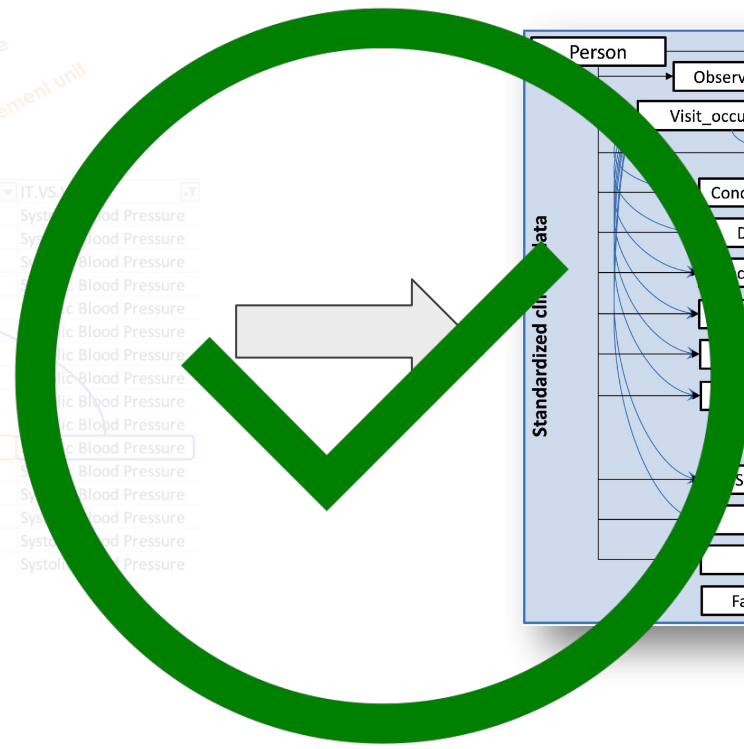
IT_STUDYID	IT_USUBJID	IT_VS_VISIT	IT_VS_VSDTC	IT_VS_VSPOS	IT_VS_VSSTRESC	IT_VS_VSSTRESN	IT_VS_VSSTRESU	IT_VS_VSSTRESV
CDISC01	CDISC01.100008	SCREEN	4/15/03	SITTING	122	122	mmHg	Systolic Blood Pressure
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CDISC01	CDISC01.200002	BASELINE			142	142	mmHg	Systolic Blood Pressure
CDISC01	CDISC01.200002	WEEK 2			160	160	mmHg	Systolic Blood Pressure
CDISC01	CDISC01.200002	WEEK 24			142	142	mmHg	Systolic Blood Pressure

Vital Signs

Study Trial visit

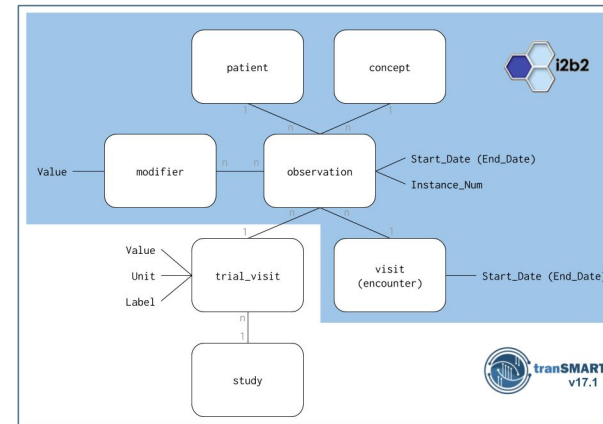
Derive person id  
Derive visit id  
Measurement date

measurement concept  
4232915 - Sitting systolic blood pressure (LOINC)  
measurement value  
measurement unit



# Findings OMOP CT requirements

1. Trial visit
2. Study
3. Measurement Modifiers
4. Include new vocabularies for e.g.:
  - a. Biomarkers
  - b. Novel drug assets
  - c. Hierarchy of indication subtypes



# tranSMART/i2b2 - Trial visit & Study

Study/  
Trial visit

Study	Label	Unit	Value
RCT1	Cycle1	Days	10
RCT1	Cycle2	Days	50

Observation  
fact

Subject	Trial visit label	Concept	Value
1	Cycle1	Heart rate (BPM)	85
1	Cycle2	Heart rate (BPM)	98
2	Cycle1	Heart rate (BPM)	51
2	Cycle2	Heart rate (BPM)	116





# Trial Visit

- ▶ 12 visit concepts, all observational concepts
- ▶ Include concepts for clinical trial visits
  - ▶ visit day
  - ▶ cycle number

## 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 S system. Visits are classified into 4 settings: out room, and long-term care. Persons may transiti episode of care (for example, treatment of a dis

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



# Trial Visit

<b>IT.STUDYID</b>	<b>IT.TV.DOMAIN</b>	<b>IT.TV.TVSTRL</b>	<b>IT.TV.VISIT</b>	<b>IT.TV.VISITDY</b>
CDISC01	TV	Start of Screening	SCREEN	-13
CDISC01	TV	Start of Baseline Assessments	BASELINE	1
CDISC01	TV	End of week 2 treatment	WEEK 2	15
CDISC01	TV	End of treatment	WEEK 24	169



# Structural extension: Study

## **Issue**

No study or arm assignment in the OMOP CDM

## **Proposed solution**

Add a custom study domain

- ▶ Pro: all studies in one schema, custom study-level data
- ▶ Con: current tooling needs to be adapted



# As observation (proposal Vojtech)

## **entering a trial - Enrollement (start)**

*Observation\_concept\_id:* <http://www.ohdsi.org/web/atlas/#/concept/4163733> 11 (Patient consented to clinical trial)

*value\_as\_string:* NCT000035135

## **leaving the trial early (due to a decision of a patient (no longer interested) or researcher (non compliance) (end)**

\**Observation\_concept\_id:* <http://www.ohdsi.org/web/atlas/#/concept/4087907> (Patient withdrawn from trial)

*value\_as\_string:* NCT000035135

## **fully completing the trial (end)**

*Observation\_concept\_id:* <http://www.ohdsi.org/web/atlas/#/concept/40482840> Completion of clinical trial

*value\_as\_string:* NCT000035135

<http://forums.ohdsi.org/t/omop-cdm-and-clinical-trials/2109/6>



# Structural extension: Modifier

## Issue

Not all measurement attributes can be stored in the OMOP domains

## Proposed solution

Add new Modifier domain

- ▶ Pro: flexible, reuse of concepts
- ▶ Con: adapt current tooling

Field	Example
domain_concept_id	56 ('Condition')
fact_id	93269
relationship_id	'Has intensity'
concept_id	8523639 ('Grade 1')

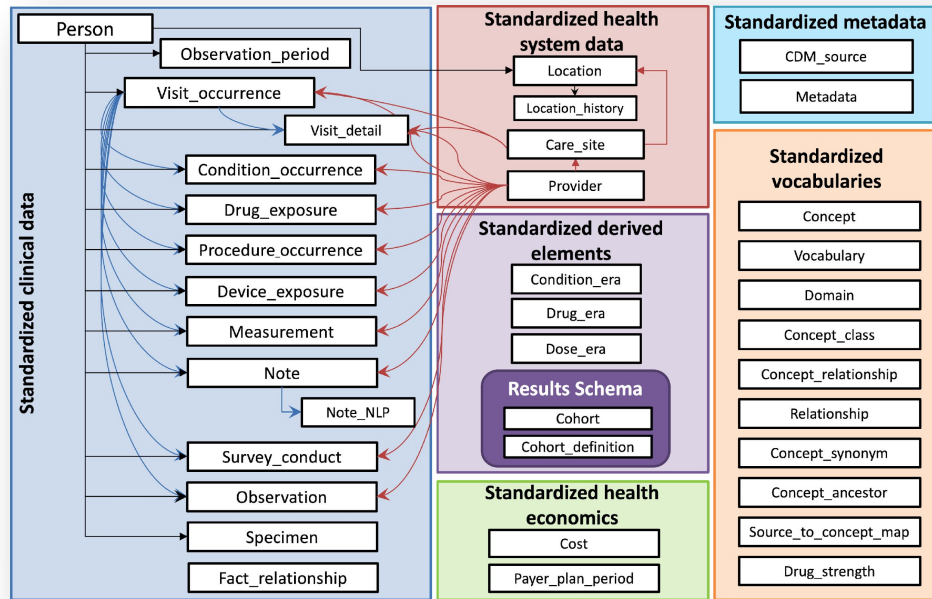


# Structural extension: Modifier - example

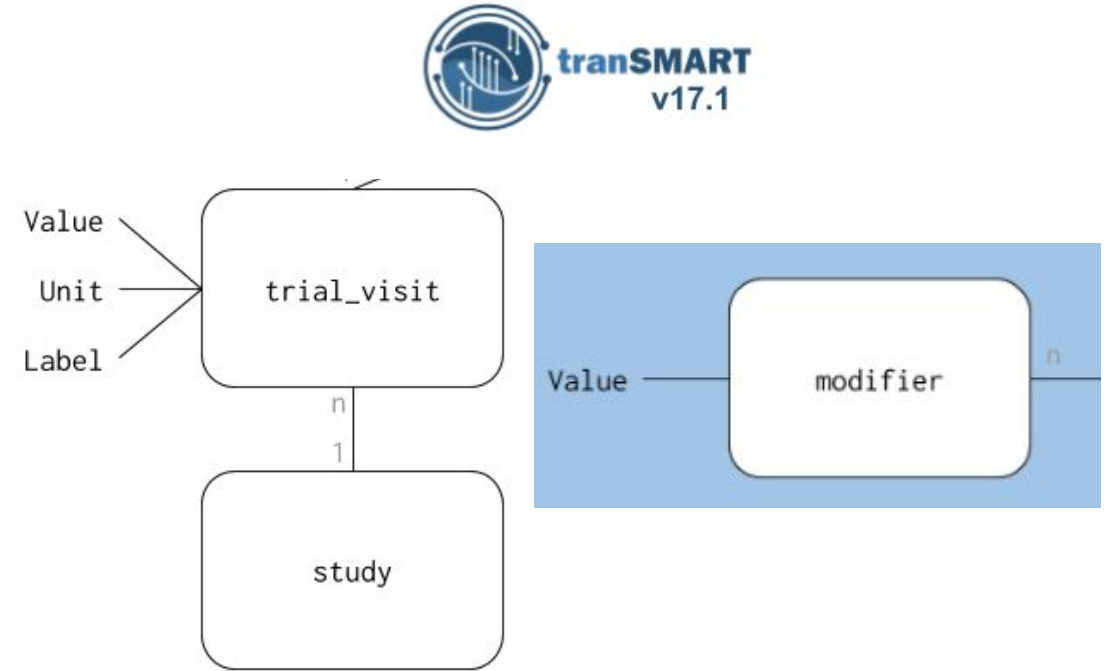
Fieldname	Value	OMOP fit (condition)
IT.USUBJID	'CDISC01.100008'	✓
IT.TV.VISIT	'WEEK 2'	✓
IT.AE.AESTDY	84	✓
IT.AE.AEDECOD	'Nausea'	✓ SNOMED CT
IT.AE.AESEV	'MODERATE'	✗
IT.AE.AEREL	'POSSIBLY RELATED'	✗



# Conclusion



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We empower scientists by building on open source software