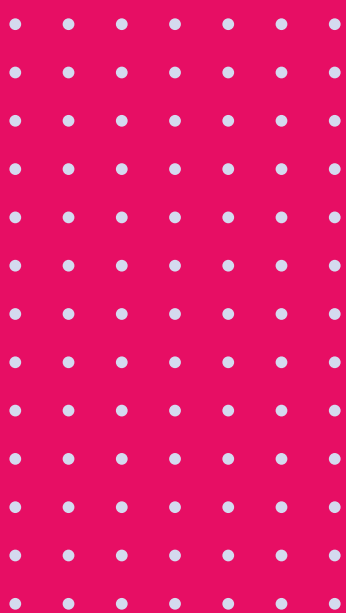




End-to-end automation using a model-driven development (MDD) workbench

Ceci n'est pas une présentation

Stuart Malcolm
Head of Standards, Efficiency and Automation
Veramed.

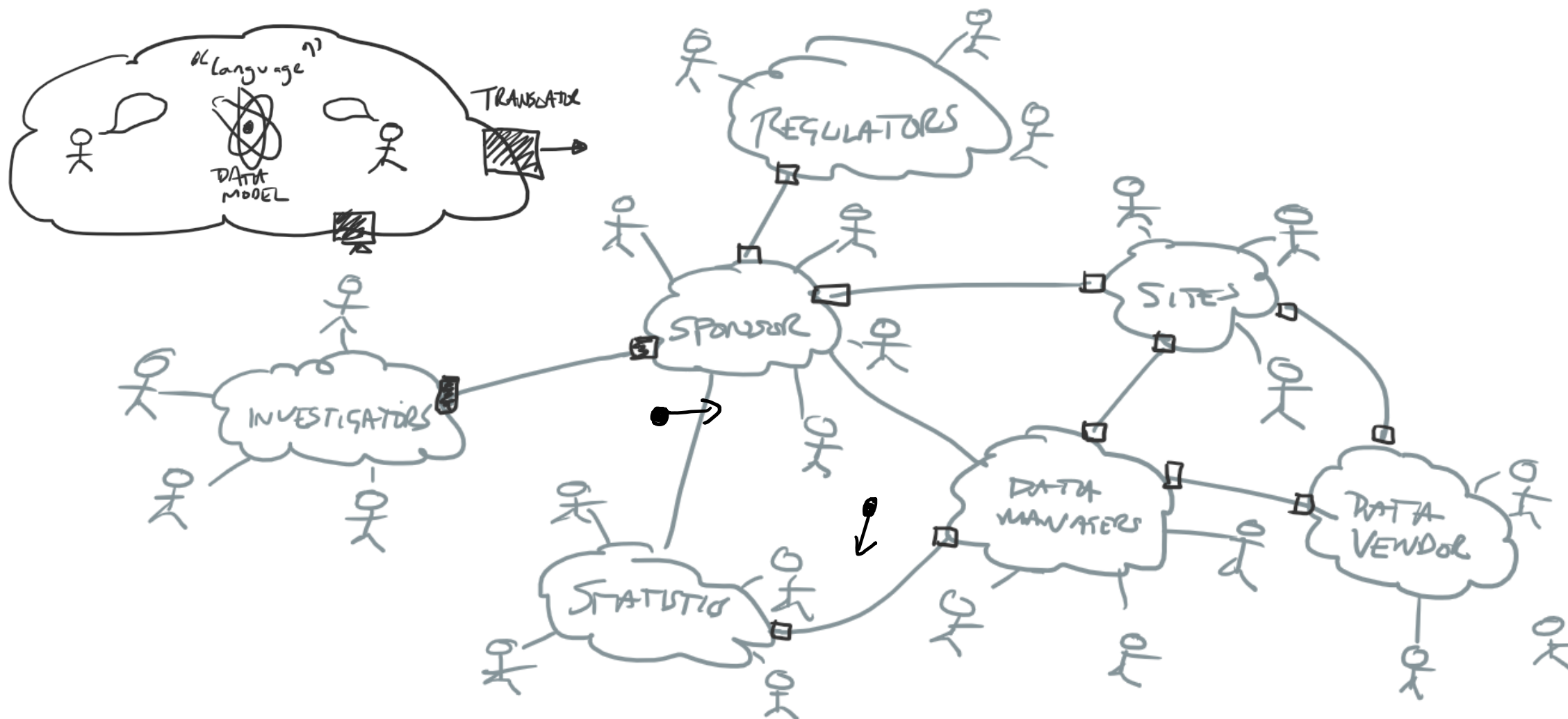
AD09 PHUSE EU Connect 2024





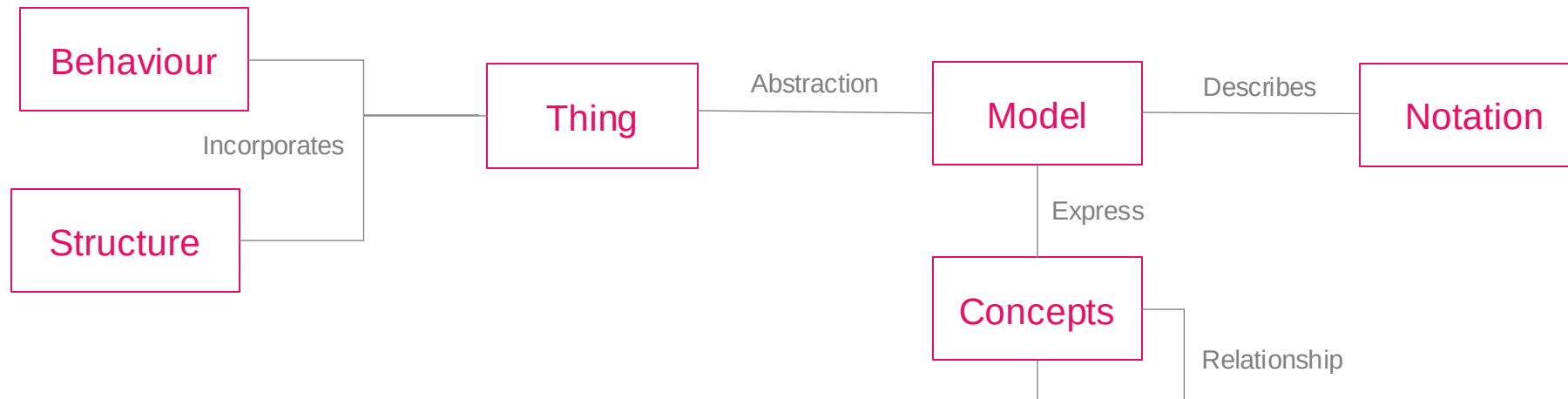
Ceci n'est pas une pipe.

Ceci n'est pas une CLINICAL TRIAL



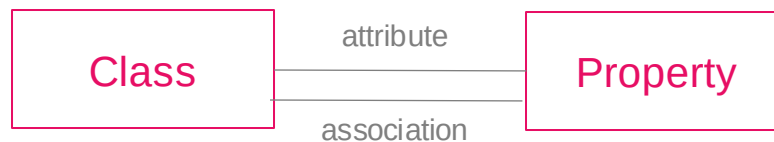
What is a model?

- [**mod-I**] **noun**; abstraction of things in the real world that incorporates both behavior and structure
 - aims to express the meaning of terms and concepts used by domain experts to discuss the problem
 - ..and to find the correct relationships between different concepts
 - ..is described using defined notation



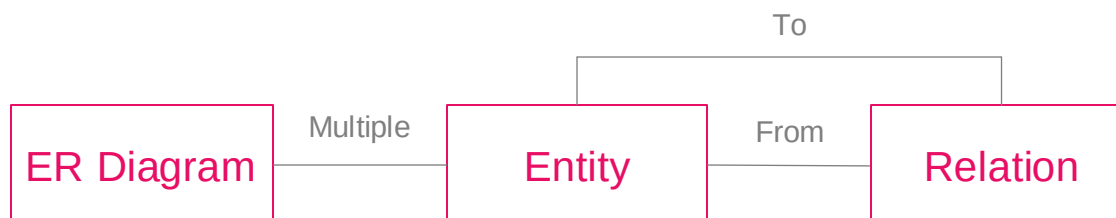
Ceci n'est pas une MODEL

M3



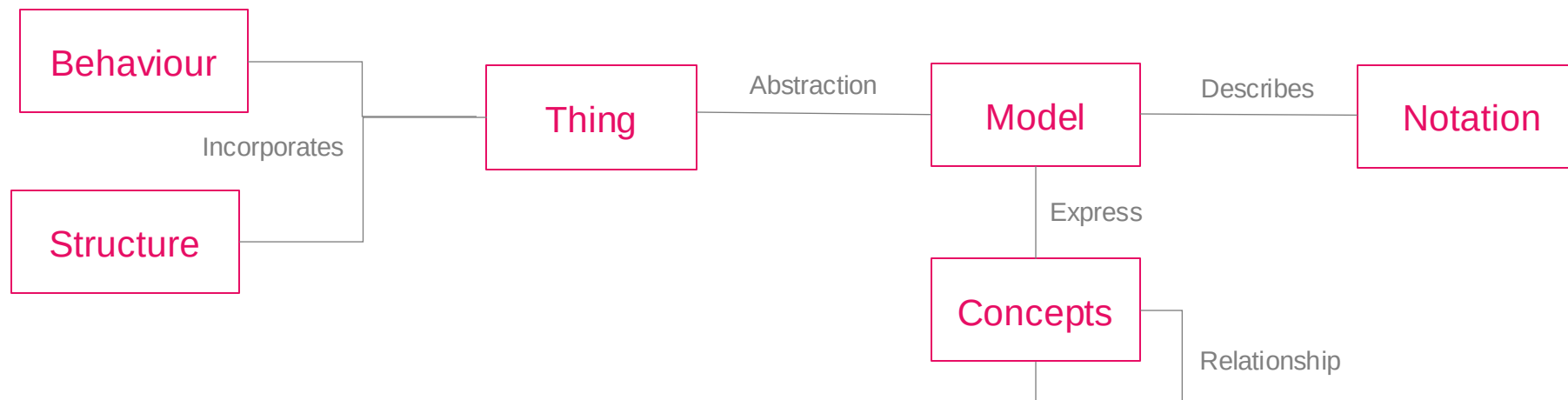
META
META
MODEL

M2



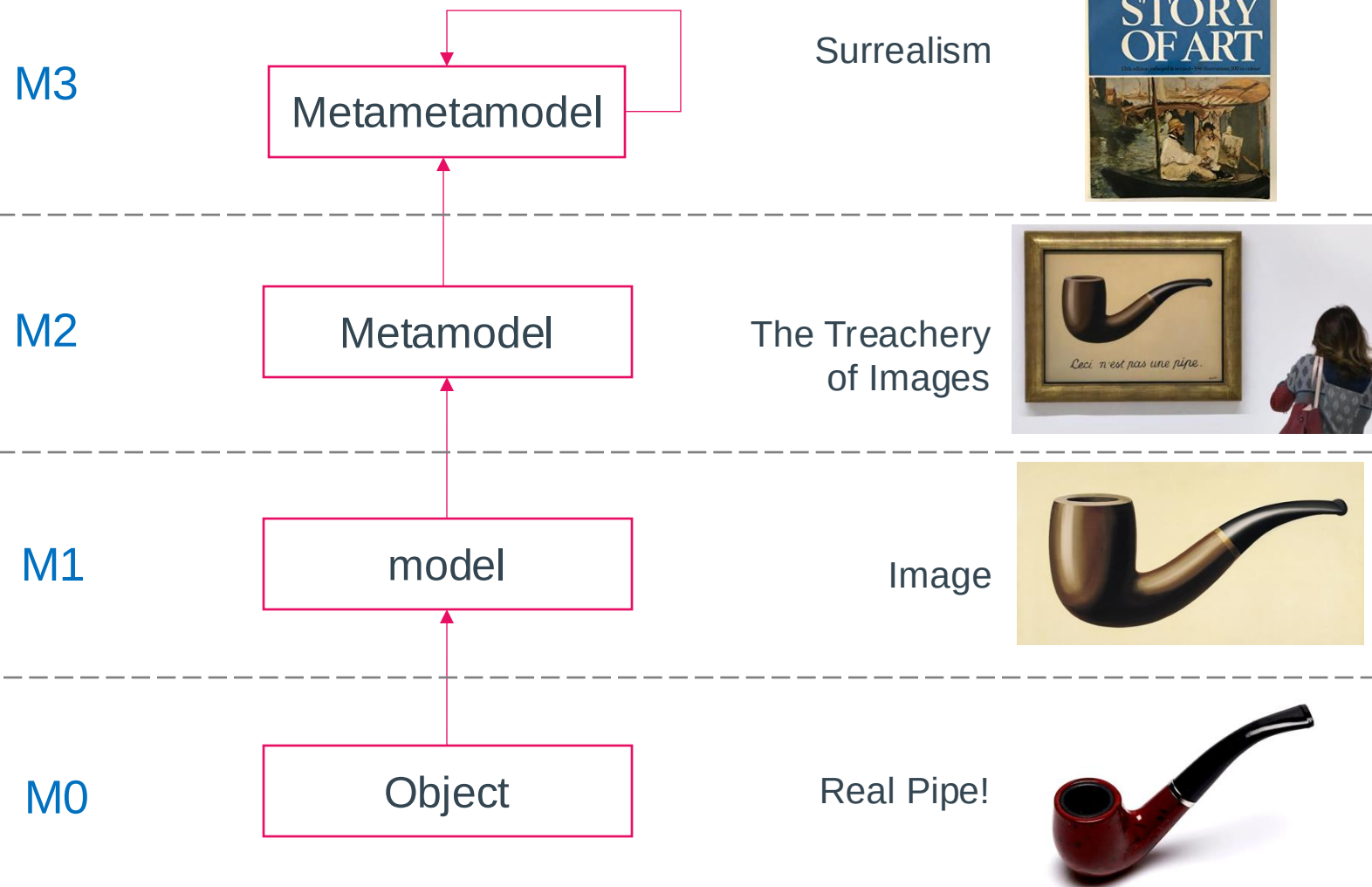
META
MODEL

M1



MODEL

Ceci n'est pas une MODEL



Ceci n'est pas une CLINICAL TRIAL

M3

Metametamodel

Standard

Modelling
Framework



M2

Metamodel

Metadata

Modelling
Language

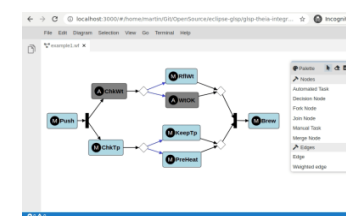


M1

model

Data

Modelling
Workbench



STUDYID	DOMAIN	USUBJID	SUBJID	W1STRTC	W1ENDC	W2STRTC	W2ENDC
X12	DM	X12101	101	2017-05-16T00:25	2017-05-11	2017-05-16T00:25	
X12	DM	X12102	102	2018-05-16T00:36		2018-05-16T00:36	
X12	DM	X12103	103	2018-04-24T00:39		2018-04-24T00:39	
X12	DM	X12104	104	2017-05-16T00:25	2017-05-20	2017-05-16T00:25	
X12	DM	X12105	105	2018-05-28T00:02		2018-05-28T00:02	
X12	DM	X12106	106				
X12	DM	X12107	107				
X12	DM	X12108	108	2017-11-29T00:18	2018-02-27	2017-11-29T00:18	
X12	DM	X12109	109				
X12	DM	X12110	110	2018-06-20T00:23		2018-06-20T00:23	
X12	DM	X12111	111				
X12	DM	X12112	112	2017-10-10T00:00	2017-05-23	2017-10-10T00:00	
X12	DM	X12113	113	2018-02-16T00:40	2018-02-19	2018-02-16T00:40	
X12	DM	X12114	114				
X12	DM	X12115	115				
X12	DM	X12116	116	2018-05-23T00:40		2018-05-23T00:40	

M0

Object



Clinical Trial

2 Model Concepts and Terms – Organization of the SDTM

The SDTM provides a general framework for describing the organization of information collected during human and animal studies. The model is built around the concept of *observations*, which consist of discrete pieces of information collected during a study. Observations normally correspond to rows in a dataset. A *domain* is a collection of observations on a particular topic (see Concept Map, below). For example, "Subject 101 had an adverse event of mild nausea starting on study day 6" is an observation belonging to the Adverse Events domain in a clinical trial.

The primary purpose of the SDTM is to represent data about study subjects—which may be humans or animals—or medical devices. The SDTM includes a general model for representing data in 3 "general observation" classes. Within those classes, data are grouped by topic into domains, represented in separate datasets. The 3 general observation classes (i.e., Interventions, Events, Findings) are described further in Section 3.1, [The General Observation Classes](#). Additional special-purpose datasets about individuals are described in Section 3.2, [Special-purpose Domains](#).

2.1 Model Concepts and Terms – Variables

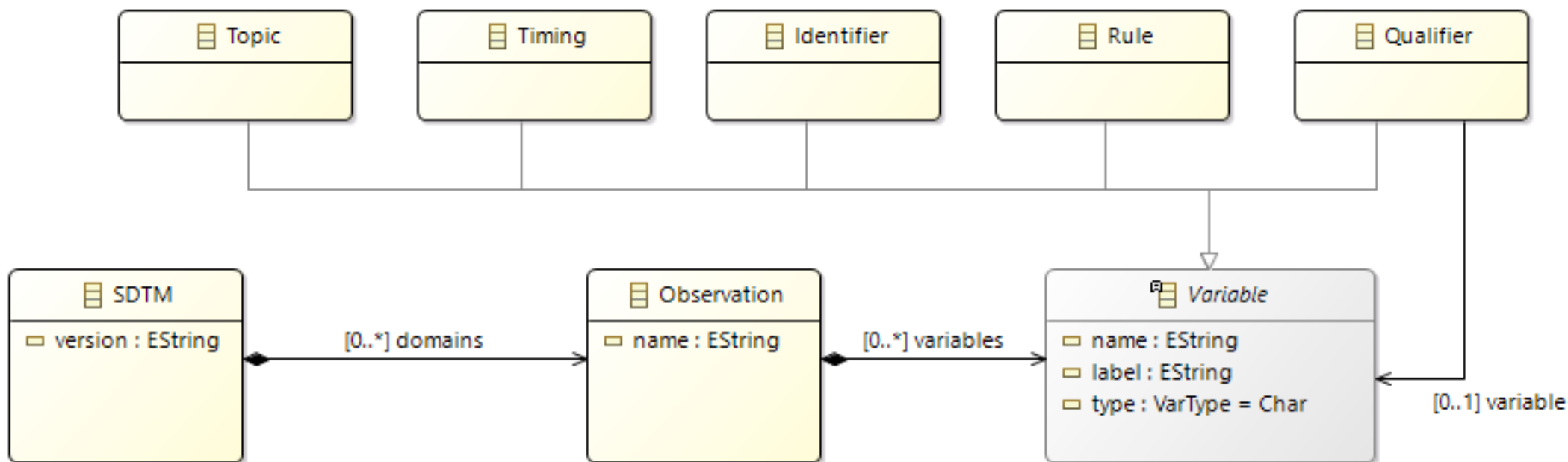
All datasets are structured as flat files with rows representing observations and columns representing variables; each dataset is described by metadata definitions that provide information about the variables used in the dataset.

Metadata are described in the CDISC Define-XML specification, available at <https://www.cdisc.org/standards/data-exchange/define-xml>.

Each observation consists of a series of named **variables**. Each variable, which normally corresponds to a column in a dataset, can be classified according to its role. A *role* describes the type of information conveyed by the variable about each distinct observation and how it can be used. There are variables which play different roles in different datasets. This is most common for variables which appear in both trial design datasets and general observation class datasets. For example, ARMCD is the topic variable in Trial Arms (TA), but a record qualifier in Demographics (DM) and Trial Visits (TV). Variables which appear in multiple general observation classes have the same role, although the variable qualified by a variable qualifier or synonym qualifier can be different in different general observation classes. For example, --MODIFY qualifies --TRT in interventions, --TERM in events, and --ORRES in findings.

SDTM variables can be classified into **5 major roles**:

Structure of Standard Data Tabulation Model





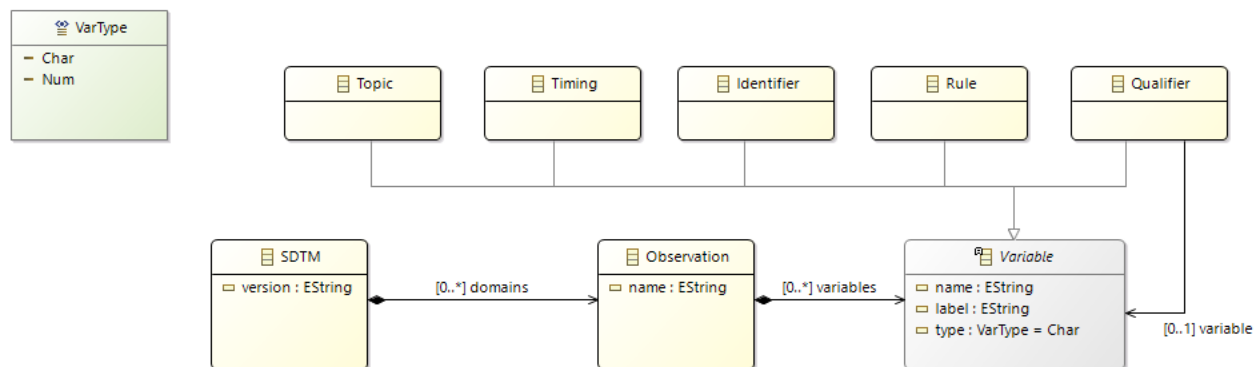
Model Explorer

type filter text

- > arctica.model.dataset.model
- > arctica.model.dataset.model.edit
- > arctica.model.dataset.model.editor
- > arctica.workbench.pipeline.dsl
- > arctica.workbench.pipeline.dsl.ide
- > arctica.workbench.pipeline.dsl.tests
- > arctica.workbench.pipeline.dsl.ui
- > arctica.workbench.pipeline.dsl.ui.tests
- > arctical.model.dataset.dsl
- > arctical.model.dataset.dsl.ide
- > arctical.model.dataset.dsl.tests
- > arctical.model.dataset.dsl.ui
- > arctical.model.dataset.dsl.ui.tests
- > demo1.sdtm.model
- > demo1.sdtm.model.edit
- > demo1.sdtm.model.editor
- > demo2.sdtm.model
 - Project Dependencies
 - > src [in demo2.sdtm.model]
 - > JRE System Library [JavaSE-17]
 - > Plug-in Dependencies
 - > META-INF
 - > model
 - > sdtm.aird
 - > sdtm.ecore
 - > sdtm
 - > sdtm
 - > Observation
 - > Variable
 - > VarType
 - Topic -> Variable
 - Qualifier -> Variable
 - Identifier -> Variable
 - Rule -> Variable
 - Timing -> Variable

model class diagram sdtm model

100%



- Navigate
- Edit
- Refresh F5
- Unsynchronized
- Export diagram as image
- Show/Hide
- Select
- Layout
- Reset Origin Ctrl+Home
- Validate diagram
- Find Ctrl+Alt+Shift+F
- Quick search Ctrl+O
- Profiles
- Show EClass information
- Show References
- OCL
- Generate
 - All
 - Model Code
 - Edit Code
 - Editor Code
- CDO Native
- Add Related Elements
- Open User Guide
- Remove from Context Ctrl+Alt+Shift+Down

Palette

- Existing Elements
 - Add
 - Remove
- Classifier
 - Class
 - Datatype
 - Enumeration
 - ETypeParameter
- Feature
 - Literal
 - Operation
 - Attribute
- Relation
 - SuperType
 - Reference
 - Bi-directional Reference
 - Composition
- Dynamic
 - Dynamic instance
- Package

Properties

sdtm

Ecore

Documentation

Annotation

Generation

Rulers & Grid

Name: ? sdtm

Ns URI: ? http://www.example.org/sdtm

Ns Prefix: ? sdtm

Problems

Git Repositories

Git Staging

Console

Templates

No consoles to display at this time.

Editors generated from the model

*My.sdtm

Resource Set

platform:/resource/demo2/My.sdtm

SDTM 2.0

Observation Interventions

Topic TRT

Qualifier MODIFY

Qualifier DECOD

Qualifier MOOD

Qualifier CAT

Qualifier SCAT

Observation Events

Observation Findings

Properties

Property	Value
Label	Standardized Treatment Name
Name	DECOD
Type	Char
Variable	Topic TRT Qualifier CAT Qualifier DECOD Qualifier MODIFY Qualifier MOOD Qualifier SCAT Topic TRT



Project Ex... x *foo.sdtm x

demo2
foo.sdtm
My.sdtm

Model Exp... x

No Model Available

Outline x

2.0
Interventions
TRT
MODIFY
DECOD

```
/*
 * SDTM v2.0 example
 */
SDTM {
  version "2.0" // version number
  domains {
    Observation "Interventions" {
      variables {
        Topic "TRT" {
          label "Name of Treatment"
          type Float
        },
        Qualifier "MODIFY" {
          label "Modified Treatment Name"
          type Char
          variable TRT
        },
        Qualifier "DECODE" {
          label "Standardized Treatment Name"
          type Char
          variable TRT
        }
      }
    }
  }
}
```

- ◆ DECOD - Interventions.DECOD
- ◆ MODIFY - Interventions.MODIFY
- ◆ TRT - Interventions.TRT

Topic TRT

Press 'F2' for focus

Writable

Insert

16 : 33 [3]



EXPLORER



Terminal 9 X



> OPEN EDITORS

WORKSPACE

.gitignore

.gitkeep

clean.sh

init.sh

README.md

theia@c70fd3b39d46:/home/project/workspace\$

I



Summary

Model-driven development as an agile approach to standards-based automation throughout the clinical research lifecycle.

Model



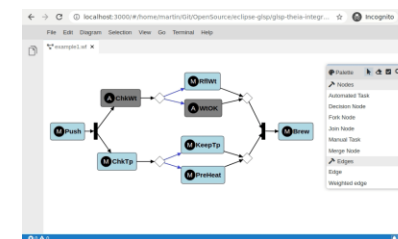
- Definition of a Model
- Domain Experts
- Levels of Abstraction

Driven



- Standard Notation
- Structure and Behaviour
- Machine Readable

Development



- CDISC Example
- Editor Generator
- Code Generator

Thanks!

Questions?

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<https://www.linkedin.com/in/stuart-malcolm/>

