

An Industry Ontology for the Identification of Medicinal Products (IDMP)

OMG 2022 Q2 TC Meeting



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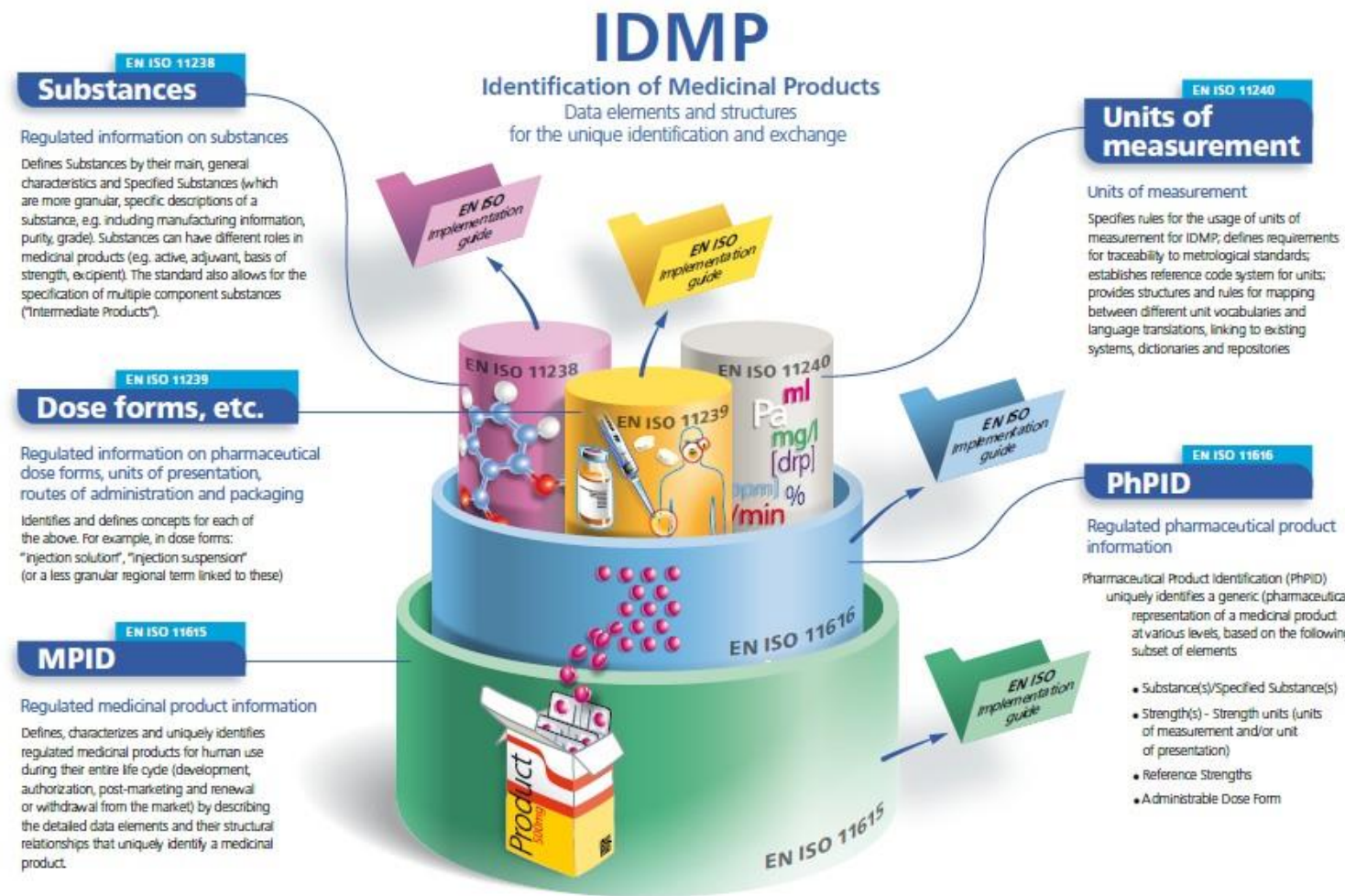
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Agenda

1. Intro to ISO IDMP and the Project
2. Pharma Use Cases
3. IDMP Ontology
 - Ontology Modelling Approach
 - Example Modelling Patterns
4. Demo of the Ontology Usage
5. Q&A



ISO Standard: Identification of Medicinal Products



The ISO standards for Identification of Medicinal Products (IDMP) provide an internationally accepted framework to uniquely identify and describe medicinal products. Driven by regulatory requirements, the role of IDMP is to align the pharmaceutical industry on data standards around product and substance information.

Problem Statement: Diverging IDMP implementations are a risk

Diverging implementations are likely to lead to huge integration and interoperability costs and data consistency issues

- Inconsistencies of interpretation by implementing organizations
- Diverging implementation of IDMP across regions and jurisdictional domains
- Missing semantic alignment between regulatory implementations
- Essential governance of the IDMP standards and implementations is not assigned to a specific overarching governing body



IDMP Ontology Project

April-October 2022: MVP Implementation Phase 1

Value Proposition:

Build an IDMP Ontology that enables deep, semantic interoperability based on FAIR data principles to augment the existing ISO IDMP standards of the European Medical Agency.

Project Deliverables defined by Steering Committee:

The phase 1 goal in 2022 is to create an MVP (Minimal viable product) ontology that demonstrates the added value to the ISO IDMP standards for data usability and advanced collaboration across organizational boundaries and regulatory jurisdictions.

Project Champions:

- Sheila Elz, Bayer
- Joerg Werner, Merck KGaA
- Jean-Gonzague Fontaine, GSK

Project Manager:

Gerhard Noelken



Sponsoring Organizations:

\$50K per year ensures a seat on the Steering Committee



MERCK



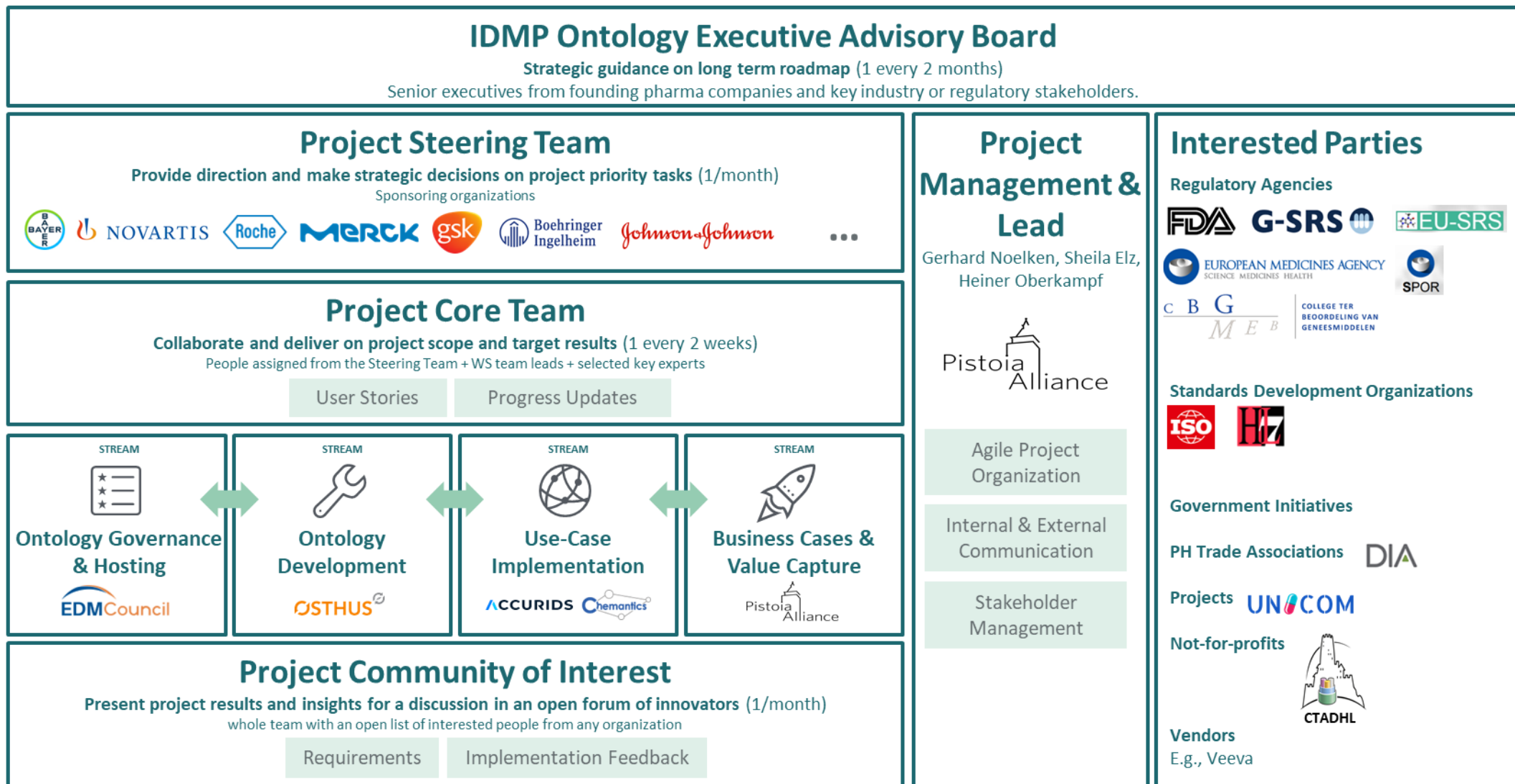
NOVARTIS



Typical Project Member Roles:

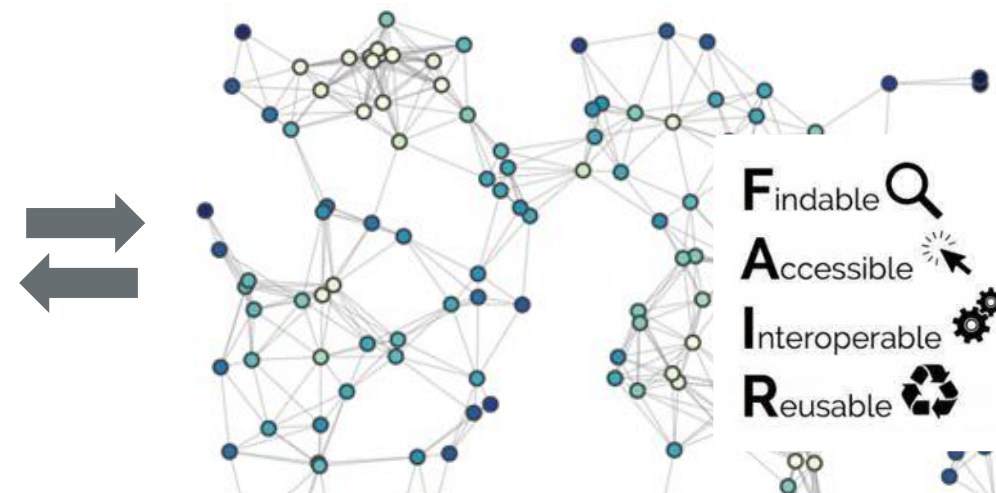
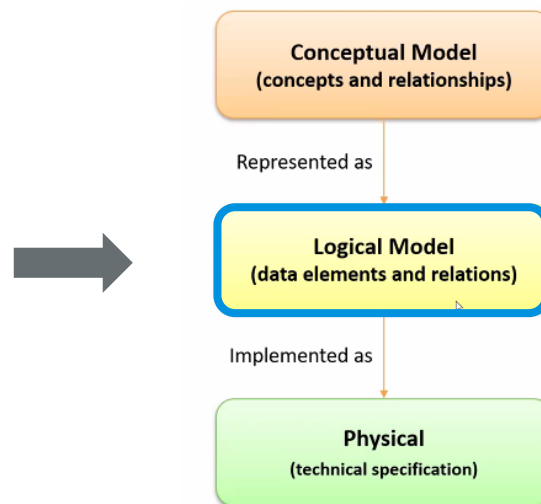
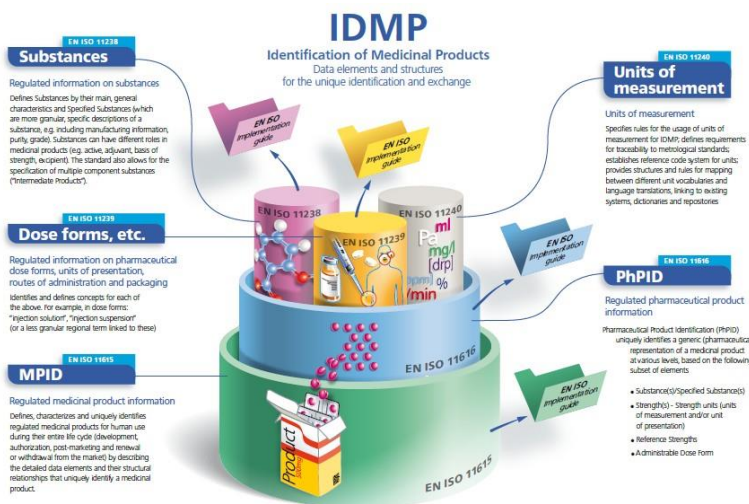
Master Data Manager, Corporate Data Owner, Regulatory Affairs, Drug Safety/ PV, Ontologist, FAIR Data Scientist

Project Setup for the Phase 1 Implementation



IDMP Ontology: Creating interoperability by design

Work together with the IDMP Logical Model to achieve a FAIR* semi-automatic implementation



ISO standards to ensure **patient safety** with unambiguous identification of medicinal products.



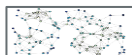
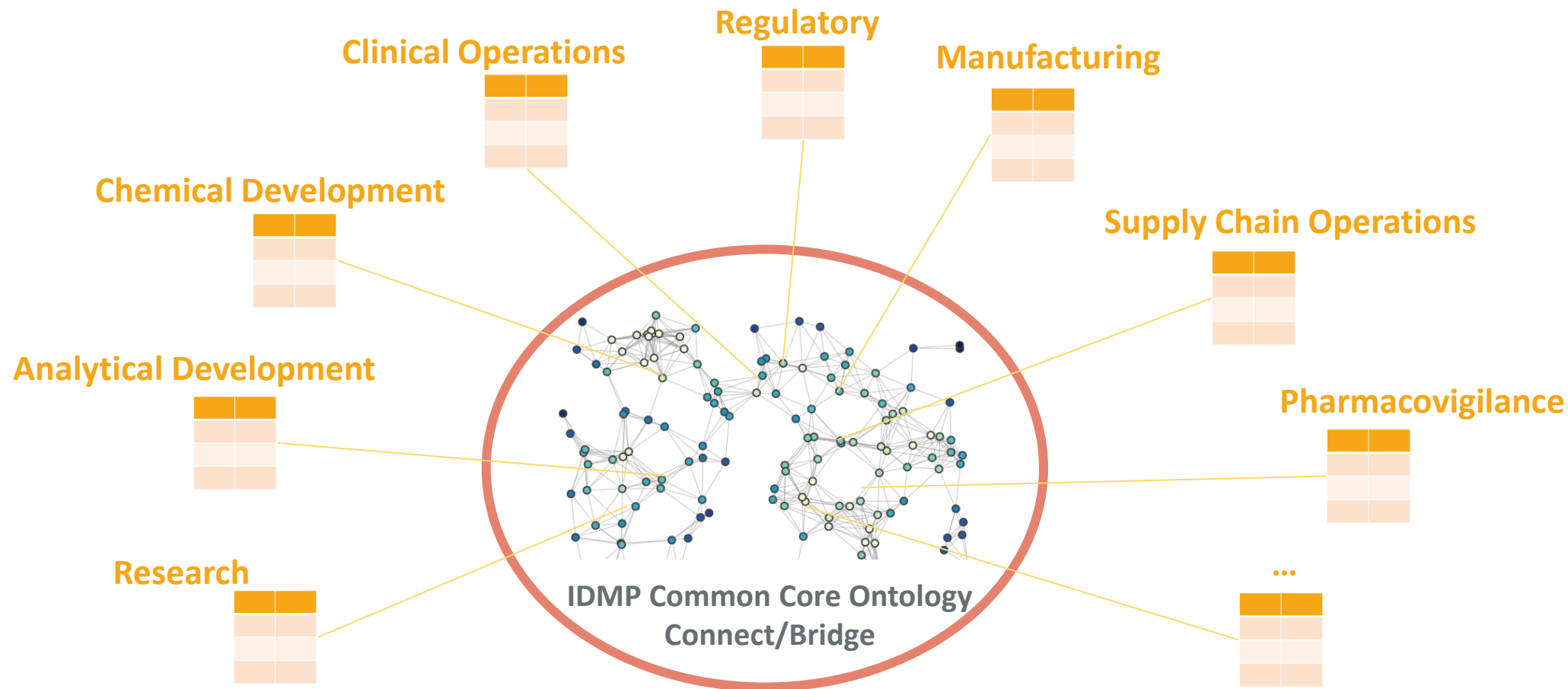
Facilitate **implementation** and **automate** connectivity with an agnostic data architecture.



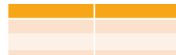
Enable **interoperability** and **connectivity** across regulatory jurisdictions with a **FAIR implementation**.

IDMP Common Core Ontology as the connecting bridge

Advancing cross-functional collaboration: Bridging different regional or functional perspectives on common substance-related data objects requires a well-defined common core ontology that connects the perspectives to global and scientifically objective representations.



Semantic Integration capturing the full complexity objectively with a scientifically correct model.



Simplified dimensions for efficient business operations in regional or functional settings. Local systems represent the reality in a pragmatic but incomplete or oversimplified way.



Use Case 1: Parent Substance – Clinical Use Case

In the context of a query by health authorities, the goal is to answer the question *“In which clinical trials were the substance X, ingredient in product Y registered in region <region Z> administered to patients?”*

Scenarios:

1. Link substance to manufactured item and medicinal product
2. Unambiguous identification of substance - gain and keep oversight of involved substance identifiers
3. Ingredient role mapping
4. ...

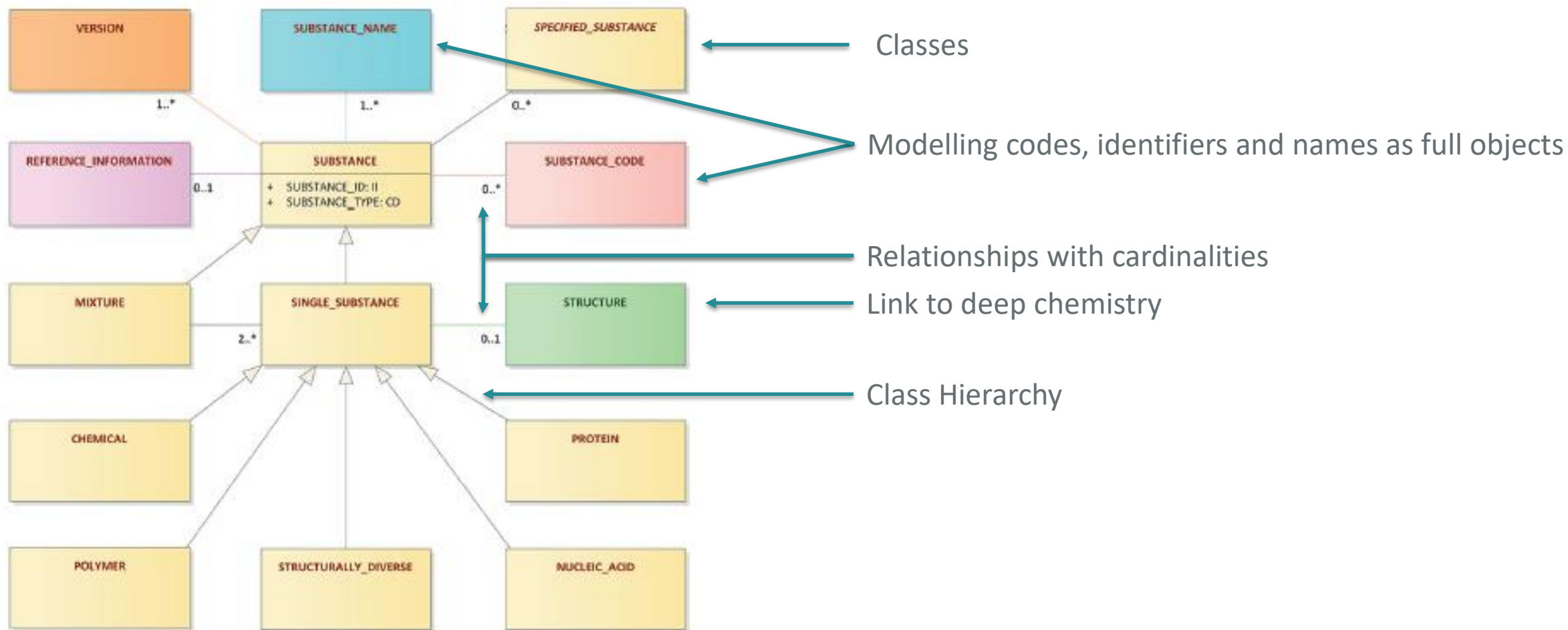
Competency Questions

1. Give me all substances that have a common active moiety <active moiety x>
2. What is the active moiety of <substance y>?
3. Which EV code (future SMS code) does the substance <substance> have?
4. What are the products that contain substances with common active moiety <active moiety x>?
5. In which clinical trials were the registered products administered?
6. Which investigational / authorized medicinal products contain the substance x and active moiety?
7. Which manufactured items contain substance <x> as ingredient of type “active”?
8. Which investigational medicinal products are related to this manufactured item?

IDMP Ontology

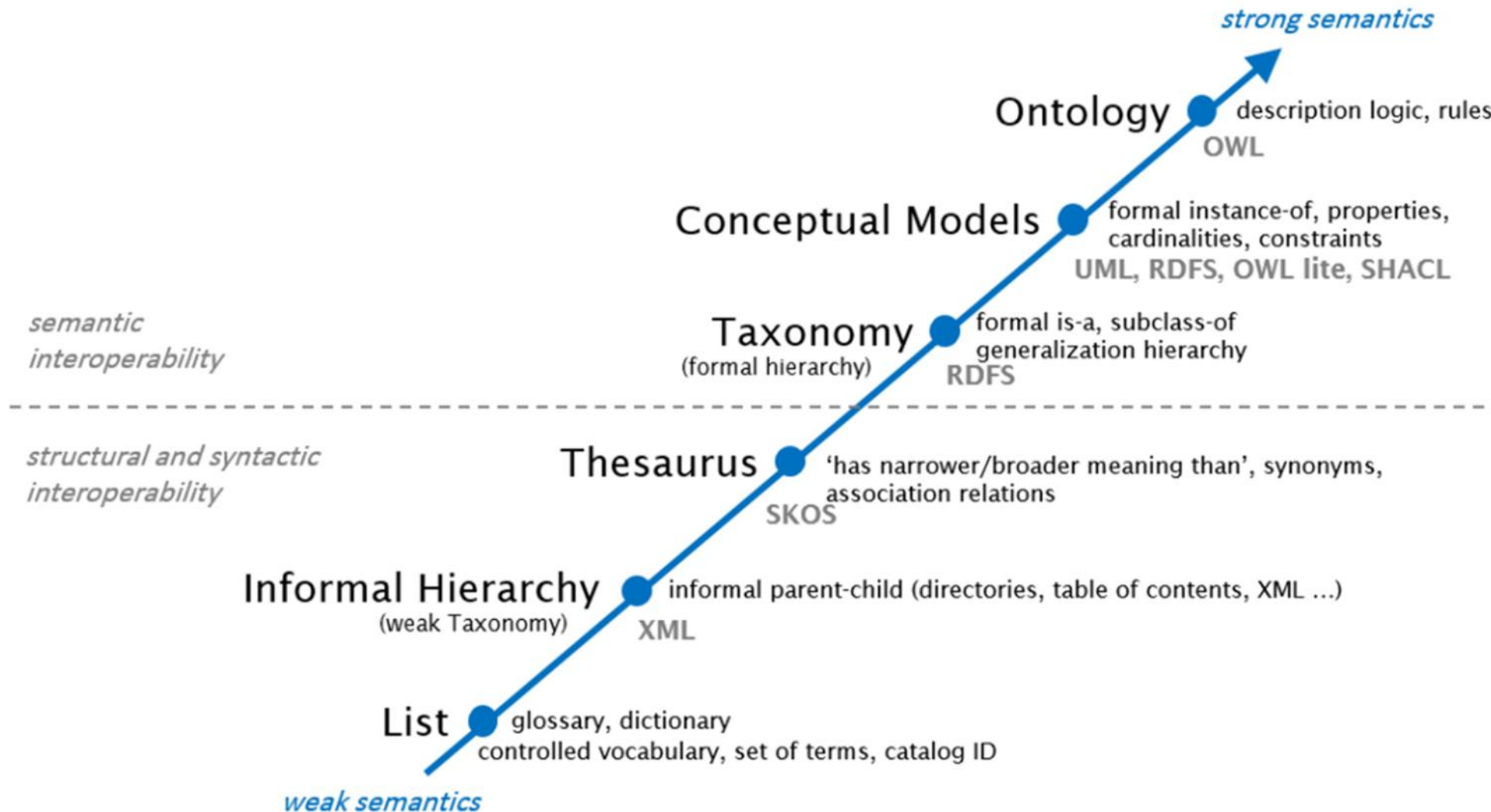
- Ontology Modelling Approach
- Example Modelling Patterns

From ISO Standards to an IDMP Ontology

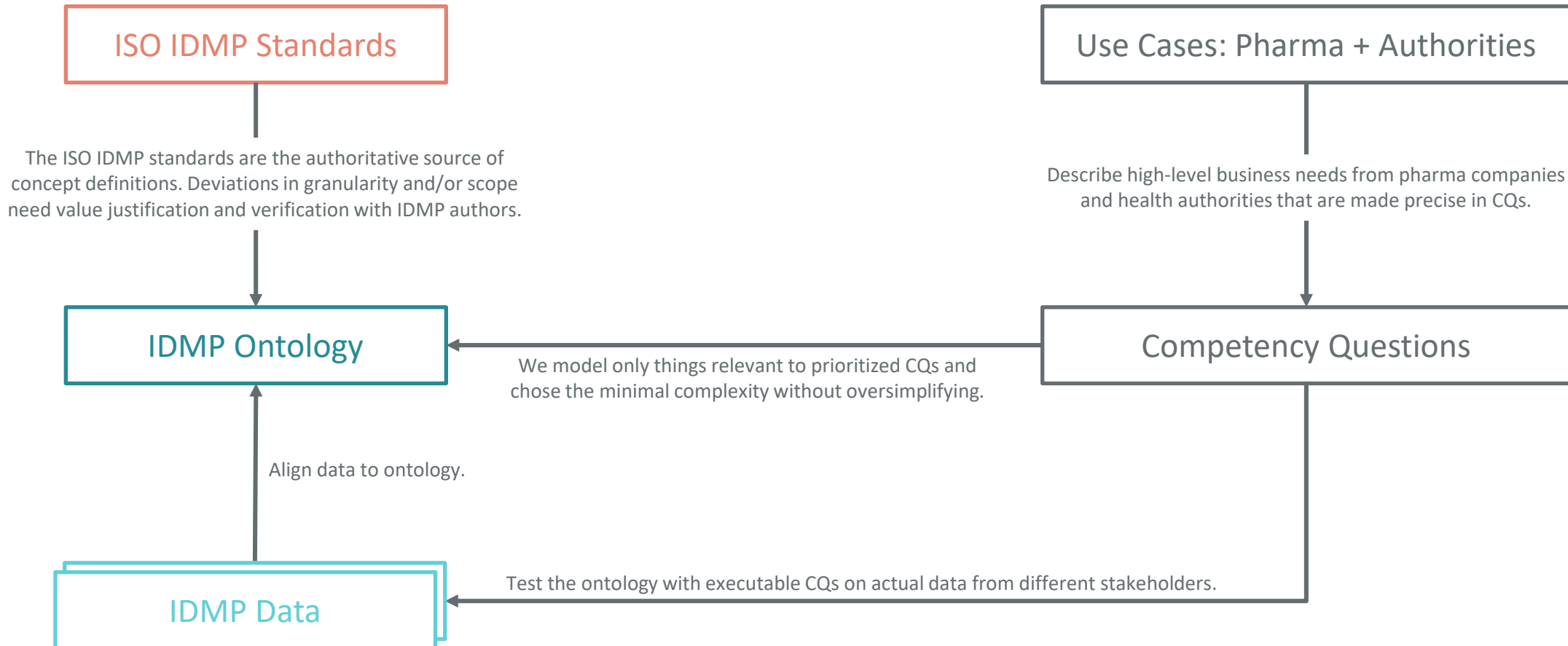


ISO 11238:2018 Data elements and structures for the unique identification and exchange of regulated information on substances

The Spectrum of Knowledge Organization Systems



High-level Ontology Modelling Approach



Modularized Approach for the IDMP Ontology

IDMP Ontology Alignments

The Connect to Related Standards & Data

IDMP Ontology

ISO 11238 Substance

Registration Authorities

ISO 11239 Dose Forms

ISO 11616 Pharmaceutical Product

ISO 11240 Units of Measurement

ISO 11615 Medicinal Product

...

The Modularized IDMP Ontology

Reused ISO Standards

Datatypes, Designators, Countries, Identifiers, Quantities and Units, etc.

ISO 21090 Harmonized Datatypes

Commons Ontologies



Our Foundational Ontology Patterns

Semantic Web Standards

RDF(S), OWL, SKOS, DCTerms

Our Modelling Framework

Persistent Identifier Policy

Addressing the 1st of the FAIR principles.

1 IDMP Ontology

<https://spec.pistoiaalliance.org/idmp/ontology/ISO/ISO11238-Substances/Stereochemistry>

base namespace

module

Further modules

ISO/ISO-11239-DoseForms

ISO/ISO-11240-UnitsOfMeasurement

ISO/ISO11615-MedicinalProducts

ISO/ISO11616-PharmaceuticalProducts

...

local identifier

Taken exactly from ISO standard
whenever possible

2 IDMP Data*

Adhering to the reuse principle from FAIR we create new persistent IDs only when they are not existing elsewhere reliably.

<https://data.pistoiaalliance.org/idmp/<authority>/<local-identifier>>

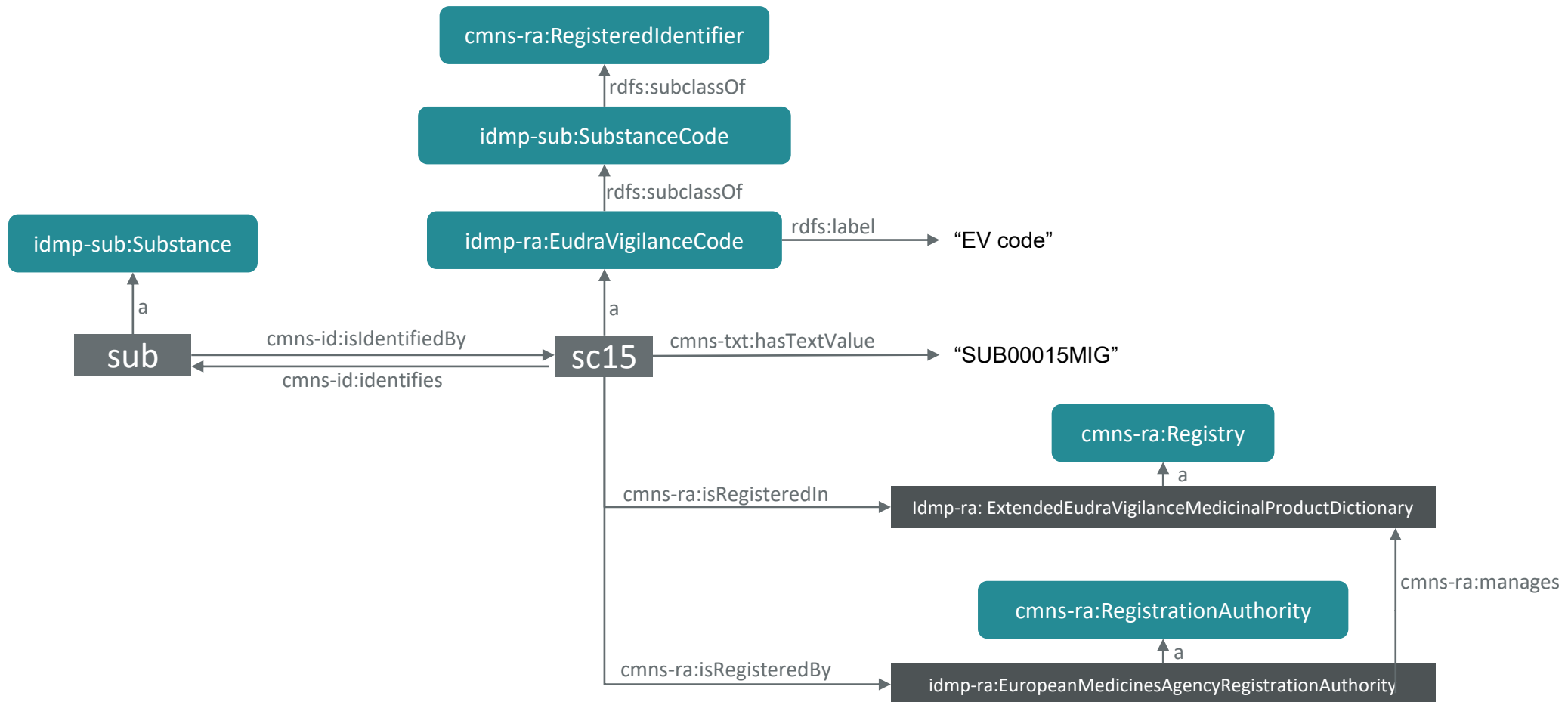
Imported Commons Ontologies

prefix cmns-id:	< https://www.omg.org/spec/Commons/Identifiers/ > .
prefix cmns-cds:	< https://www.omg.org/spec/Commons/CodesAndCodeSets/ > .
prefix cmns-clc:	< https://www.omg.org/spec/Commons/Classifiers/ > .
prefix cmns-col:	< https://www.omg.org/spec/Commons/Collections/ > .
prefix cmns-cstdsg:	< https://www.omg.org/spec/Commons/ContextualDesignators/ > .
prefix cmns-cxtid:	< https://www.omg.org/spec/Commons/ContextualIdentifiers/ > .
prefix cmns-dsg:	< https://www.omg.org/spec/Commons/Designators/ > .
prefix cmns-dt:	< https://www.omg.org/spec/Commons/DatesAndTimes/ > .
prefix cmns-prd:	< https://www.omg.org/spec/Commons/ProductsAndServices/ > .
prefix cmns-pts:	< https://www.omg.org/spec/Commons/PartiesAndSituations/ > .
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prefix cmns-ra:	< https://www.omg.org/spec/Commons/RegistrationAuthorities/ > .
prefix cmns-txt:	< https://www.omg.org/spec/Commons/TextDatatype/ > .



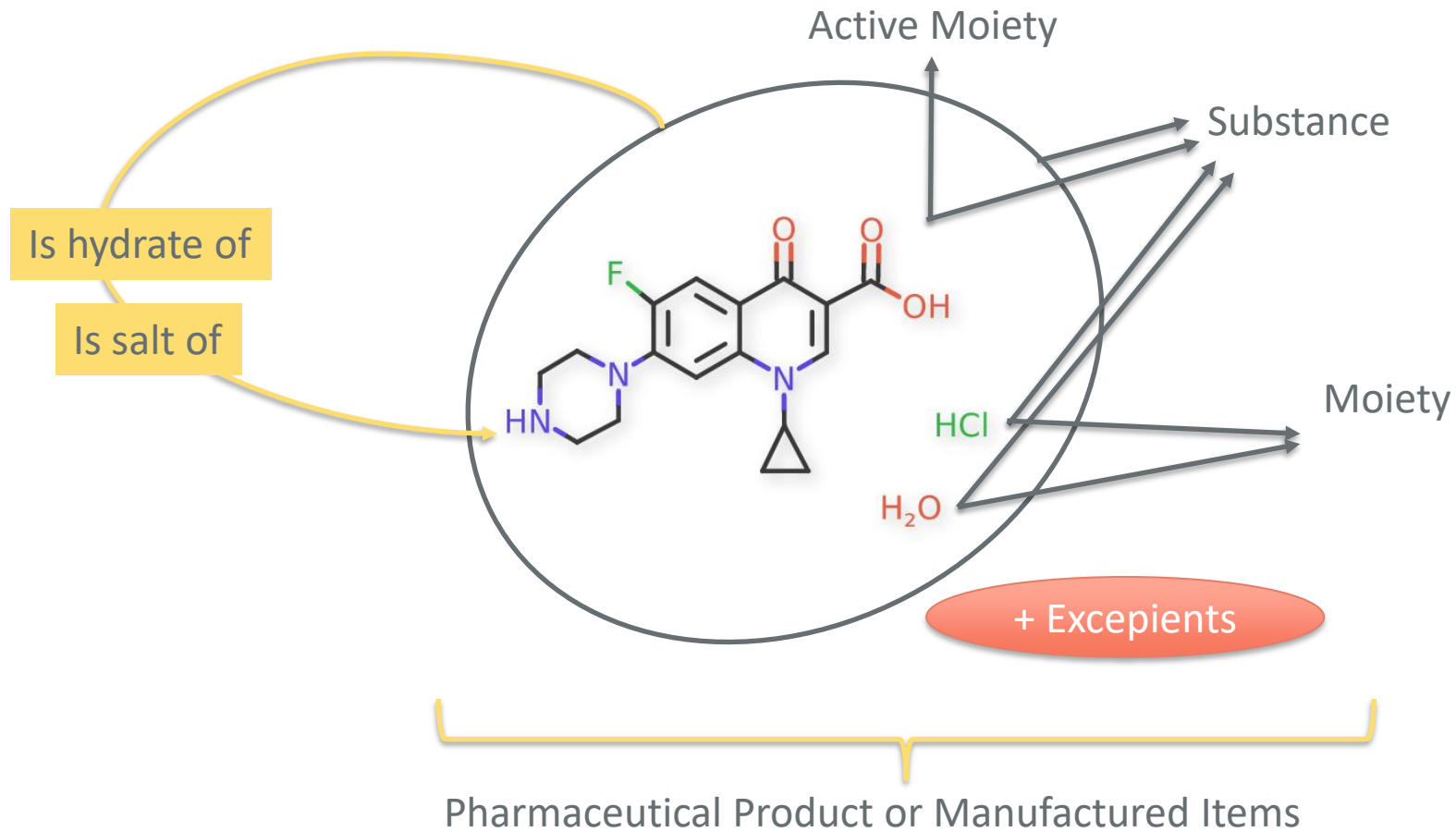
Reusing the Commons Ontologies allowed us to jump start the IDMP Ontology development and focus on pharma aspects.

Modelling Pattern for Codes & Registered Identifiers



cmns: Commons Namespace from OMG based on ISO standards

Active Moiety of a Substance: **CIPROFLOXACIN HYDROCHLORIDE**



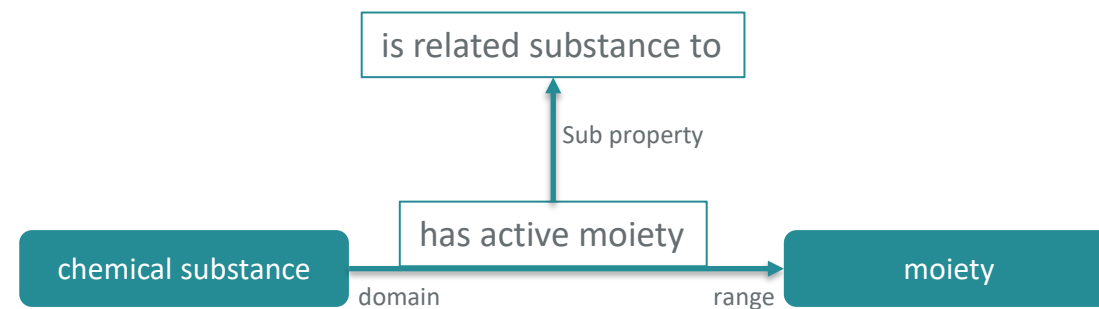
Modelling Active Moiety

ISO-11238

moiety = “Entity within a substance that has a complete and continuous molecular structure”

“The **active moiety** of a stoichiometric or non-stoichiometrical substance molecule is considered that part of the molecule that is the base, free acid or ion molecular part of a salt, solvate, chelate, clathrate, molecular complex or ester.”

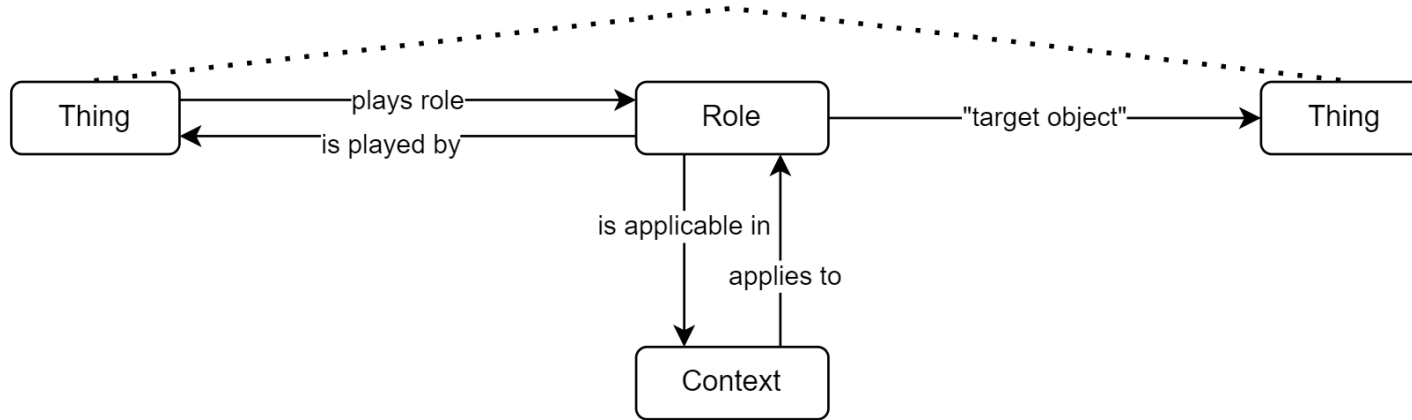
IDMP Ontology (DRAFT)



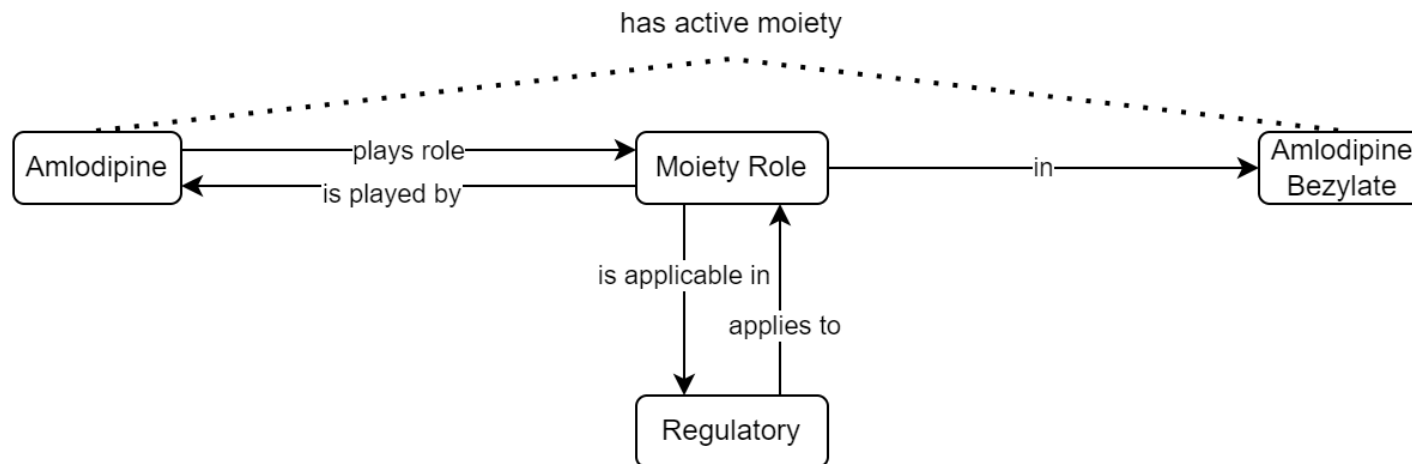
➔ **Found:** the naming and usage of the **active moiety** concept (aka ‘parent substance’) is different in different organizations or even within one organization. There are multiple different contexts, e.g., regulatory, chemical, biological. This requires IDMP refinement to disambiguate roles correctly.

General Pattern for Contextualized Roles

DRAFT



Generic



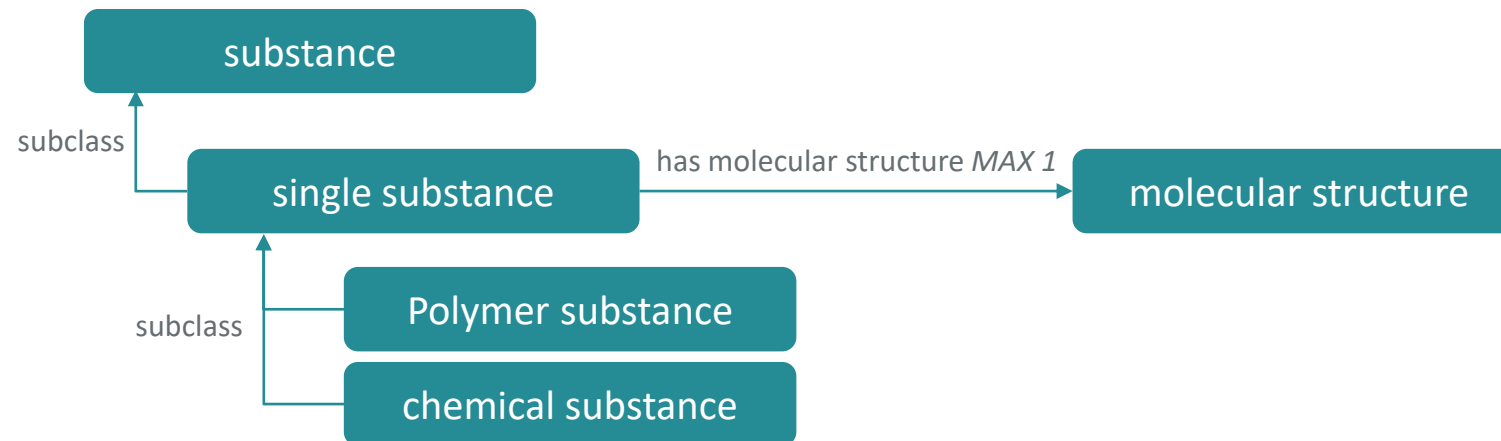
*Application for modelling
active moiety relationships*

IDMP Ontology + IDMP Data Graph

IDMP Ontology

Formal semantic definition of concepts, relationships and attributes from the ISO IDMP standards.

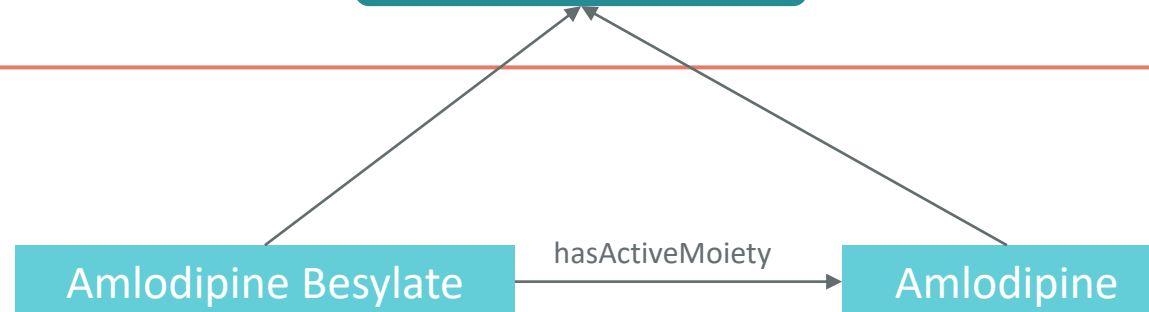
- *A few hundred concepts*
- *Need accurate and agreed patterns*



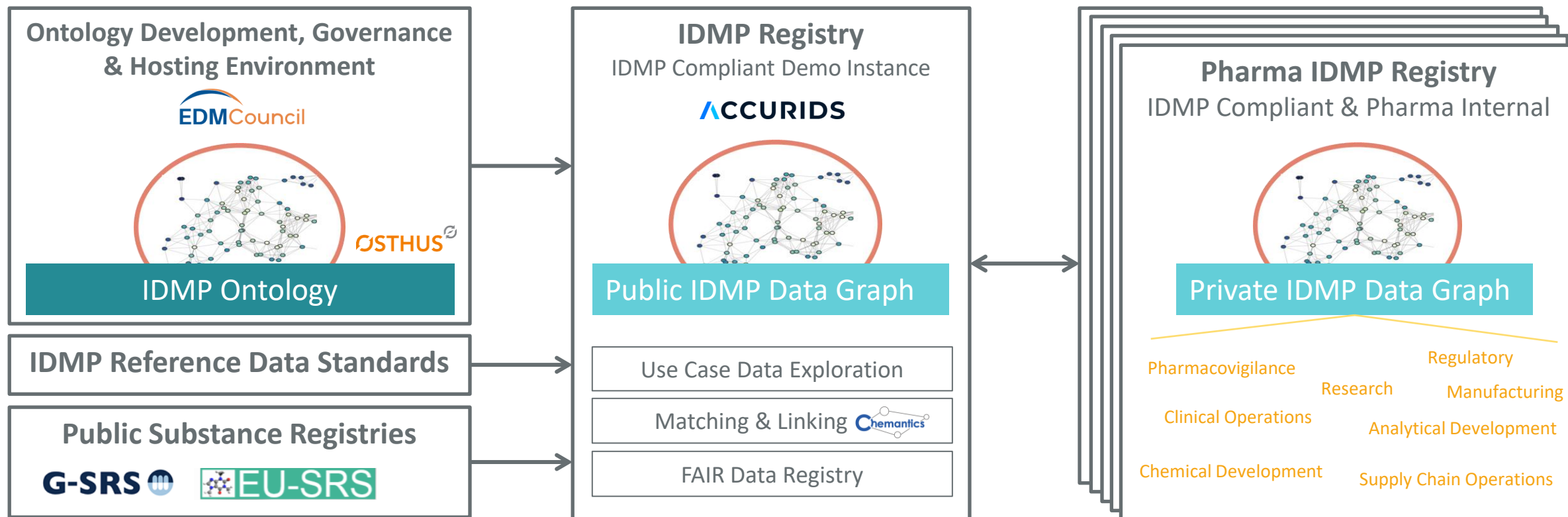
IDMP Data Graph

Any data object that are described by the concepts of the IDMP Ontology

- *Many millions of objects*
- *Our test data*



High-level Implementation Components



Demo

- IDMP Ontology
- Answer Competency Questions with data from FDA

Key Milestones



Consolidation of ontology pre-work & definition of foundational modelling patterns
May 2022



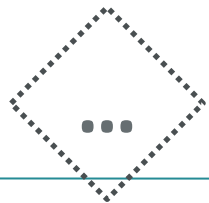
Draft ontology and first use case demos with publicly available data
July 2022



Governance use case & demo of at least 1 pharma implementation
August 2022



Project Delivery and Ontology MVP release
September 2022



Phase 2
From October/November 2022

Q&A



Learn More

www.pistoiaalliance.org



Contact Us

ProjectInquiries@PistoiaAlliance.org



Join the Initiative

IDMP Ontology