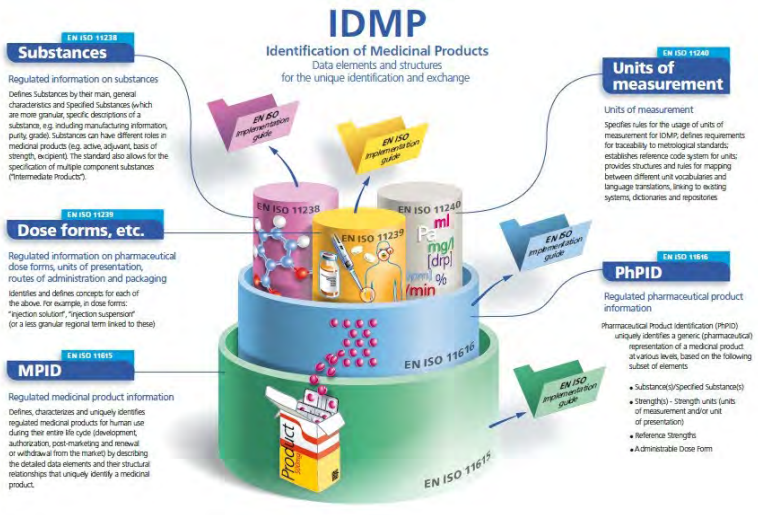
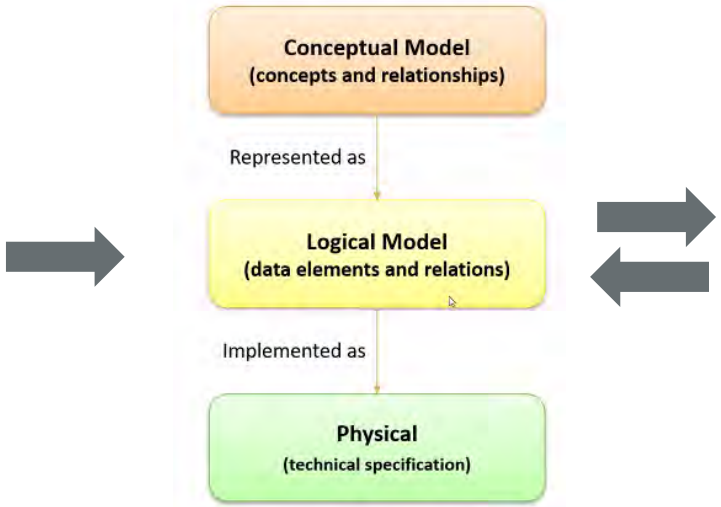
IDMP Common Core Ontology

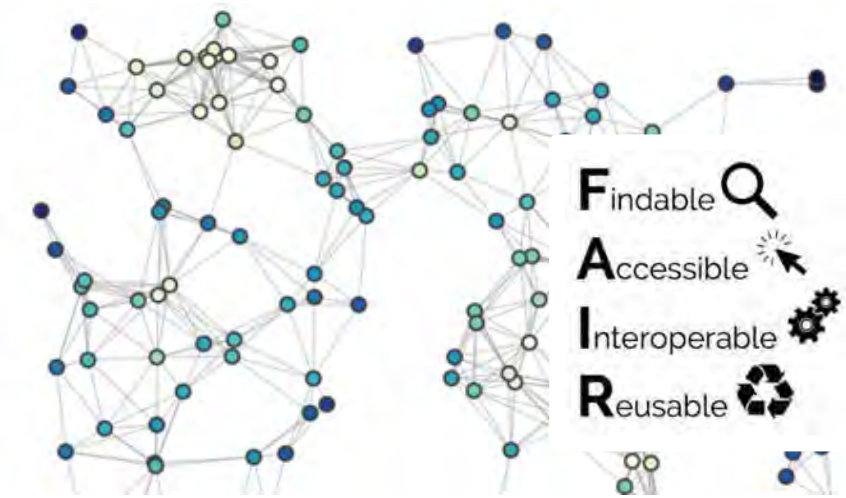
Info Package for the Cross-Industry Initiative

IDMP Common Core 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.

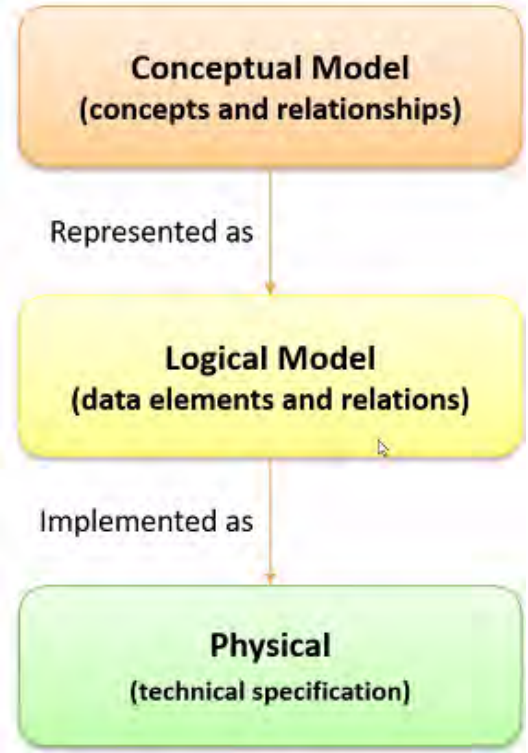
Facilitate implementation and **automate** connectivity with an agnostic data architecture.

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

IDMP Logical Model Requirements

IDMP Logical Model shall be related to relevant business processes

- **Definitions of elements** linked to a **single glossary** of terms referenced by the conceptual model
- **Describe** the structure of and the relations between the **data elements** supporting exchange of information related to **medicinal products**
- **Specify** the data types for the data elements and cardinality of the relations between groups of data elements.
- **Map** to other logical data models
- **Independent** of any **technology or implementation** environment



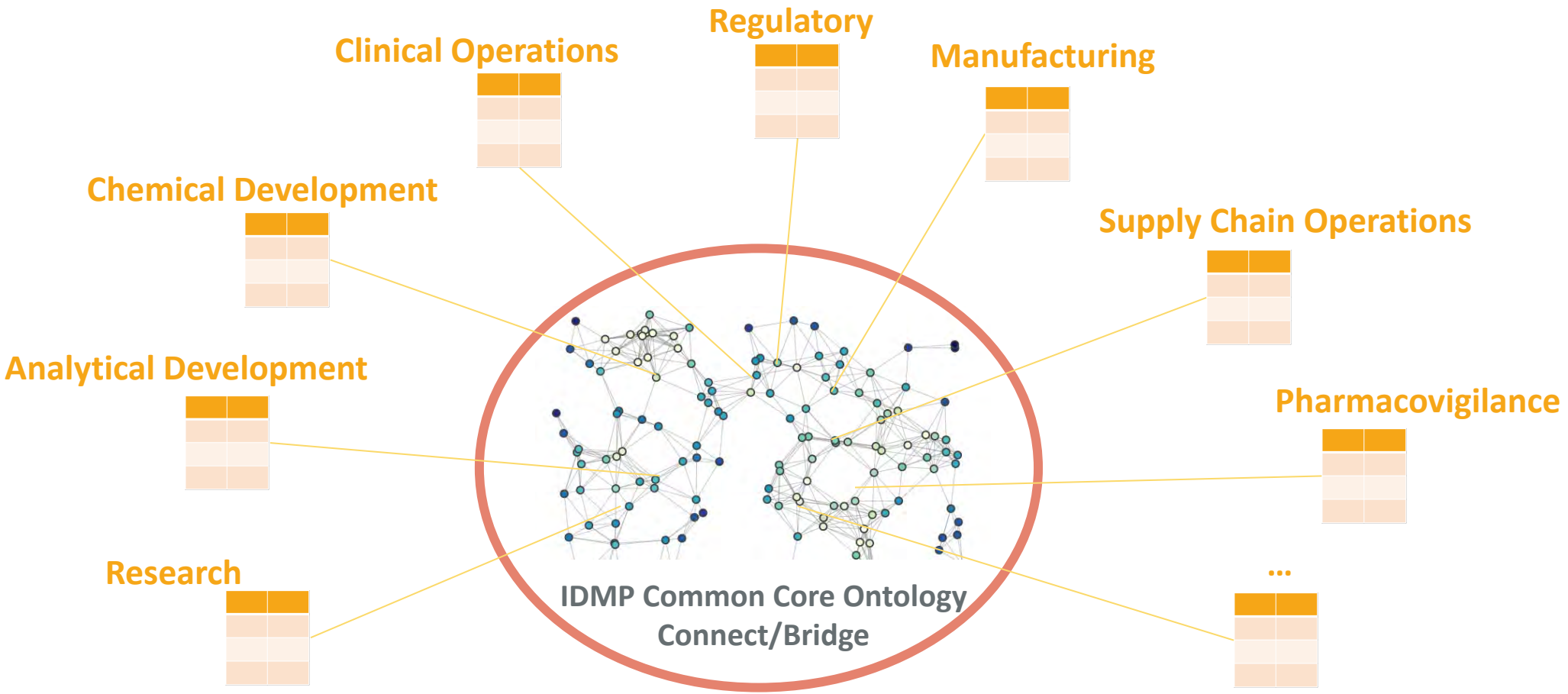
Project objectives and value proposition for the MVP

Demonstrate the added value of a common core **ontology for the ISO IDMP standards** to enable data usability on a wide scale and advance **collaboration** across organizational boundaries.

The MVP implementation is a prototypic approach to provide insight on how we may realize this value later with a comprehensive ontology for the pharmaceutical industry on a larger scale in a collaborative environment, starting with **substance** information.

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.

IDMP Common Core Ontology as the connecting bridge

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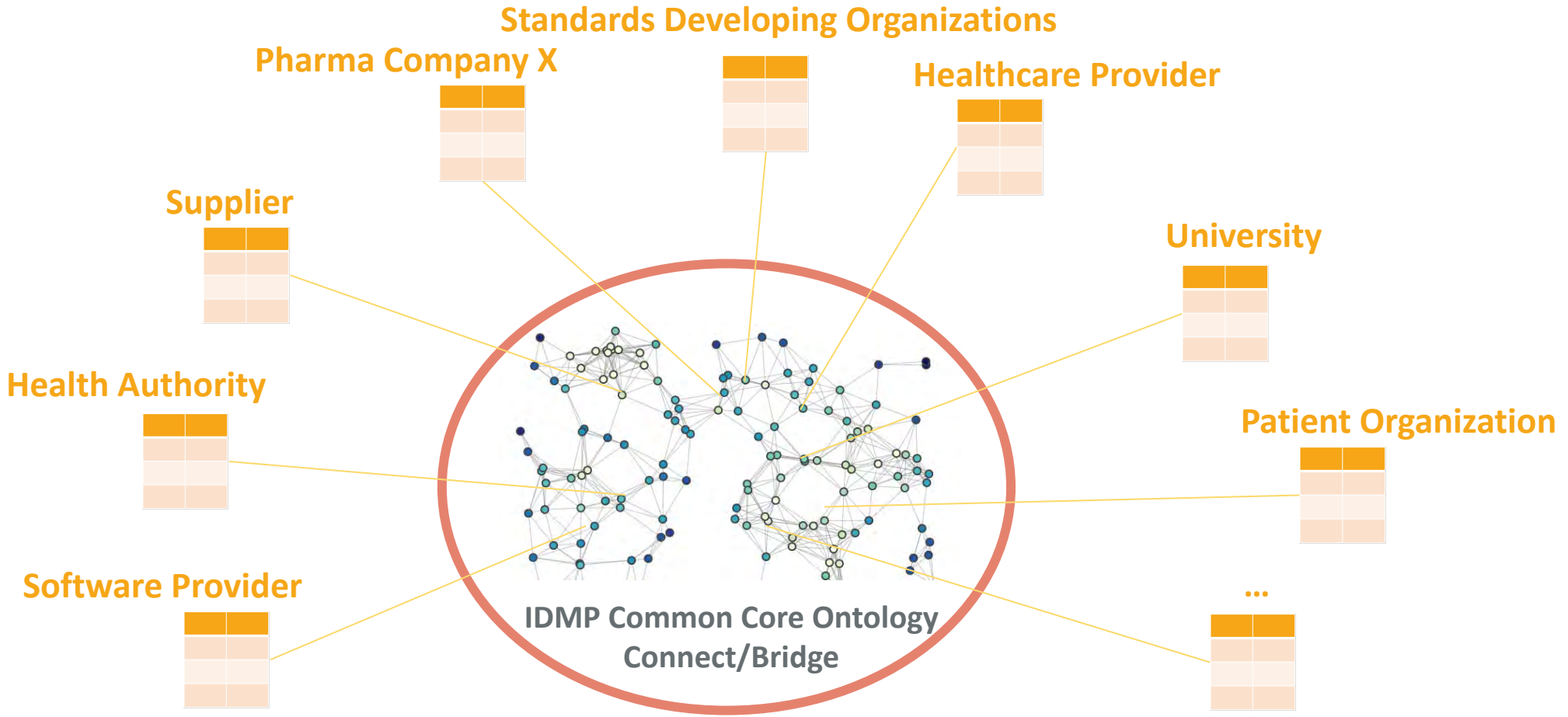

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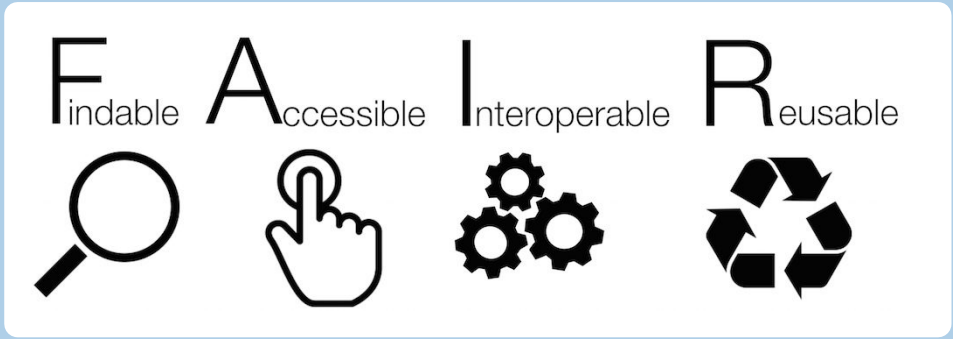
Problem Statement: Diverging IDMP implementations are a risk

There is a risk that the diverging implementations lead to huge integration and interoperability costs.

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

IDMP Common Core Ontology for Global Implementation Approach

- ✓ **Cross-industry collaboration with an iterative implementation approach**
- ✓ **Implementation of the ISO IDMP Logical Model with a FAIR ontological approach**
- ✓ **Enable the interoperability of data and metadata across the value chain**
  - Support the automation of regulatory processes
  - Reduce mapping and governance strains
  - Support the unambiguous communication across jurisdictions



IDMP Common Core Ontology MVP

Why?

1. Current IDMP implementations are diverse / non-standardized on the key data objects

2. Opportunity: There is big interest in a FAIR implementation of the IDMP standard

3. Opportunity: There is pre-work so we don‘t start from scratch

What is critical for success?

1. Creation of a quality MVP release that is useful (implementable, actually used) for pharma companies and others.

2. Demonstration of the use and added value of the ontology to obtain post-MVP funding.

3. Demonstration of governance capabilities.

4. Open communication to all relevant stakeholders, making all results openly available.

Project setup for the MVP phase

Steering Team

Provide strategic direction and make decisions priority tasks (1/month)

Sponsoring organizations

Project Core Team

Collaborate and deliver on project scope and target results (1/week)

People assigned from the Steering Team + WS team leads + selected key experts

User Stories | Progress Updates

STREAM

Governance Framework

EDMCouncil

STREAM

Ontology Development

OSTHUS

STREAM

Use-Case Implementation

ACCURIDS Chemantics

STREAM

Business Cases & Value Capture

Pistoia Alliance

Project Extended Team

Present project results and insights for a discussion in an open forum of innovators (1/month)

whole team with an open list of interested people from any organization

Requirements | Implementation Feedback

Project Management & Lead

Gerhard Nölken, Sheila Elz & Heiner Oberkampf

Pistoia Alliance

Agile Project Organisation

Internal & External Communication

Stakeholder Management

Interested Parties

Regulatory Agencies

FDA G-SRS

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH SPOR EU-SRS

CBG MEB COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Standards Development Organizations

ISO HL7

Government Initiatives

PH Trade Associations DIA

Projects UNICOM

Not-for-profits CTADHL

Vendors Veeva

Intensive cross workstream collaboration

Overview of target deliverables

ID	Deliverable
1	**Project Organization, Stakeholder Management and Alignments**
2	**High-Level Overarching Story for Decision Makers (upfront)**
3	**Specification of use-cases**, usage scenarios and competency questions
4	**IDMP Common Core Ontology Model MVP:** fit for use at pharma and authorities
5	**Use-Case Data/Content Mapping:** Pharma, GSRS, EUSRS …
6	**Use-Case Demonstrations:** Unique Identification, Linking, Inference, … WOW
7	**Ontology Governance MVP:** collaborative development, Ontology MVP release
8	**Describe Value Capture:** quantify and qualify the benefit of having an ontology

Use case structure for iterative implementation

1. **Unambiguous substance identification in Clinical context** (Bayer, Merck, Novartis)
   Scenario 1: Ingredient role mapping
   Scenario 2: Registered products administered during clinical trials (Ingredient role „active“)

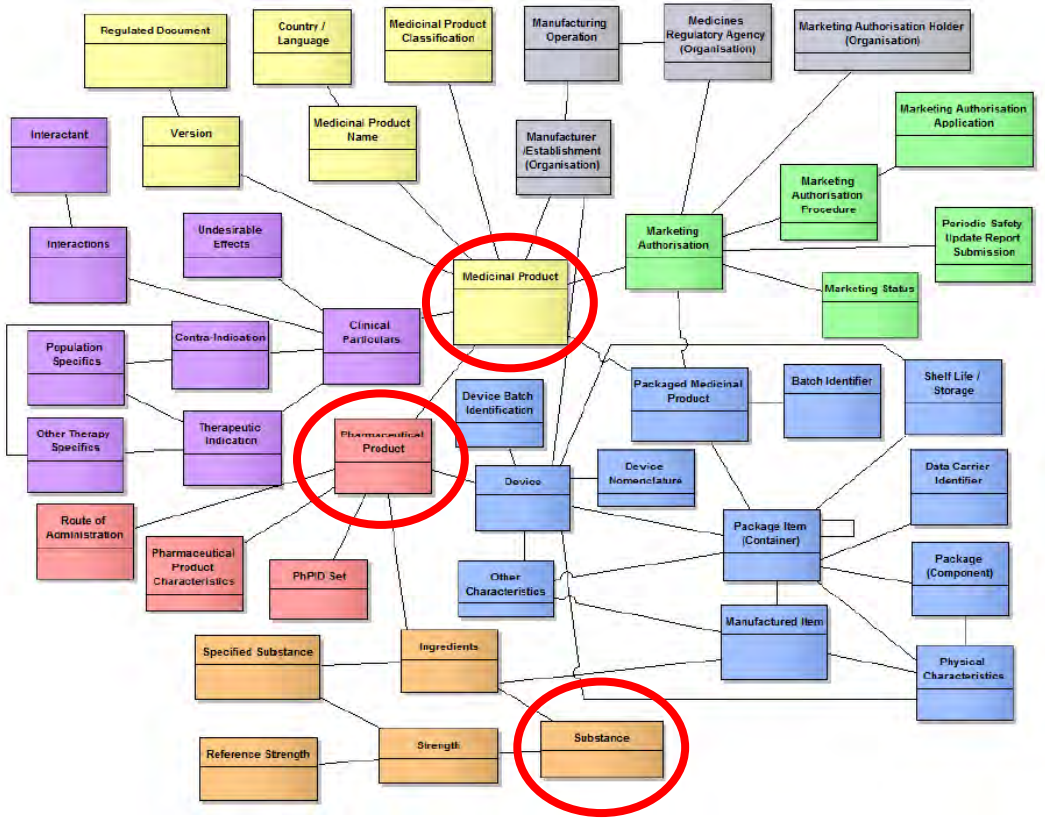
2. **Governance in a collaborative environment**
   Include stakeholders and interested parties in decisions reflected in an agile manner in the ontology (e.g., WHO, ISO, FDA, EMA…).

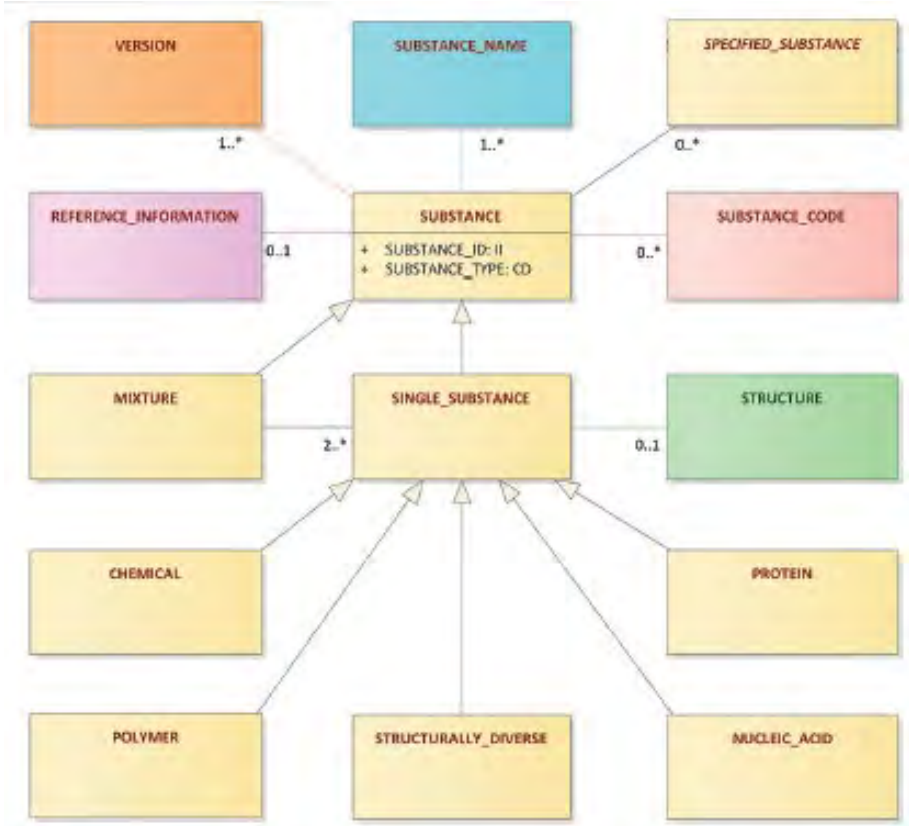
3. **Substance characteristics linked to safety profiles** (GSK, ingredient role Adjuvant)

4. **Substance contaminants tracking – Nitrosamine** (GSRS)
   Scenario: ingredient role
   Scenario: Governance decisions incorporated into ontology – FDA, EMA use cases

Starting Data Domain: Substance

Substance-Product connection as bridge between different functions, e.g., Regulatory-Manufacturing





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

Milestones

M1: Consolidation of pre-work

M2: Demonstrations of prioritized usage scenarios on substance

M3: Demonstrations of collaborative governance framework

M4: MVP ontology release

How to get involved?
Contact Us!

Gerhard Noelken

Business Development Europe at Pistoia Alliance, Inc.
Project Lead for IDMP Common Core Ontology
gerhard.noelken@pistoiaalliance.org
https://www.pistoiaalliance.org/