

PISTOIA ALLIANCE 2024 LONDON

Focus on Ontologies session

2024-04-24 London

Focus on Ontologies session

- **Clinical Operations**

Aditya Tyagi, Project Manager, Pistoia Alliance and Cameron Gibbs, Ontologist, Crownpoint Technologies

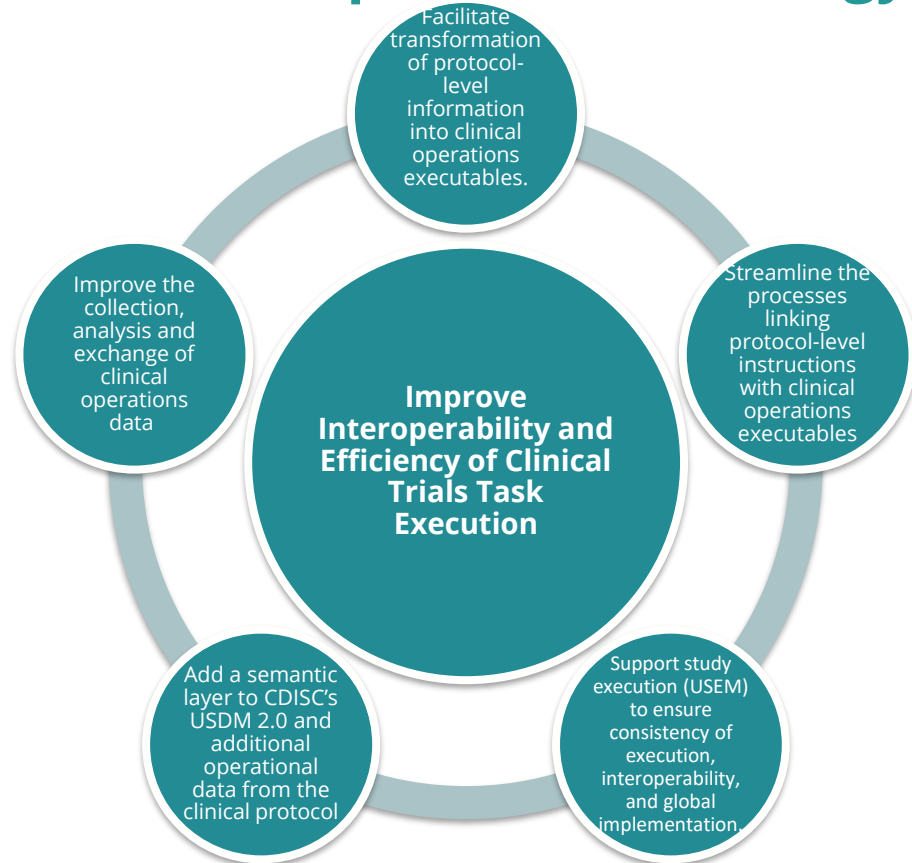
- **CMC (ISA88) Process Ontology**

Birthe Nielsen, Project Manager, Pistoia Alliance and Cameron Gibbs, Ontologist, Crownpoint Technologies

- **Pharma General Ontology (PGO)**

Giovanni Nisato, Project Manager, Pistoia Alliance

Clinical Operations Ontology



Site Feasibility Requirements

Continue to Site Feasibility

Please review the requirements for site feasibility.

Informed Consent Administrative Action

MRI procedure - Data Missing Procedure

Medical Device *
Week: 5
+ Add Medical Device

Required field
Personnel *
+ Add Personnel

PET Scan - Possib Procedure

Medical Device *
+ Add Medical Device

Required field
Personnel *
+ Add Personnel

Required field

Add Medical Device

Procedure: MRI procedure

Medical Device

SNOMED Lookup

Magnetic resonance imaging workstation (physical object)	113091000
Positron emission tomography unit, device (physical object)	39821008
Computed tomography device (physical object)	77477000
X-ray system (physical force)	52250000
Ultrasound Imaging System (physical object)	16310003



Clinical Operations Ontology

Clinical Operations Ontology

Pharmaceutical CMC Process Ontology

Project objective:

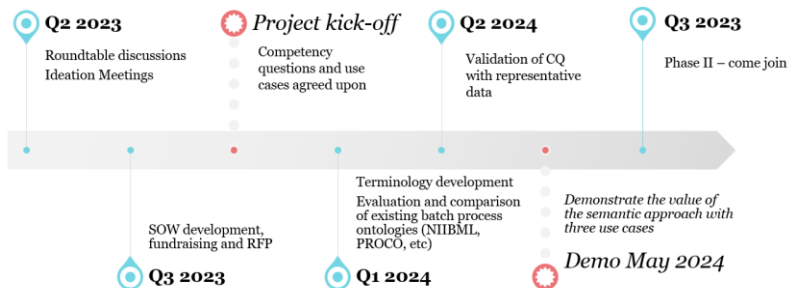
To build a pharmaceutical (CMC) process ontology based on the ISA88 framework to standardize laboratory and plant production process recipes to establish standardized definitions, facilitate digital technology transfers, and integration with execution systems in order to capture structured process data for material lot genealogy tracking, streamlined technology transfers, and advanced process analytics, thereby enhancing efficiency and transparency throughout the pharmaceutical production lifecycle.

Project scope:

- CMC laboratory & manufacturing scale
- API & Pharmaceutical Product processes
- Biologics & Synthetics with an initial focus on protein and chemical processes

Key Deliverables:

- A semantic architectural design for a Process Ontology, featuring integration with the established Product (IDMP-O), Analytical (AFO), and Unit of Measure (QUDT) ontologies.
- A taxonomy and controlled vocabulary based on the ISA88/95 framework for Process/Stage /Operation/Action, Process Parameters, Process Performance Indicators, and their definitions.
- An implementation guideline of the Process Ontology to process recipes within electronic Laboratory Notebooks (eLN) and Manufacturing Execution Systems (MES), and the creation of ePTDs.



Steering committee:

Gang Xue
Wes Schaefer
Tom Mistretta

\$40K to join the steering committee



Define a process at the general and site recipe levels. Specific needs include:

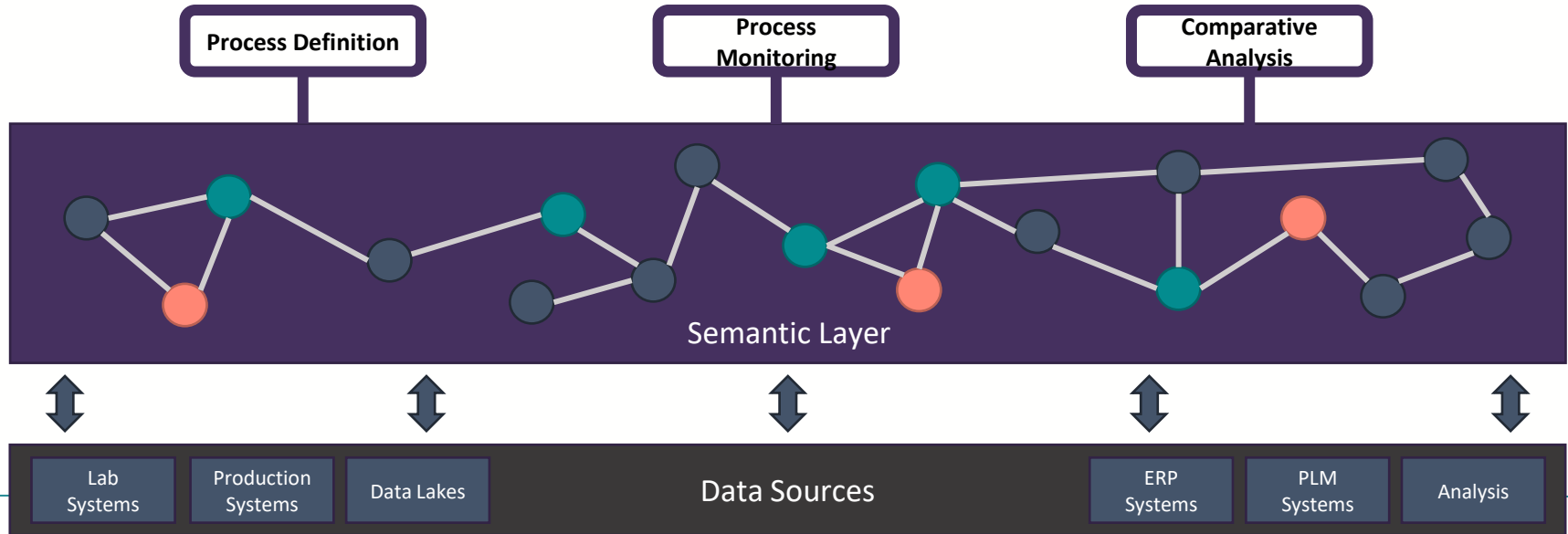
- Process
- Process Stage
- Process Operation
- Process Action

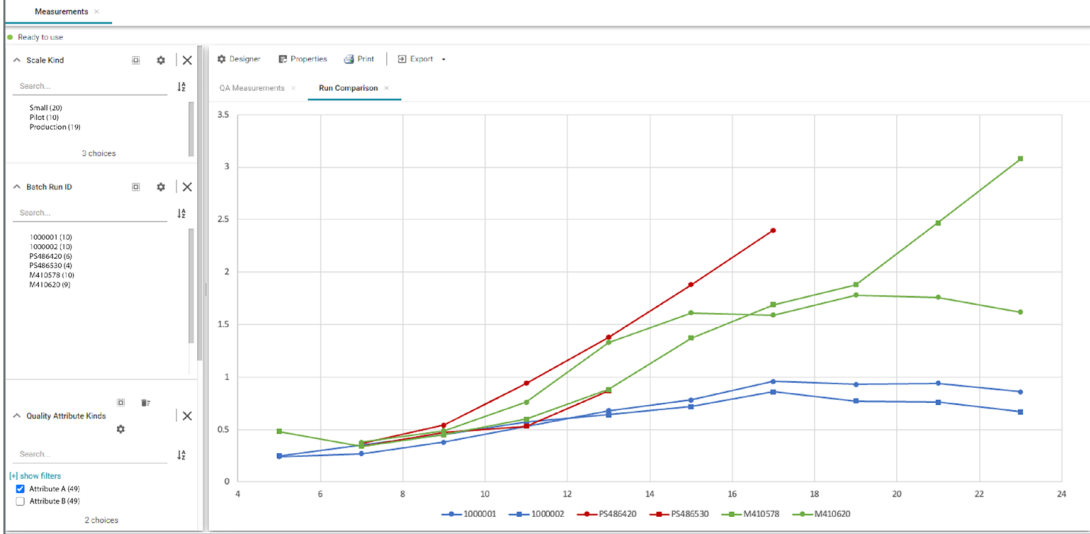
Track sample data across process steps and runs to support trend analysis.

- Master & control recipes
- Procedure recipe components
- Process Parameters & associated metadata
- Performance Indicators & associated metadata
- Quality Attributes & associated metadata

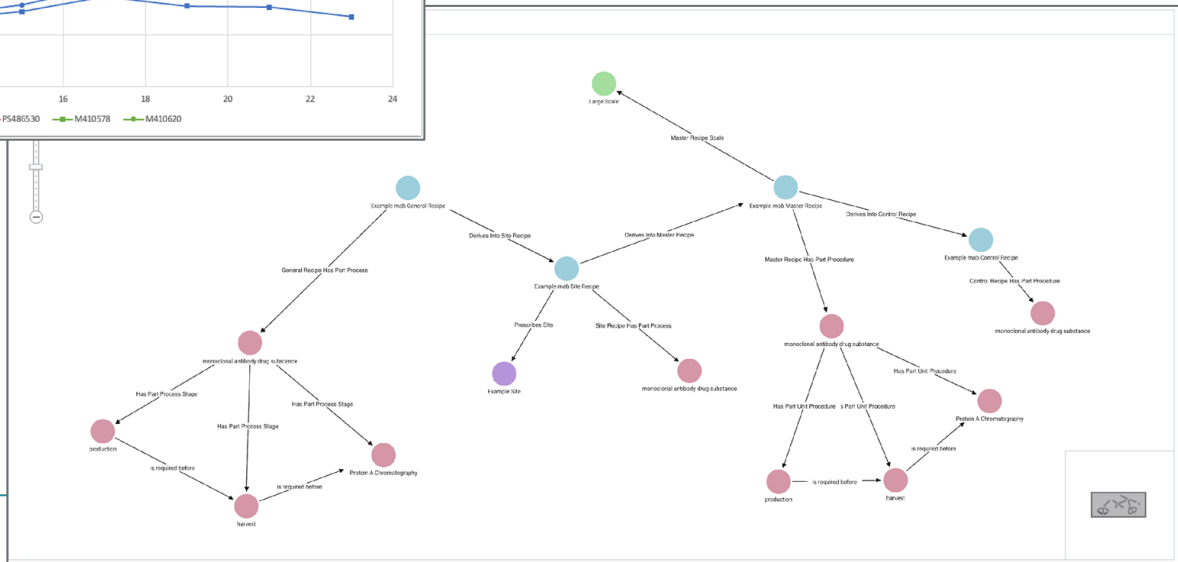
Aggregate and compare data across runs within a process or across scales and sites, independent of source systems or formats.

- Recipe to recipe analysis
- Site to site analysis
- Equipment to equipment analysis





Knowledge Graph Output



How to get involved?

Get in touch:

cmcproject@pistoiaalliance.org

birthe.nielsen@pistoiaalliance.org

ontologies@pistoiaalliance.org

Join now to help plan and prioritize for Phase 2



Key information:

Birthe Nielsen, Project Manager
Tom Mistrzeta (Amgen) Champion
Gang Liu (MS) Champion
Wes Schäfer (Merck) Champion

More info:
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birthe.nielsen@pistoiaalliance.org

This poster has been prepared by
Birthe Nielsen, PA
Melissa Welser, CPT
Cameron Gibbs, CPT

Sponsors/partners:



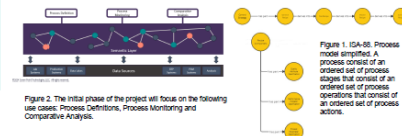
Call for participation

For the next phase of the project, we would like to engage more members from the vendor side to ensure implementation and integration within electronic Laboratory Notebooks (eLN) and Manufacturing Execution Systems (MES). Please email: CMCProject@pistoiaalliance.org

Pharmaceutical CMC Process Ontology Project

The project

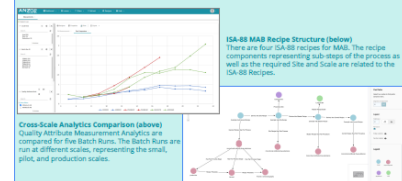
A key strategic priority of the Pistoia Alliance is to Deliver Data Driven Value. The Pharmaceutical Chemistry, Manufacturing and Control (CMC) Process Ontology project aims to build the semantic architecture around the ISA-88/95 framework (Fig 1) to standardize laboratory and plant production process recipes (Fig. 2).



What you cannot do with a taxonomy alone but can with an ontology:

Ontologies surpass traditional data management systems by offering a semantic layer that adds context, meaning, and relationships to data. This gives you the ability to query and link between datasets and not just search for content. With our CMC Process ontology, you will be able to:

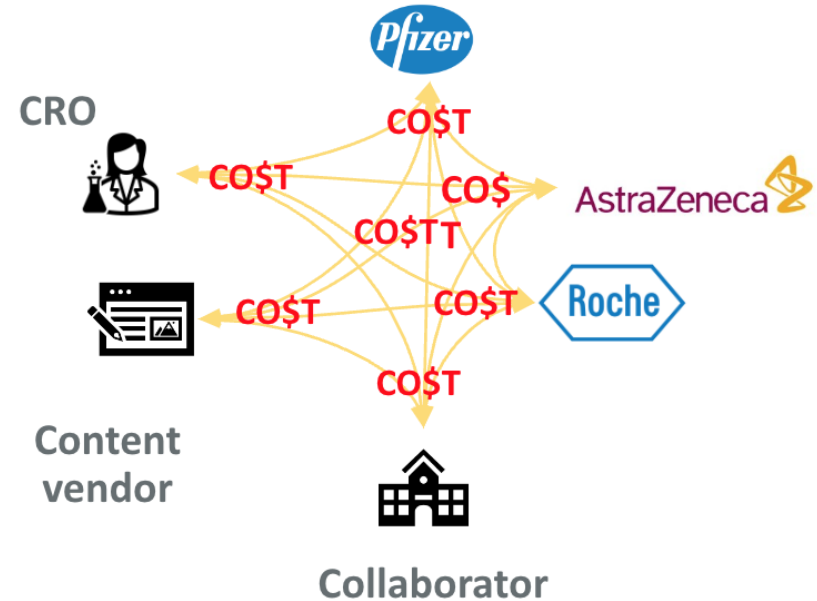
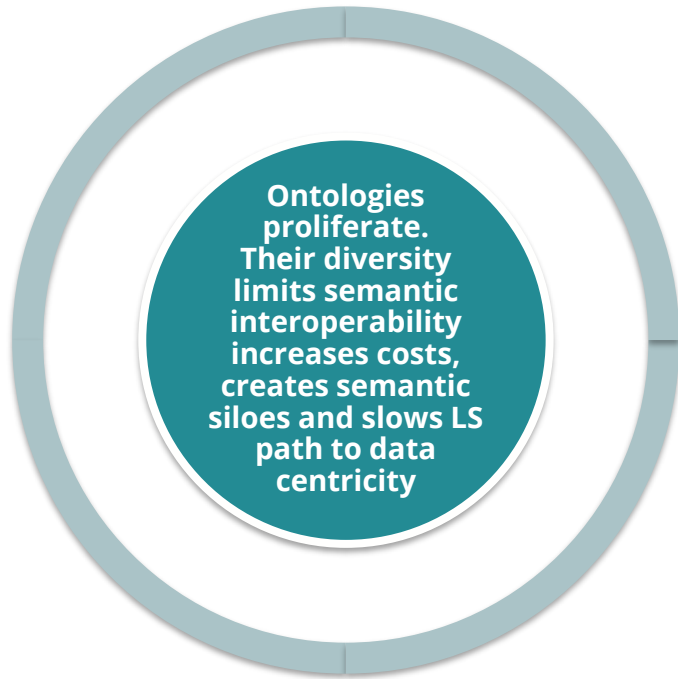
- Define a process at general and site recipe levels (protein and chemical processes)
- Track sample data across process steps and runs to support trend analysis
- Aggregate and compare data across runs within a process or across scales and sites, independent of source systems or formats
- Enable advanced process analytics across laboratory and process batches across scale.



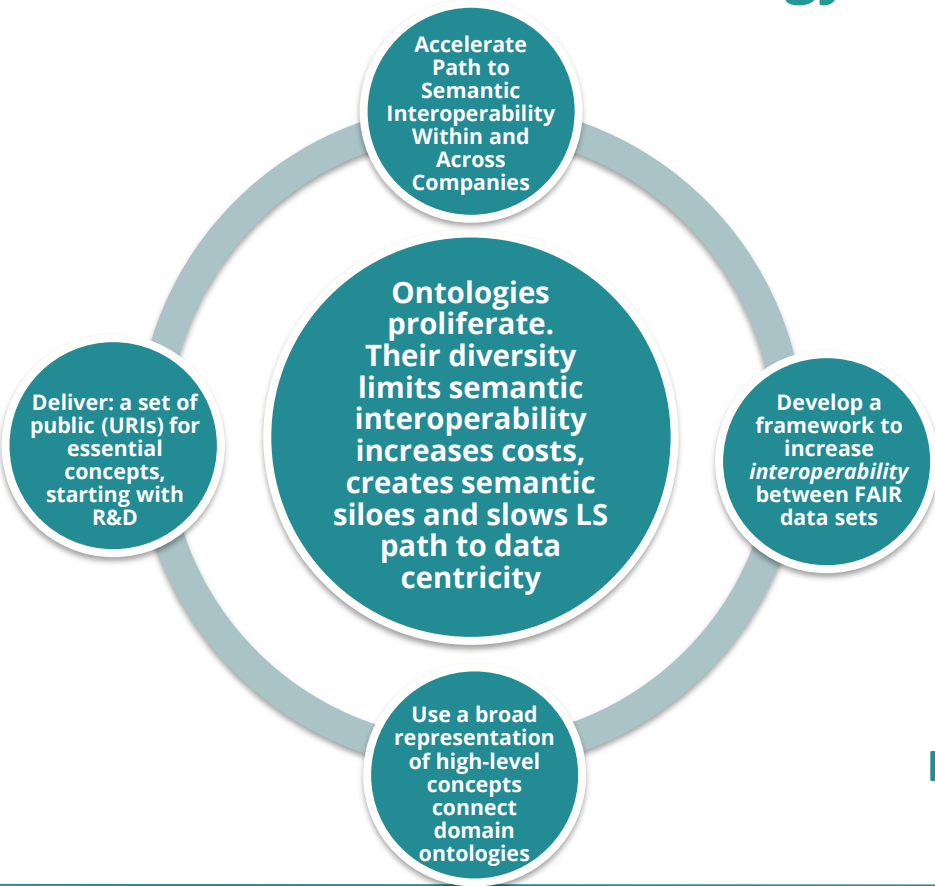
Ensuring interoperability.

We are actively working towards making all Pistoia Alliance ontologies interoperable as well as ensuring seamless integration with established Product (DMP-Q), Analytical (APQ) Biopharmaceutical Manufacturing (VIB/MAL) and Unit of Measure (QUT) ontologies.

Pharma General Ontology



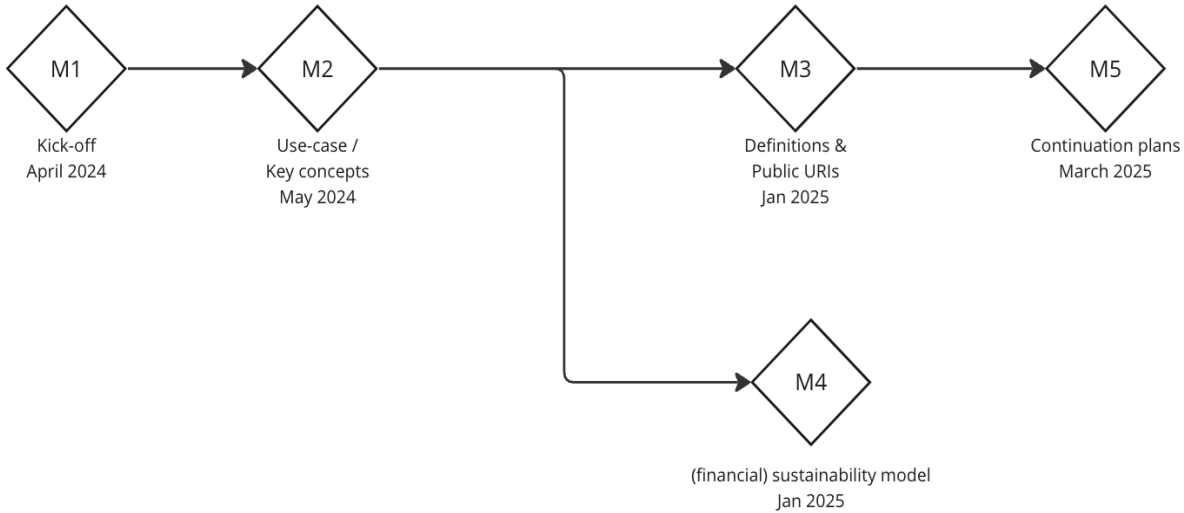
Pharma General Ontology



PGO acts as a 'Rosetta Stone' providing Interoperability across and within companies

PGO: plan and outcomes

- **Set of public identifiers (URIs) for key concepts across R&D to start**
- **Recommendation to Pistoia: sustainable business model for upkeep of PGO**
- **Publication about the project outcomes**



PGO is starting: to get involved please contact
giovanni.nisato@pistoiaalliance.org
ontologies@pistoiaalliance.org

Thank you for your attention!

Process : from ideation to delivery

HOW AN IDEA BECOMES A PROJECT AT THE PISTOIA ALLIANCE

Project flow



Ideation



Communities of interest (CoI)

Validation discussions
Business case exploration



Project starts to take shape

Clear problem statement
Business case written



Member funded project



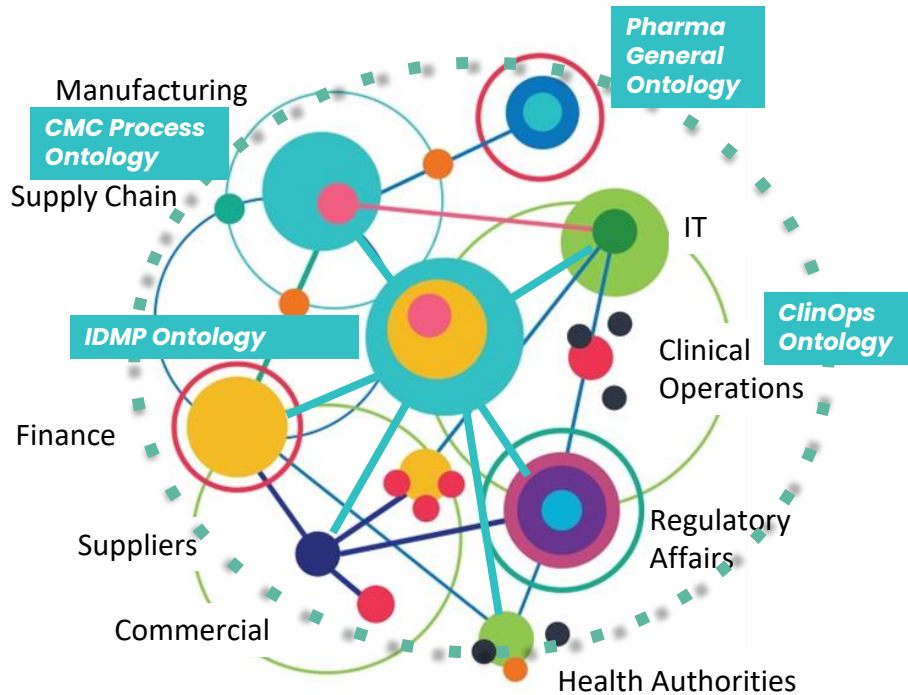
Member funded Community of Experts (CoE)

PROMOTING GLOBAL COLLABORATION FOR LIFE SCIENCE AND HEALTHCARE RESEARCH & DEVELOPMENT

Member fees

Sponsor fees

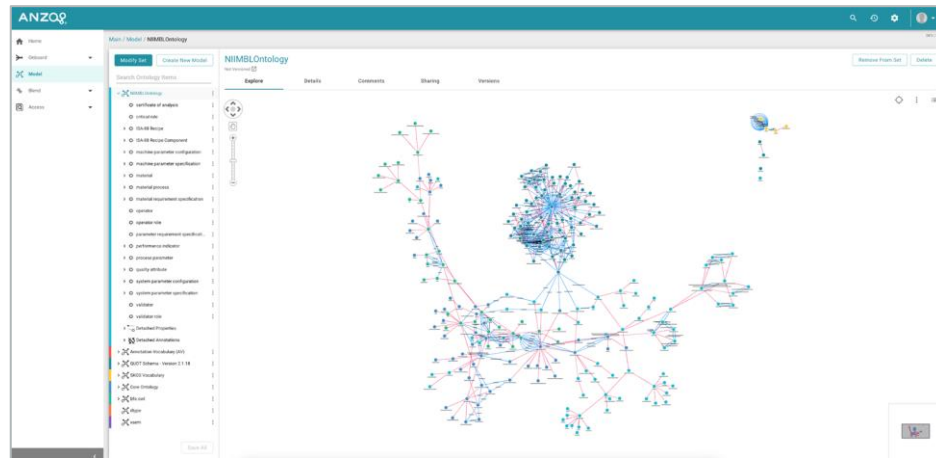
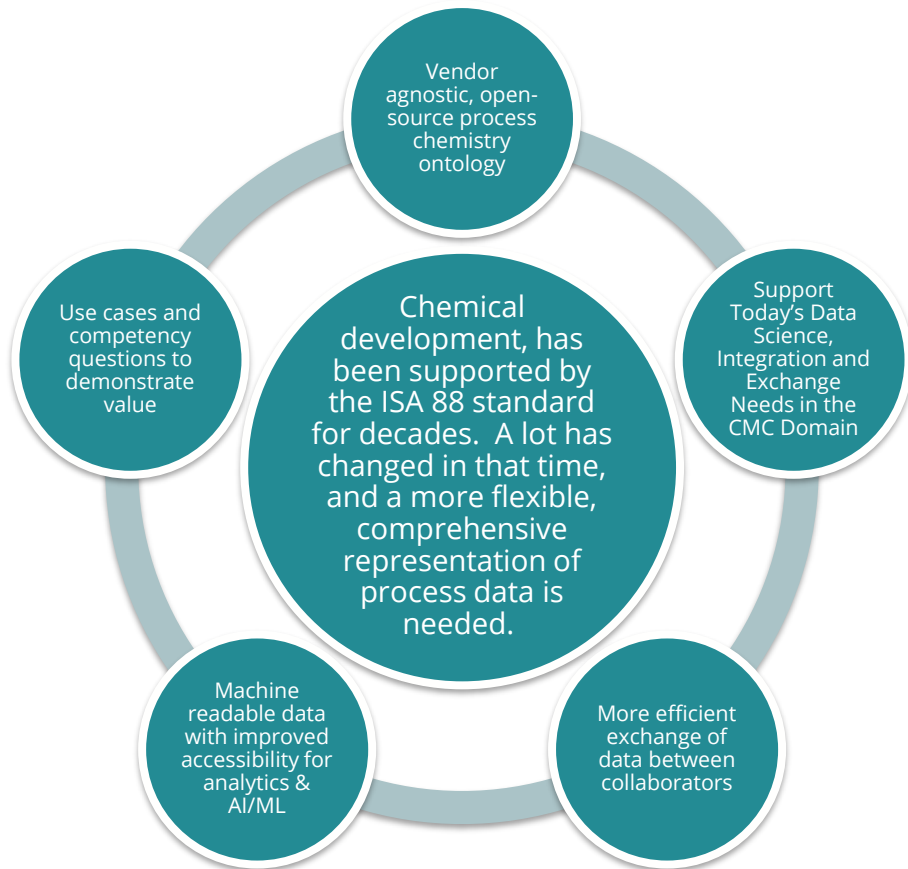




Pistoia Alliance is building a sustainable ontology portfolio for life sciences

Additional slides

Pharmaceutical CMC Process Ontology



Aligned with NIMBL Ontology for Biologics Processes

