PISTOIA ALLIANCE 2024 LONDON

Focus on Ontologies session

2024-04-24 London

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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

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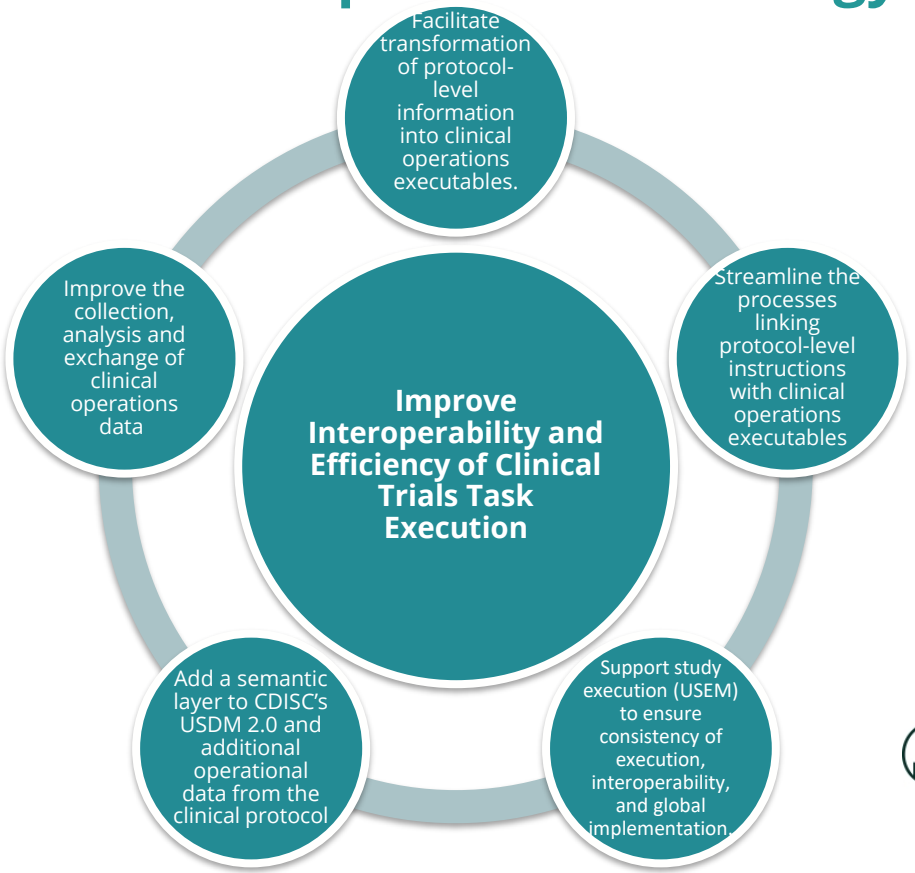
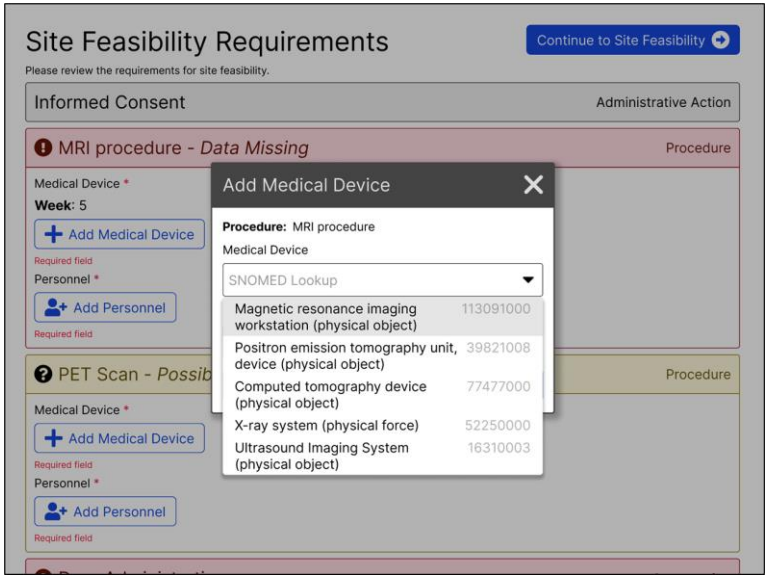
Clinical Operations Ontology





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Clinical Operations Ontology

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Clinical Operations Ontology

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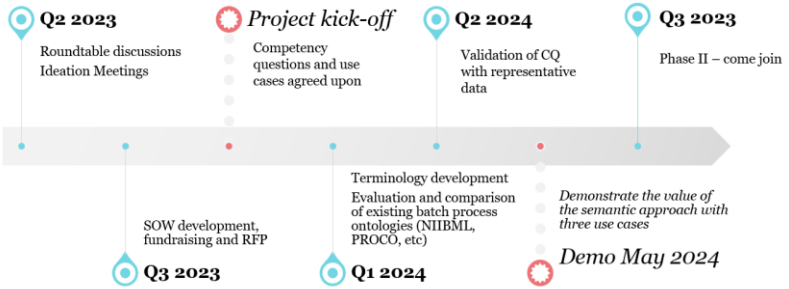
Pharmaceutical CMC Process Ontology

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

Steering committee:

Gang Xue
Wes Schaefer
Tom Mistretta

$40K to join the steering committee

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.

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

- Process
- Process Stage
- Process Operation
- Process Action

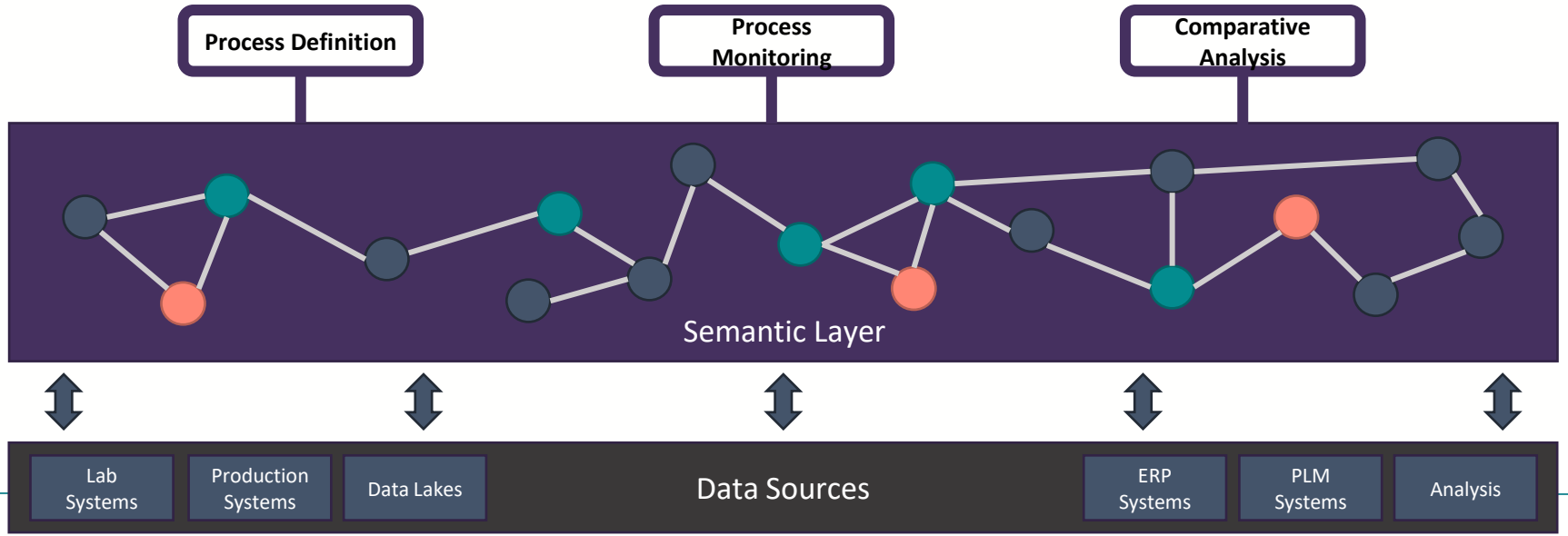
Track sample data across process steps and runs to support trend analysis.

- 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

CROWN POINT TECHNOLOGIES



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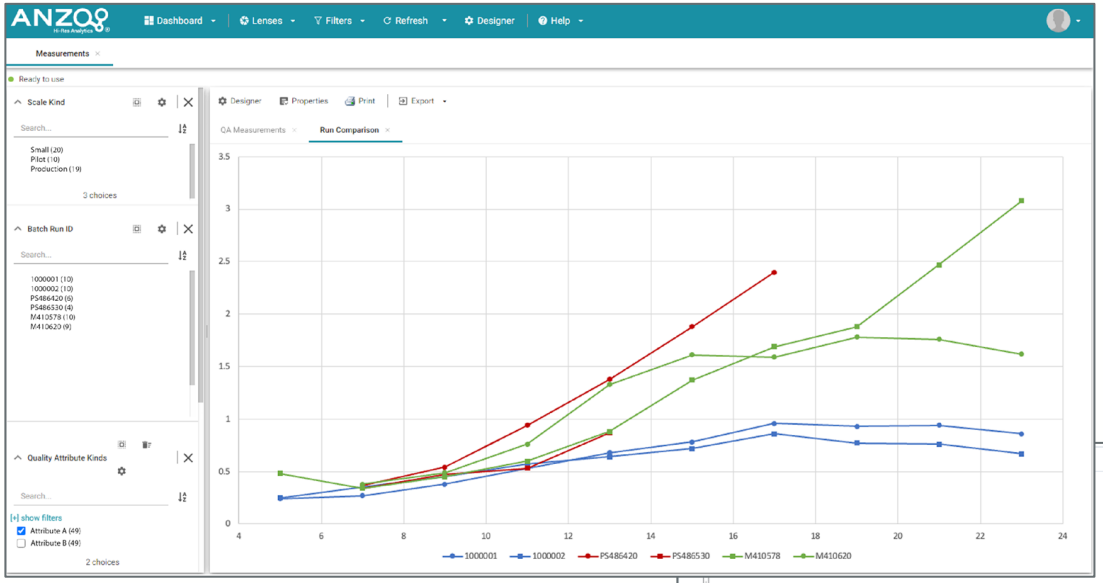
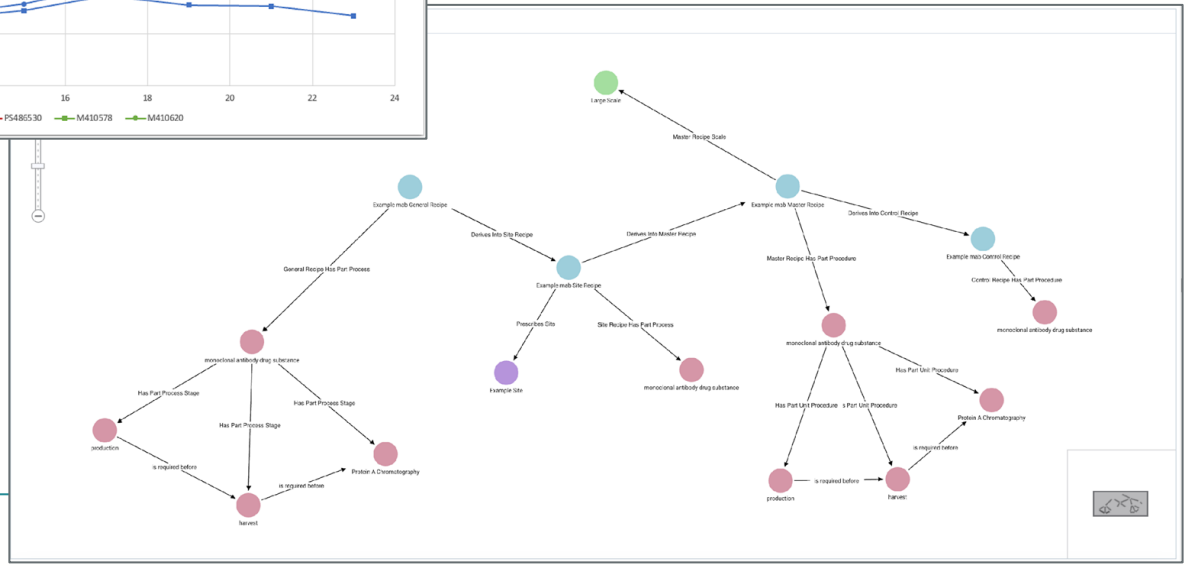
Knowledge Graph Output





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How to get involved?

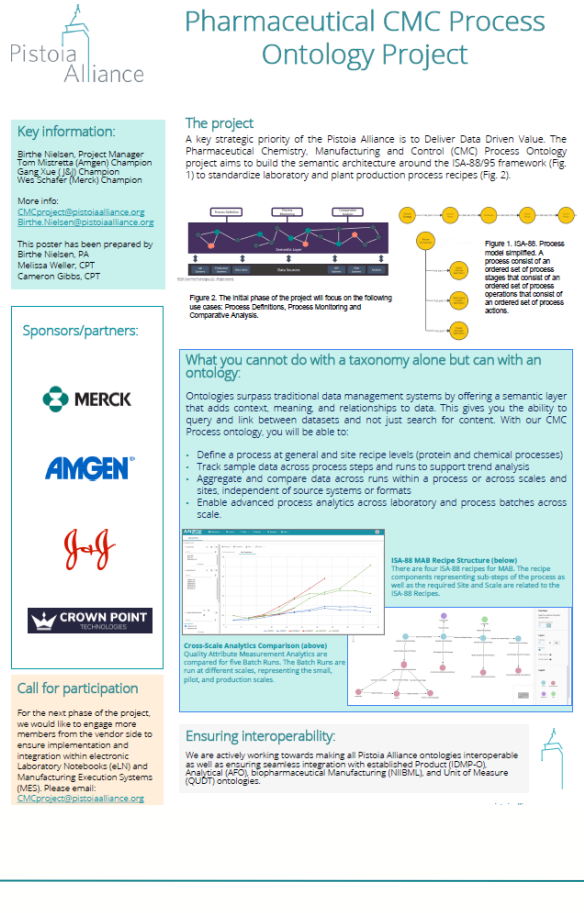
Get in touch:

cmcproject@pistoiaalliance.org

birthe.nielsen@pistoiaalliance.org

ontologies@pistoiaalliance.org

Join now to help plan and prioritize for Phase 2



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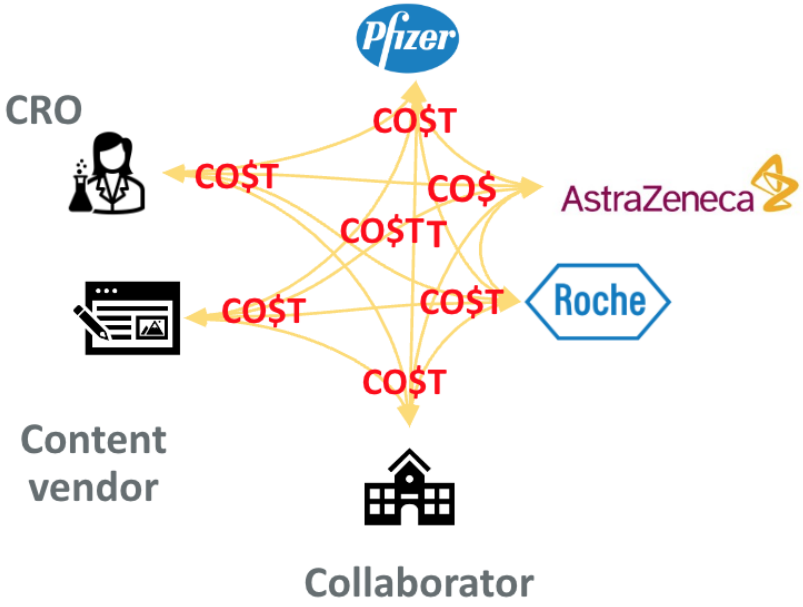
Pharma General Ontology



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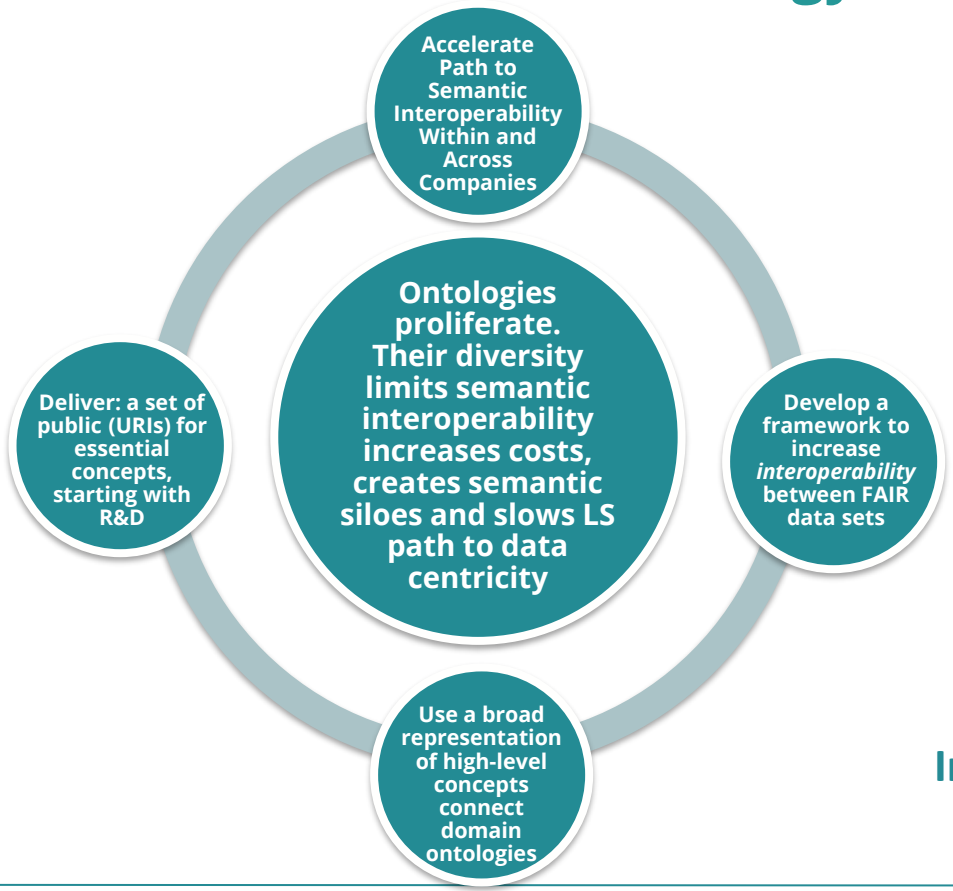
Pharma General Ontology



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

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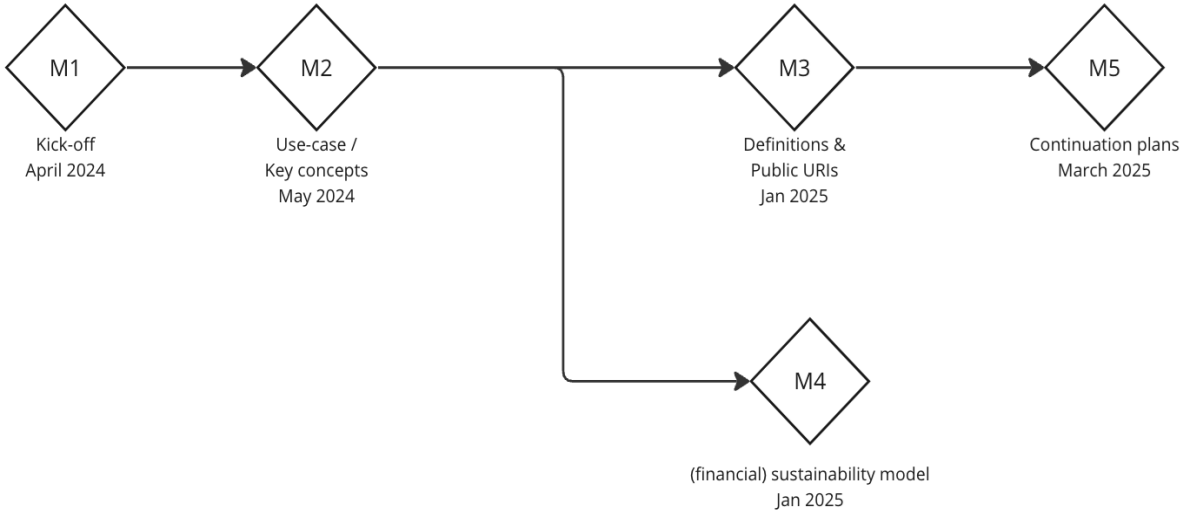
PGO: plan and outcomes

- **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

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Thank you for your attention!

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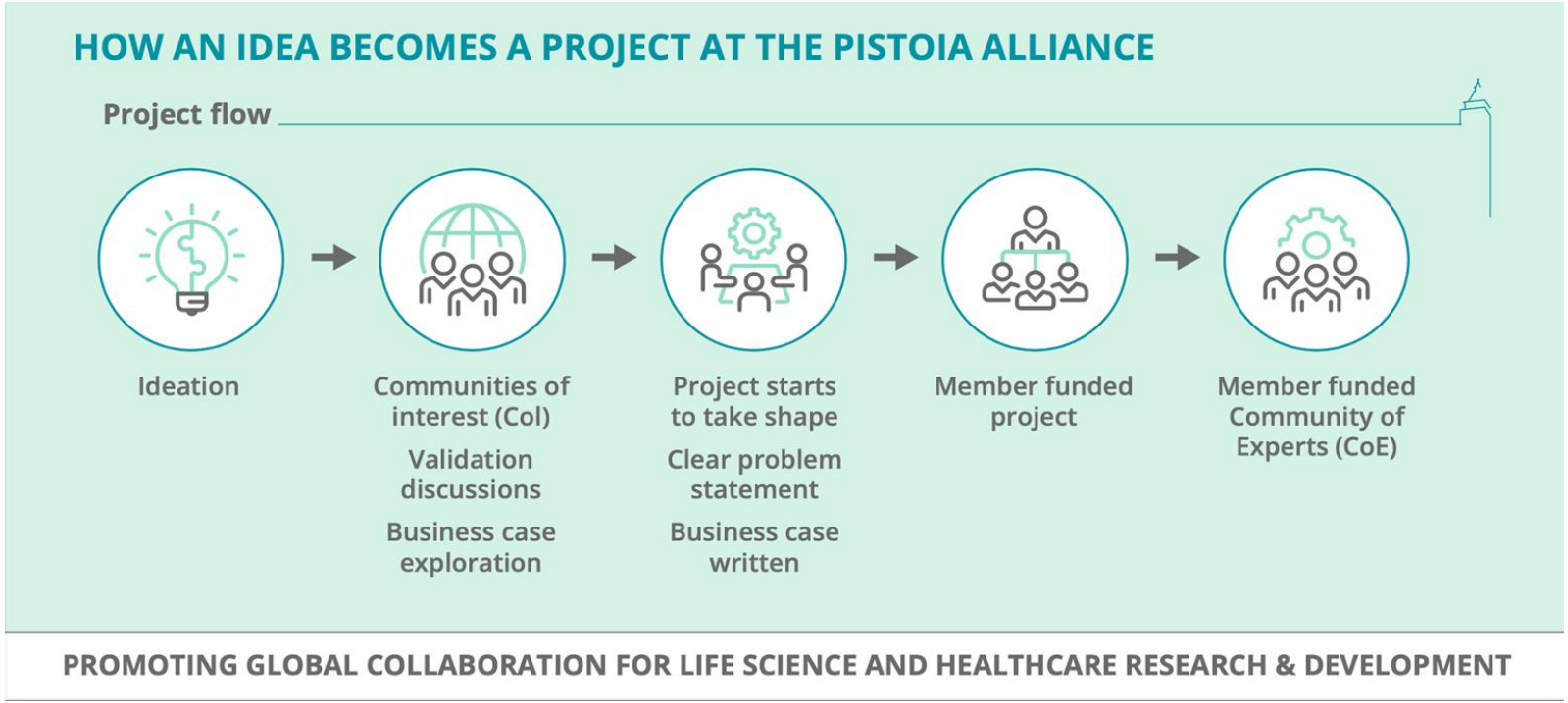
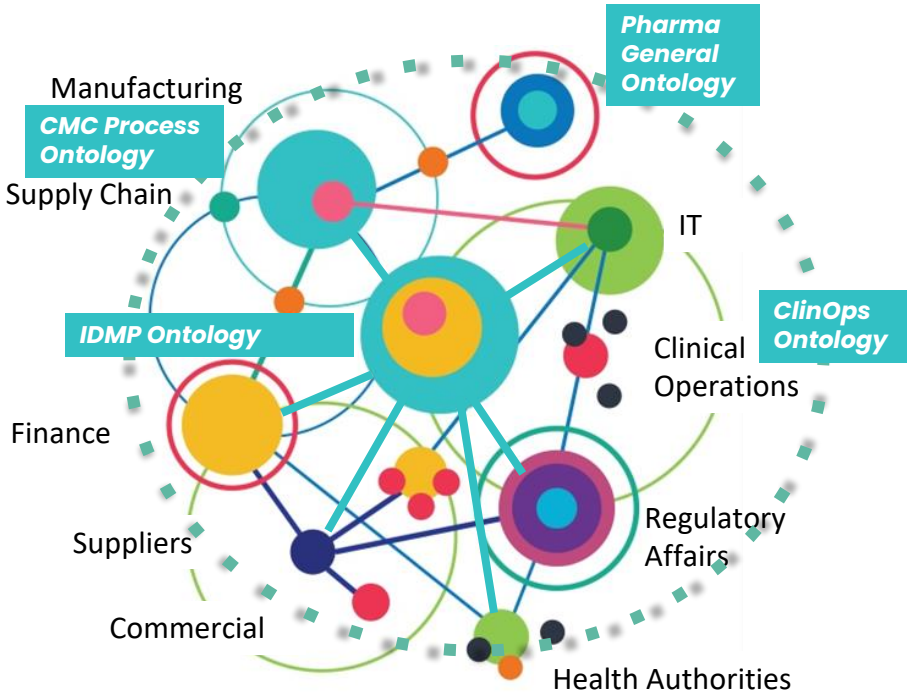
Process : from ideation to delivery



Member fees ⟷ **Sponsor fees**



Pistoia Alliance is building a sustainable ontology portfolio for life sciences

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Additional slides

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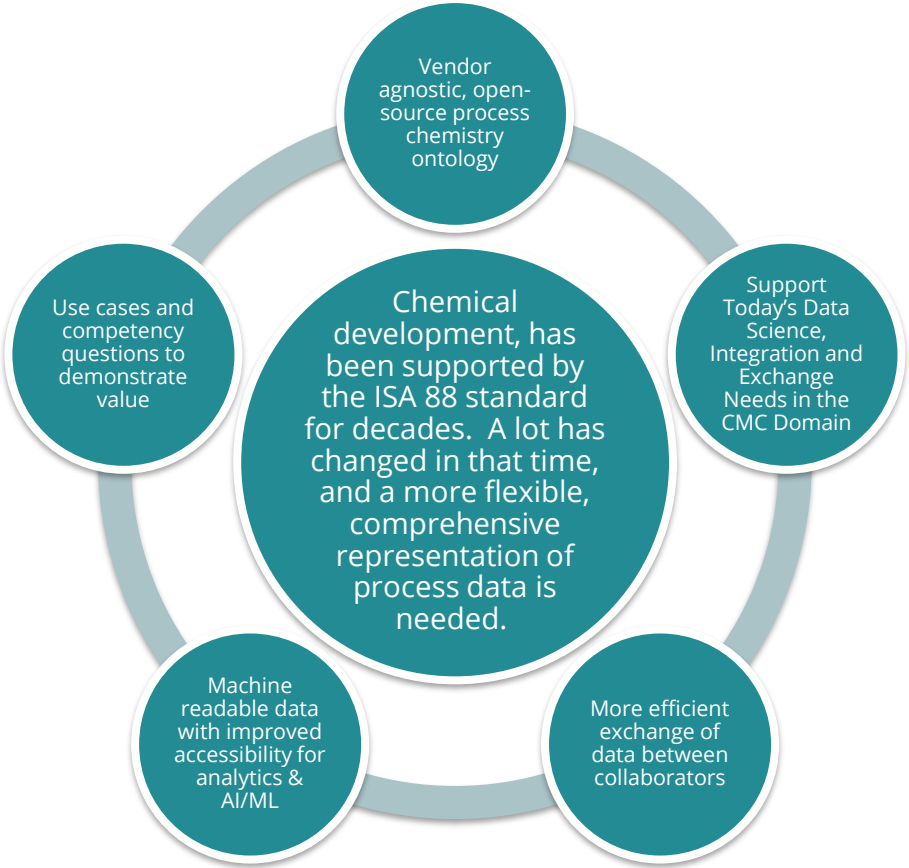
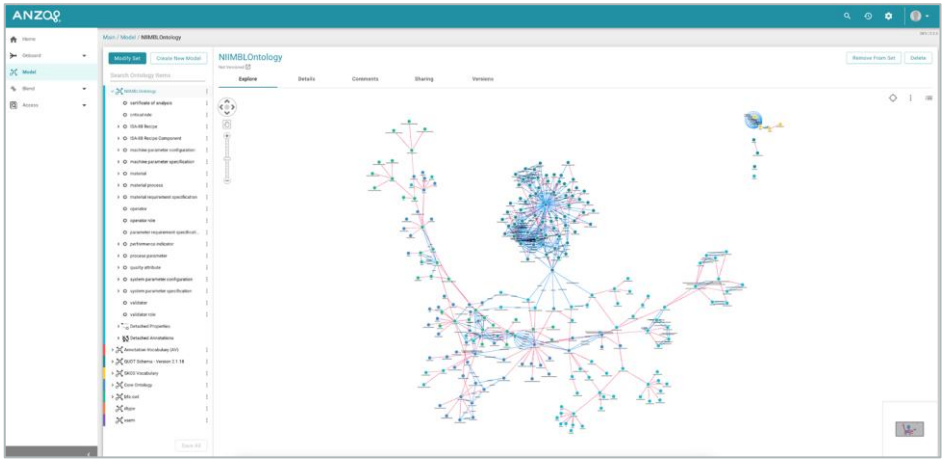
Pharmaceutical CMC Process Ontology





Aligned with NIMBL Ontology for Biologics Processes

MSD AMGEN J&J

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