

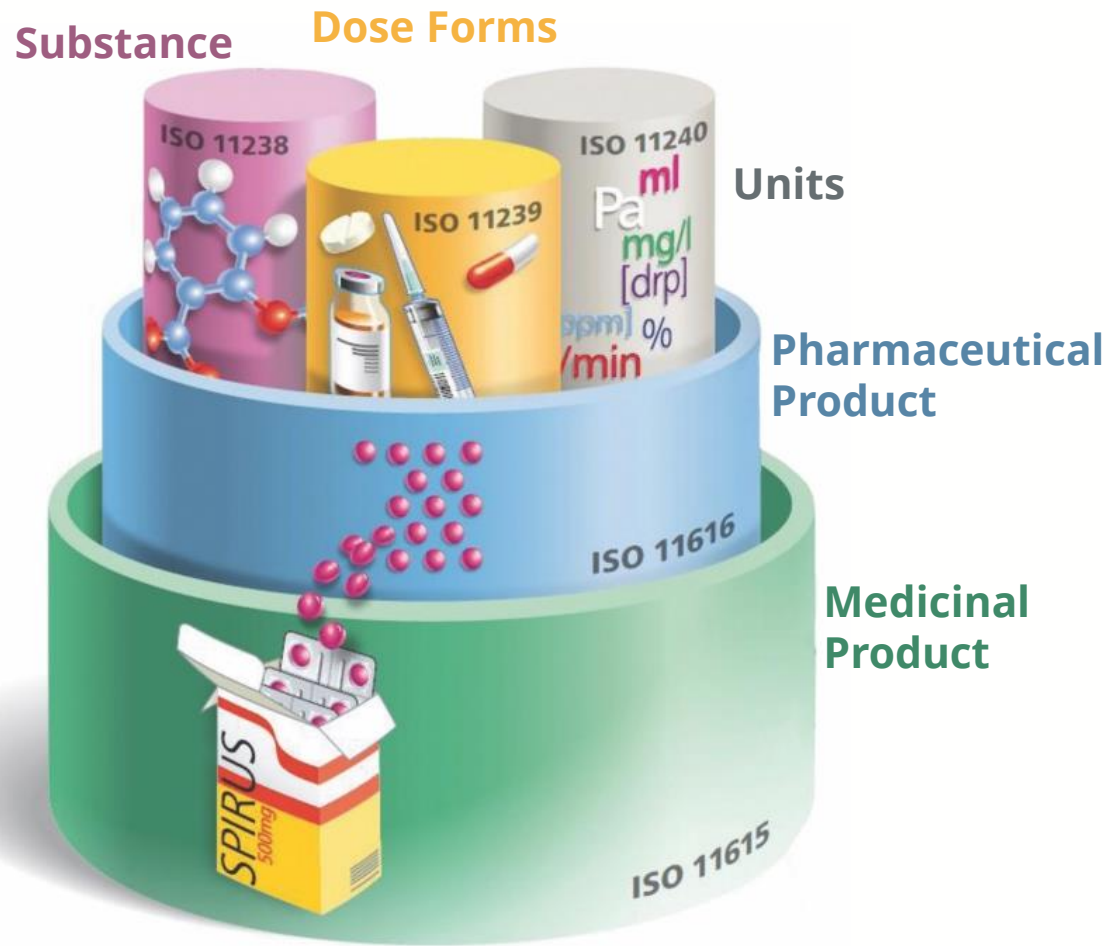
## **AFO + IDMP-O:**

Connecting pharma data across the entire value chain with a network of interoperable industry ontologies

Heiner Oberkamp - ACCURIDS

# We need a shared data language to solve global challenges together





ISO IDMP Standards



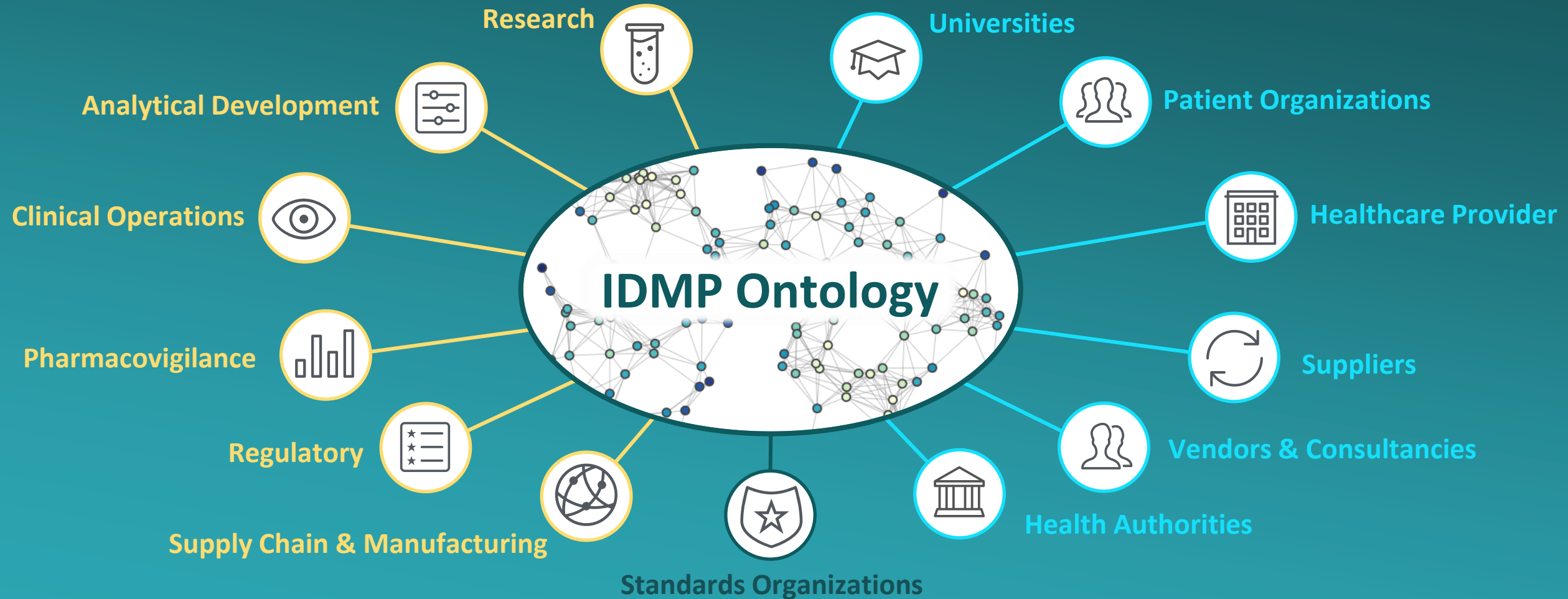
# ISO IDMP

ISO standards for unique identification and exchange of information about medicinal products to improve patient safety and facilitate the data-driven collaboration between authorities, healthcare professionals, and pharmaceutical companies.

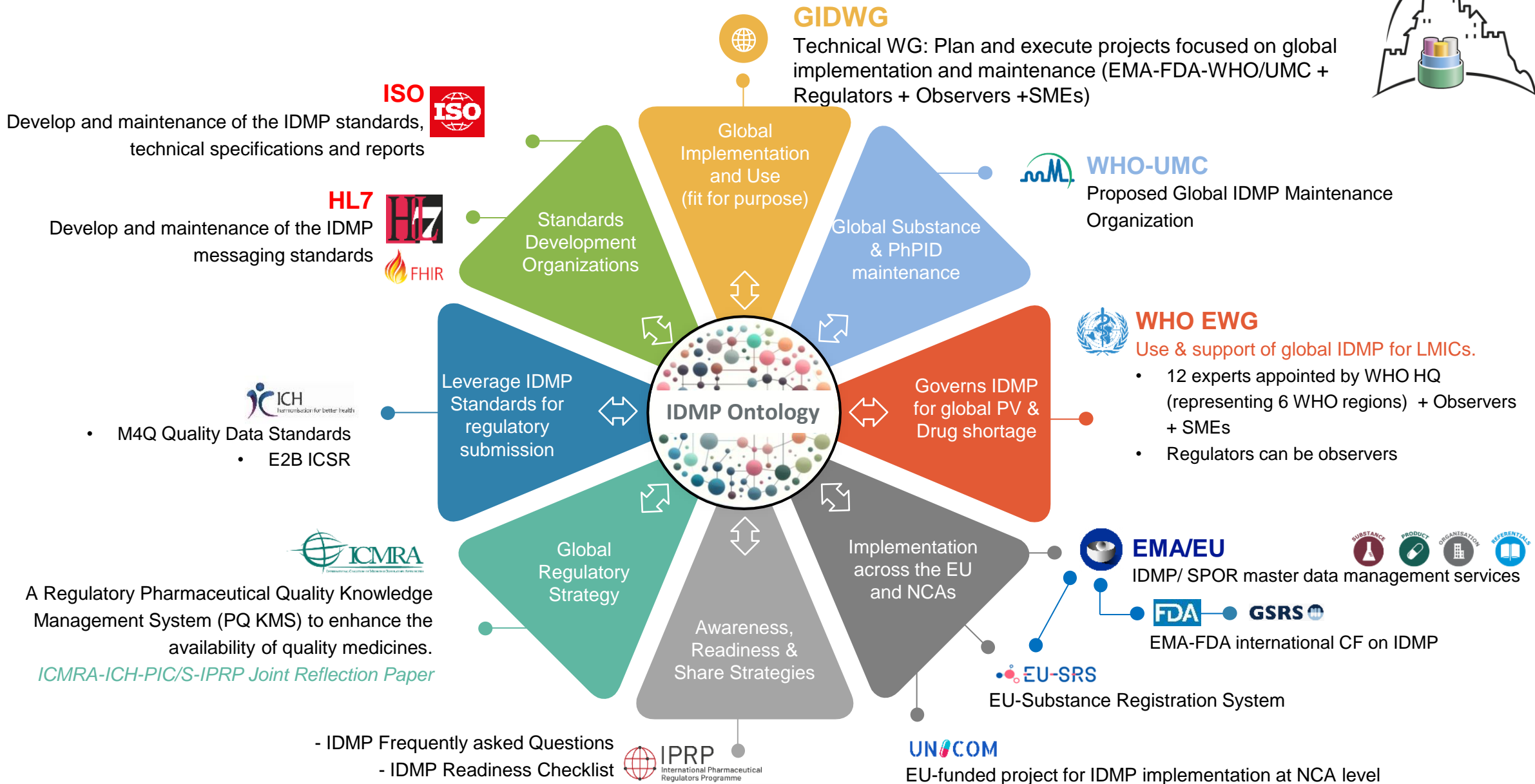
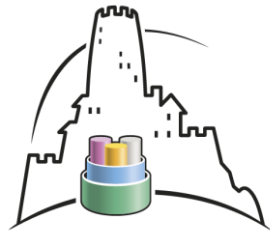


# IDMP Ontology: shared data language for medicinal products

## Pharma internally ... and across the industry



# IDMP landscape is a complex one..



# Achievements

1. **Our approach to building IDMP-O becomes an ISO Technical Specification**

2. **Successful pharma pilot implementations**

With business value in many different use case areas



3. **Release of IDMP-O v1.0 in January 2024**

Open-source and ready for production implementation

4. **Successful collaboration with IDMP stakeholders**

Tested IDMP-O with data from



5. **Bio-IT World Conference Innovative Practices Award 2024 for Pre-Competitive Collaboration**

## Architecture proposal - OneDigiReg

A data-centric architecture as a foundation to digitally transform regulatory business

### Sources

#### Internal systems

- MDMS
- RIM

#### External systems

- GSRS
- SPOR
- WHO drug

### Core regulatory digital assets



**The digital brain (RMD hub 2.0)**

- Semantics, governance, architecture
- Master, reference and meta- data
- Rules, logic, transformation recipes



incl. IDMP-O



#### **The digital hands (Data science platform)**

- Data/documents preparation, curation
- AI, ML, NLP pipelines
- Digital products and service



incl. neural search and chatbots

### Targets

#### Vendor solutions

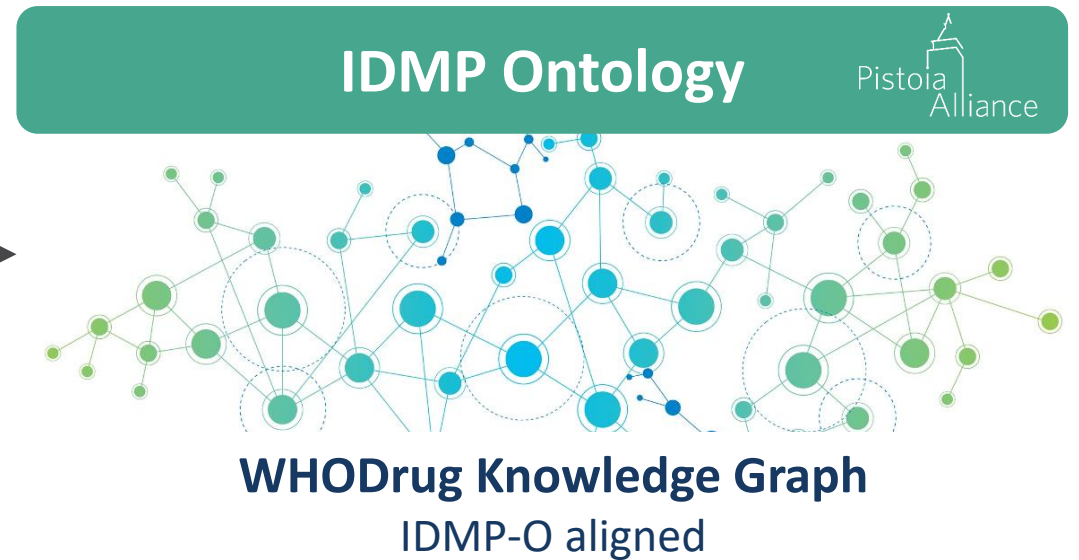
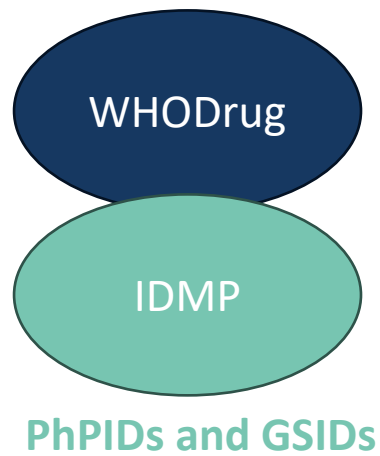
- RIM

#### Roche solution

- Chatbots
- Automatic text writing
- Browser plugins

# WHODrug as a Knowledge Graph within the IDMP Ontology

**Idea:** Support current and new use cases for WHODrug with IDMP within pharma by seamless integration with other IDMP-O aligned data sources (connecting to e.g., pharma, EMA SPOR, FDA GSRS)





# PROJECT PRISM

A Regulatory Cloud Collaborative Initiative



## precisionFDA Regulatory Information Service Module FDA-Industry Research Collaboration Agreement (Public-Private Partnership)

Vada A. Perkins  
VP/Global Head of Regulatory Intelligence & Policy  
Boehringer Ingelheim  
PRISM Principal Investigator

April 2024



# Our Trajectory & Outlook

**Phase 4 and Beyond:  
Production & Sustainability  
Planning for 2025**

**Phase 3:  
Pharma Implementation &  
Industry Adoption  
2024**

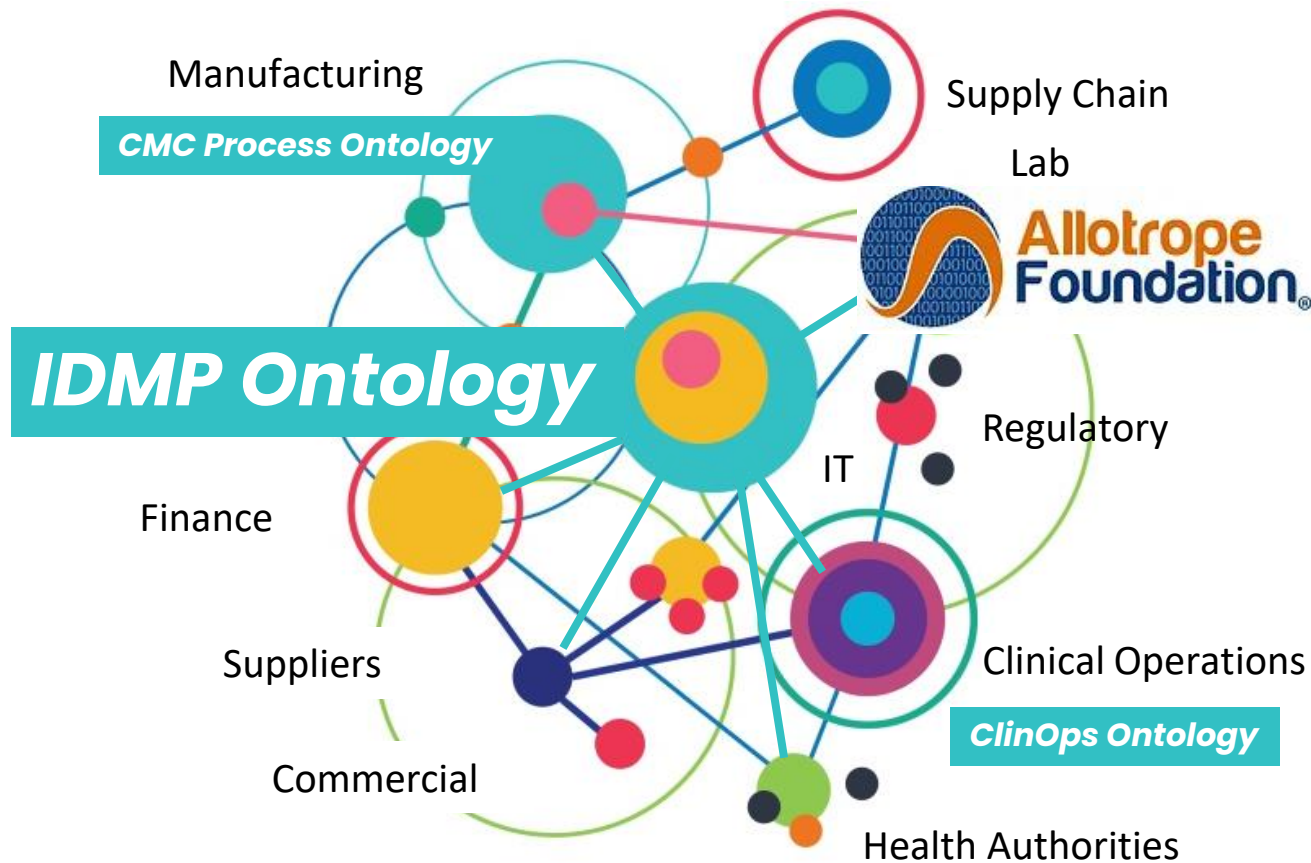
- Focus on production implementations
- Collaboration with Health Authorities
- Interoperability with other domains
- Opening to vendors and consultancies
- Introduction of Open Core Model
- Release v1.1 in April

**Phase 2:  
Build IDMP-O 1.0  
for Production Use  
Released in  
January 2024  
2023**

**Phase 1:  
IDMP-O  
MVP  
2022 Apr-Oct**

Initiation  
2021

## Global Governance & Data Standards



Infrastructure as a Service

Pistoia Alliance is building a sustainable, coordinated, ontology project portfolio with IDMP-O at its core.

*Connecting to Allotrope® Foundation Ontology (AFO) with many bridge concepts through IDMP-O and CMC Process Ontology*

# AFO + IDMP-O: Bridge Concepts & Use Cases

## Use Cases related to ...

































































- 1. Stability and shelf-life data**
  - Better clinical supply
  - Drug shortage monitoring
- 2. PQ CMC - Quality data**
  - data-driven submission
  - process optimization
- 3. Materials & batches**
  - material alternatives (ESG)
  - material supplier alternatives
  - batch release
- 4. Product labeling**
  - update packaged product labels in manufacturing
- 5. Substance**
  - globally unique identification
- 6. Lab tests and units**
  - bridge clinical, lab, regulatory
- 7. ...**
  - ...





# Datasets

 iso  

Status 	Name	Tag	Created	Content Updated	Action
  	ISO11238 Substances	ISO11238-Substances	04.10.2023	4 days ago	   
  	ISO11615 Medicinal Products	ISO11615-MedicinalProducts	04.10.2023	4 days ago	   
  	ISO11240 Units Of Measurement	ISO11240-UnitsOfMeasurement	04.10.2023	6 months ago	   
  	ISO21090 Harmonized Datatypes	ISO21090-HarmonizedDatatypes	04.10.2023	4 days ago	   
  	ISO11616 Pharmaceutical Products	ISO11616-PharmaceuticalProducts	04.10.2023	never	   
  	ISO11238 Registration Authorities	ISO11238-RegistrationAuthorities	04.10.2023	25 days ago	   
  	ISO11239 Pharmaceutical Dose Forms	ISO11239-PharmaceuticalDoseForms	04.10.2023	7 months ago	   
  	ISO5218 Representation Of Human Sexes	ISO5218-RepresentationOfHumanSexes	04.10.2023	4 days ago	   
  	Metadata ISO	MetadataISO	04.10.2023	never	   



subClassOf

- 
- organism part
- other therapy specifics
- + pharmaceutical dose form
- pharmacopoeial grade
- + process specification
- + product specification
- route of administration
- substance
  - acid
  - base
  - ester
  - hydrate
  - + polydisperse substance
  - polymer starting material
  - salt
  - single substance
    - monodisperse substance
      - chemical substance
        - chemical element
        - isotope
        - chemical mixture
        - + portion of compound
        - portion of element
        - sugar
        - nucleic acid substance
        - protein substance
        - polymer substance

# chemical substance

ISO11238-Substances AFO



Search

Label	chemical substance
URI	<a href="http://purl.allotrope.org/ontologies/material#AFM_0001097">http://purl.allotrope.org/ontologies/material#AFM_0001097</a> <a href="https://spec.pistoiaalliance.org/idmp/ontology/ISO/ISO11238-Substances/ChemicalSubstance">https://spec.pistoiaalliance.org/idmp/ontology/ISO/ISO11238-Substances/ChemicalSubstance</a>
type	Class
synonym	simple chemical   simple chemical substance
definition	<p>A chemical substance is a portion of material that is matter of constant composition best characterized by the entities (molecules, formula units, atoms) it is composed of. [IUPAC]</p> <p>single substance that can be described as a stoichiometric or non-stoichiometric single molecular entity and is not a protein, nucleic acid or polymer substance</p>
note	Chemical substances are generally considered 'small' molecules which have associated salts, solvates or ions and may be described using a single definitive or representative structure.
direct source	ISO 11238:2018 Health informatics - Identification of medicinal products (IDMP) - Data elements and structures for the unique identification and exchange of regulated information on substances, clauses 3.11 and 7.3
disjointWith	nucleic acid substance polymer substance protein substance structurally diverse substance






comprises

- **Bevacizumab**
  - + L1 PhP of Bevacizumab
  - + L2 PhP of Bevacizumab, 25.00 mg/ml
  - + L3 PhP of Bevacizumab, Concentrate for s
  - + L4 PhP of Bevacizumab, 25.00 mg/ml, Co
- + Goserelin acetate
- + Ibuprofen
- + Ibuprofen sodium
- + Paracetamol

# Bevacizumab

WHODrug SPOR-Substances

    
🔍 Search ✕

Label	Bevacizumab   Bevacizumab <i>(en)</i>
URI	 <sup>4</sup> <a href="ema-sms:100000089535">ema-sms:100000089535</a>  <a href="https://who-umc.org/whodrug/whodrug-global/gsid/GSID6PND7BSX6E">https://who-umc.org/whodrug/whodrug-global/gsid/GSID6PND7BSX6E</a> 
type	Protein protein substance substance
synonym	BEVACIZUMABUM <i>(en)</i>   BI 695502 <i>(en)</i>   BP01 <i>(en)</i>   BS-503A <i>(en)</i>   HLX04 <i>(en)</i>   PF-06439535 <i>(en)</i>   RHUMAB VEGF <i>(en)</i>   RHUMAB-VEGF <i>(en)</i>   BEVACIZUMABUM <i>(la)</i>   BEVACIZUMAB <i>(da)</i>   BEVACIZUMAB <i>(de)</i>   BEVACIZUMAB <i>(el)</i>   BEVACIZUMAB <i>(es)</i>   BEVACIZUMAB <i>(fr)</i>   BEVACIZUMAB <i>(hr)</i>   BEVACIZUMAB <i>(hu)</i>   BEVACIZUMAB <i>(it)</i>   BEVACIZUMAB <i>(mt)</i>   BEVACIZUMAB <i>(nl)</i>   Bevacizumab <i>(no)</i>   BEVACIZUMAB <i>(pt)</i>   BEVACIZUMAB <i>(ro)</i>   BEVACIZUMAB <i>(sk)</i>   BEVACIZUMAB <i>(sl)</i>   BEVACIZUMAB <i>(sv)</i>   BEVACIZUMABAS <i>(lt)</i>   BEVACIZUMABUM <i>(cs)</i>   BEVACIZUMABUM <i>(lv)</i>   Bevacízumab <i>(is)</i>   BEVASITSUMABI <i>(fi)</i>   BEVATSIZUMAB <i>(et)</i>   BEWACYZUMAB <i>(pl)</i>   BÉVACIZUMAB <i>(fr)</i>   бевацизумаб <i>(bg)</i>
has name	Bevacizumab BEVACIZUMABUM BI 695502 BP01 BS-503A HLX04 PF-06439535 RHUMAB VEGF RHUMAB-VEGF



comprises

- Bevacizumab
  - + L1 PhP of Bevacizumab
  - + L2 PhP of Bevacizumab, 25.00 mg/ml
  - + L3 PhP of Bevacizumab, Concentrate for s
  - + L4 PhP of Bevacizumab, 25.00 mg/ml, Co
- + Goserelin acetate
- + Ibuprofen
- + Ibuprofen sodium
- + Paracetamol

# Bevacizumab

WHODrug

📄 | ⚙️ | 👁️

View dataset details for SPOR-Substances



🔍 Search [×](#)

Label	Bevacizumab   Bevacizumab <small>(en)</small>	
URI	 <sup>4</sup> <a href="ema-sms:100000089535">ema-sms:100000089535</a>  <a href="https://who-umc.org/whodrug/whodrug-global/gsid/GSID6PND7BSX6E">https://who-umc.org/whodrug/whodrug-global/gsid/GSID6PND7BSX6E</a> 	
type	<div>Protein</div> <div>protein substance</div> <div>substance</div>	
synonym	<div>BEVACIZUMABUM <small>(en)</small>   BI 695502 <small>(en)</small>   BP01 <small>(en)</small>   BS-503A <small>(en)</small>   HLX04 <small>(en)</small>   PF-06439535 <small>(en)</small></div> <div>  RHUMAB VEGF <small>(en)</small>   RHUMAB-VEGF <small>(en)</small>   BEVACIZUMABUM <small>(la)</small>   BEVACIZUMAB <small>(da)</small>  </div> <div>BEVACIZUMAB <small>(de)</small>   BEVACIZUMAB <small>(el)</small>   BEVACIZUMAB <small>(es)</small>   BEVACIZUMAB <small>(fr)</small>  </div> <div>BEVACIZUMAB <small>(hr)</small>   BEVACIZUMAB <small>(hu)</small>   BEVACIZUMAB <small>(it)</small>   BEVACIZUMAB <small>(mt)</small>  </div> <div>BEVACIZUMAB <small>(nl)</small>   Bevacizumab <small>(no)</small>   BEVACIZUMAB <small>(pt)</small>   BEVACIZUMAB <small>(ro)</small>  </div> <div>BEVACIZUMAB <small>(sk)</small>   BEVACIZUMAB <small>(sl)</small>   BEVACIZUMAB <small>(sv)</small>   BEVACIZUMABAS <small>(lt)</small>  </div> <div>BEVACIZUMABUM <small>(cs)</small>   BEVACIZUMABUM <small>(lv)</small>   Bevacízumab <small>(is)</small>   BEVASITSUMABI <small>(fi)</small>  </div> <div>BEVATSIUMAB <small>(et)</small>   BEWACYZUMAB <small>(pl)</small>   BÉVACIZUMAB <small>(fr)</small>   бевацизумаб <small>(bg)</small></div>	
has name	<div>Bevacizumab</div> <div>BEVACIZUMABUM</div> <div>BI 695502</div> <div>BP01</div> <div>BS-503A</div> <div>HLX04</div> <div>PF-06439535</div> <div>RHUMAB VEGF</div> <div>RHUMAB-VEGF</div>	





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  - + L2 PhP of Bevacizumab, 25.00 mg/ml
  - + L3 PhP of Bevacizumab, Concentrate for sol
  - L4 PhP of Bevacizumab, 25.00 mg/ml, Conce
    - Abevmy (MedProd)
    - Avastin (MedProd)**
    - Avastin (MedProd)
    - Avastin (MedProd)
    - Aybintio (MedProd)
    - Onbevzi (MedProd)
    - Vegzelma (MedProd)
- + Goserelin acetate
- + Ibuprofen
- + Ibuprofen sodium
- + Paracetamol

# Avastin (MedProd)

WHODrug

✎ 📦 🖨  
🔍 Search ✕

Label	Avastin (MedProd)
URI	<a href="https://who-umc.org/whodrug/whodrug-global/mpid/3182215">https://who-umc.org/whodrug/whodrug-global/mpid/3182215</a>
type	medicinal product
comprises	L4 PhP of Bevacizumab, 25.00 mg/ml, Concentrate for solution for infusion, Injection
hasPhPIDLevel1	L1 PhP of Bevacizumab
hasPhPIDLevel2	L2 PhP of Bevacizumab, 25.00 mg/ml
hasPhPIDLevel3	L3 PhP of Bevacizumab, Concentrate for solution for infusion
hasPhPIDLevel4	L4 PhP of Bevacizumab, 25.00 mg/ml, Concentrate for solution for infusion, Injection
is identified by	3182215
plays role	Avastin in Brazil by Roche (AMP)



Heiner Oberkamp

what is the active ingredient of avastin?



Accurids

The active ingredient of Avastin is Bevacizumab<sup>1</sup>. Bevacizumab is an anti-VEGF humanized murine monoclonal antibody that inhibits VEGF receptors and helps to prevent pathologic angiogenesis<sup>1</sup>.

## Sources

1. [Bevacizumab - Accurids ↗ ↗<sup>2</sup>](#)



Heiner Oberkamp

where is avastin registered? by which company?



Accurids

Avastin is registered in various countries, and some of the registrations include:

1. Avastin in Norway by Roche<sup>1</sup>.
2. Avastin in the United States of America by Genentech<sup>2</sup>.

These registrations indicate that the company responsible for Avastin is Roche, and its subsidiary Genentech is responsible for the product in the USA.

## Sources

1. [Avastin in Norway by Roche - Accurids ↗](#)
2. [Avastin in United States of America by Genentech - Accurids ↗](#)

Type a message ...



*Standards-based  
knowledge graphs  
enable AI-powered  
chats based on facts  
with data references*

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