



## What is the Pistoia Alliance?

The Pistoia Alliance is a not-for-profit member organization that brings together pharmaceutical companies, technology vendors, regulators, academics, and standards bodies to solve pre-competitive data and technology challenges that no single organization can tackle alone.

We are not software vendors. We do not build or sell products. Our role is to convene, govern, and accelerate shared standards and tools that the whole industry can build on.

### **Registered not-for-profit organization.**

No commercial interest in any implementation, tool, or vendor. Surplus is reinvested into the mission.

**Member of the American National Standards Institute (ANSI)**, connecting our work to the US and international standards infrastructure.

**Registered in the European Medicines Agency stakeholder database**, giving us a formal standing in EU regulatory processes and consultations.

A track record of trusted regulatory collaboration, with two completed **public-private partnerships** with the US Food & Drug Administration (FDA).

**Life Sciences ecosystem representation.** Members span pharmaceutical companies, biotechs, technology vendors, CROs, CDMOs, regulators, and academic institutions.

**Vendor-neutral governance.** No single member, sponsor, or implementation partner controls the direction of Pistoia Alliance projects. Governance documents are publicly available.

# IDMP Ontology

An expert-built, vendor-neutral framework providing a shared and consistent digital language for medicinal product data across systems, companies, and borders.

An **ontology** is a formal way of defining concepts and the relationships between them in a way that computers can read and reason with. The structured vocabulary includes:

- **Concepts:** the things that exist
- **Relationships:** how concepts connect
- **Rules:** what is valid

The difference from a simple spreadsheet or database schema is that an ontology captures meaning, not just structure. Thus, two systems using the IDMP Ontology will interpret data the same way.

## What is the IDMP Ontology?

The **IDMP Ontology** is the pharmaceutical industry's implementation layer for the five ISO standards for the Identification of Medicinal Products (ISO 11615, 11616, 11238, 11239, 11240). It provides a shared, vendor-neutral, machine-readable framework for medicines data to give organizations a directly deployable foundation for internal data management, regulatory submission, and cross-system interoperability.

Think of it as a shared grammar: rather than each organization interpreting the ISO standards independently, the IDMP Ontology provides the shared digital language that makes medicinal product data consistent, connected, and interoperable across the pharmaceutical value chain.

### The problems it solves

- Harmonizes multiple names and IDs for the same product across R&D, regulatory, manufacturing, and commercial systems.
- Unifies interpretations of the ISO standards to ensure consistent data labeling, processing, and sharing.
- Structures medicinal product data, which unlocks automation and AI applications.
- Builds on semantic web standards OWL/RDF facilitating integration and deployment.



## Who hosts and oversees the IDMP Ontology?

As a non-profit consortium representing the entire Life Sciences ecosystem, the **Pistoia Alliance** owns and governs the IDMP Ontology. It sets strategic direction via the Steering Committee, which is open to any Pistoia Alliance member and currently includes J&J, Boehringer Ingelheim, Merck & Co., Amgen, and Global Value Web. **Decisions about the evolution of the ontology are made collectively.**

**ACCURIDS** is currently our strategic technical stewardship partner, based on an awarded three-year contract. ACCURIDS provides ontology engineering, maintenance, quarterly releases, and enhancements. As a co-founder of the ontology, ACCURIDS has deep domain expertise and is one of several software vendors that implement the IDMP Ontology. The Pistoia Alliance remains responsible for the sustainability and continued maintenance of the ontology into the future.

## What does stewardship and maintenance of the IDMP Ontology entail?

- 1 Guaranteed maintenance, quarterly update releases, and planned enhancements.
- 2 Strategic and incremental refactoring of the IDMP Ontology to reduce its complexity and make it deployable without being an ontology expert.
- 3 Vocabularies, knowledge graphs, and implementation guides to lower the barrier to entry for organizations at any stage of their IDMP journey.
- 4 Design to standardize product data once, allowing compliance, internal integration, partner exchange, and AI tooling to benefit from the same structure.

## How is the IDMP Ontology currently used?

### EMA Product Management System (PMS)

Maps directly to ISO IDMP standards and EMA PMS requirements, eliminating gaps that cause inconsistent filings.

### National Competent Authorities vs PMS

Mapping product data across EU member states by dose form, ATC code, and strength.

### Multi-market submissions

Consistent product representation across jurisdictions.

### Internal data integration

Supports a single digital thread for every product entity within RIM platforms that connects product data across functions.

### Partner and vendor exchange

Eliminates bespoke manual transformation of data from CDMOs, CROs, and commercial partners.

### AI and automation readiness

Structured, semantically consistent data for reliable AI discovery, analytics, and agents.



## How do you access the IDMP Ontology?

The IDMP Ontology is a publicly available asset for any organization. Quarterly updates to the ontology are released in a tiered cadence where ontology sponsors and Pistoia Alliance members gain initial access to support the validation of enhancements and the development of use cases. This ensures the robustness of the public version.

### TIER 1: Public

- Public version available via GitHub.
- Access via open-source MIT license.
- Version 1.5 to be released in December 2026.
- Full ontology files via an open-source repository.
- Community documentation and release notes.
- Sufficient for most use cases, including EMA data alignment workflow.
- Access to trainings.

Public notes about the ontology are available [here](#).

### TIER 2: Members

- Access via a members-only platform.
- Version 1.6 to be released in November 2026.
- Community documentation and release notes.
- Quarterly Community of Interest meetings covering expert insights and showcased use cases.
- Peer network across the ecosystem.
- A feedback channel to inform enhancements and roadmap.
- Access to trainings.

Learn how to become a Pistoia Alliance member [here](#).

### TIER 3: Sponsors

- Access via a project-specific platform.
- Version 1.7 released in July 2026.
- Community documentation and release notes.
- Quarterly Community of Interest meetings covering expert insights and showcased use cases.
- A seat on the Steering Committee to collectively define the ontology roadmap and prioritize enhancements.
- Develop implementation guides, knowledge graphs, and controlled vocabularies.
- Engage with the community in user group meetings.
- Access to trainings.

Interested in sponsorship? Contact [idmpo@pistoiaalliance.org](mailto:idmpo@pistoiaalliance.org)

**Note: Regulators have free access to the latest version. Please contact [idmpo@pistoiaalliance.org](mailto:idmpo@pistoiaalliance.org)**

## How can you get started with the IDMP Ontology?

There are three broad levels of implementation depending on what you need:

|                                       |                                                                                                                                                                                                                                                                                                                                   |
|---------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>LEVEL 1</b><br>Read and map        | Use the ontology as a reference model (no new infrastructure needed). Take your existing product data and map your internal field names to IDMP Ontology concepts. A data analyst can do this in a spreadsheet or mapping tool. This is the entry point and what the National Competent Authorities vs. PMS comparison demo uses. |
| <b>LEVEL 2</b><br>Validate against it | Load the ontology into a tool (Protege is free and open source; ACCURIDS is a commercial option) and run your data through it to check for inconsistencies, such as missing required fields, invalid combinations, or conflicting entries across markets.                                                                         |
| <b>LEVEL 3</b><br>Build on it         | Store your data in a knowledge graph (RDF/OWL format) and query it using SPARQL. This is a full enterprise knowledge graph where every function links their data to the shared product backbone. It requires more infrastructure but unlocks the AI and cross-system integration benefits.                                        |



## Voices from the community



*"IDMP gives us a global standard, but implementation remains fragmented across organizations. We asked whether we could tackle this challenge collaboratively in a pre-competitive setting, and the Pistoia Alliance made that collaboration possible."*

Sheila Elz, Boehringer Ingelheim

*"The IDMP ISO standards and the Ontology give us a very good, solid framework. It also helps the internal conversation. It stops the debate. This is the industry standard we should go after."*

Gang Xue, J&J Innovative Medicine



*"At its core, we are implementing and using the IDMP Ontology as a shared semantic backbone."*

Gerd Kleemann, Amgen

*"By leveraging the IDMP Ontology to structure and manage regulatory data, we can compare our internal data against authority data, helping to ensure data quality, consistency, and greater operational efficiency."*

Fabian Muttach, Boehringer Ingelheim



### Find more information about the IDMP Ontology

- Public ontology on GitHub: <https://github.com/Pistoia-Alliance-Inc/Pistoia-Alliance-Ontologies/tree/main/IDMP-O>
- The IDMP Ontology webpage: <https://pistoiaalliance.org/project/idmp-o/>
- Browse concepts and view a demo: <https://pistoiaalliance accurids.com>
- Report a bug, request access, or general inquiries: [idmpo@pistoiaalliance.org](mailto:idmpo@pistoiaalliance.org)
- Training recordings: <https://pistoiaalliance.org/eventdetails/idmp-ontology-training-recordings-2025/>