Product Data Quality Across Sources – A Scalable Approach

Aligning EMA PMS with Pharma RIM via the IDMP Ontology

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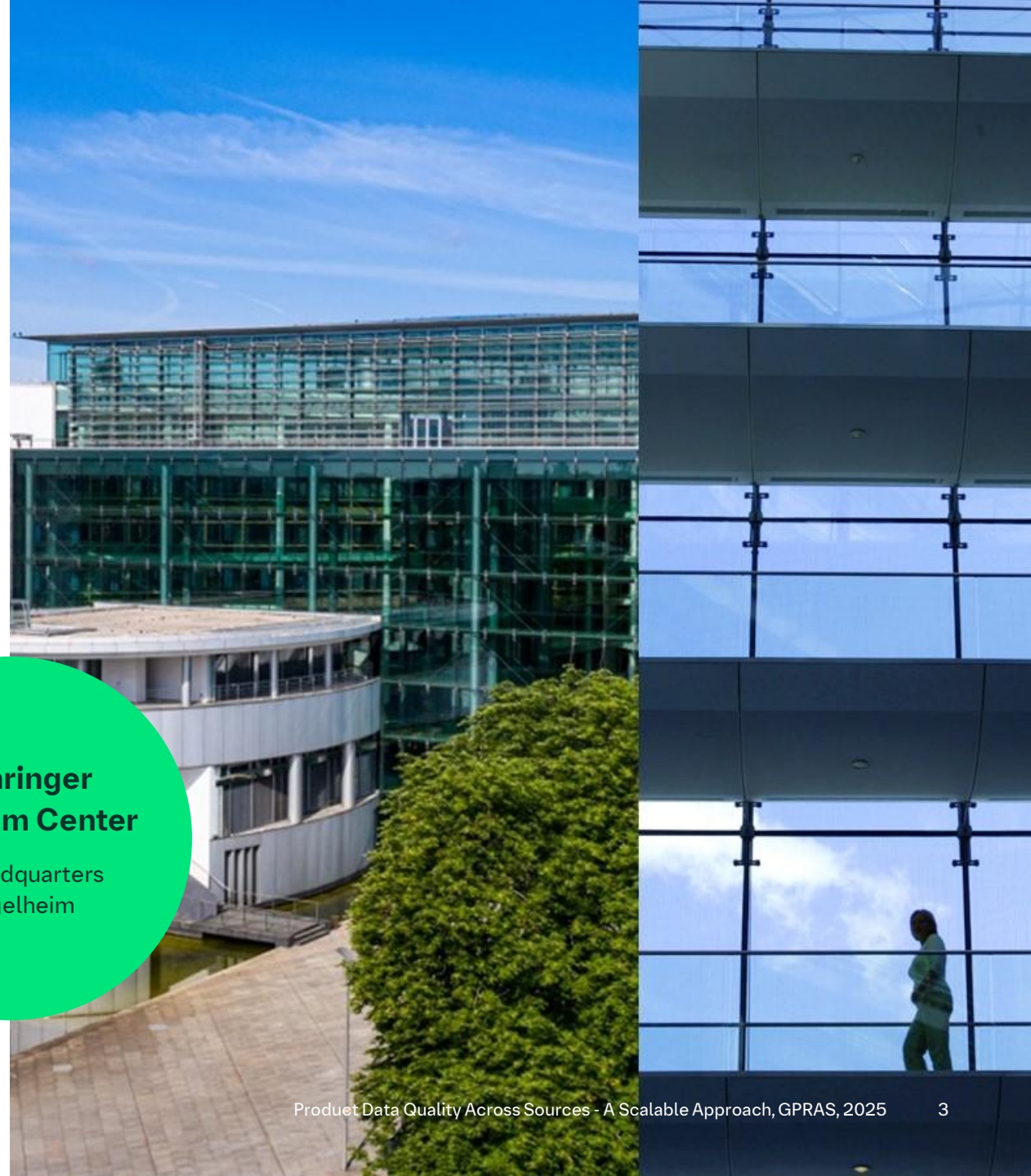
Boehringer Ingelheim in brief

- Family-owned pharmaceutical company
- Founded 1885 in Ingelheim, Germany
- Focus on Human Pharma and Animal Health
- About 54,500 employees worldwide
- R&D expenses of 6.2 billion EUR
- 26 R&D sites worldwide for Human Pharma and Animal Health
- Net sales of 26.8 billion EUR



Boehringer Ingelheim Center

Our headquarters in Ingelheim

Status: 31/12/2024

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The Situation

Company Source Systems

General (e.g., Master Data System)
Functional (e.g., Development, Clinical, Supply Chain, Operations)

Reg. Information Management

Collecting and distributing correct information internally and externally to Health Authorities

Regulatory Agency Systems

Local/Regional (e.g., EMA, European NCAs, FDA, Health Canada, Swissmedic, Anvisa)

Stand alone or part of platform

Platform approach

Stand alone or part of architecture allowing interoperability within one agency, but not across industry or other agencies

May not or only in parts be interoperable

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Knowledge graph technology as an enabler for interoperability

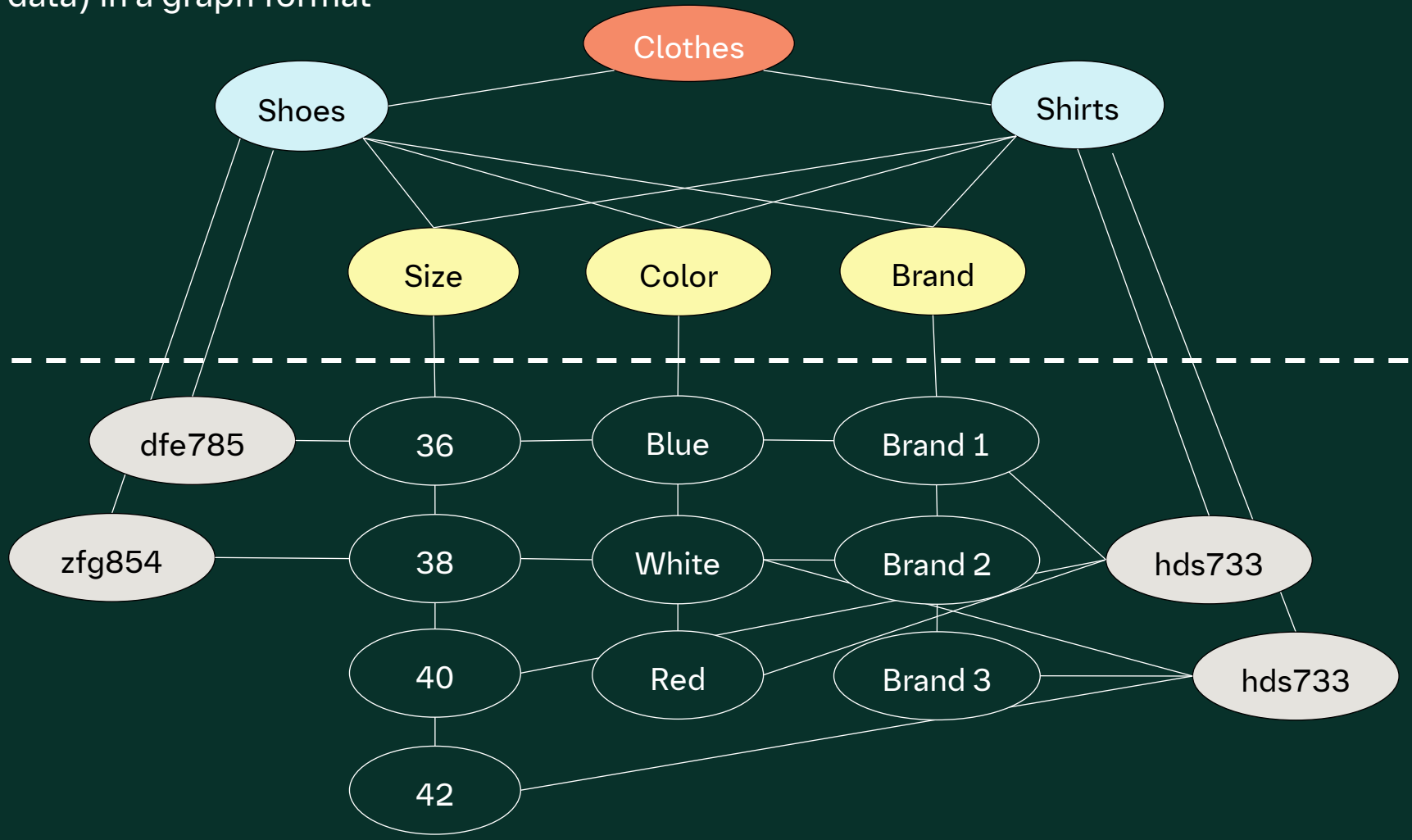
Knowledge graph = (ontology + data) in a graph format

Ontology

Model / schema

Data

Instances / data



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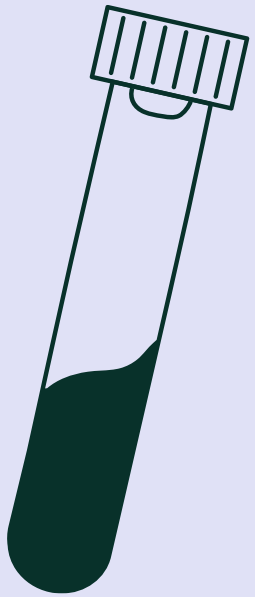
Motivation:
High Data Quality and determining the “TRUTH” for Regulatory Processes



01

Functional company systems

- May be using standards
- May be old and not IDMP compliant
- May contain redundant data

02

RIM

- Built to be IDMP compliant
- Serves to consume and to distribute true data within interoperable processes

03

Agency systems

- May be IDMP compliant
- May be older and hence not IDMP compliant
- May contain redundant data
- May need / contain additional agency specific data

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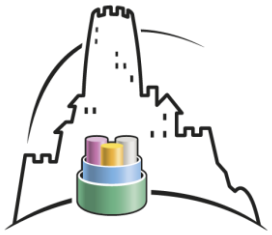
IDMP landscape is a complex one…



GIDWG

Technical WG: Plan and execute projects focused on global implementation and maintenance (EMA-FDA-WHO/UMC + Regulators + Observers +SMEs)

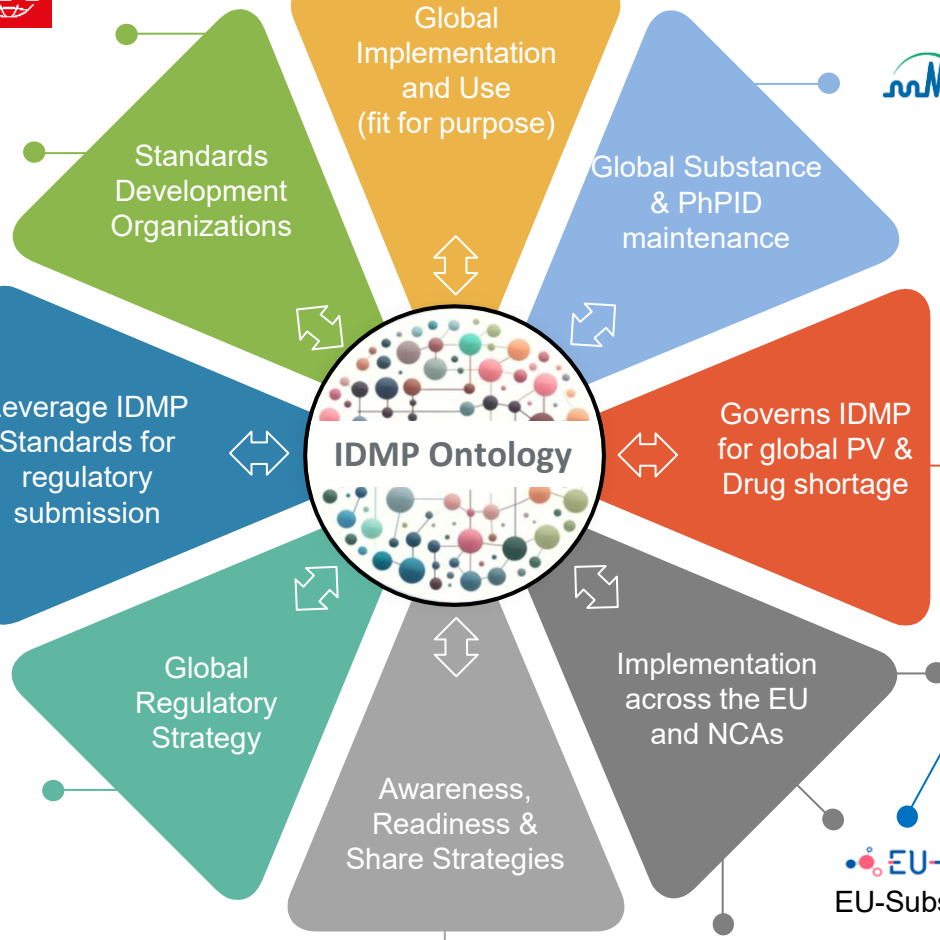
ISO

Develop and maintenance of the IDMP standards, technical specifications and reports

HL7

Develop and maintenance of the IDMP messaging standards

FHIR



WHO-UMC

Proposed Global IDMP Maintenance Organization

WHO EWG

Use & support of global IDMP for LMICs.

- 12 experts appointed by WHO HQ (representing 6 WHO regions) + Observers + SMEs
- Regulators can be observers

ICH

- M4Q Quality Data Standards
- E2B ICSR

ICMRA

A Regulatory Pharmaceutical Quality Knowledge Management System (PQ KMS) to enhance the availability of quality medicines.

ICMRA-ICH-PIC/S-IPRP Joint Reflection Paper

EMA/EU

IDMP/ SPOR master data management services

FDA GSRS

EMA-FDA international CF on IDMP

EU-SRS

EU-Substance Registration System

- IDMP Frequently asked Questions
- IDMP Readiness Checklist

IPRP International Pharmaceutical Regulators Programme

UNICOM

EU-funded project for IDMP implementation at NCA level

Source: EMA

The EMA PMS / Boehringer Ingelheim Use Case

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WHY EMA?

Why PMS?

Why the Boehringer RIM ?

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Reasoning

Central agency in Europe with a high commitment to standardization and very good contacts to industry and other regulatory agencies

Central Master Data System for product data in the EU

Data do come from various sources with not aligned quality and granularity

Data scope is gradually increasing, no big bang

Data will be /are used for important regulatory processes (e.g., shortages, eAF, etc.) **with a clear ask to industry to secure data quality**

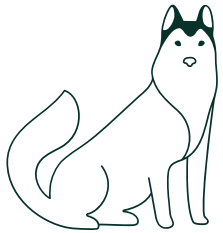
High internal data quality

1:1 match to each PMS entry

Data Challenges: Why this use case is far from trivial...

What is what?

While EMA data undergo a match & merge process, we need to map those data to our own ones ideally automatically



Iterative Data updates

Data at EMA do change frequently as well do ours.

How often do we need to compare?

Data not in focus at EMA may be wrong and do not need to be corrected. Really?

Data Processes

We find differences in data, but who is right?

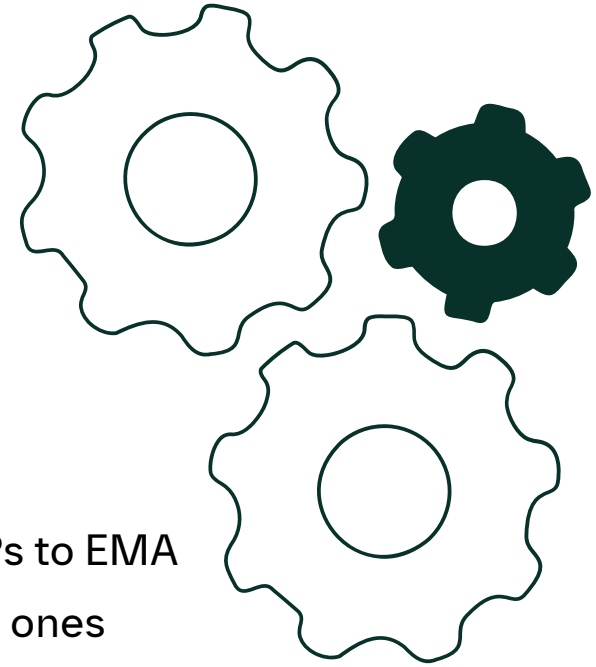
The evaluation process, internal and EMA communication pathways need to be defined.

How long do we need to wait for corrections?

EMA timelines for PMS updates

Data in scope of eAF, PSUR, etc.

- Should be correct at the latest when eAF is mandatory;
- However, the use of the variations form is already strongly recommended



NCA Data

- NCAs should map all no- CAPs to EMA systems by Dec 2026 (ULCM ones already by Dec 2025)
- Industry has no insight on NCA data truth

New data for manufacturers and packaging

- Manufacturer´s data and structured pack sizes for non-CAPs (ULCM) until Jun 2026.
- Strutured pack sizes for all other non-CAPs by June 2027

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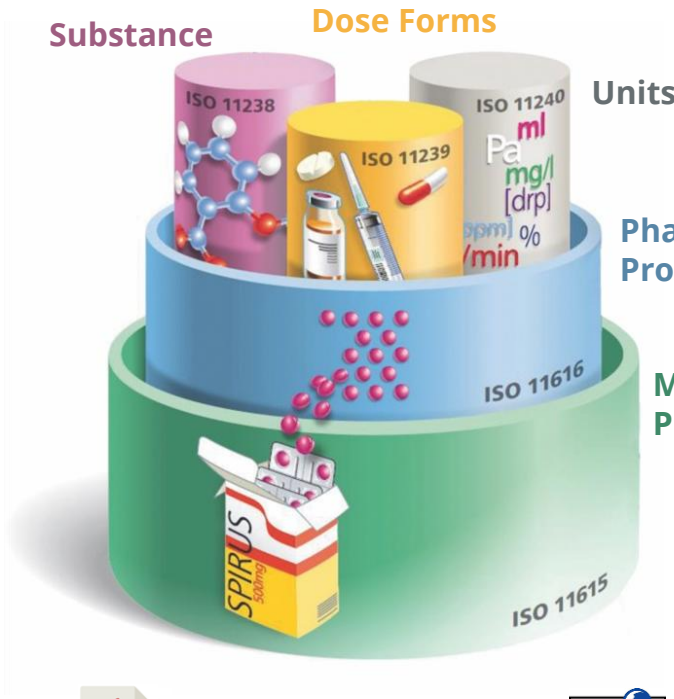
IDMP Ontology: Collaborative IDMP Standards Implementation



Ref: Présentation Power Point (unicom-project.eu)

ISO IDMP is a set of global standards about medicinal product information to improve patient safety and facilitate the exchange of information between regulatory authorities, healthcare professionals, and pharmaceutical companies.

The IDMP Ontology is a collaborative development by several pharma companies of the IDMP product data model in an open-source semantic ontology under the umbrella of the member-driven not-for-profit Pistoia Alliance.

12 Pharma Sponsors (2021-2025)

abbvie, AMGEN, AstraZeneca, BAYER, Boehringer Ingelheim, GSK, Johnson&Johnson, MERCK, MSD, NOVARTIS, Roche, Pfizer

Implementation Partners:

EDMCouncil, ACCURIDS, CROWN POINT TECHNOLOGIES

Interested Parties:

FDA, EUROPEAN MEDICINES AGENCY, Uppsala Monitoring Centre, CTADHL, ISO, HL7, UNICOM, SNOMED CT, MedDRA, DIA

Project Website: https://www.pistoiaalliance.org/project/idmp-o/

We integrated heterogenous datasets/data sources

Master Data Stock Keeping Units

Master database for SKU information

Master Data Product

Master database for product information

Master Data Business Partner

Master database for business partners

RIM system

Database for regulatory information, i.e. marketing authorization

Quality Assurance Agreement

Documents about contract manufacturers

S231- RIM system

Documents about API starting materials and related manufacturers

Long-Term Forecast

XLSX sheet about forecasts for SKUs

Enterprise Reference Data

Database for main-taining vocabularies

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IDMP-O journey of Boehringer Ingelheim

2023/04

Start - IDMP-O

Implementation start at Boehringer Ingelheim as part of Pistoia Alliance.

2023/11

Pistoia Conference, Boston

Presentation of core product implementation (Substance to Packaged Product).

2023/12

Start - Supply Chain Insights

Integrating heterogenous data sources for enabling advanced supply chain insights.

2024/07

Start – PMS Data Comparison

PoC to showcase comparison of EMA PMS data with Boehringer Ingelheim internal data.

2024/10

Go Live – Supply Chain Insights

Ability to give insights e.g.

- Financial impact on SC disturbance

2025/10

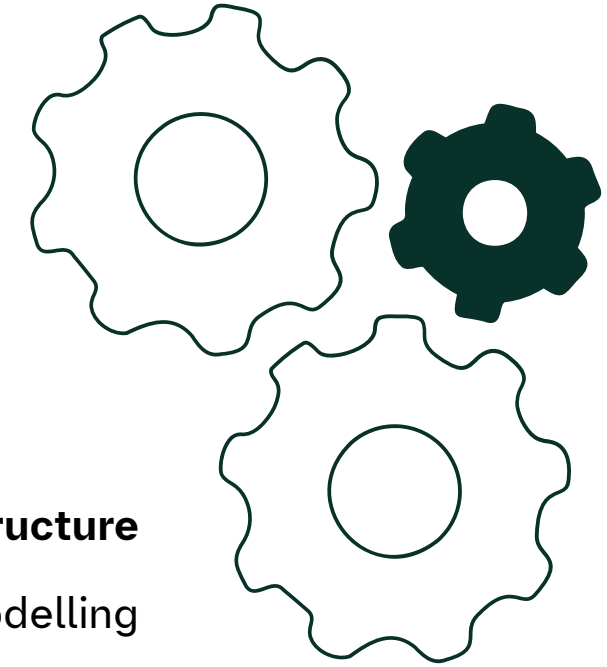
EMA PMS Pilot completed

Moving towards further business use case implementation of IDMP-O incl jurisdiction independent set ups.

Successful IDMP-O Implementation Requires Cross-Functional Collaboration

Project Management

Business and IT stakeholders need to be aligned for IDMP-O use case implementations



Management Endorsement

IDMP-O implementation needs to be understood and supported as a long-term strategic goal for data FAIRification

IT Infrastructure

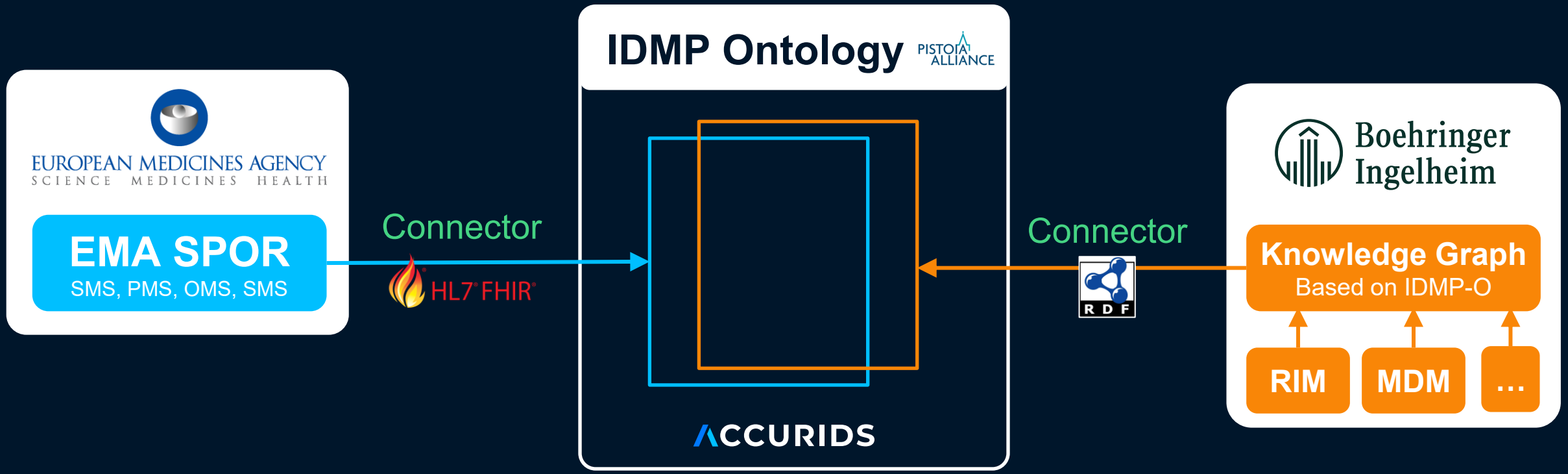
System for semantic knowledge modelling needs to be provided and maintained

Semantic Engineering

Data needs to be ingested from various source systems and formats to build the knowledge graph based on IDMP-O

Scalable Standards-based Data Alignment

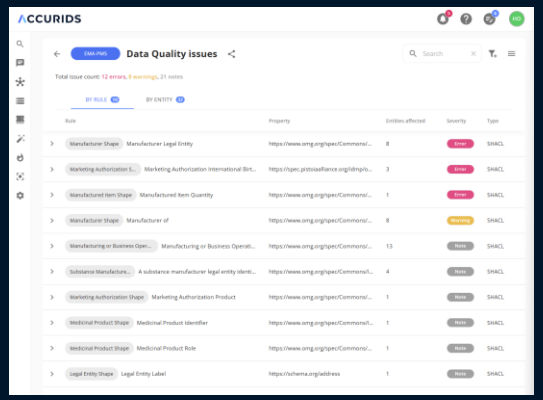
Automated alignment and comparison
with guided issue resolution by experts



How it Works

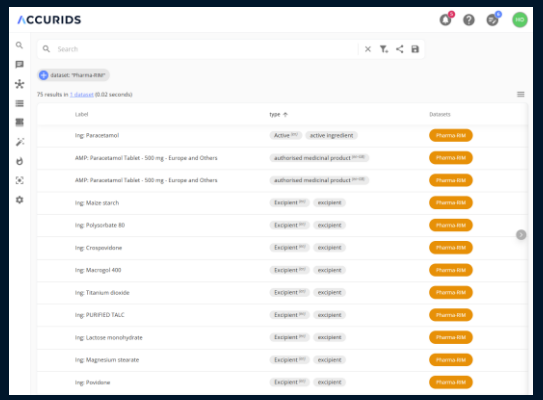
1

Connect EMA PMS and get Data Quality Report



2

Onboard Internal Product Data



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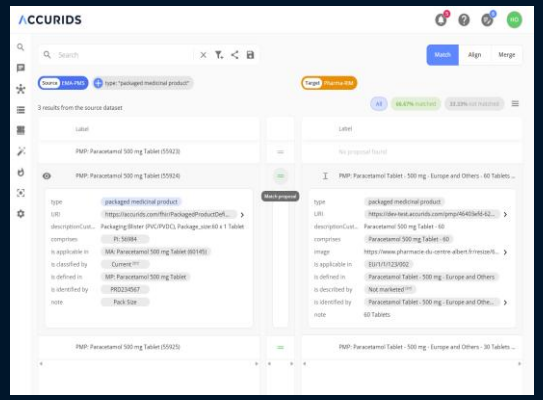
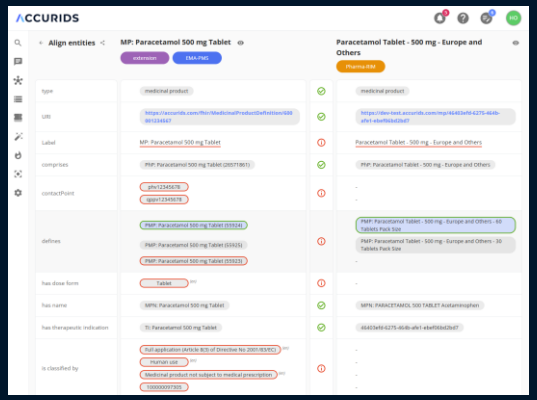
Data Auto-Matching with Rules and AI

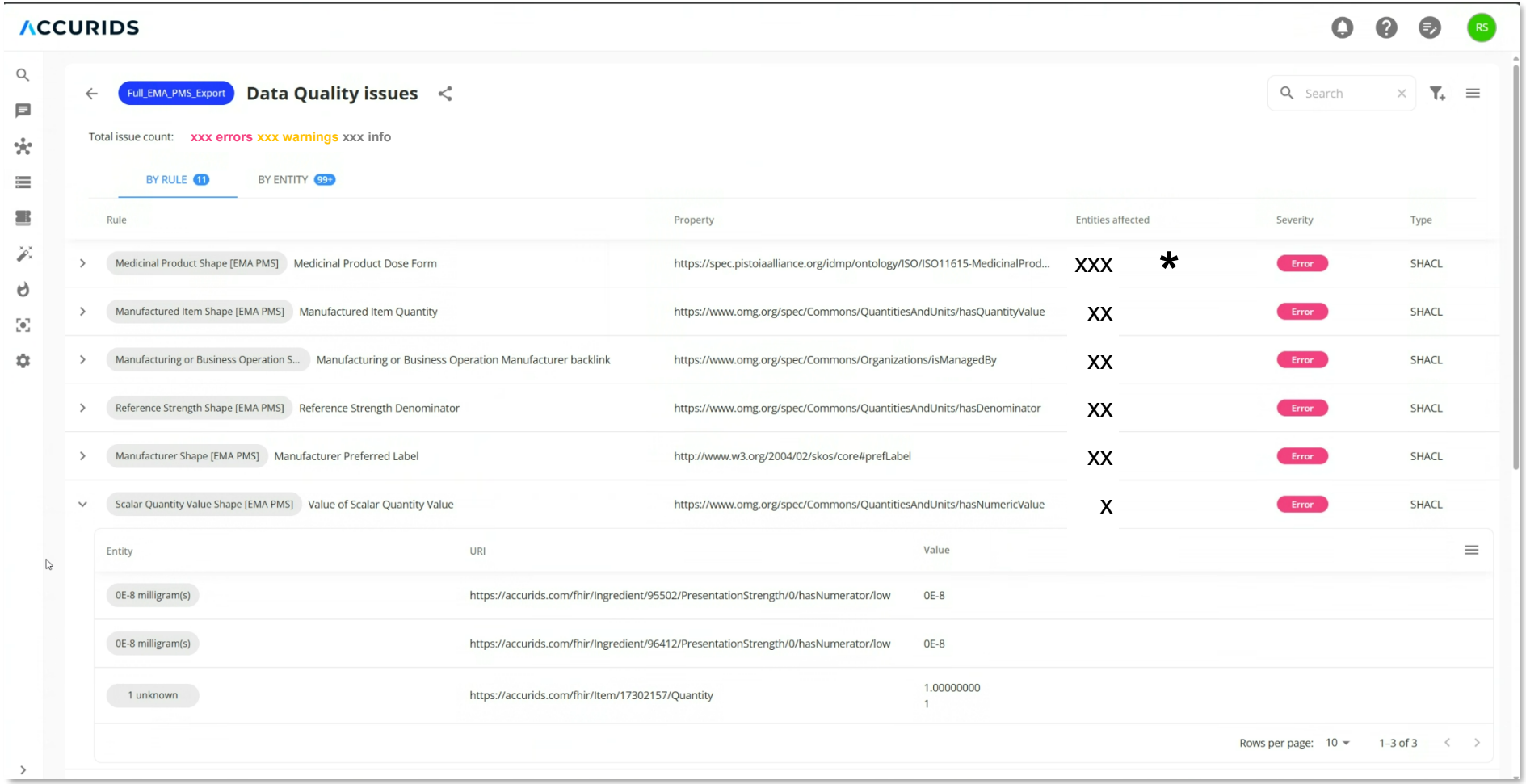


4

Compare and Align with Progress Monitoring



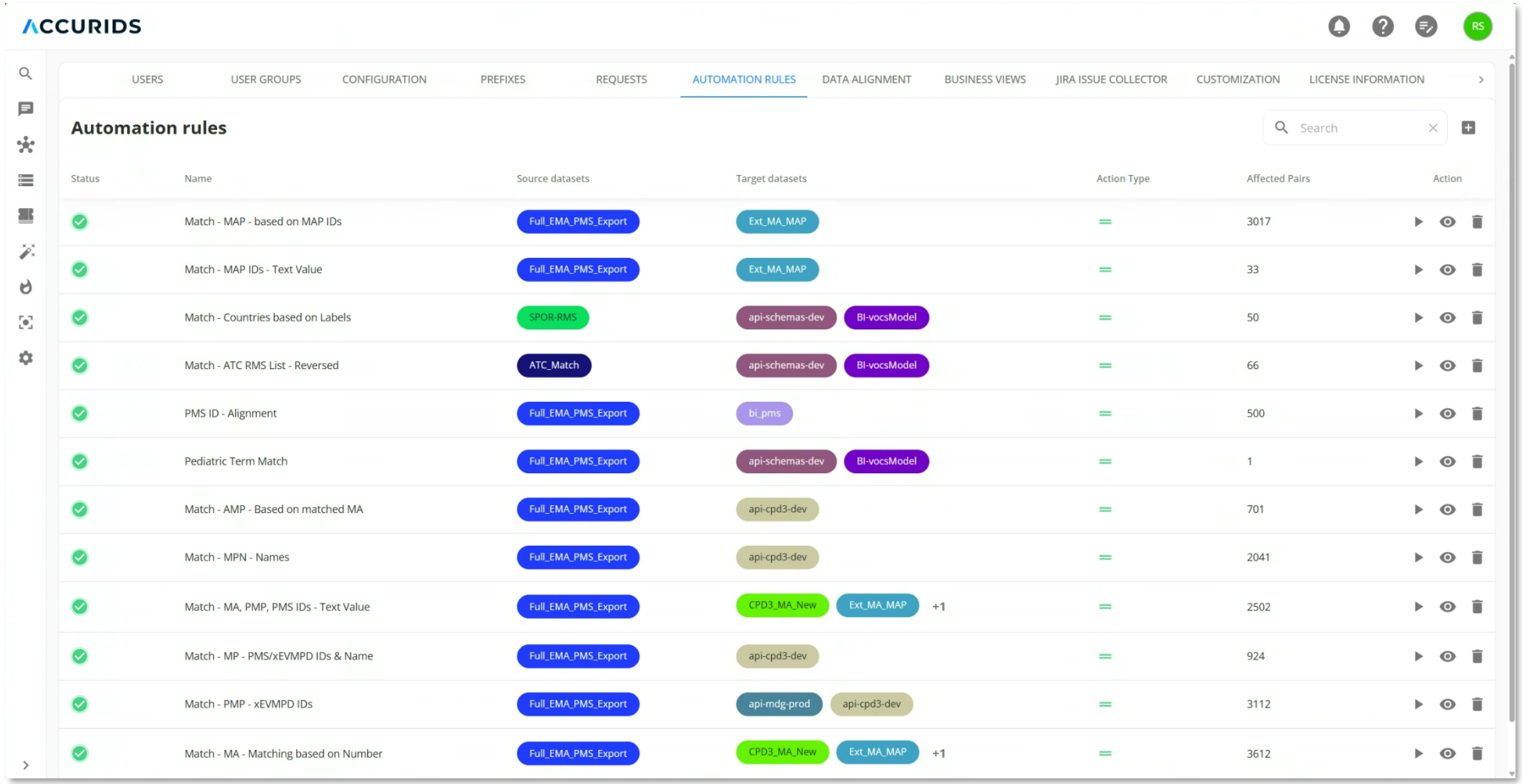
EMA PMS Data Quality Report



- ✓ Automatic transformation of EMA PMS FHIR messages.
- ✓ Data quality rules for EMA PMS requirements are pre-configured
- ✓ Custom data quality rules can be added
- → **Fully automated process to get an actionable EMA PMS data quality report for entire product portfolio.**

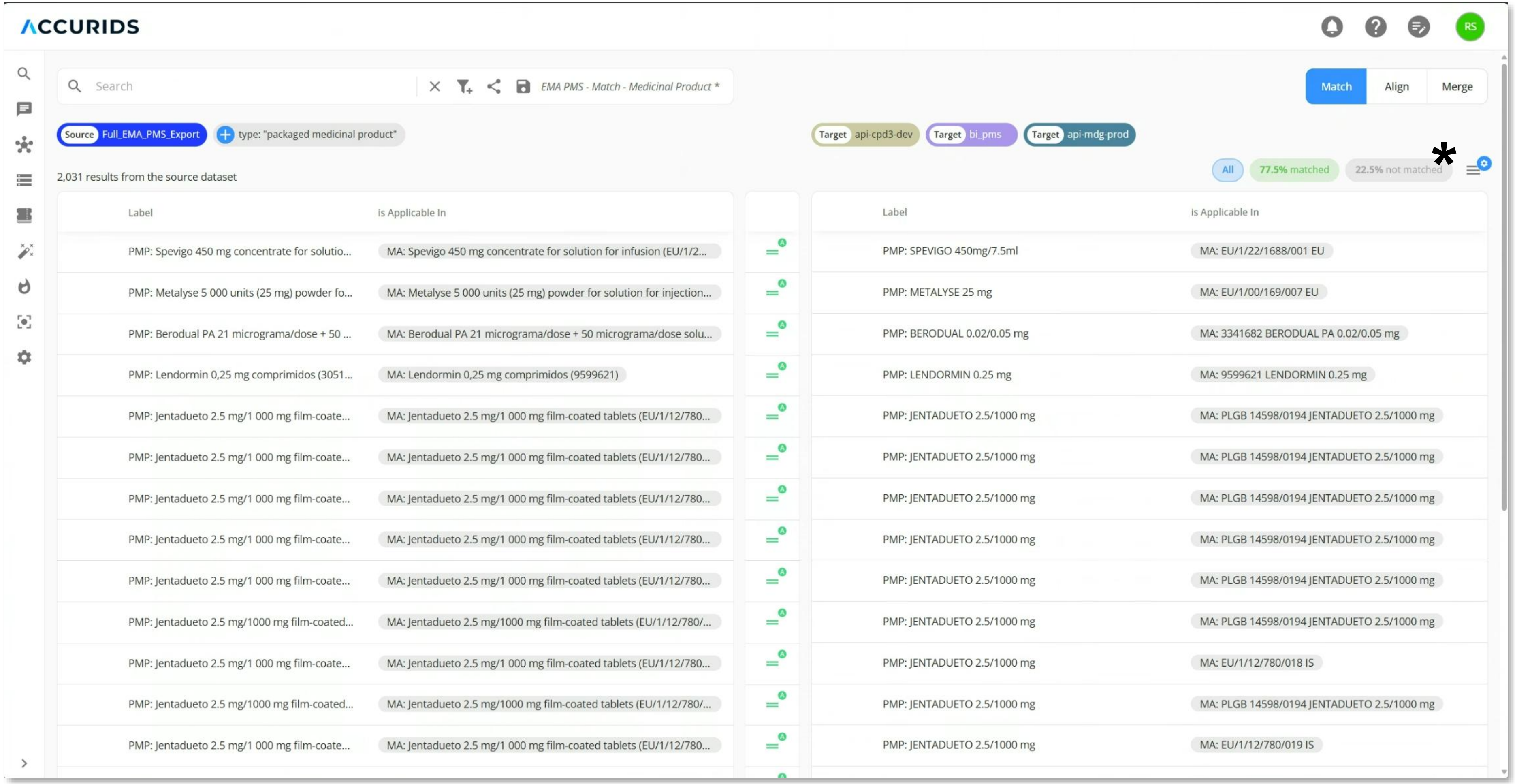
*Dose form issues due to wrong EMA RMS list usage in PMS by EMA

Auto-Matching Rules



- ✓ Standard matching rules based on EMA SPOR and IDMP-O
- ✓ Rule hierarchies with basic vocabulary matches before product data object matching
- ✓ Rule impact preview enables effective rule configuration governance
- → **Most of the EMA data is auto-aligned to internal product data.**

Review of Auto-Matched Product Data: PMPs

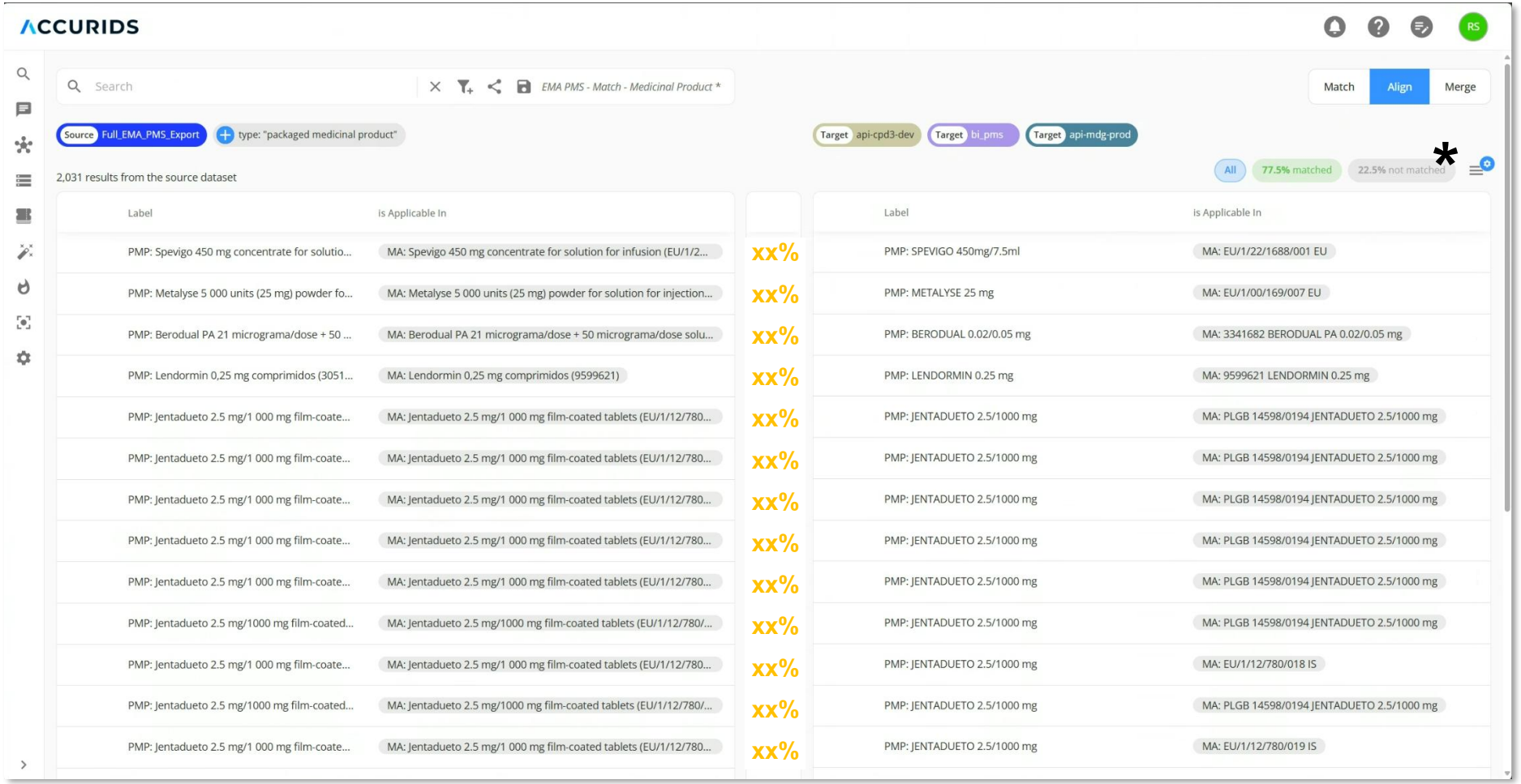


- ✓ Side-by side view to inspect auto-matched results
- ✓ Filters allow to focus on specific subset of the EMA data
- ✓ Directly visible insights on match % over selected dataset

→ **Allows SMEs to identify and focus their work on the problematic cases**

*Internal Product Knowledge Graph contains only marketed products

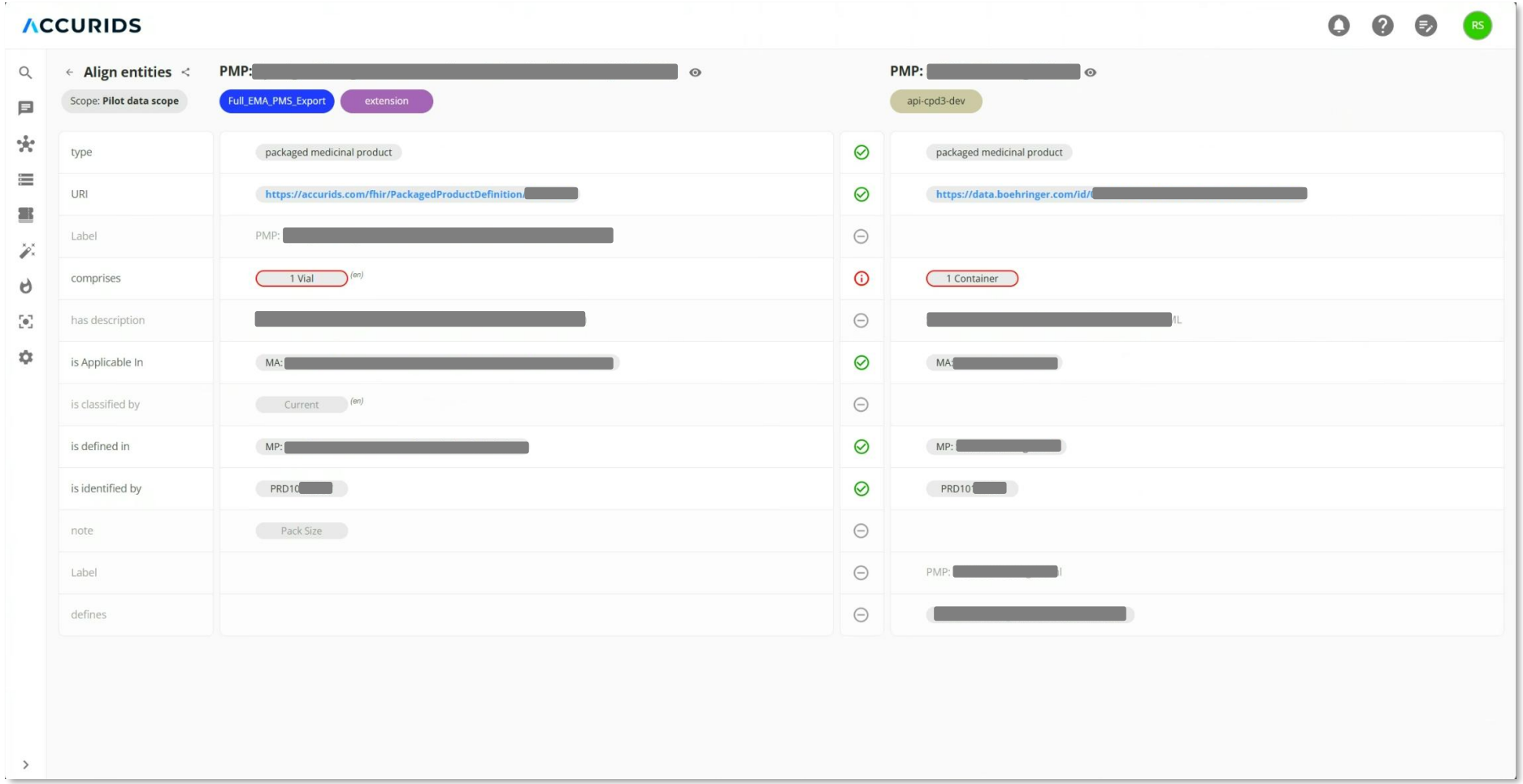
Data Alignment Status: PMPs



- ✓ See % of aligned data attributes per matched record
- ✓ Data alignment scope is configurable to different regulatory requirements, e.g., EMA ESMP vs. full PMS or other jurisdictions
- → **Allows to monitor progress towards increasing regulatory requirements from different jurisdictions**

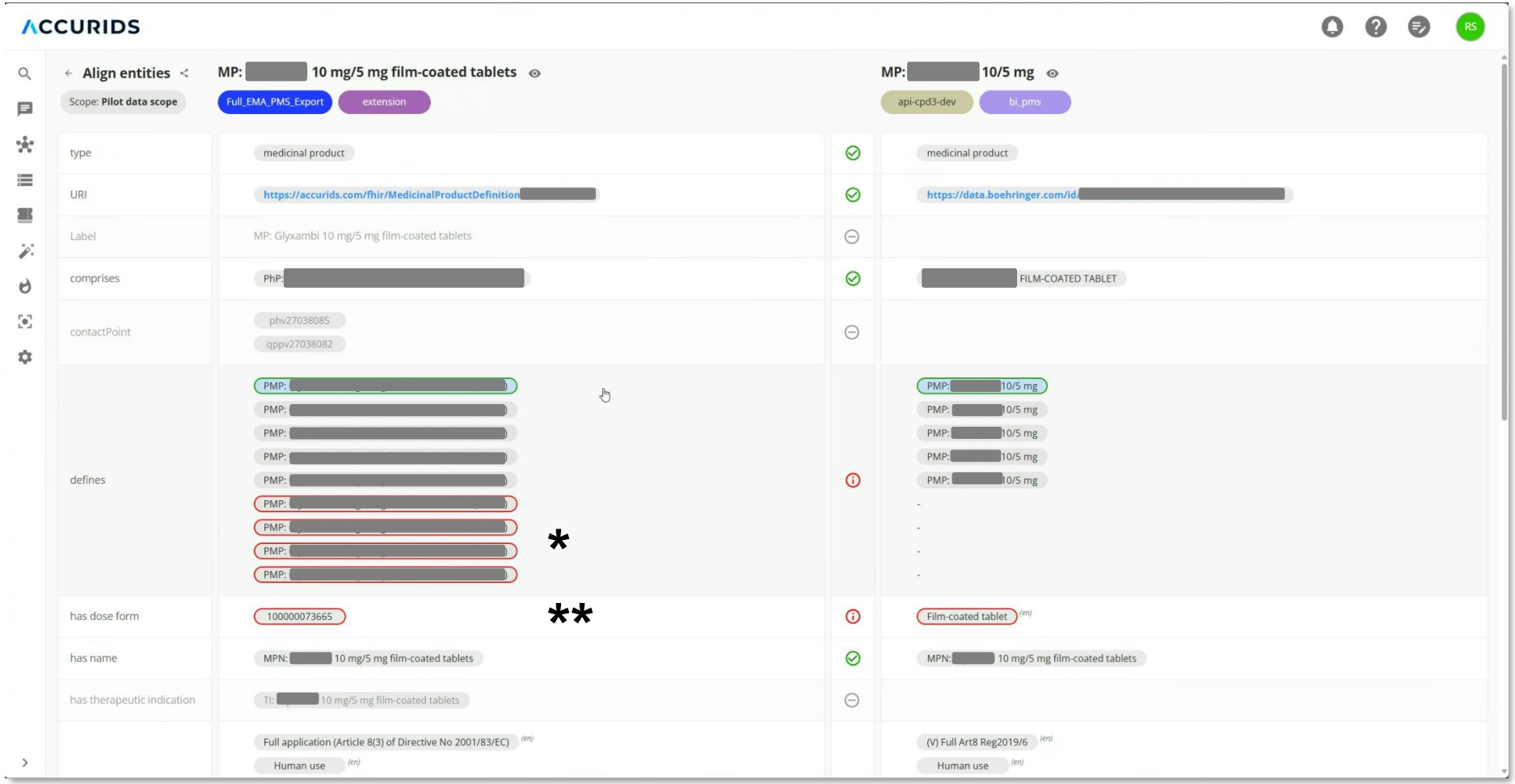
*Internal Product Knowledge Graph contains only marketed products yet

Compare Data Content in Detail: PMP



- ✓ Easily spot discrepancies vs. aligned data
- ✓ Allows to review and refine matched contents
- ✓ See data that is not yet to be compared given the selected comparison scope
- → **Allows SMEs to efficiently resolve discrepancies**

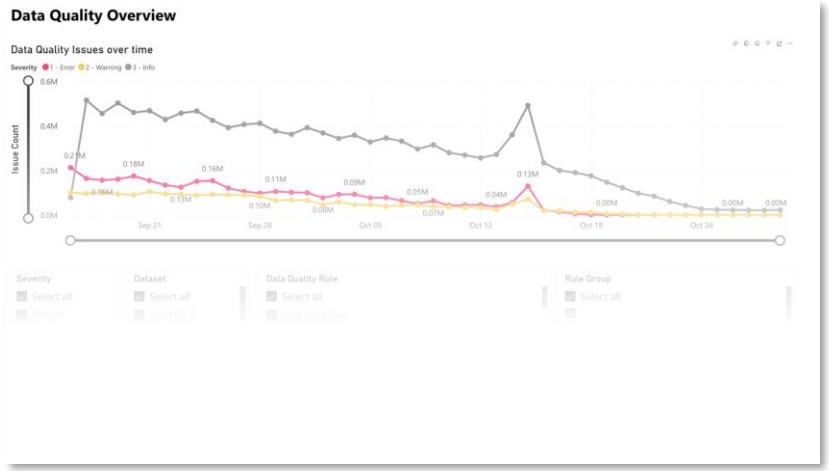
Compare Data Content in Detail: MP



- ✓ Easily spot discrepancies vs. aligned data
- ✓ Allows to review and refine matched contents
- ✓ See data that is not yet to be compared given the selected comparison scope
- → **Allows SMEs to efficiently resolve discrepancies**

*Boehringer Knowledge Graph currently includes PMPs, only if there are corresponding SKUs. The 4 additional unmatched PMPs, from EMA side are registriered, but there was no SKU created for the package sizes so the corresponding data is not in the Knowledge Graph.
**EMA PMS wrongly references to Combined Pharmaceutical Dose Form list instead of the Pharmaceutical Dose Form list (known issue)

Outlook: Monitor Data Quality & Alignment Progress



Work-in-Progress development by ACCURIDS to **allow plan and review the progress so that regulatory deadlines are met with confidence.**

- ✓ Visualization in ACCURIDS or dashboard tools like PowerBI
- ✓ Monitor data quality by: Severity, Data Objects (PMP, MP…), Data Quality Rules
- ✓ Similar monitoring for data matching and alignment progress for internal data vs. the different jurisdictions.

The IDMP Data Standardization Fabric
accurids.com

Summary and Outlook from Boehringer Ingelheim perspective

Proof of Concept

Conducted in 2024

- With 4 Boehringer Products (simple/complex/multiple languages)
- Principle suitability demonstrated

Pilot

Conducted in 2025

- With entire portfolio as in our RIM system
- Further development and adjustments of the Boehringer Ingelheim IDMP knowledge graph
- Iterative feedback and testing of solution
- Feasibility, Scalability and Maintainability demonstrated

Productive use

Now to 2026

- Implementation in production as **D**ata **A**nalysis and **C**omparison **S**ystem (**DACS**)
- Definition and implementation of Data Quality processes for PMS data Quality Management
- Productive run in 2026

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Thanks for the collaboration

Boehringer Ingelheim Team: Fabian Muttach, Max Fink, Mengzhe Wang, Sheila Elz, Thomas Hoehne (ext)

ACCURIDS Team: Raphael Sergent, Daniel Plagge, Ali Ariff, Alex Kleiber, José Guerreiro, Kamila Ciupak (ext)

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IDMP-O Team: Elisa Kendall

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QUESTIONS ?

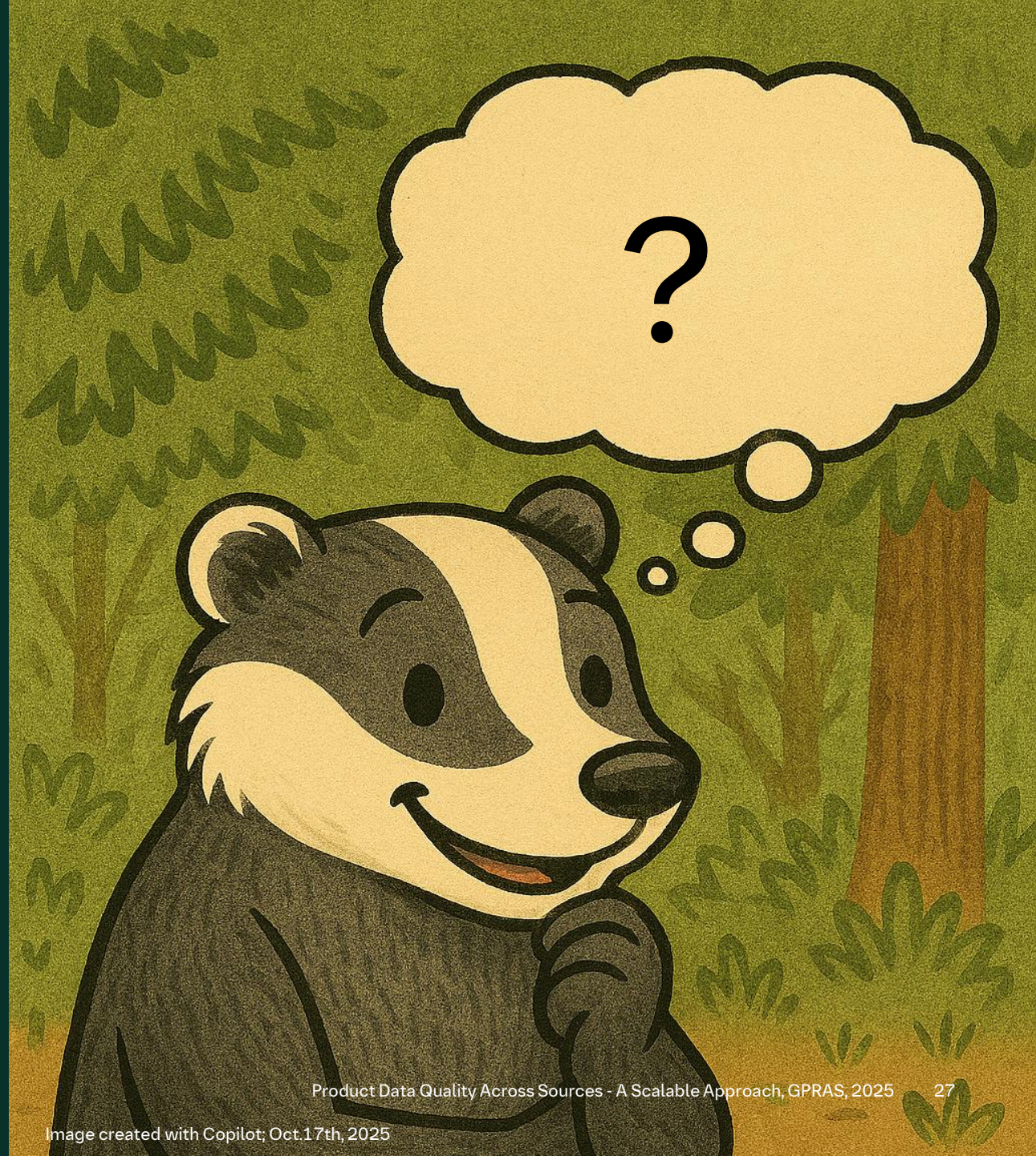

Image created with Copilot; Oct.17th, 2025

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