The Unified Product Data Strategy

IDMP Data Standardization Fabric to Master Your Product Data Lifecycle for Faster, and Streamlined Submissions

IDMP-ONTOLOGY
PISTOIA ALLIANCE
IMPLEMENTATION PARTNER
ACCURIDS
2025

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EMA PMS Mandate

Compliance is non-negotiable

European Medicines Agency requires marketing authorization holders (MAHs) to submit their data in IDMP-Format, also for existing authorizations

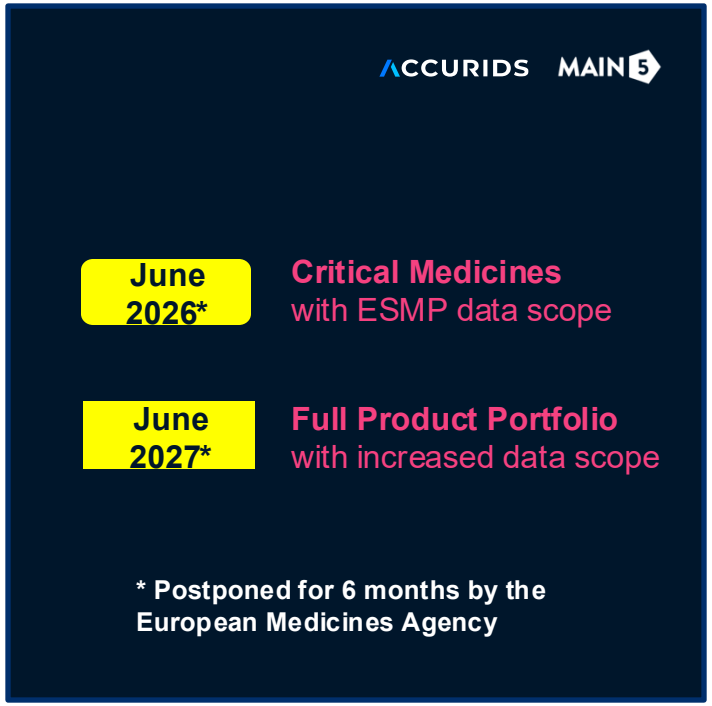
- **Focus on critical medicine in first phase**
- **Extension to full product scope in next phase**

- **Shift to Structured Data in Centralized System**

- **Objectives:** enhance pharmacovigilance, improve data integrity across the EU, and enable more proactive safety monitoring

- Non-compliance might lead to loss of marketing authorizations

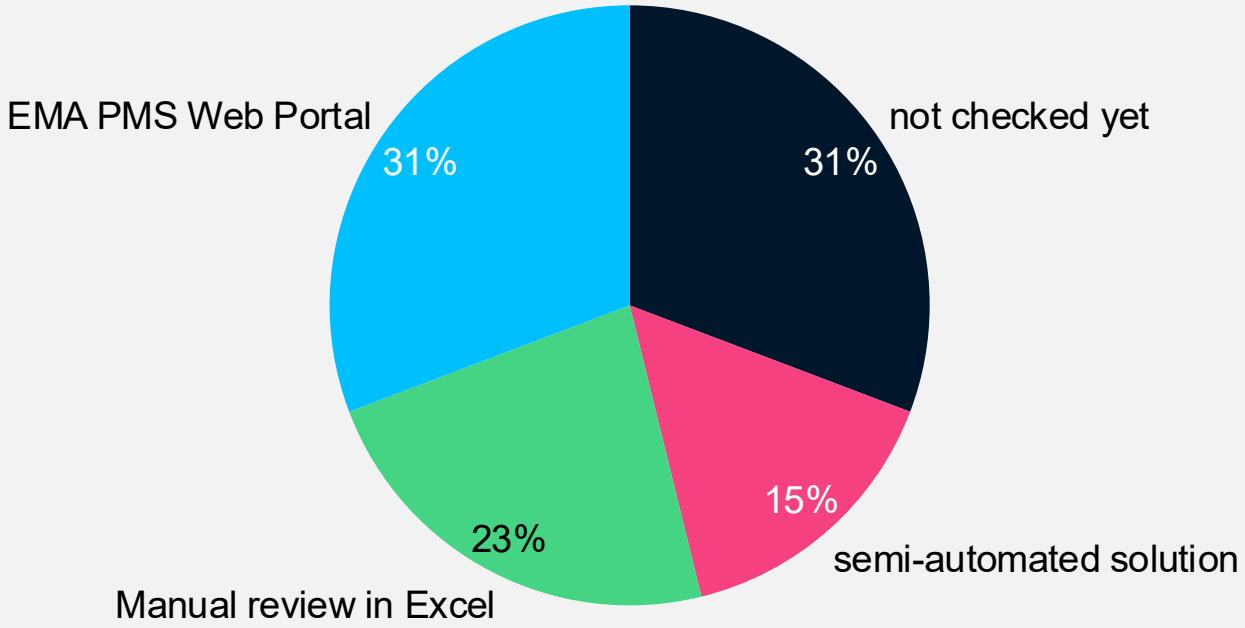
Upcoming EMA PMS Deadlines



EMA PMS Compliance Status Quo

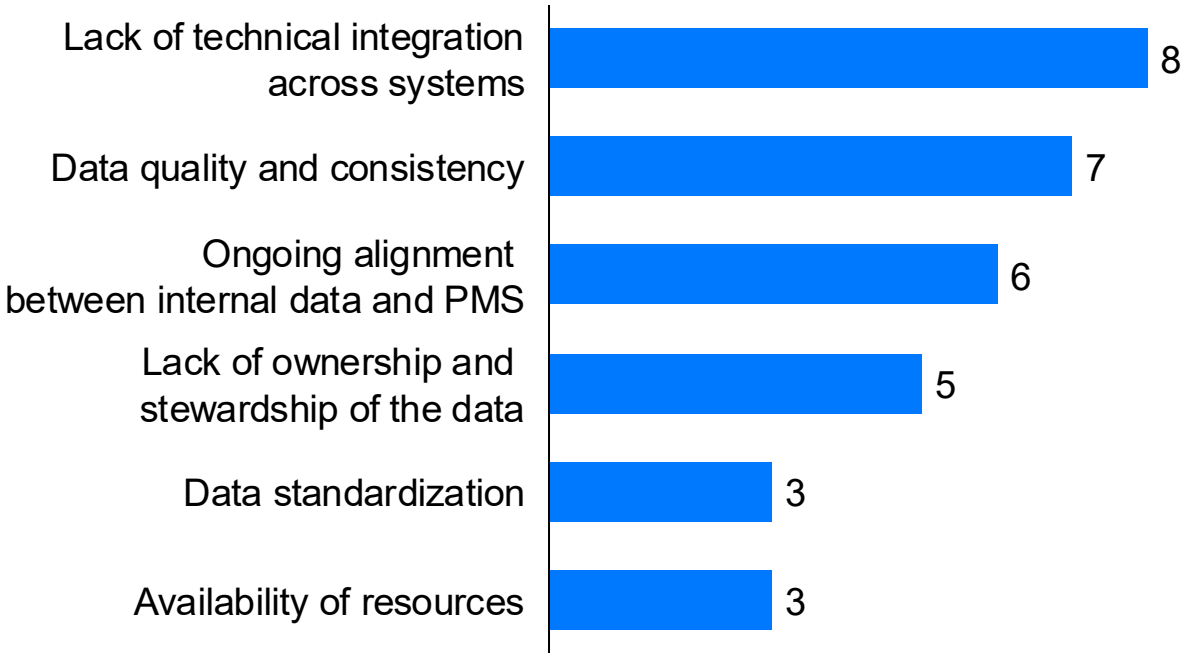
Accurids Survey Shows Approach to EMA PMS Mandate and Main challenges

How do you check EMA data completeness and IDMP-conformance?



Percentage of response, single forced choice
n=13

What are the main challenges you face?



Number of response, multiple mentions possible
n=13

Key data challenges in pharma

In context of decreasing pharma margins, data issues cannot be ignored any longer.

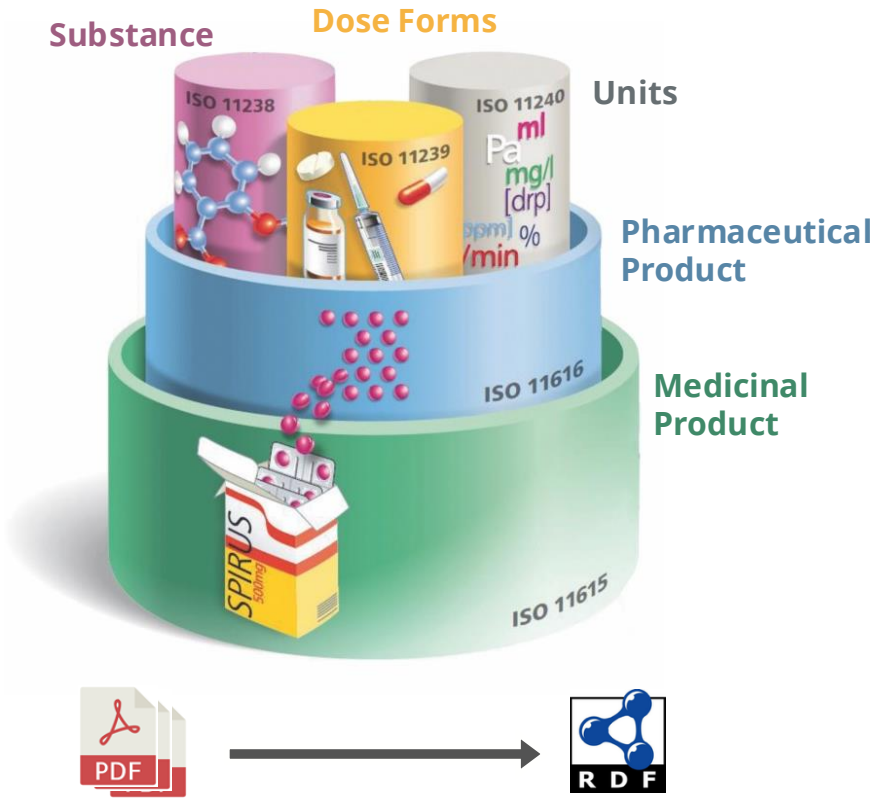
Regulatory requirements becoming stricter

Manual compliance is costly and unsustainable

Data silos undermine efficiency and accuracy

Poor data quality stifles innovation

IDMP Ontology: Collaborative IDMP Implementation



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:

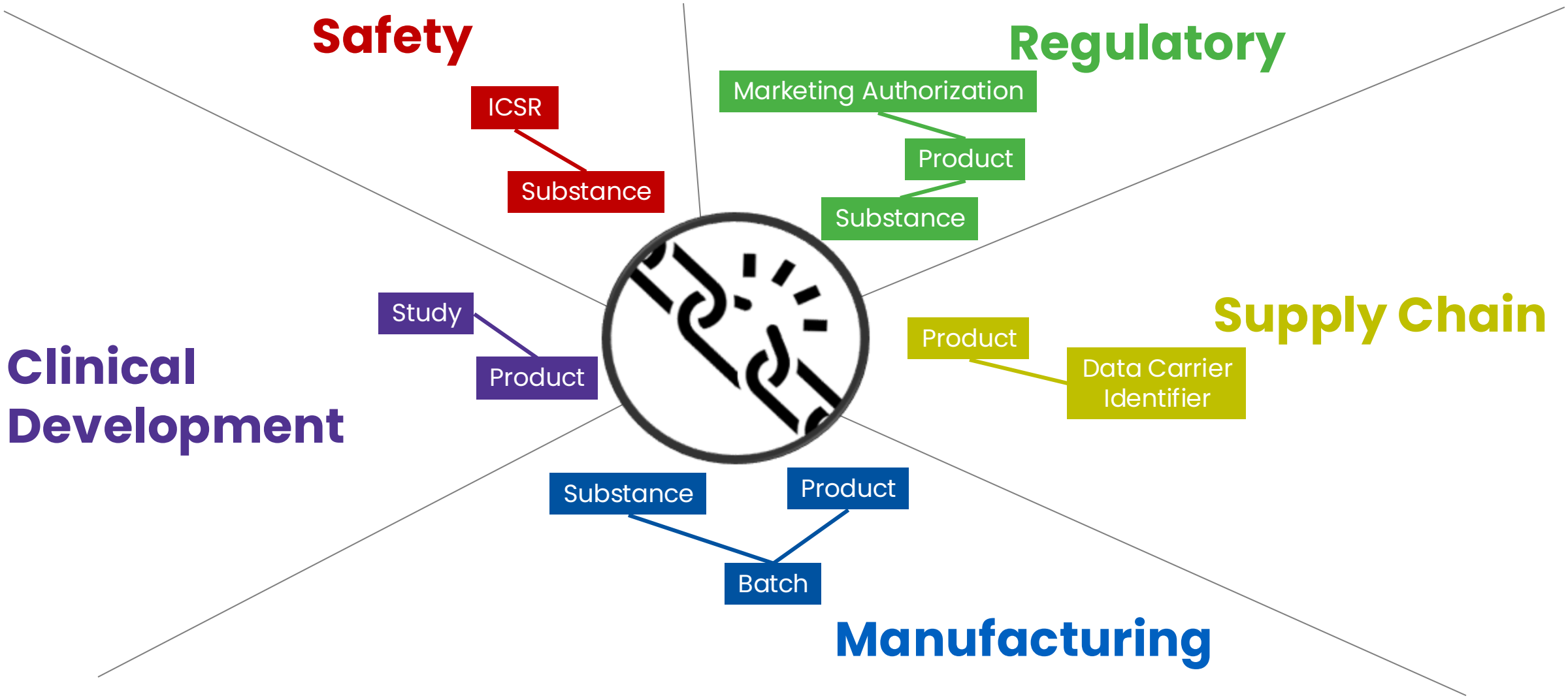
EDMCouncil, ACCURIDS, CROWN POINT TECHNOLOGY

Interested Parties:

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

Connecting different functions with IDMP at the core

Every perspective contributes to the creation of the Medicinal Product



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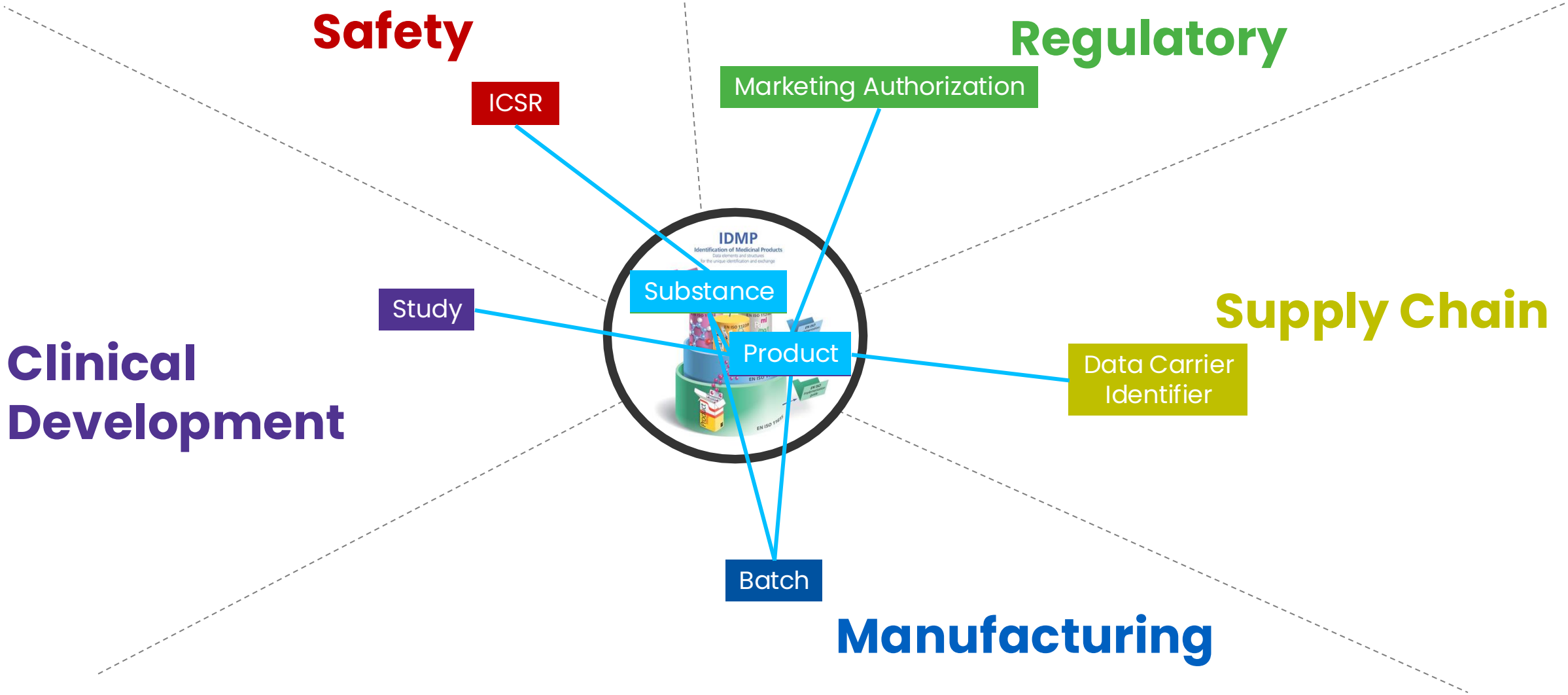
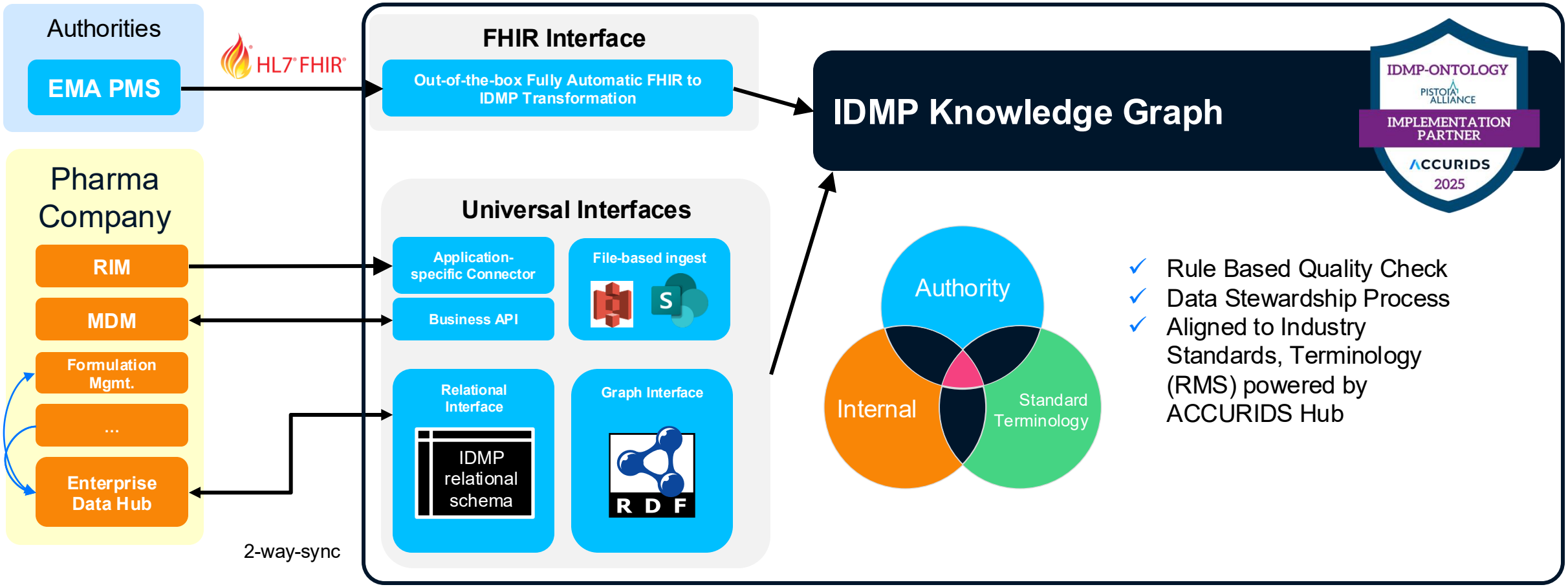


ACCURIDS IDMP Data Standardization fabric

Building the IDMP Knowledge Graph and getting value out of it



ACCURIDS

Data Standardization Fabric

Where to begin?

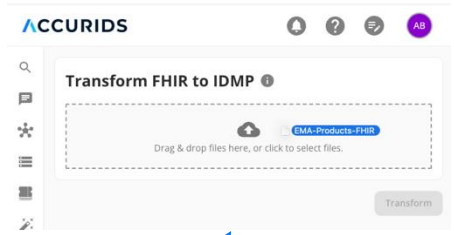
Get ready for EMA PMS Alignment in 5 minutes

5 minutes

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

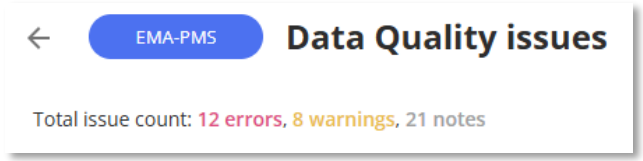
EMA PMS

Download your EMA Product data as FHIR messages



HL7® FHIR®

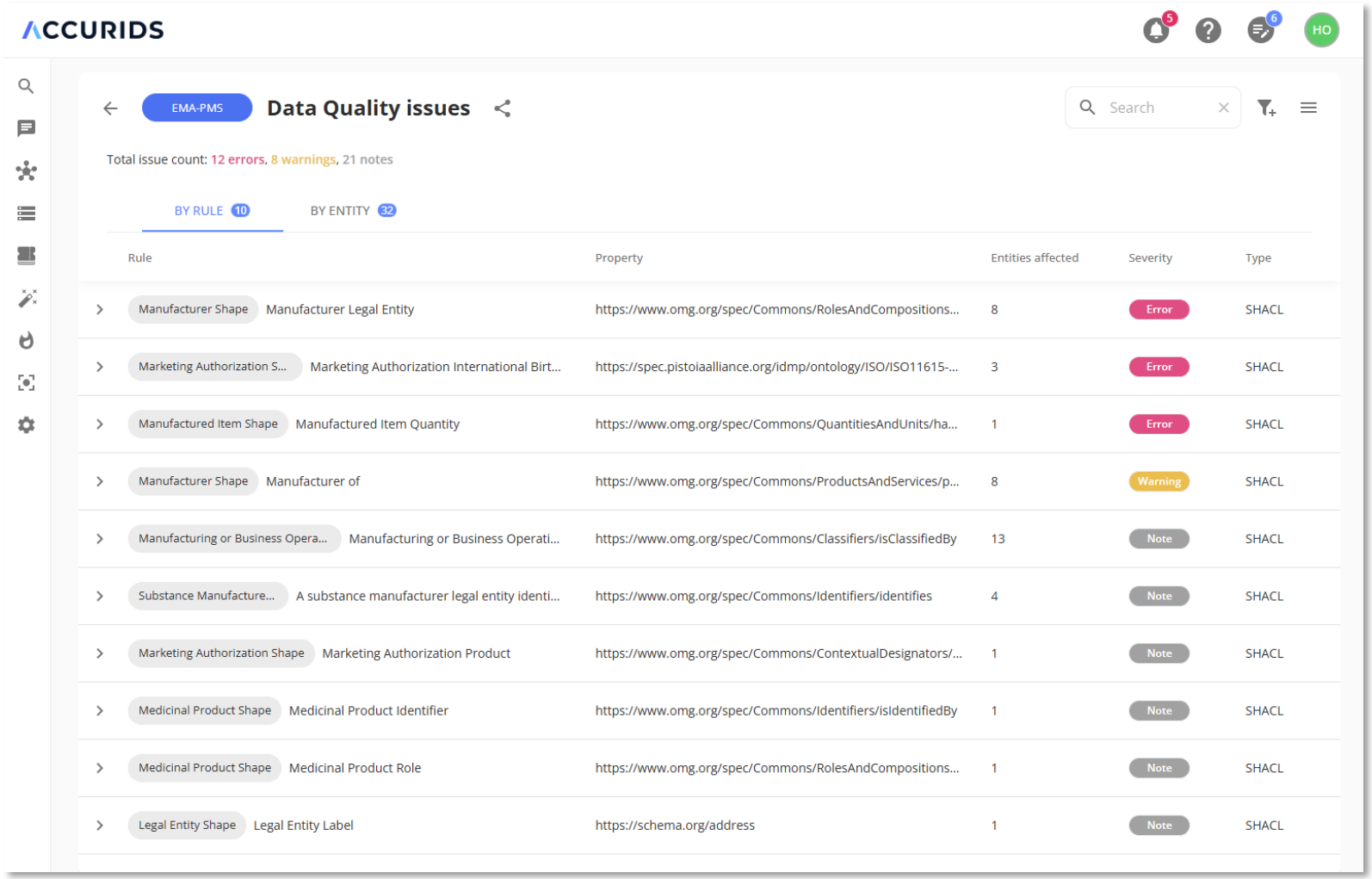
Drop File into Accurids



Get an instant Quality Report

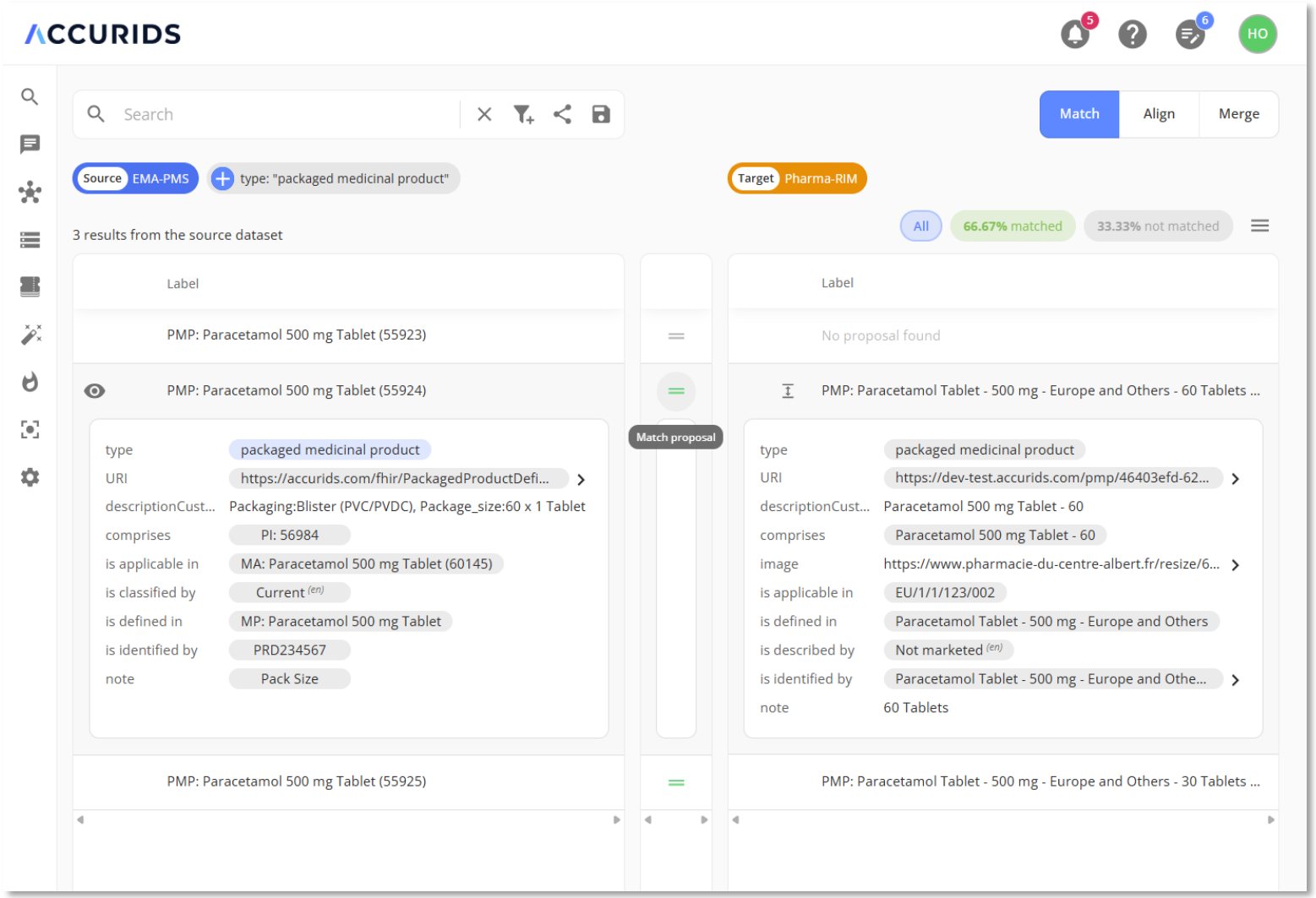
Ready for alignment with internal data

Instant EMA PMS Data Quality Report



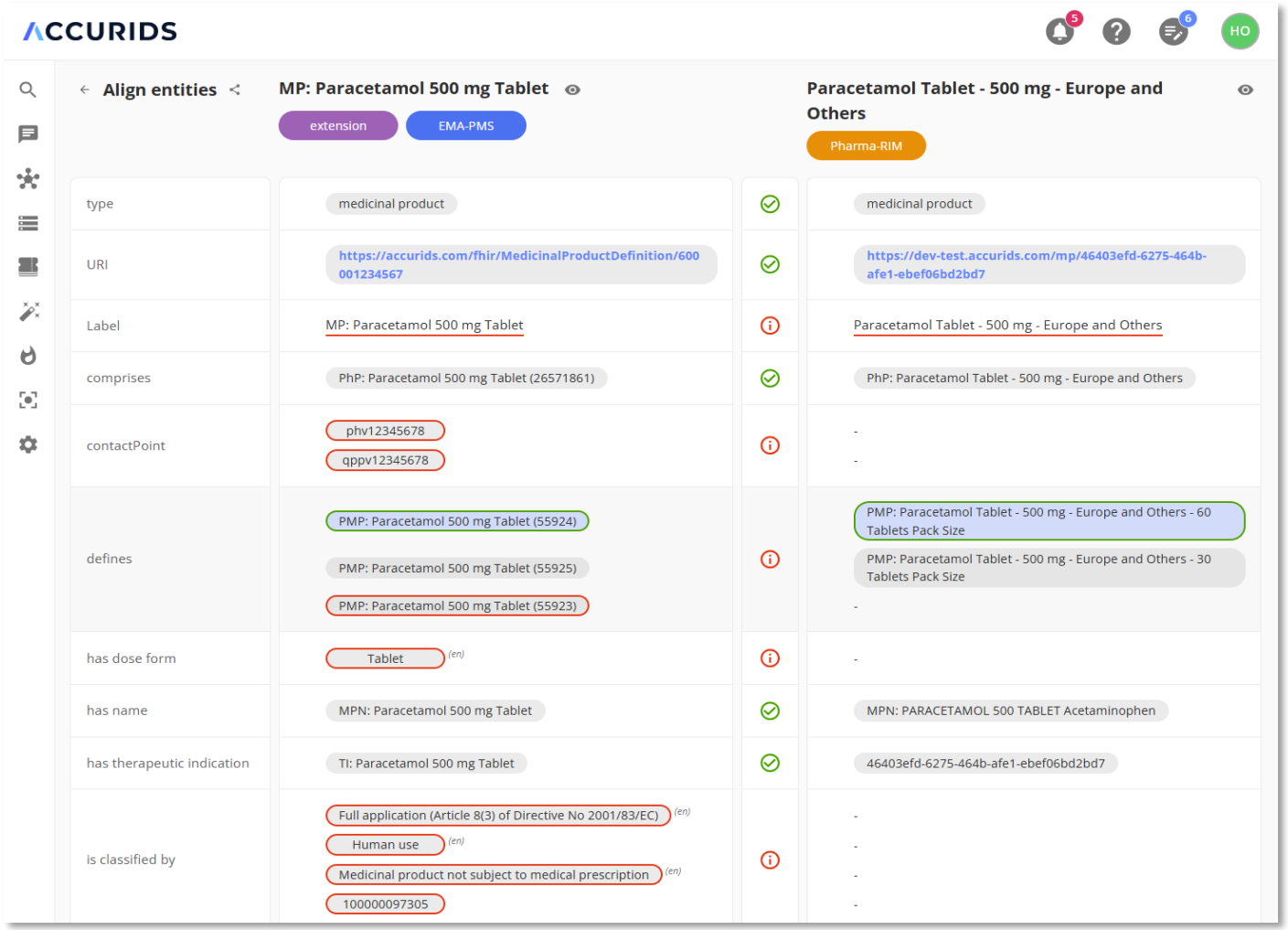
- ✓ Based on automatic transformation of EMA PMS FHIR messages
- ✓ Data Quality Rules for EMA PMS Requirements preconfigured
- → **Fully automated process to get an EMA PMS data quality report for entire product portfolio in minutes**

Automated comparison with internal data



- ✓ Can efficiently build internal Product Knowledge Graph with RIM (e.g., Veeva) data exports.
- ✓ AI-enabled auto-generate mapping proposals for data stewards to confirm.
- ✓ Possibility to upload existing mapping data if available.
- ✓ UI allows to compare data between EMA PMS and internal data.
- → **Identify discrepancies across all products efficiently.**

Fixing Data Quality and Alignment Issues



- ✓ Capture assessment of alignment issues in ACCURIDS.
- ✓ Track progress of issue resolution (in EMA PMS or RIM) with %.
- ✓ Manage resolution coordination through ticket system.
- ✓ Planned integration with EMA ticketing.
- → **Manage SME's issue resolution work efficiently according to management priorities.**

EMA PMS Structured Data Deadlines

What MAHs need to deliver & by when

Category	What needs to be submitted / enriched	Deadline	Notes for MAHs
CAPs (Centrally Authorised Products)	Already in EMA systems (PMS enrichment mostly minor).	Ongoing	Ensure migrated data is correct. Less urgent vs. non-CAPs.
non-CAPs on ULCM (Union List of Critical Medicines)	Structured **pack sizes** & **manufacturers' data** in PMS (via PUI/API).	**June 2026** *(extended from Dec 2025)*	Priority group – ensure critical medicines are enriched first.
All other non-CAPs – Pack size data	Structured **pack sizes** in PMS (via PUI/API).	**June 2027** *(extended from Dec 2026)*	Large volume of products → start planning resources early.
All other non-CAPs – Manufacturer data	Structured **manufacturer's data** in PMS (via PUI/API).	**December 2026** *(unchanged)*	Do not miss this – applies across all non-CAPs.
Optional: Data Carrier IDs (GTIN, etc.)	Pack-level identifiers (via PUI, API support in Q3 2025).	From Q2 2025 (optional) → recommended before final deadlines	Will tie into ePI and supply chain traceability.

Sources: EMA Article 57(2) guidance; EMA PMS Implementation Guide (IDMP Europe, Ch. 3); EMA PLM Portal KA-01134 (Sept 2025, extended deadlines); EMA PLM Portal KA-01100 (PMS roadmap); EMA PMS FAQs.

Our phase approach for EMA PMS Data Alignment

Doable steps towards a company-wide data fabric

	Phase 1 Data Quality Risk Assessment 	**Phase 2** Data Alignment of Key Products 	**Phase 3** Data Alignment of Full Portfolio 	**Phase 4** Cross-functional harmonization 
Description	Get first report of data quality issues of EMA PMS and internal data.	Get first alignments of product data to inform creation of prioritized resolution roadmap.	Full resolution of EMA PMS data alignment issues	Leverage and expand the aligned product data to connect internal silos.
Duration	2 weeks	4 weeks	1-6 months	6-12 months
Key Value	Automated EMA PMS DQ Reporting	Onboard internal product data for comparison with EMA PMS	Resolve data quality and alignment issues at EMA PMS or internal source systems	Integrations with key systems
Outcomes	1. EMA PMS Knowledge Graph 2. EMA PMS Data Quality Report	1. Internal Knowledge Graph 2. EMA-Pharma data alignment for selected products	1. EMA PMS compliance 2. Continuous monitoring of changes	1. Use Case Roadmap 2. Business process improvements

Return on Investment: Turning Business Cases into Real Value

Clear costs, tangible benefits, and when the break-even point is reached

Customer story

A company has a product portfolio of **2800 products**. **1400 of these products** need to be updated per year. The update is done manually over the PUI of EMA (https://plm-portal.ema.europa.eu/Guidance/article/KA-01036/en-us/). The hourly labor rate is **160 Euros**. The Time Frame is **3 years**. → 4200 product updates in total → **6.3 hours** per update (* the calculation is based on customer information; work effort may vary)

Key Metrics	Manual Data Alignment	Automated Data Alignment
Total cost (3 years)	4.256.000 Euro	1.350.200 Euro
Return on Investment (%)	-	215%
Break Even Point (months)	-	< 12 months

Marketing study shows

Structured data can reduce intensive information alignment labor. With increasing product portfolio an automated solution is more efficient than a manual data alignment process. **In this case a total of 2.905.800 Euros will be saved.**

🚀 EMA PMS API – Why the Change?

From manual data to **connected, automated compliance**

Automation & Interoperability → **Direct link** between MAH systems and EMA, fewer manual errors.

Data Accuracy & Enrichment → Structured pack sizes, manufacturer info, GTINs in one place.

Efficiency → No more re-keying; reduces duplication across regulatory systems.

Lifecycle Integration → Supports authorisations, variations, renewals, and pharmacovigilance.

🛟 How It Supports Patient Safety

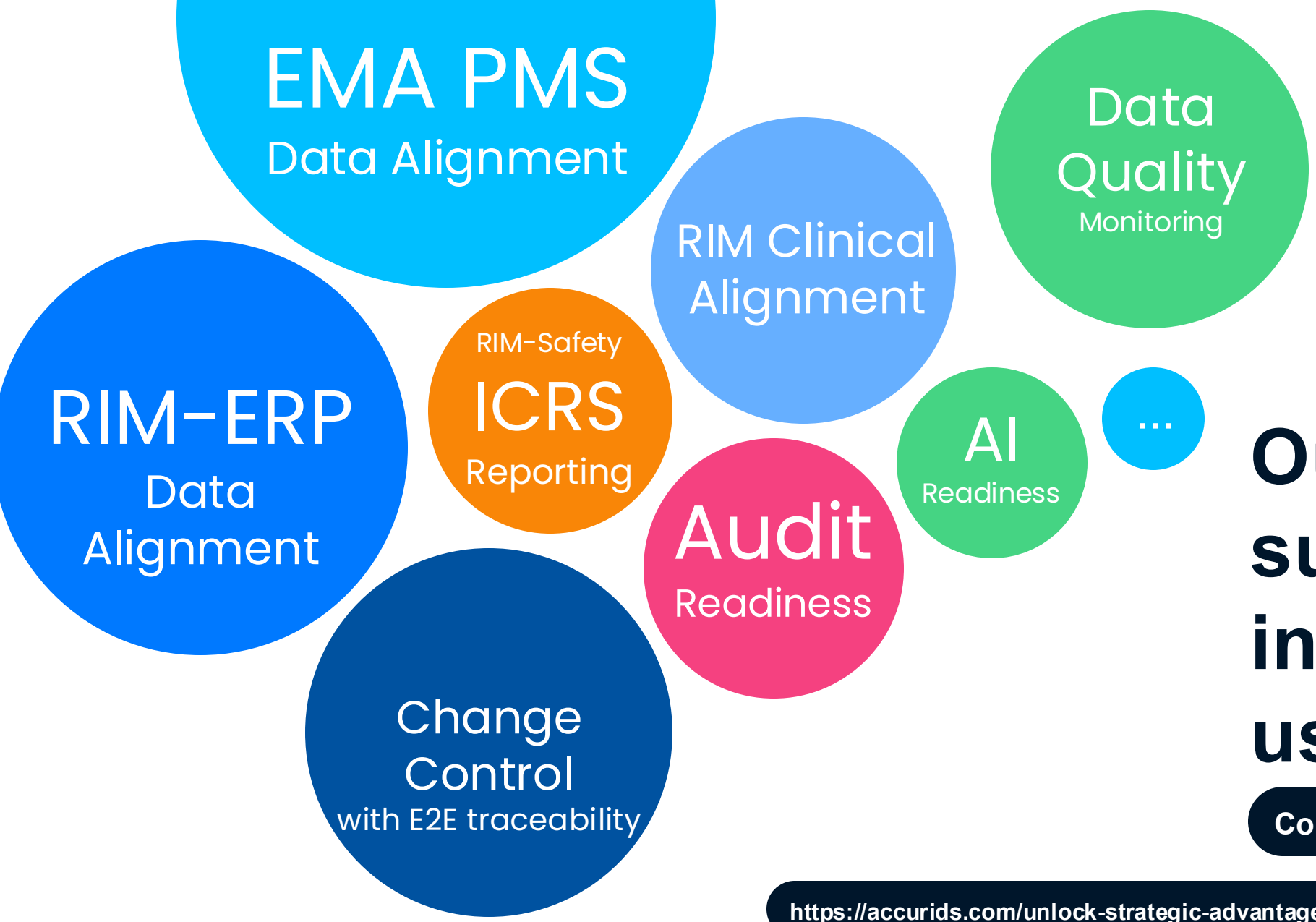
Accurate data = faster, safer decisions

Traceability → Correct identifiers help track medicines and recalls.

Pharmacovigilance → Clean product data ensures **adverse events** are linked to the right product.

Faster Updates → **Safety changes** (SmPC, labels, manufacturers) propagate quickly via API.

Consistency → Everyone (EMA, NCAs, industry) uses the same standard, reducing confusion.



Our solution supports you in many more use cases

Contact us to learn more

https://accurids.com/unlock-strategic-advantages-with-ema-pms-compliance/