



The Unified Product Data Strategy

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

Arne Balzer, Life Science Expert

Dr. med. Heiko Waldmueller, MD, Senior Consultant: Pharma & Digital Health Solutions



EMA PMS Mandate

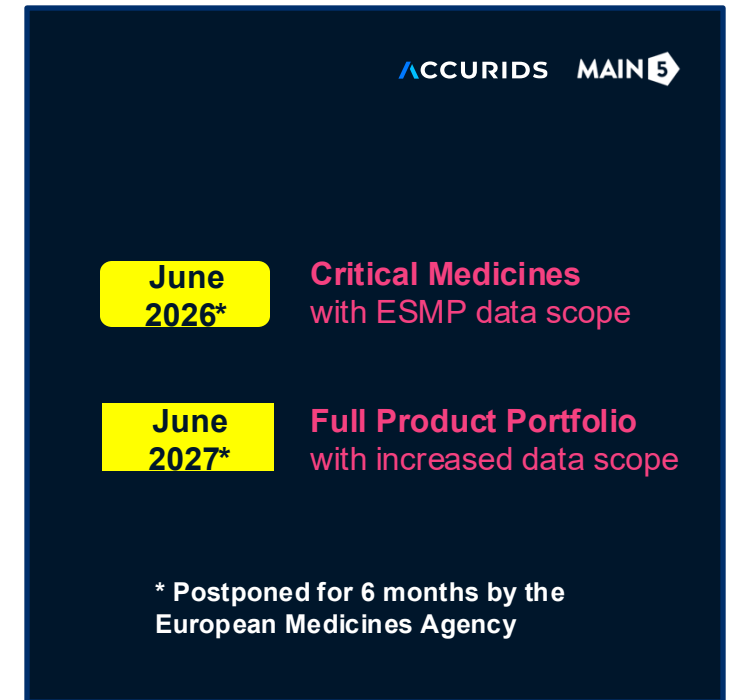
Compliance is non-negotiable

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

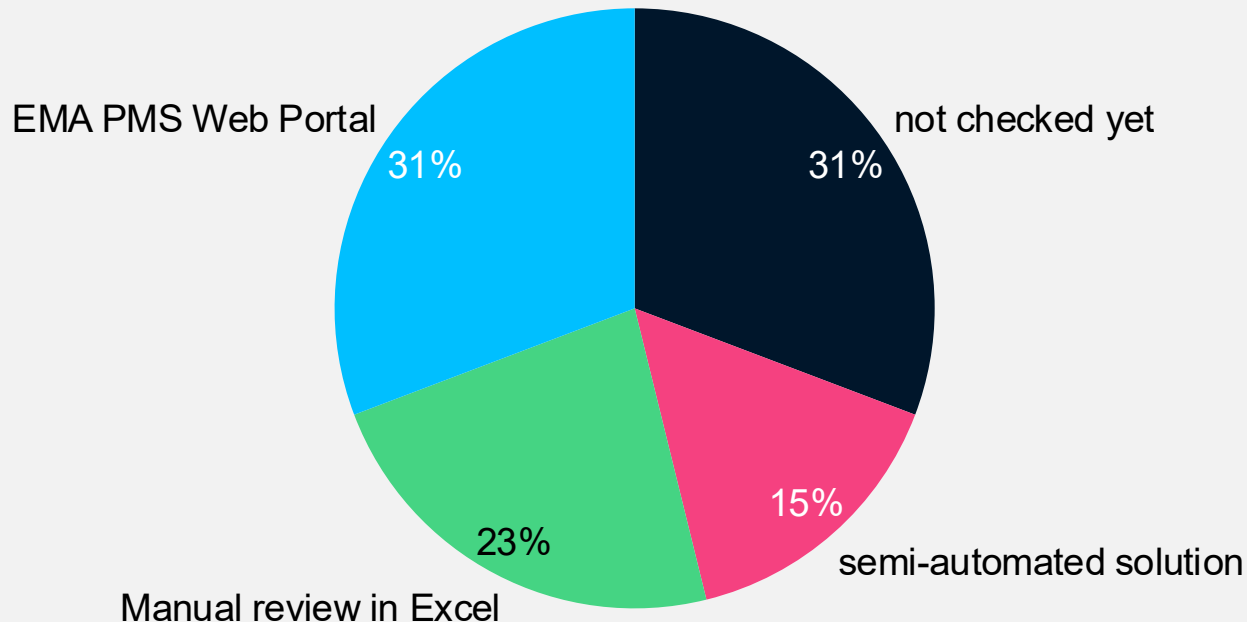


EMA PMS Compliance Status Quo

Accurids Survey Shows Approach to EMA PMS Mandate and Main challenges

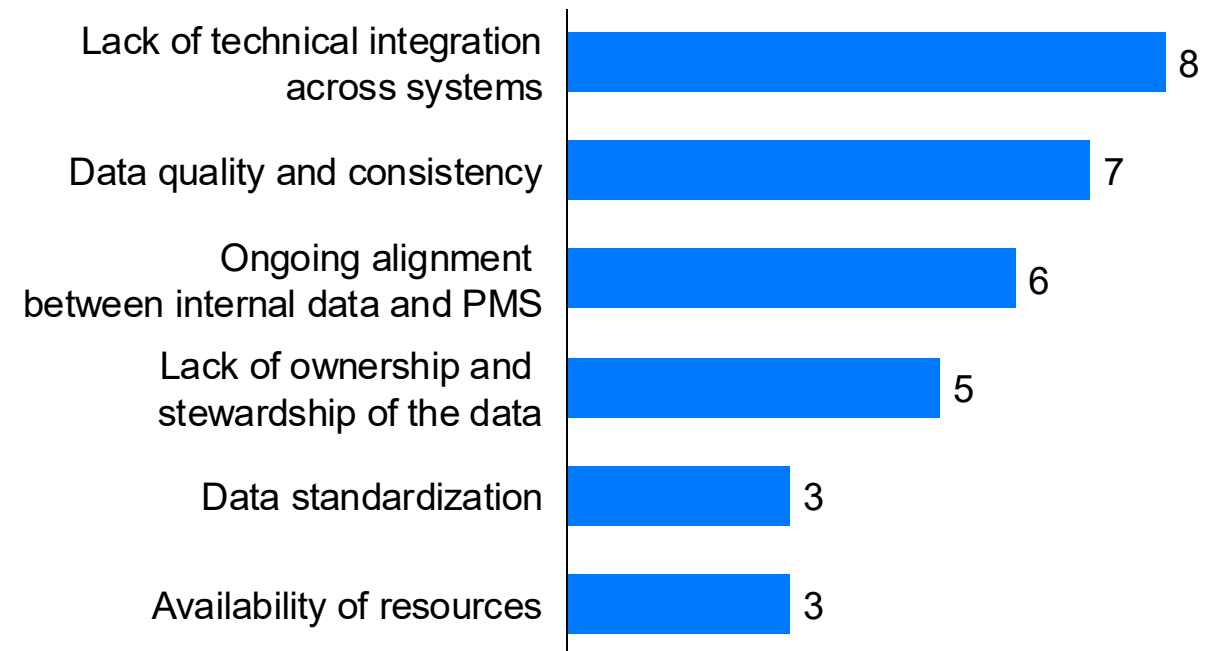


How do you check EMA data completeness and IDMP-conformance?



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**

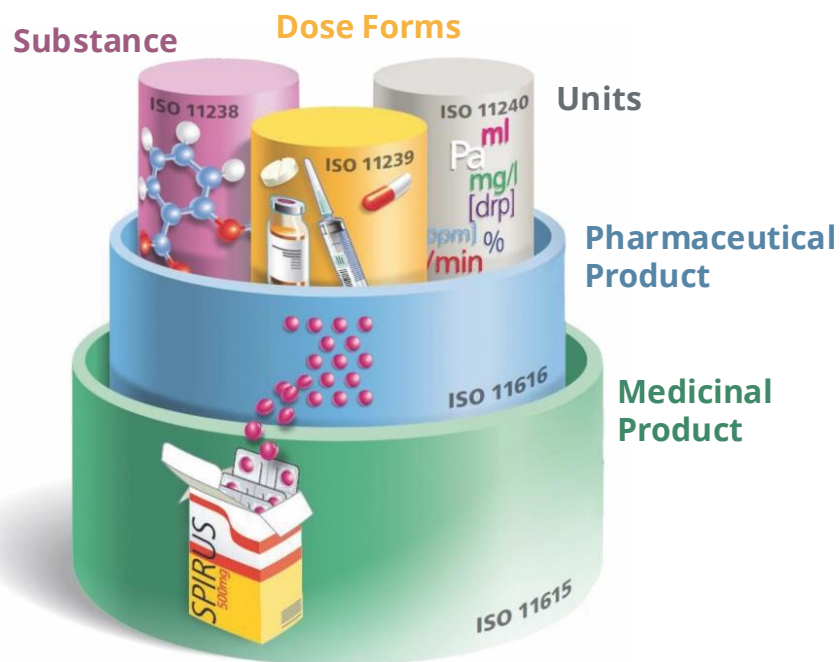


**Data silos undermine
efficiency and accuracy**



**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)



Implementation Partners:



Interested Parties:



ISO IDMP Standards

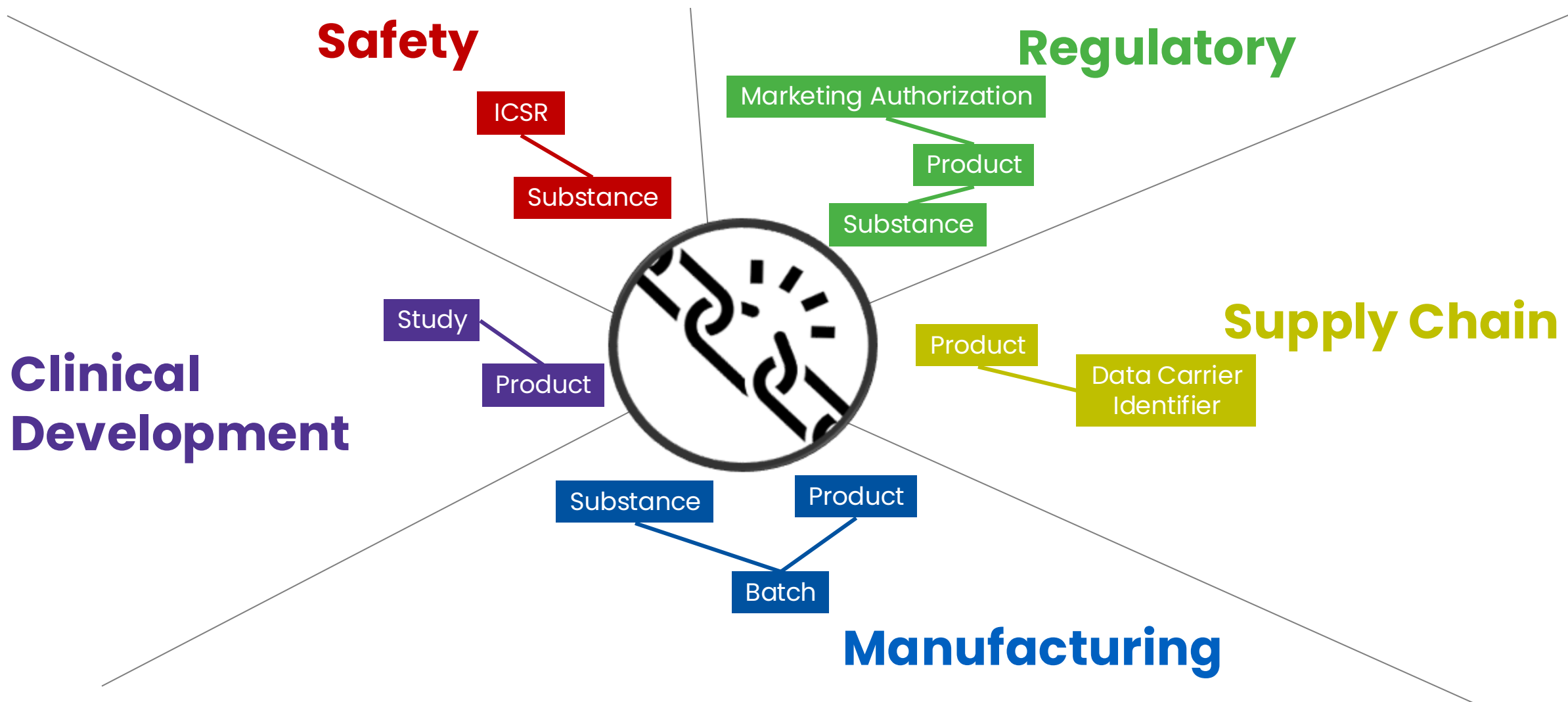


IDMP Ontology

Connecting different functions with IDMP at the core



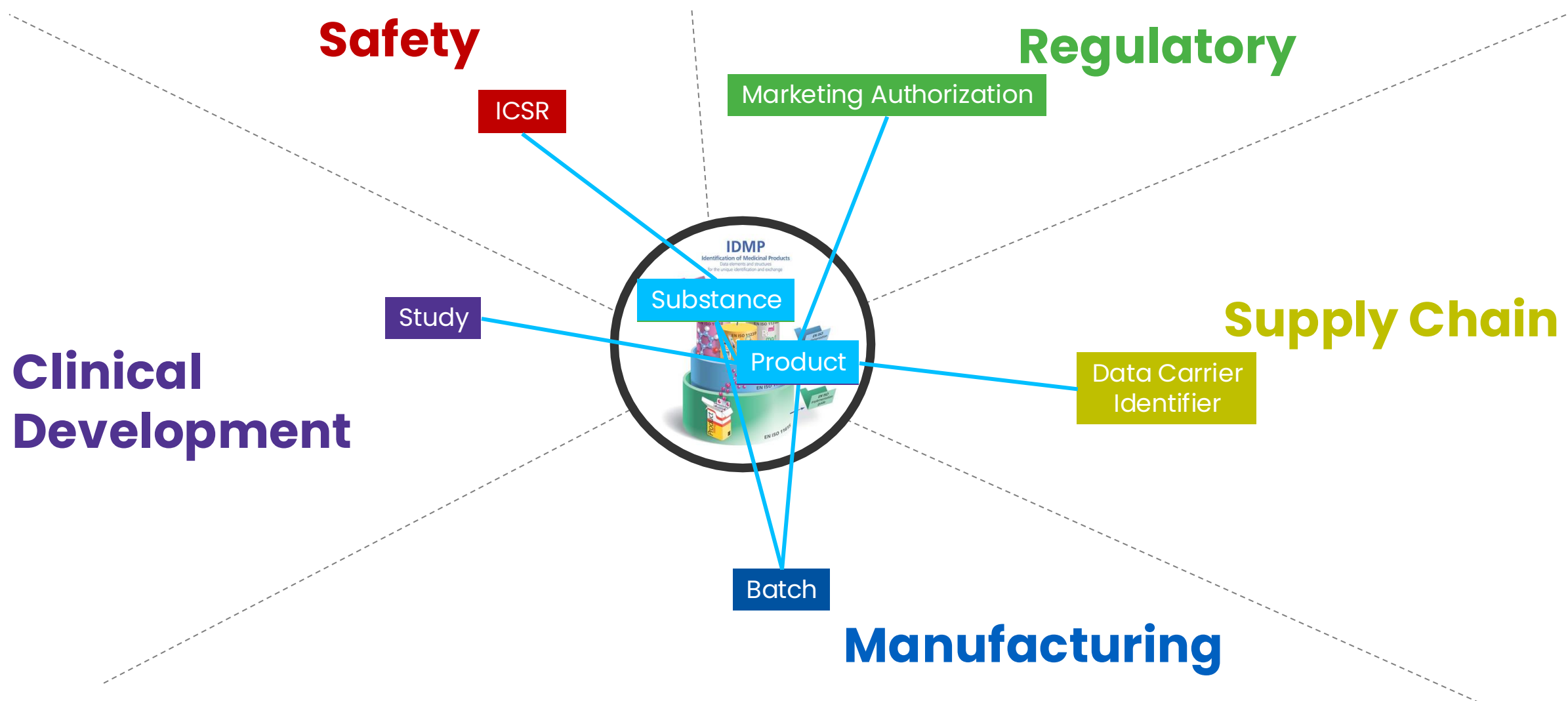
Every perspective contributes to the creation of the Medicinal Product



Connecting different functions with IDMP at the core

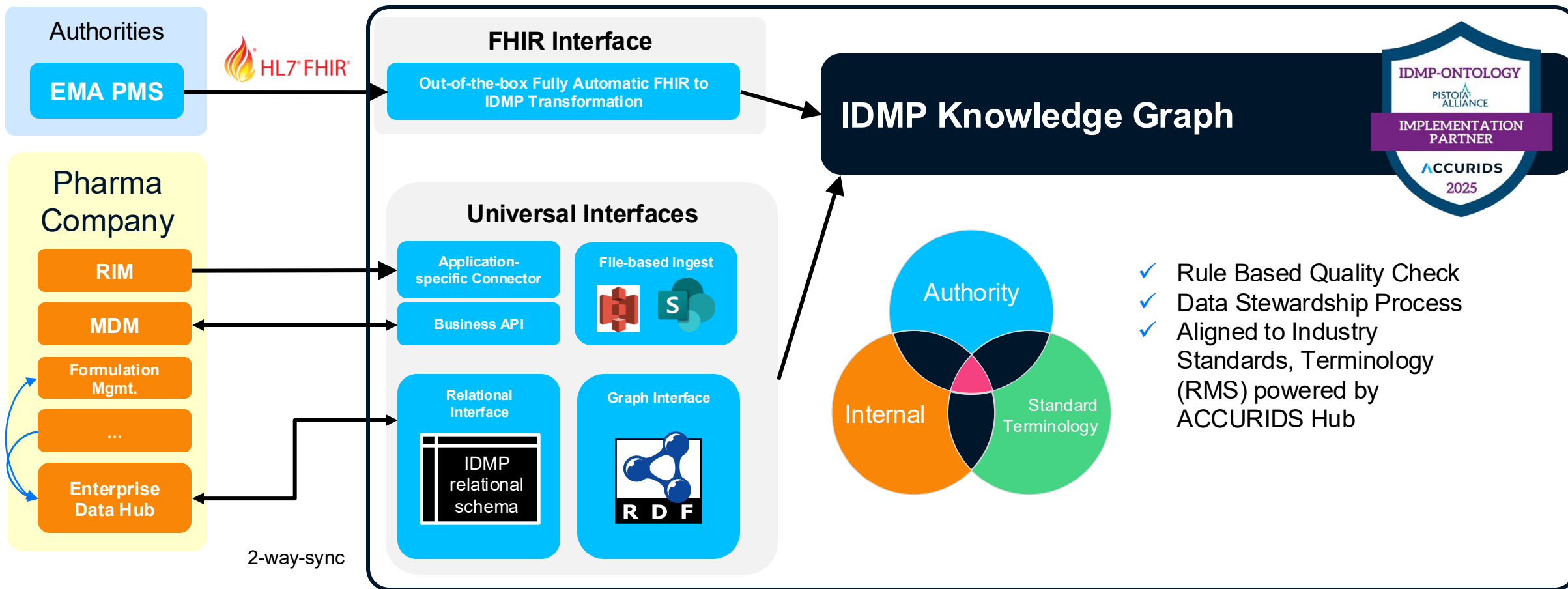


Every perspective contributes to the creation of the Medicinal Product



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

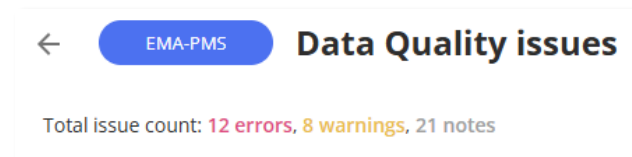
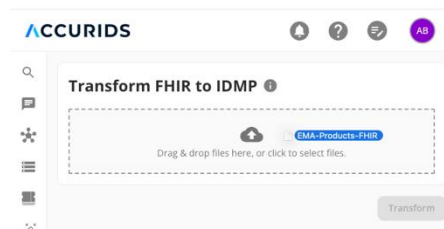


Download your EMA Product data as FHIR messages



HL7[®] FHIR[®]

Drop File into Accurids



Get an instant Quality Report

Ready for alignment with internal data

Instant EMA PMS Data Quality Report



ACCURIDS

5

?

6

HO

Q

←

EMA-PMS

Data Quality issues

Q

Search

×

+

≡

Total issue count: 12 errors, 8 warnings, 21 notes

BY RULE 10

BY ENTITY 32

Rule	Property	Entities affected	Severity	Type
> <div>Manufacturer Shape</div> Manufacturer Legal Entity	https://www.omg.org/spec/Commons/RolesAndCompositions...	8	Error	SHACL
> <div>Marketing Authorization S...</div> Marketing Authorization International Birt...	https://spec.pistoiaalliance.org/idmp/ontology/ISO/ISO11615-...	3	Error	SHACL
> <div>Manufactured Item Shape</div> Manufactured Item Quantity	https://www.omg.org/spec/Commons/QuantitiesAndUnits/ha...	1	Error	SHACL
> <div>Manufacturer Shape</div> Manufacturer of	https://www.omg.org/spec/Commons/ProductsAndServices/p...	8	Warning	SHACL
> <div>Manufacturing or Business Opera...</div> Manufacturing or Business Operati...	https://www.omg.org/spec/Commons/Classifiers/isClassifiedBy	13	Note	SHACL
> <div>Substance Manufacture...</div> A substance manufacturer legal entity identi...	https://www.omg.org/spec/Commons/Identifiers/identifies	4	Note	SHACL
> <div>Marketing Authorization Shape</div> Marketing Authorization Product	https://www.omg.org/spec/Commons/ContextualDesignators/...	1	Note	SHACL
> <div>Medicinal Product Shape</div> Medicinal Product Identifier	https://www.omg.org/spec/Commons/Identifiers/isIdentifiedBy	1	Note	SHACL
> <div>Medicinal Product Shape</div> Medicinal Product Role	https://www.omg.org/spec/Commons/RolesAndCompositions...	1	Note	SHACL
> <div>Legal Entity Shape</div> Legal Entity Label	https://schema.org/address	1	Note	SHACL

- ✓ 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



The screenshot displays the ACCURIDS web application interface. At the top, the ACCURIDS logo is on the left, and navigation icons (notifications, help, settings, and user profile) are on the right. Below the header, there's a search bar and a filter section. The filter section shows 'Source: EMA-PMS' and 'type: "packaged medicinal product"'. The 'Target' is set to 'Pharma-RIM'. The interface shows '3 results from the source dataset' and a comparison status of '66.67% matched' and '33.33% not matched'. The main area is divided into three columns: Source, Match, and Target. The Source column lists three results, with the first two expanded to show details like type, URI, description, and packaging. The Match column shows a 'Match proposal' button. The Target column shows 'No proposal found' for the first two results and a proposal for the third result, which is expanded to show details like type, URI, description, and packaging. The interface is designed for efficient comparison and mapping of product data between different datasets.

- ✓ 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



ACCURIDS			
<div> <div>Align entities</div> <div>MP: Paracetamol 500 mg Tablet</div> <div>Paracetamol Tablet - 500 mg - Europe and Others</div> </div>			
<div>extension</div> <div>EMA-PMS</div>		<div>Pharma-RIM</div>	
type	medicinal product	✓	medicinal product
URI	https://accurids.com/fhir/MedicinalProductDefinition/600001234567	✓	https://dev-test.accurids.com/mp/46403efd-6275-464b-afe1-ebef06bd2bd7
Label	MP: Paracetamol 500 mg Tablet	ⓘ	Paracetamol Tablet - 500 mg - Europe and Others
comprises	PhP: Paracetamol 500 mg Tablet (26571861)	✓	PhP: Paracetamol Tablet - 500 mg - Europe and Others
contactPoint	phv12345678 qppv12345678	ⓘ	-
defines	PMP: Paracetamol 500 mg Tablet (55924) PMP: Paracetamol 500 mg Tablet (55925) PMP: Paracetamol 500 mg Tablet (55923)	ⓘ	PMP: Paracetamol Tablet - 500 mg - Europe and Others - 60 Tablets Pack Size PMP: Paracetamol Tablet - 500 mg - Europe and Others - 30 Tablets Pack Size
has dose form	Tablet ^(en)	ⓘ	-
has name	MPN: Paracetamol 500 mg Tablet	✓	MPN: PARACETAMOL 500 TABLET Acetaminophen
has therapeutic indication	TI: Paracetamol 500 mg Tablet	✓	46403efd-6275-464b-afe1-ebef06bd2bd7
is classified by	Full application (Article 8(3) of Directive No 2001/83/EC) ^(en) Human use ^(en) Medicinal product not subject to medical prescription ^(en) 100000097305	ⓘ	-

- ✓ 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 (<i>extended from Dec 2025</i>)	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 (<i>extended from Dec 2026</i>)	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 (<i>unchanged</i>)	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	<u>Automated</u> EMA PMS DQ Reporting	Onboard <u>internal product data for comparison with EMA PMS</u>	<u>Resolve data quality and alignment issues</u> at EMA PMS or internal source systems	<u>Integrations with key systems</u>
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

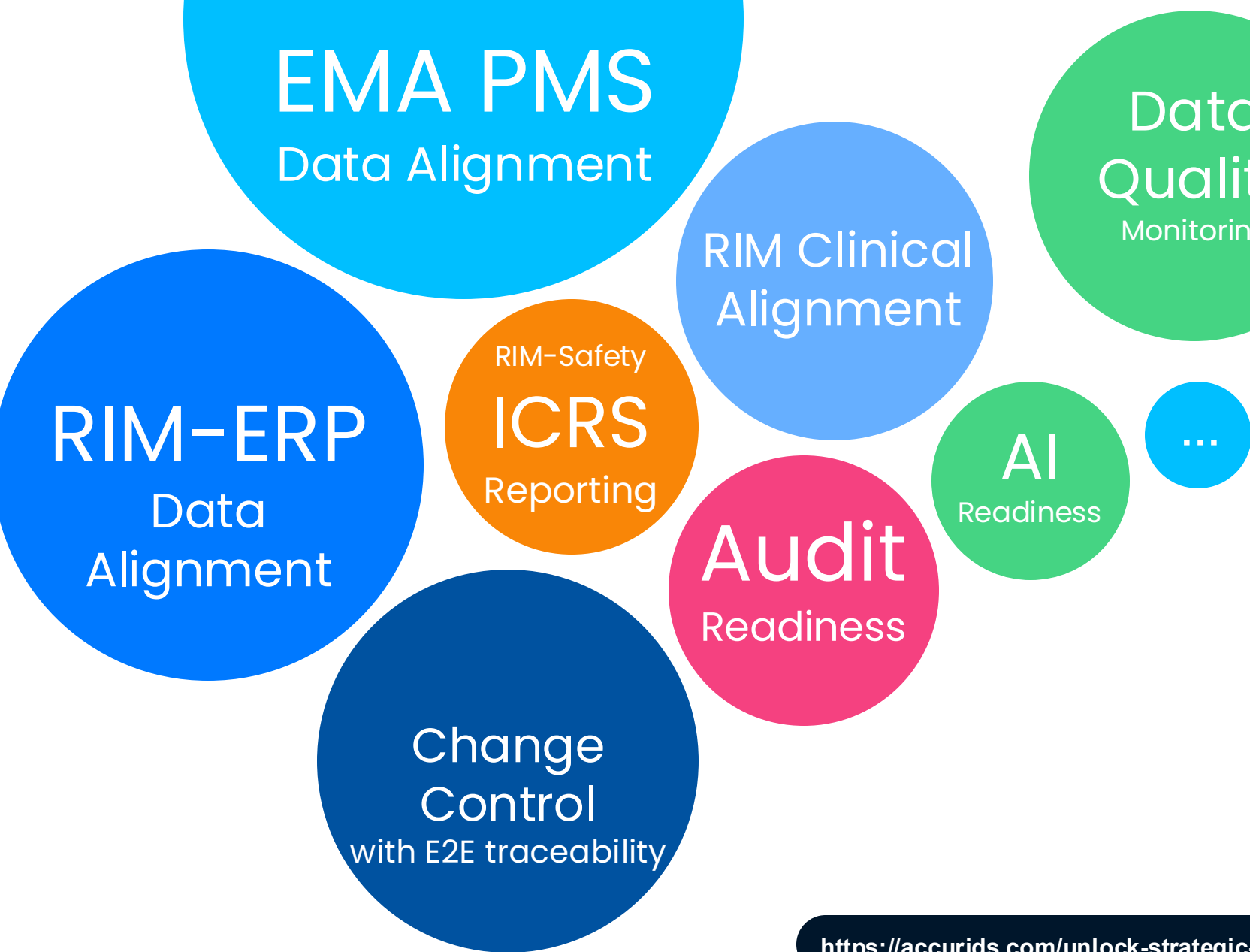
Accurate data = faster, safer decisions

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/>