

EMA PMS Data Alignment

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Trusted Product Data

The Foundation for the Next Generation Regulatory Operating Model

- The Novartis Journey: Where We Started, What We Learned, and What Industry can do Now

The Shift was Already Underway

WHERE WE STARTED

Structured product data was moving from a compliance deliverable to an operational dependency.

Our Starting Reality

1 Fragmented Product Data

The same product existed in EMA PMS, in xEVMPD and in our internal RIM system, each with different structure, granularity and update timing, and no reliable shared identifier.

2 Manual Verification

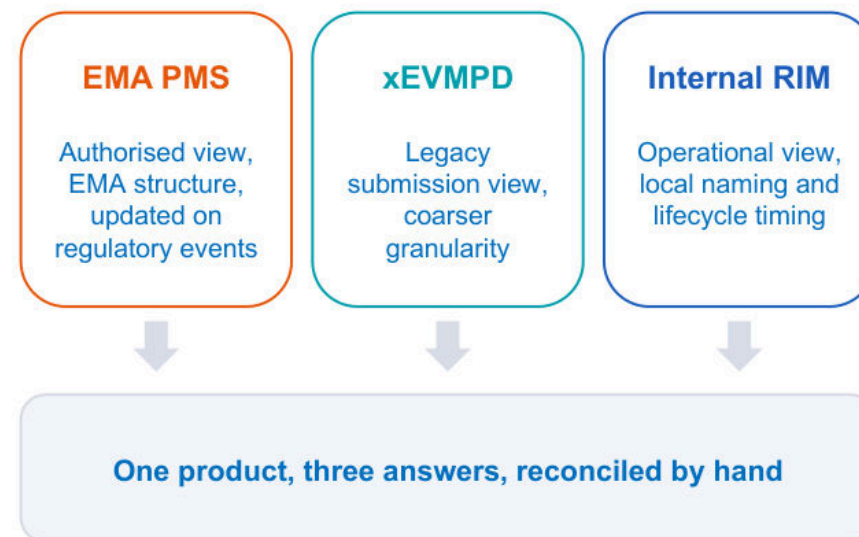
The PMS interface allowed record-by-record review only. Verifying the CP, MRP and DCP portfolio by hand took four people close to a year.

3 Evolving Expectations

Requirements arrived in waves: June and December milestones, wider enrichment by June 2027, API access and quality guidance still maturing, NCAs yet to onboard.

The Opportunity: Use PMS as a Catalyst to Understand, Improve and Govern Product Data.

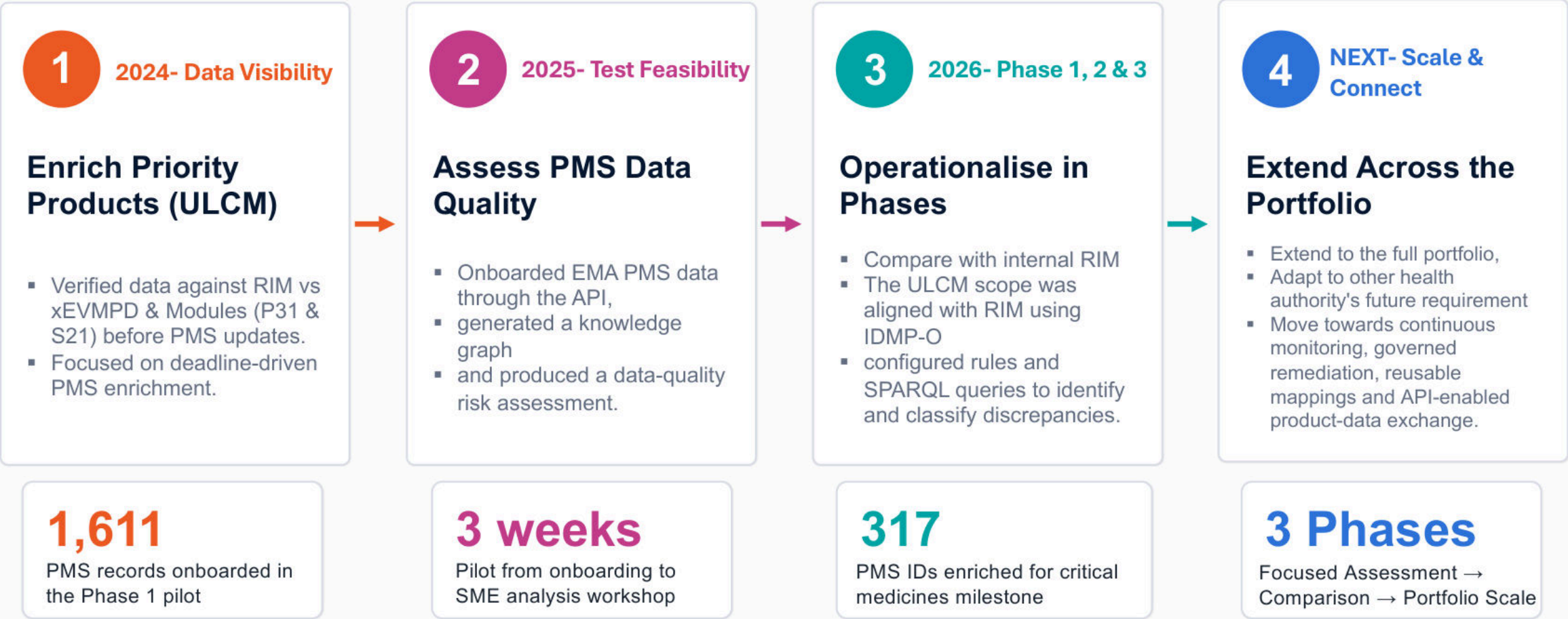
Our starting point: EMA enabled the PLM portal in 2022 and PMS records became visible, but there was no comparison tooling and no agreed view of which product data was authoritative.



The Data Quality Journey

FLAGSHIP EXAMPLE

From 2024 readiness checks to 2026 systematic tooling and scale next, combining enrichment with phased data quality.



The Journey did not Begin with Full Automation. It Began with Focused Comparison and Progressively Stronger Evidence.

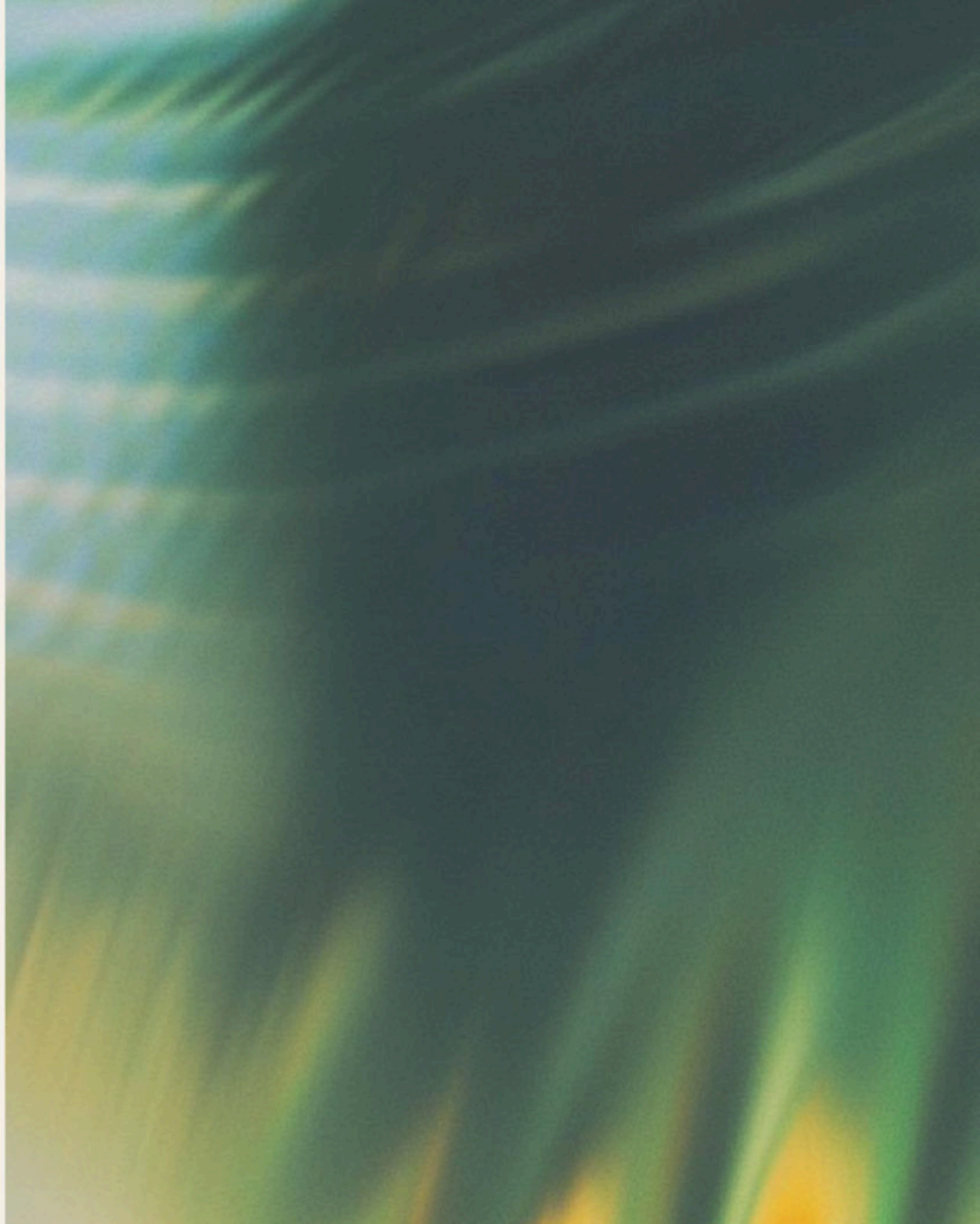


GPRAS 2026, 29 SEPTEMBER

EMA PMS Data Alignment

Raphael Sergent, ACCURIDS

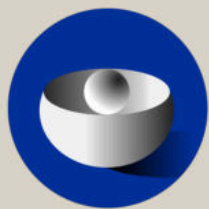
Head of QA & Senior Pharma Solutions Lead



As Easy as 1, 2, 3!

Getting Operational with Modern Tools in no time!

Go Digital!



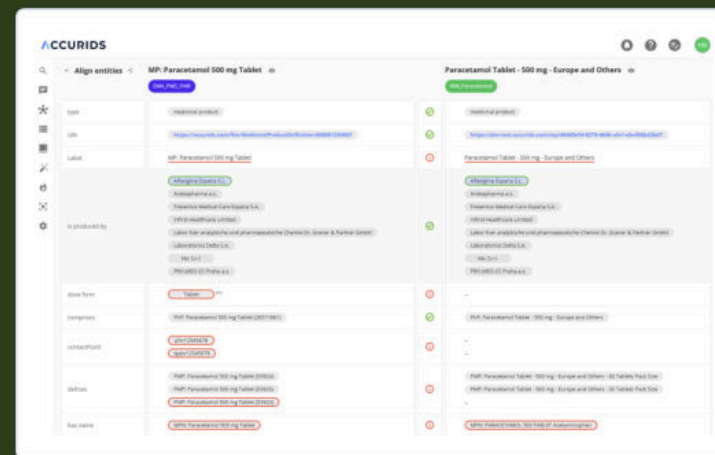
1 EMA PMS

Data Import and
Quality Report

RIM

2 Internal RIM

Data Import and
Quality Report



3 Compare

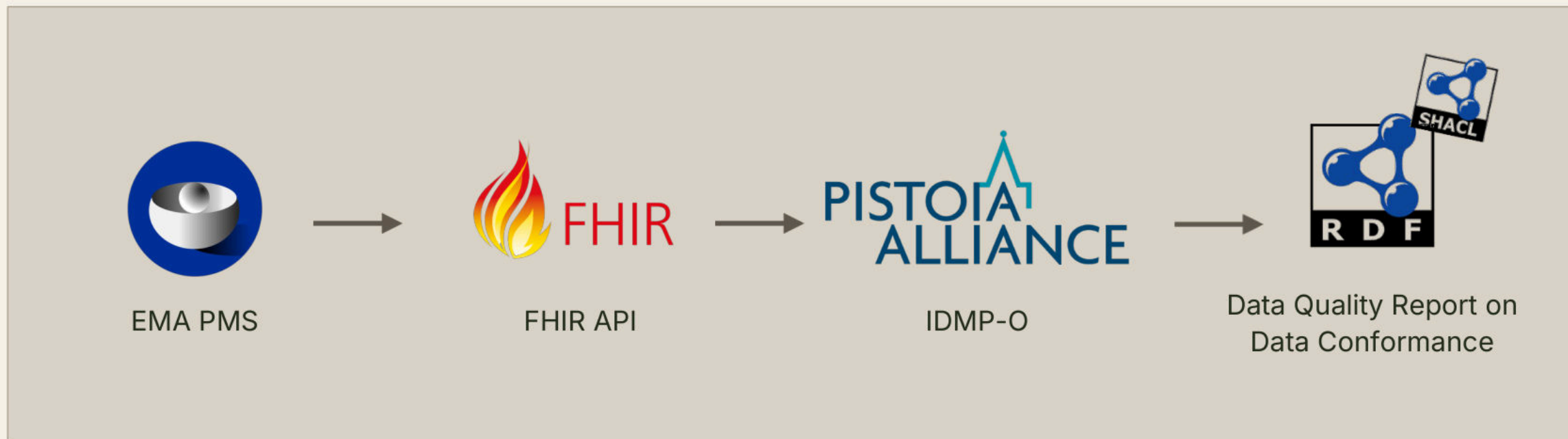
Comparing External to Internal Data
Easily

1 Import EMA PMS

Using FHIR API

Get your EMA PMS Portfolio in Minutes!

- Using PMS credentials to collect all the PMS IDs
- FHIR to IDMP-O automated transformation
- Data Quality Report on Data Conformance



2 Import RIM Data

Custom import of RIM

Import your Internal RIM Data easily!

- Using internal data to collect all the Novartis' Medicinal Products
- Custom transformation to align to IDMP-O
- Data Quality Report on Data Conformance



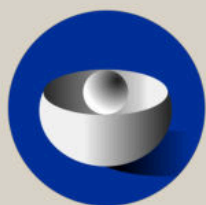
3 Compare!

Compare Data Easily

Comparison made easy and convenient for Business

- Easily align data based on the ISO IDMP types
- Enable auto matching based on identifiers, up to 90% automatic!
- Spot immediately discrepancies and organize clean-up and data enrichment

IDMP-O: Medicinal Product



Product 1 EMA	↔	Product 1 RIM
Product 2 EMA	↔	Product 2 RIM
Product 3 EMA	⊘	Product 4 RIM
Product 4 EMA	↗ ⊘	Product 5 RIM

RIM

The Comparison Showed Progress and Exposed where Action was Needed

REAL FINDINGS

Findings mapped to the prioritised elements: product name, strength, active substance and dose form.

GOOD

88.3%

Most Critical Elements Aligned

- Of the 317 ULCM records compared with EMA PMS, **88.3% showed clean records**
- No discrepancies were found for administrable dose form or route of administration.

CHALLENGE

37 / 317

Small Gaps Still Mattered

Our team had to cross check multiple systems: xEVMPD, RIM and OMS to trace **29 MAH discrepancies and 8 PMS ID issues** back to PMS.

RESOLUTION

11.7%

Diagnosis was faster than Closure

Remediation required country, Data-Owner, Internal RIM or EMA action.

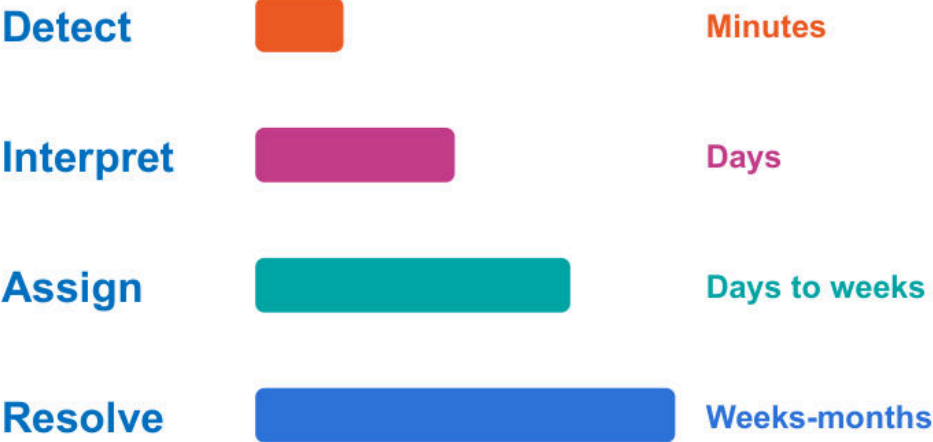
Interpret Before Remediating: A Mismatch is Evidence To Investigate, Not Automatically a Defect.

The Hard Part was Not Finding a Difference... It was Resolving It!

WHAT WE LEARNED

A technical comparison becomes valuable only when it is connected to accountable Business action.

Where the Time Goes



Detection is now automated. Closure is not.

- Automated rules surface potential differences.
- SMEs confirm whether the issue is semantic, structural, timing-related or a true defect.
- The right owner may sit in SDS, a country organisation, CMC, RIM or EMA.
- Corrections, mappings or tickets are completed and evidence is retained.

Governance Determines Whether Insight Becomes Improvement.

"We Set Out To Comply. We Ended Up With Trusted Data."

VALUE CREATED

It created a practical route from regulatory obligation to reusable data capability.

IMMEDIATE VALUE

Visibility • Prioritised Remediation •
Readiness • Confidence in Aligned Data

OPERATING MODEL

Ownership • Stewardship • Issue Routing • Governance • Cross-
Functional Action

REUSABLE CAPABILITY

Repeatable Comparisons • Reusable Mappings • Portfolio Monitoring • Data Products

FUTURE ENABLEMENT

API-enabled Exchange • Digital Variations • ePI • Analytics • Trustworthy AI

The Measure Of Success is Not the Number of Discrepancies Found. It is the Capability Created to Keep Product Data Trusted.

From Periodic Reconciliation to a Connected Regulatory Data Ecosystem

WHAT THE FUTURE LOOKS LIKE

Trusted product data becomes the shared foundation across regulators, NCAs, industry and digital services.

Trusted Core

PMS/SPOR and internal master data aligned through identifiers, standards and provenance.

Connected Flows

Stable APIs and FHIR-based exchange reduce repeated data entry and manual reconciliation.

Continuous Quality

Rules, monitoring and governed issue workflows make quality an ongoing process.

Reuse at Scale

The same trusted product data supports submissions, ePI, digital variations, analytics and AI.

Future-State Principle: Data Once, Governed Once, Reused Many Times.



What Pharmaceutical Companies can do Now

Do not wait for the complete operating model. Build evidence and capability in manageable increments.

1

Choose a Meaningful Scope

Select products linked to a real deadline or business priority, then focus on the identifiers and elements that matter.

2

Compare Before Remediating

Bring internal and external data together. Classify why values differ before launching correction activity.

3

Make Ownership Explicit

Define who investigates, decides, updates and escalates across business, data, technology and external parties.

4

Measure the Outcome

Track alignment, time to insight, remediation ageing, repeat findings and portfolio coverage rather than activity alone.

5

Scale what Proves Valuable

Use the pilot evidence to select automation, governance and integration investments for the broader portfolio.

Start Small Enough to Learn Quickly but Structure the Work so it Can Become Repeatable.

Trusted Product Data Is Not Only a PMS/ IDMP Requirement.

It is the Foundation for the Next Generation Regulatory Operating Model.

WHERE WE STARTED

Fragmented Data, Manual Verification and Evolving Regulatory Expectations.

THE JOURNEY SO FAR

Focused Enrichment, Phased PMS Data-quality Assessment and Portfolio Comparison.

WHAT COMES NEXT

Continuous Quality, Governed Remediation, API-enabled Exchange and Reuse at Scale.

START WITH COMPARISON. LEARN. GOVERN. THEN SCALE.

Thank You



Q&A