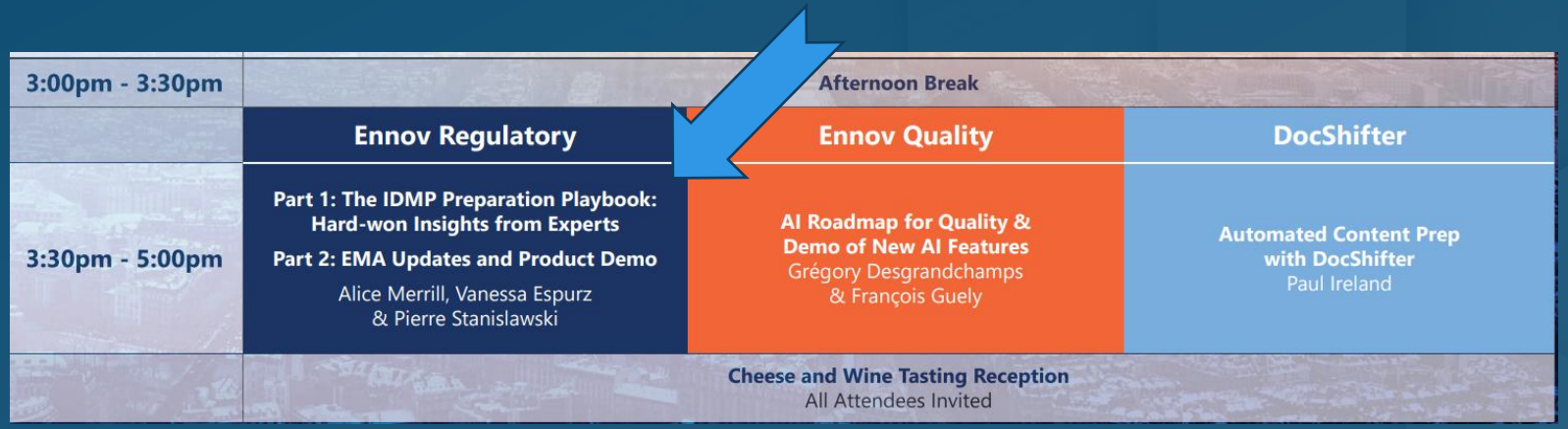
The IDMP Preparation Playbook

Hard-won Insights from Experts, EMA Updates & Product Demo

Victor Collado Gomez, Vanesa Espurz, Alice Merrill and Pierre Stanislawski



3:00pm - 3:30pm	Afternoon Break		
	Ennov Regulatory	**Ennov Quality**	**DocShifter**
3:30pm - 5:00pm	**Part 1: The IDMP Preparation Playbook: Hard-won Insights from Experts** **Part 2: EMA Updates and Product Demo** Alice Merrill, Vanessa Espurz & Pierre Stanislawski	**AI Roadmap for Quality & Demo of New AI Features** Grégory Desgrandchamps & François Guely	**Automated Content Prep with DocShifter** Paul Ireland
	Cheese and Wine Tasting Reception All Attendees Invited		

Introductions

Victor Collado Gomez

Víctor Collado has 13 years of experience in Regulatory Affairs at Laboratorios Cinfa, encompassing the entire regulatory spectrum — from defining regulatory strategies to writing generic medicine dossiers and securing agency approvals. Currently Coordinator of Regulatory Information, he leads the digital transformation and information management within the RA area, covering all product categories in the company's portfolio.

Vanesa Espurz

Vanesa Espurz is a Senior Consultant at MAIN5 with 19 years of experience in the pharmaceutical industry. She possesses extensive knowledge in global medicine regulations, regulatory processes, compliance, and regulatory systems. Currently, she is actively involved in IDMP implementation projects.

Alice Merrill

Alice has worked in Regulatory Operations for 9 years, with expertise in Regulatory Information Management, process design and documentation and user support. As a RIM consultant at Ennov, Alice brings her experience working in large pharmaceutical companies to supporting clients.

Pierre Stanislawski

Pierre has joined Ennov team 17 years ago. He has a wide experience in service/ customer implementation, validation, and product development.
He currently drives the Regulatory solutions including RIM, xEVMPD and IDMP in relation with other Core Model and Ennov modules

Agenda

1 IDMP Quiz

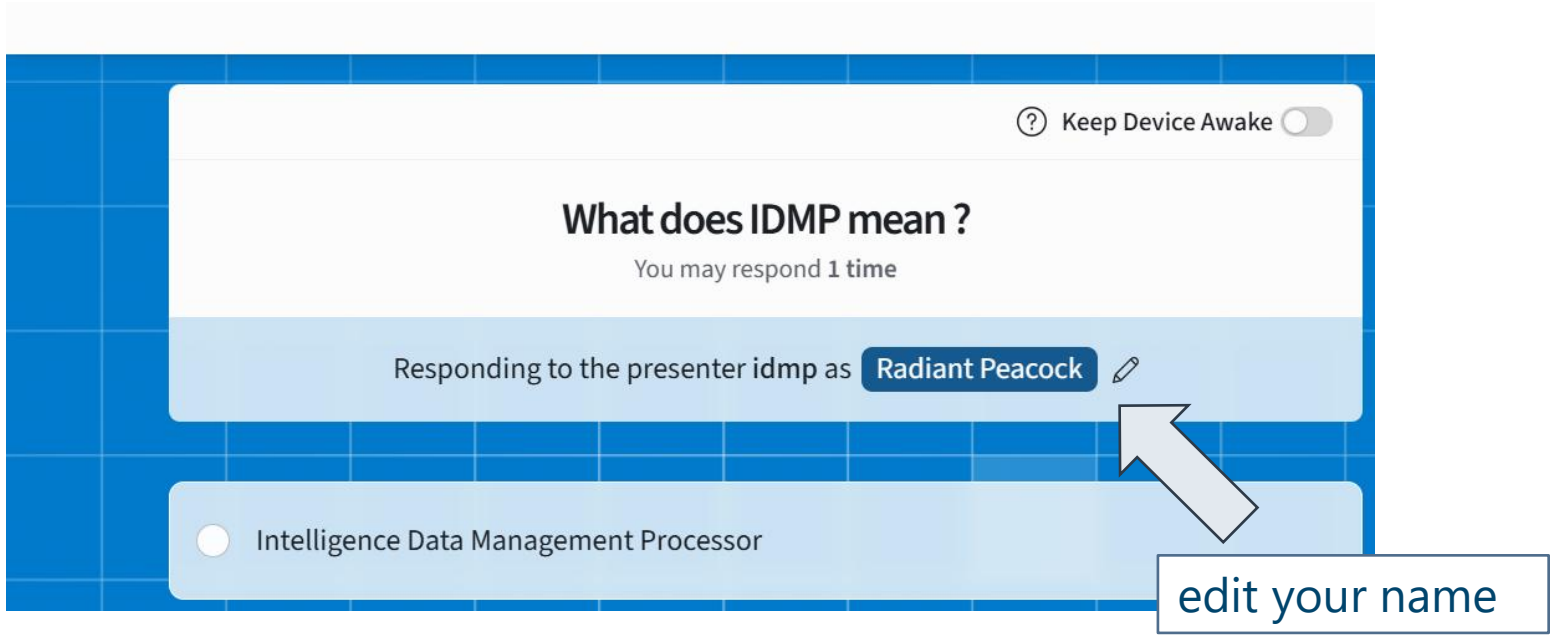
2 IDMP Implementation Insights

3 Ennov IDMP Update

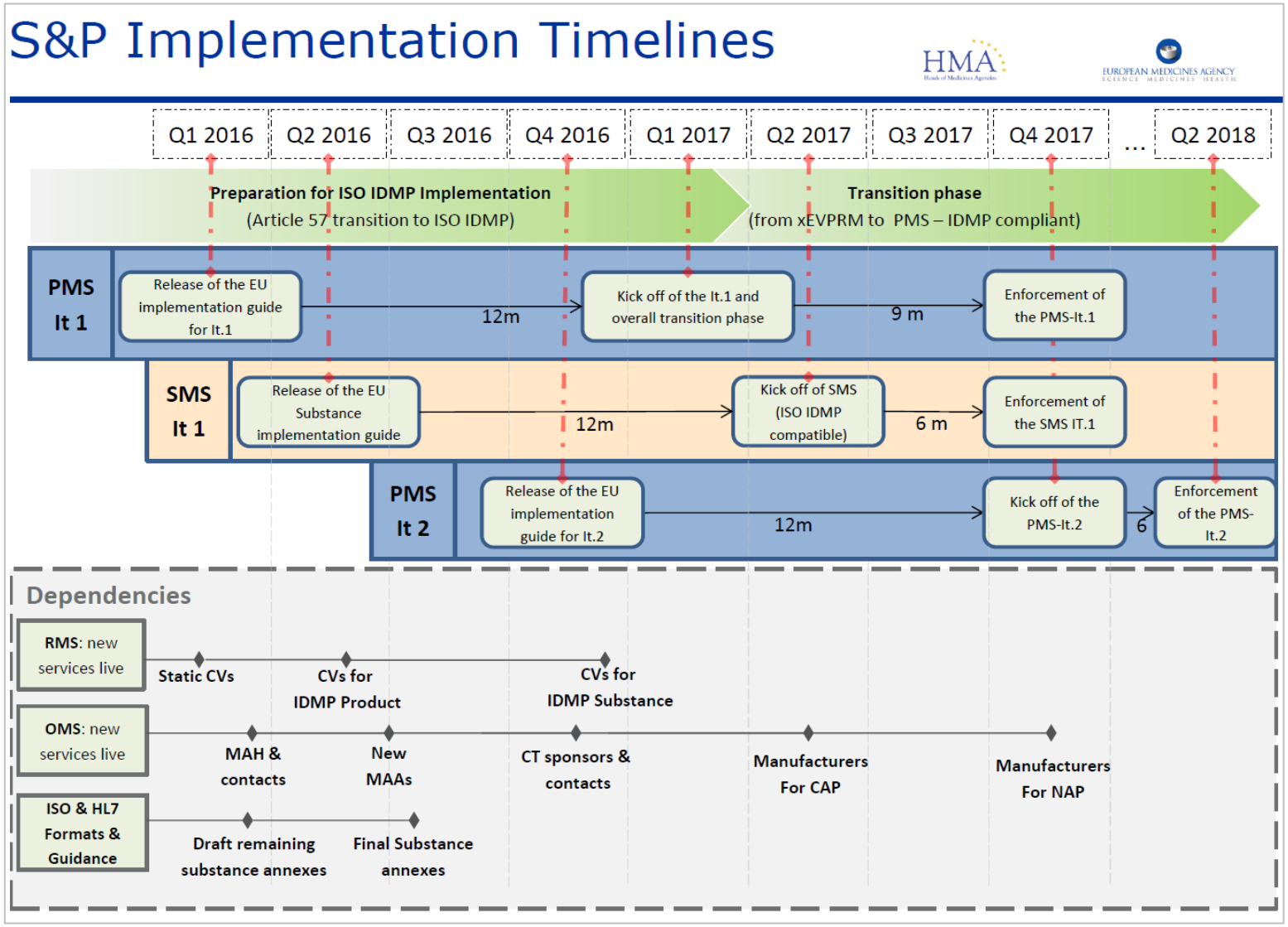
IDMP Quiz

IDMP Quiz

- https://pe.app/idmp



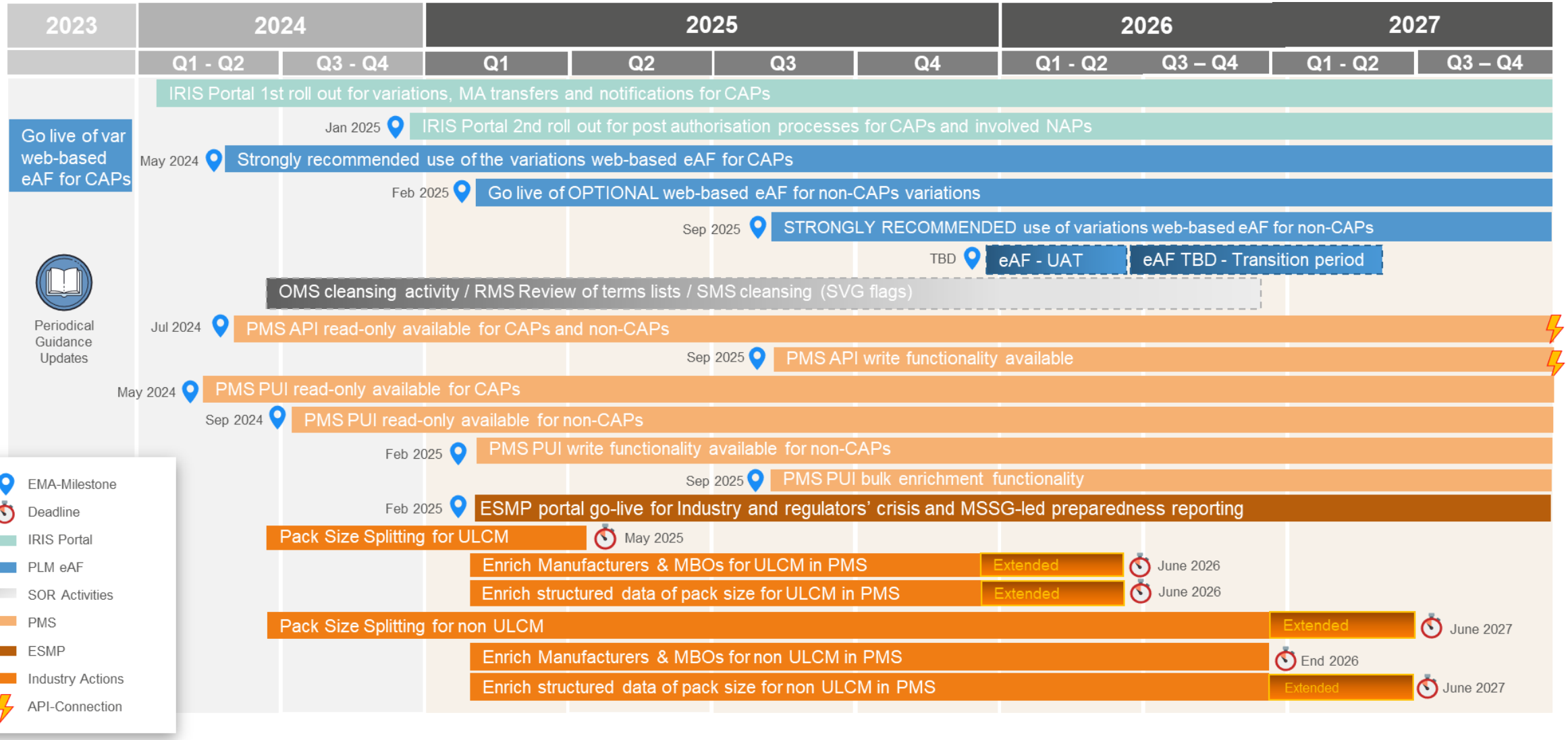
IDMP plans in June 2015



The IDMP Journey

- 2012: ISO IDMP standards released
- 2016: EMA begins the SPOR initiative
- 2020: First EMA Implementation Guides released
- Nearly ten years later…what have we learned? And how are we meeting the challenges of PMS today?

EMA Timeline



01 From a big bang to converging workstreams

Leading global pharmaceutical company

- Kicked off a major ‘IDMP project’ covering the whole dataset, triggered by the EMA SPOR initiatives
- “Not all IDMP data are equal”
  - Focus on priority data sets
  - Embedding IDMP at a global level
  - Agile, flexible approach
- IDMP data enrichment and maintenance
  - Utilise new tools to enrich existing databases
- PMS enrichment – hands on approach, challenged by XEVMPD/PMS data alignment

02 Delivering business value through data connectivity

Leading generic pharmaceutical company

- IDMP as part of the effort to move from document-based systems to structured data
  - Triggered by the selection of a new RIM vendor
- Internal motivators over external motivators
  - How can we get quicker answers?
  - Value of data connectivity
- Regulatory leading the way in implementing shared definitions grounded in IDMP standards
- 'Just in time' PMS enrichment to minimise potential re-work
- The biggest test for IDMP is Europe-wide alignment

03 Turning Compliance into an Opportunity for Digital Transformation

- Preparation and triggers
  - We began modernising our RIM and preparing for IDMP in 2019.
  - An obsolete in-house system and regulators signalling a shift to IDMP—later disrupted by COVID-19—triggered the project.
  - Modernisation provided a chance to converge with IDMP; we pursued a semi-compliant path while guidance evolved.
  - We focused on cleansing and harmonising data, adapting structures and vocabularies to the confirmed IDMP model.

03 Turning Compliance into an Opportunity for Digital Transformation

Challenges and approach

- **People**
- Build a coalition: identify data owners and engage all departments to learn what data they use, need and lack.
- Leverage dissatisfaction: use frustrations with the legacy system to build a positive case for change and involve users early to foster shared ownership.
- Secure sponsorship: frame the initiative as an internal business improvement delivering faster access and compliance; legislation and deadlines catalyse action.

- **Process**
- Two-phase upgrade: replace the home-grown RIM with a commercial, IDMP-oriented solution, then focus on an IDMP-compliant version by prioritising minimal data and critical fields like ESMP and high-impact products.
- Integrate parallel initiatives: merge projects such as Eudamed for devices and other information systems into the harmonisation roadmap, connecting them to the RIM to share common data and avoid duplicate entry.
- Focus on value: IDMP is one driver of harmonisation—efforts must deliver internal value; otherwise engagement dwindles.

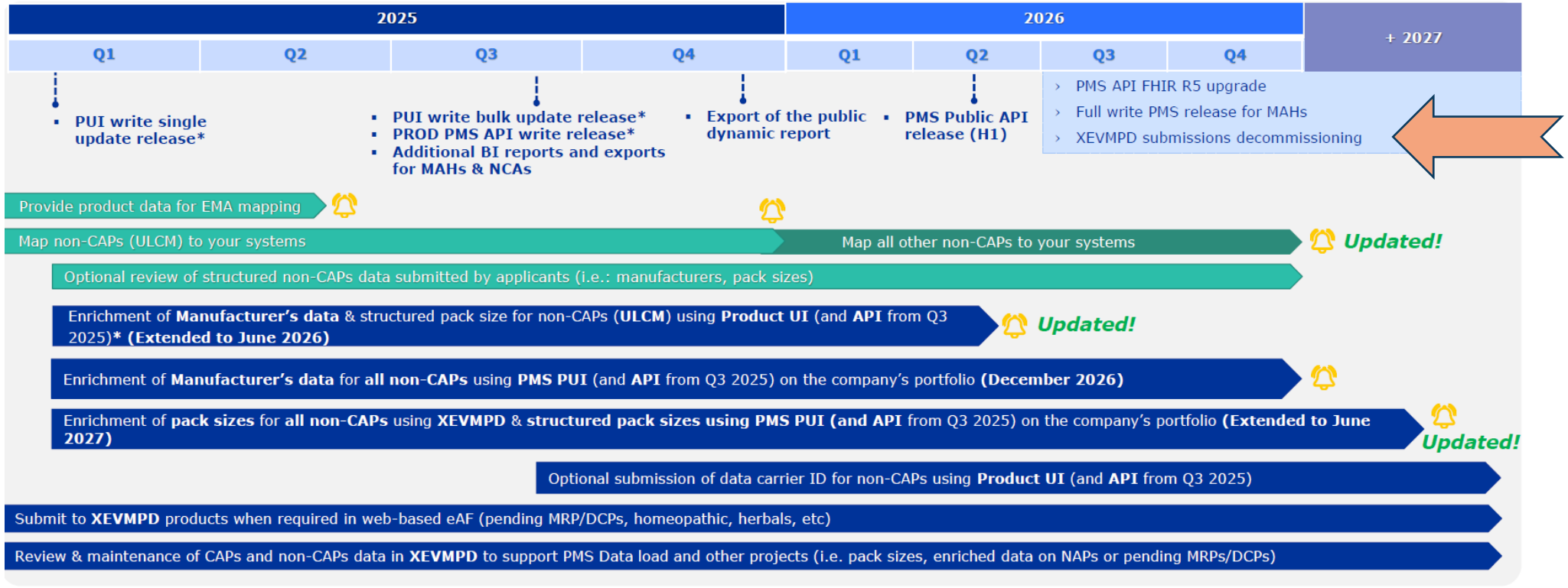
- **Unexpected challenges**: internal reorganisations, revised policies and accelerated regulatory deadlines sometimes overtook our plan, highlighting the need for flexibility and clear governance.

03 Turning Compliance into an Opportunity for Digital Transformation

- Lessons learned & recommendations
  - Estimate the true scale: scope depends on company size, product portfolio and data quality; underestimation leads to insufficient resources, unrealistic timelines and frustration.
  - Develop a pragmatic plan: balance internal expertise with external support; outsource routine tasks but keep critical decisions and knowledge in-house.
  - Set clear priorities: define mandatory, important and desirable elements; enforce boundaries so that new ideas don’t derail current phases.
  - Ensure leadership & resources: dedicate a core team of regulatory and business experts and secure executive sponsorship to navigate complexities.

EMA PMS roadmap

Product Management Service roadmap



* (MVP) limited to structured pack size, manufacturers and MBOs data for non-CAPs

Acronyms

- **API:** Application Programming Interface
- **ASU:** Antimicrobial Sales and Use
- **CAPs:** Centrally Authorised Products
- **DCP:** Decentralised Procedures
- **eAF:** electronic Application Form
- **MAHs:** Marketing Authorisation Holders
- **MRP:** Mutual Recognition Procedure
- **MVP:** Minimum Viable Product
- **NCAs:** National Competent Authorities
- **PUI:** Product User Interface
- **UAT:** User Acceptance Testing
- **ULCM:** Union List of Critical Medicines

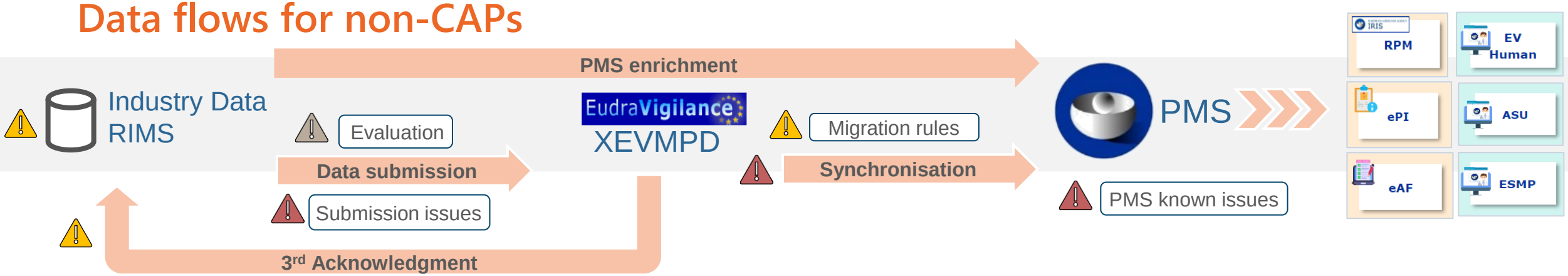
Legend

NCA action | MAH action | Milestone | Deadline

EMA

Alignment between PMS and Industry data

Data flows for non-CAPs



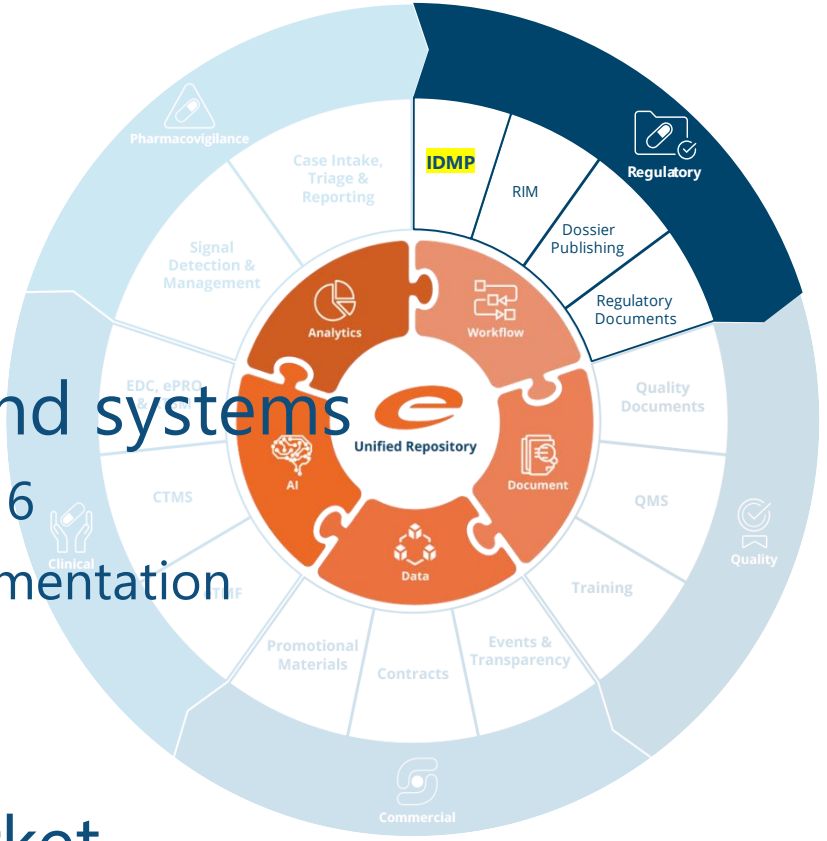
Data quality and Data Maintenance	Roles and responsibilities	Data governance	Follow up activities
Ensure data is findable, accessible, interoperable and reusable (FAIR). • **Reliable Source Documentation** • **Data Management and Submission** • **Data Accuracy and Standardisation** Identify gaps against IDMP and SPOR standards.	**Data Ownership:** Establish roles by clearly defining who is responsible for each regulatory process, decision, and data element. **EMA Platforms:** Role alignment and management for all the impacted EMA systems.	**Master Data Governance:** Manage the continuous operation of data flows according the legal requirements. **Organizational Change:** Analyse and define the processes, change points, targeted information and communications. **Internal Processes Adaptation:** Review, harmonization and improvement of regulatory key processes (including IDMP data collection, governance and submission process)	• PMS scope expansion • EMA requirements change • Impact assessment • Side related activities **Training** • Training for users • Refresher Trainings • Internal Communications

Root causes for data discrepancies between databases: Technical issues | EMA evaluation issues | Data quality and processes issues

Ennov IDMP Update

Ennov focus on IDMP

- ***Strategic*** *component of* Ennov Regulatory

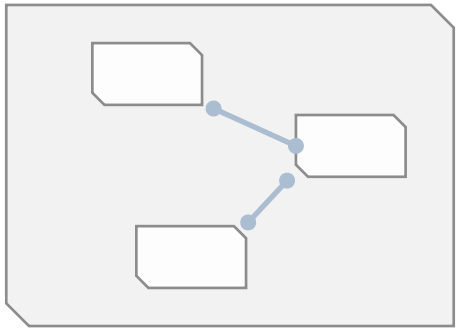


- Strong involvement with EMA on guidelines and systems
  - Ennov has participated to every test (UAT) on SPOR since 2016
  - Ennov feedbacks often impact guidelines and technical documentation

- The most advanced IDMP solution on the market
  - First to demo FHIR message generation + FHIR Viewer (IRISS vendor showcase 6 May 2021)
  - First to demo RIM – PMS data comparison (GPRAS Oct 2024)

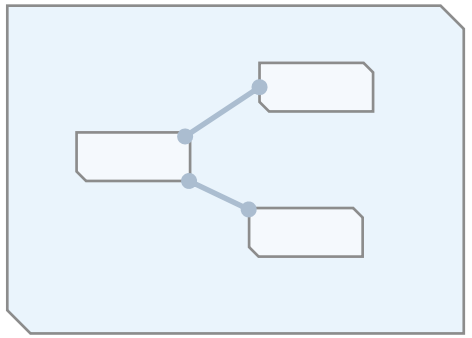
Unified *vs* Integrated platform

Typical RIM, IDMP systems



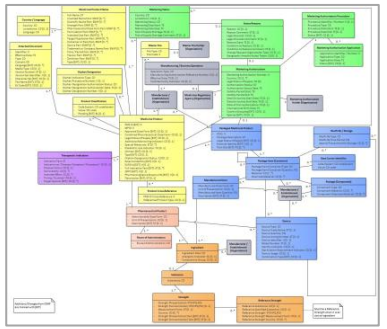
RIM data model

transform

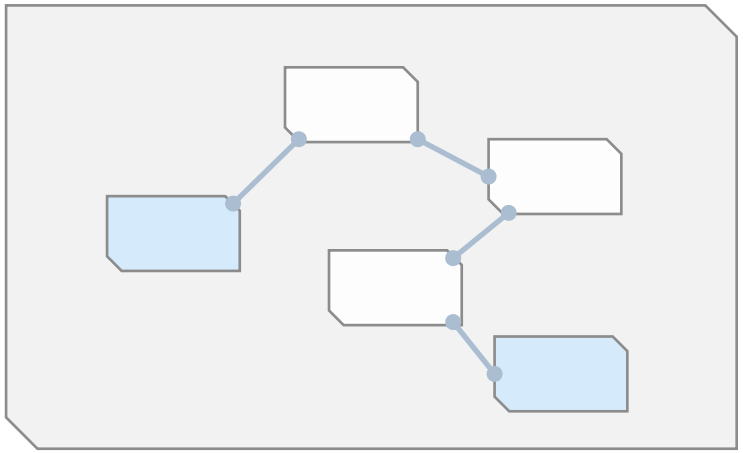


IDMP data model

generate

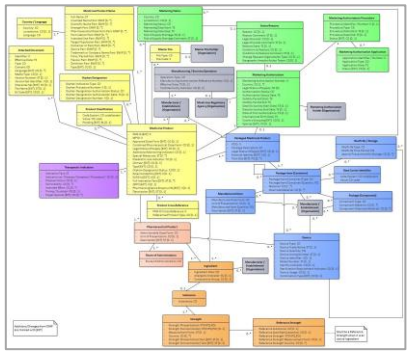


IDMP Message



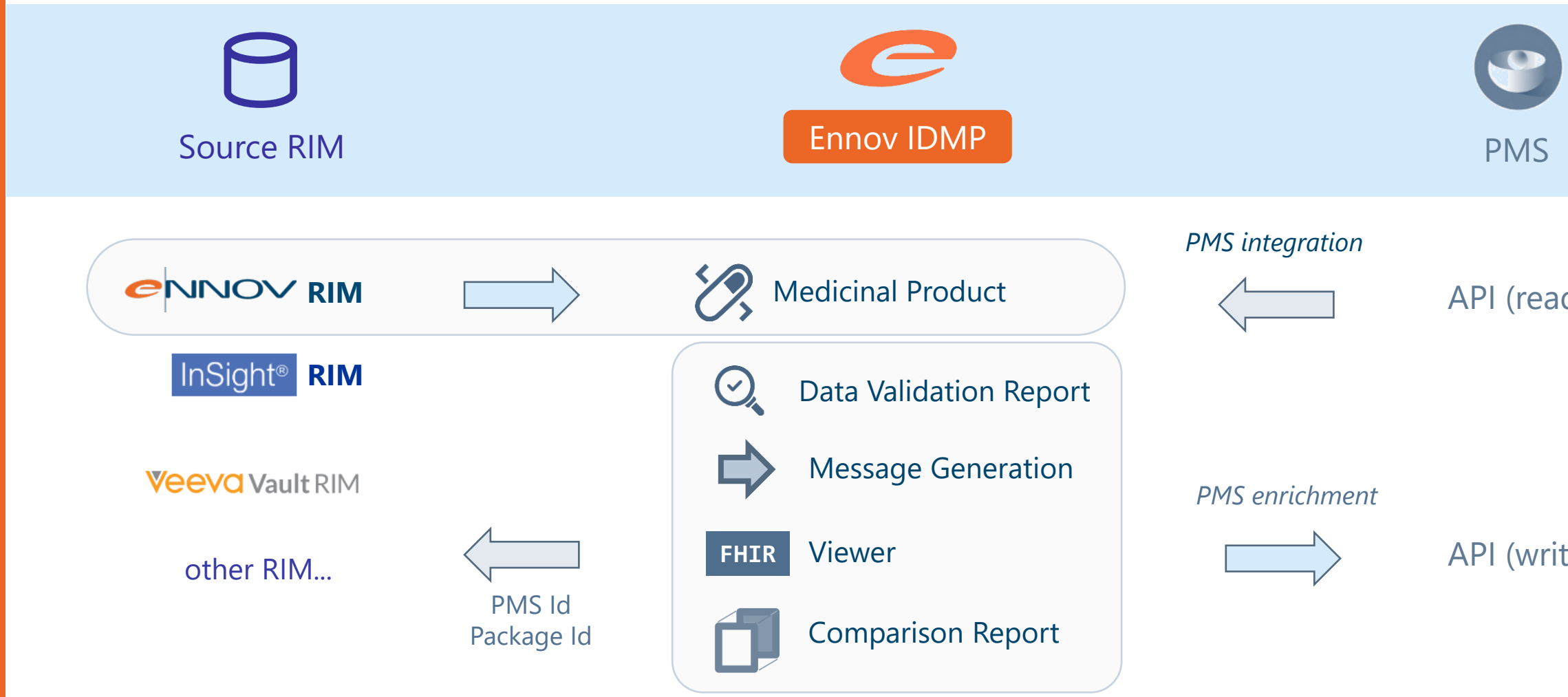
RIM + IDMP data model

generate



IDMP Message

Ennov IDMP Solution



1. PMS Integration

Source RIM

Ennov IDMP

PMS

Registered Product

Registered Packaging

- ev code

Medicinal Product

- PMS Dataset (FHIR)

synchronize

PMS Medicinal Product

PMS Packaged Product

- PMS id
- ev code

individual
by batch

Ennov FHIR viewer

EMA Product UI

2. IDMP Validation report

Source RIM

Ennov IDMP

SPOR

Product

Packaging

Manufacturer

Medicinal Product

Validation Report for IDMP readiness

- xEVMPD pack-level submission
- RMS + OMS mapping
- Mandatory fields
- Business rules (eg. manuf. auth.)

PMS

RMS

OMS

SMS

Controlled Entries

3. PMS Compare data between RIM and PMS

Ennov IDMP

PMS

IDMP Dataset

- Medicinal Product
- Product
- Packaging
- Manufacturer

Compare Data

Identify new, updated or missing data

PMS Medicinal Product

IDMP Dataset

Source Data correction

Plan PMS enrichment/corrections

4. IDMP Submission process

Source RIM

Ennov IDMP

PMS

Registered Product

Medicinal Product

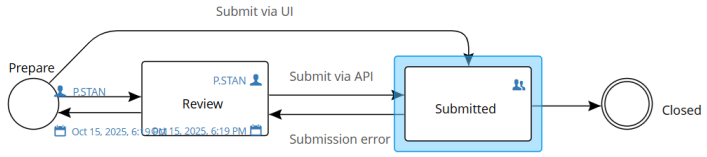
Read API

PMS Medicinal Product

Activity

with manufacturer impact

Enrichment request



IDMP Submission

Enriched PMS

FHIR Viewer

Write API

Enriched Medicinal Product *(versioned)*

PMS Enrichment: Manual *vs* API

RIM

Re-inject enriched data

PMS

Manual

Extract

PMS mapping

Med. Product → PMS Id
Packaging → PMS Id

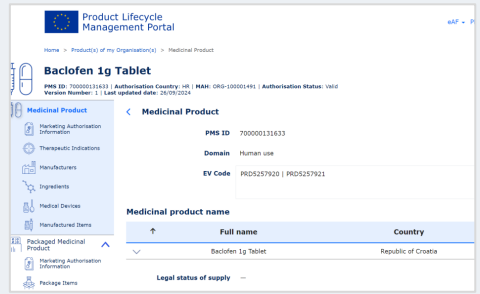
Quality Check

OMS/RMS mapping
Mandatory fields
Business rules

Data entry

one Product at a time

batch update



Product UI

via API

RIM

generate

fix data

Validation report

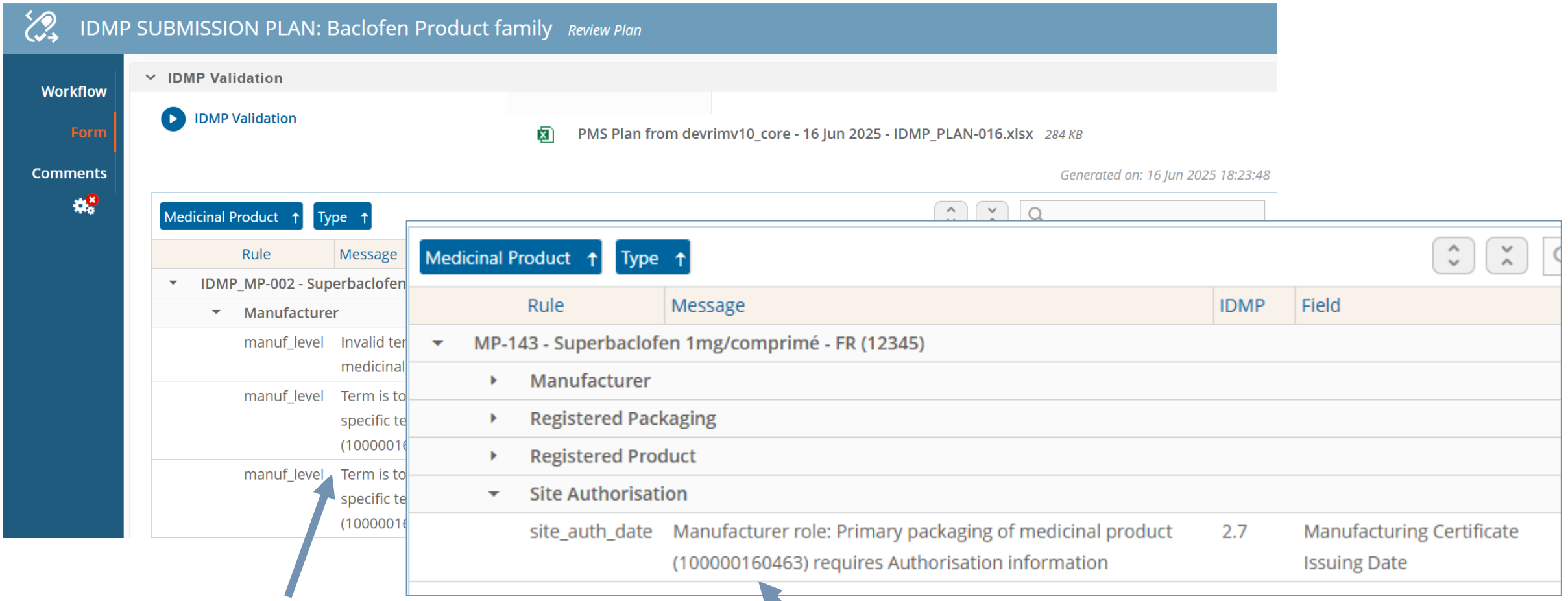
by batch

Submit

by batch

API

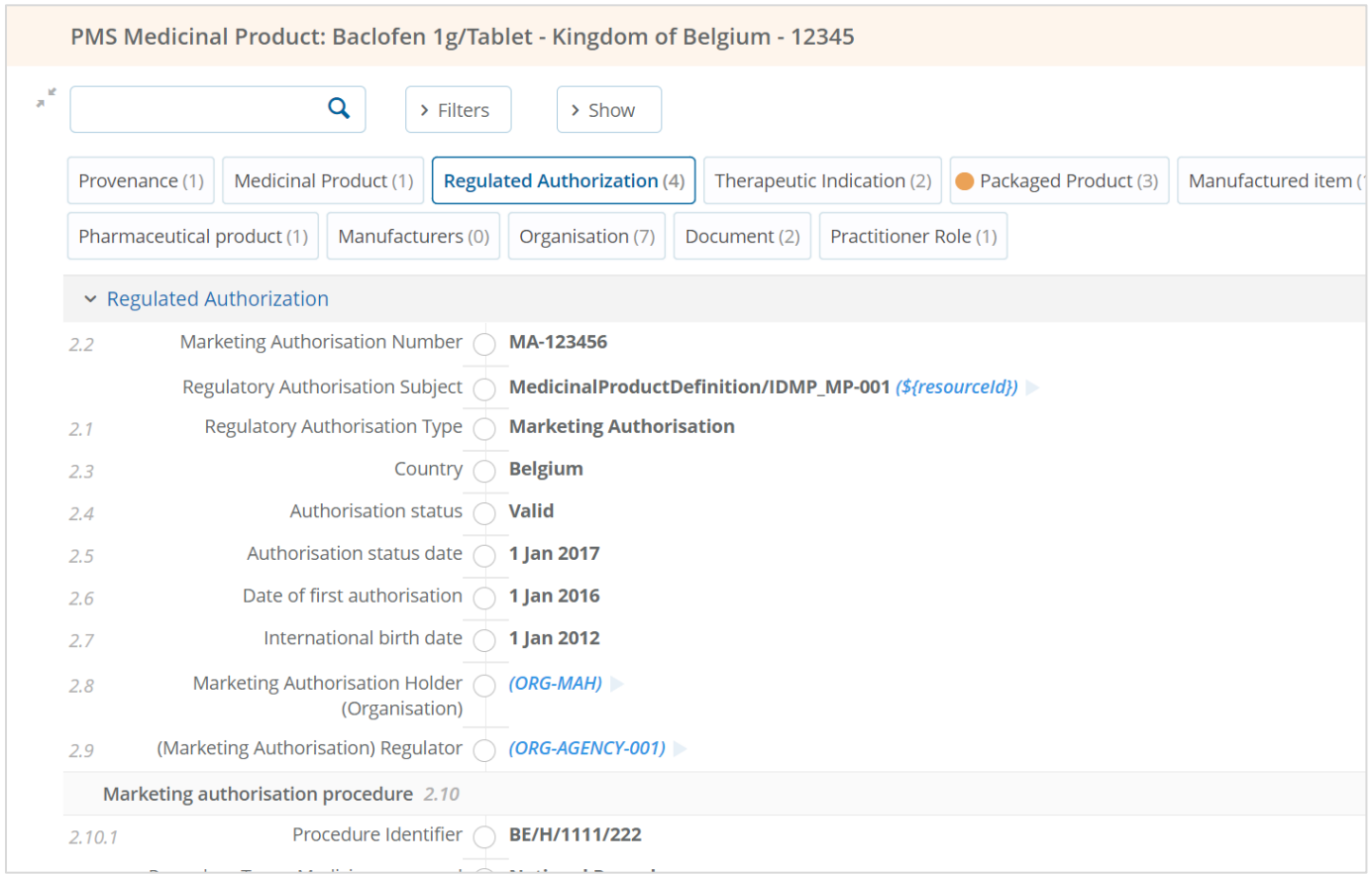
Validation report example



High level term not allowed:
Chapter 3 v3.3, 2 June 2025

Manuf. Authorisation conditionally required
Chapter 2 v2.4, 8 Aug 2025

Ennov FHIR Viewer

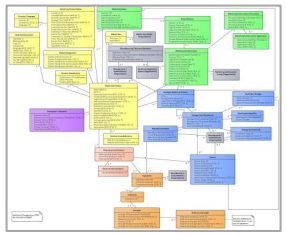


Ennov FHIR Viewer

PLM Product UI

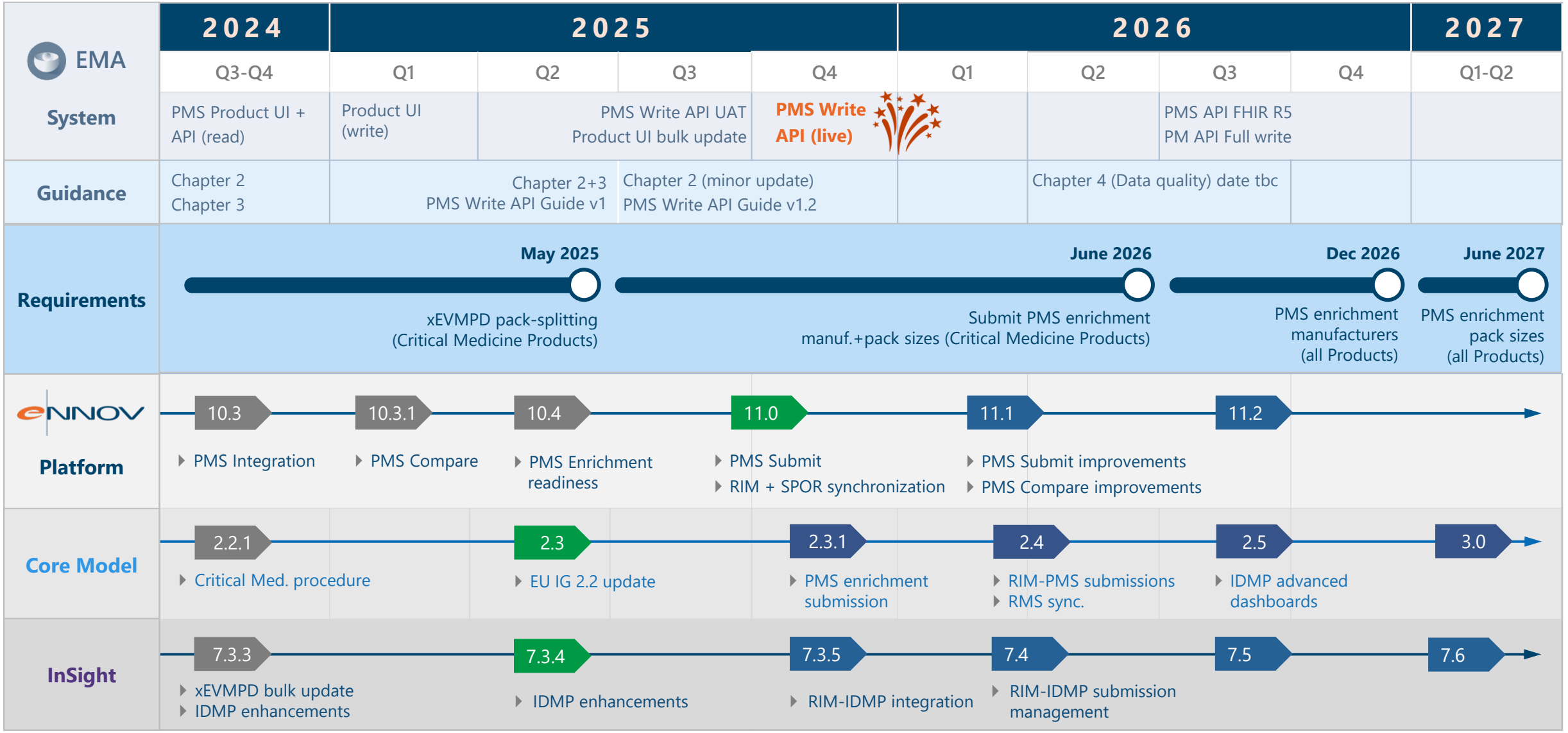
- Faster (all data loaded at once)
- Search filter
- Show changes / diff
- Message annotation

Guidance Update Impact – Data Update

	DATA MODEL	PMS INTEGRATION
Change:	New / Updated field	FHIR data element
Impact area:		message generation ⇨ data comparison ⇦ 
Change Type:	config (UI)	transformation rules
Timing:	**Hours**	**Days**

➔ **Core model update ready within week(s) with minimal validation impact**

Ennov IDMP roadmap - 6 Oct 2025



Thank you for your attention