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SCIENCE MEDICINES HEALTH

2.2 Update on ESMP development progress status

Industry Standing Group (ISG) meeting, 25 March 2024

Presented by Pedro Pina Ferreira, Monitoring VS Owner,
Sofia Zastavnik, ESMP Product Owner, and
Marcos Fernandez Gomez and Veronica Lipucci Di Paola, PMS Product Owners

The European Shortages Monitoring Platform (ESMP)

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Data collection

- Shortage information
- Supply and demand of medicines
- i-SPOC Registration

Analysis & Reporting

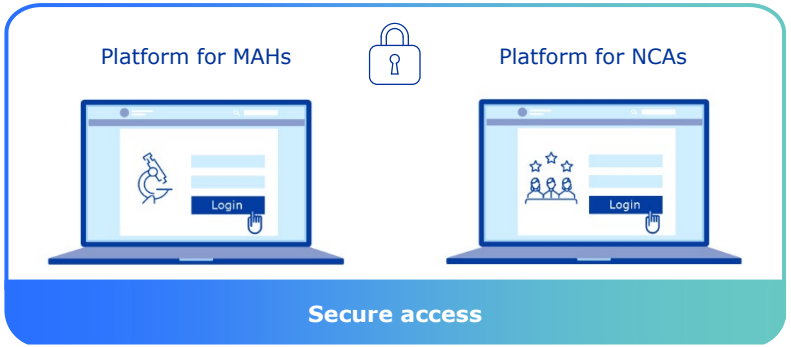
- Matching supply & demand
- Reporting findings and results
- Public reports

Shortages management

- Maintain critical medicinal product lists
- Evaluate and manage medicines shortages

Data integration

- PMS integration of CAPs and NAPs
- RMS integration
- Interoperability with NCA and Industry systems



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High level process and progress diagram

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Access Management

MAHs | NCAs | Public

Data collection

MAHs

Crisis, MSSG-led preparedness		Preparedness
User Interface	Alternative Therapies	User interface
Overview of critical medicines	Marketing status NAPs	Routine shortage reporting CAPs
Marketing status CAPs	Manufacturing details, production plan CAPs	
Availability of medicines	Production plan NAPs	

NCAs

Crisis	MSSG-led preparedness
User interface	User interface
Stock and supply	National demand
Patient estimation	
Medicine usage	

Analysis & Reporting

- Match supply and demand
- EMA dashboards and reports
- NCA dashboards and reports
- Public webpage

Shortages Management

- iSPOC registration
- Maintain lists of critical products
- Case management of CAP shortages

Data Integration

PMS integration (CAPs) | RMS integration | PMS integration (NAPs) | Interoperability

Progress on track !

Completed | In Progress | Not Started

PMS : Product Management Services

RMS : References Management Services

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ESMP Web portal

The future as of Q4 2024

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High level PI Objectives proposed for Q2 2024

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Development: focus on NCA platform

Crisis phase: development of the **bulk download** of the pre-filled template with all product authorised in their countries, data validations upload to allow **NCAs** to submit **information on stocks and supply**

Crisis phase: development of the **bulk download of a pre-filled template, data validations and upload** to allow **NCAs** to submit **information on patient estimations**

Building the **User Interface** for **NCA submissions**, linking it to the Data analytics Dashboard

Setting up the **NCA Security access**

MSSG-led Preparedness phase: development of the **bulk download** of the pre-filled template with all product authorised in their countries, data validations upload to allow **NCAs** to submit information **on national demand**

Aligning of the features previously built for MAH submissions to a single user experience flow

Bugs, minor improvements of MAH Crisis submissions and Case management features, performance testing

External testing with MAH SMEs

Dedicated **end-user quality gate assesment** with **MAH SMEs** during a fully committed **week**, ensuring active participation from **EMA business** and **technical support teams**, for robust feedback gathering, meticulous issue identification, and collaborative resolution to deliver a refined and high-quality user experience

Business analysis

Crisis phase: gather business requirements on submission of data on the **active substance and final product production plan** and **capacity** data from **MAHs** for **NAPs**

Defining requirements for a **publicly accessible webpage** with information on actual **shortages** of products included in the critical medicines lists

Defining which datasets contain **commercially confidential information** and might require additional considerations

Data Analytics

Development of the **MSSG-led preparedness Monitoring tool** for matching of supply and NCA demand estimations

Implement the **automatic calculation for hospital and ICU medicines needs** based on the average use of a medicines and the estimated patients

Implement the **automatic calculation of vaccine availability** based on average use and amount of vaccines in stock or planned supply

Implementation of the **Country Monitoring Tool UAT findings**

Allowing the possibility for the end user to select **unit of presentation** (tablets, capsules or equivalents) to display the outcomes of the analyses of the dashboard

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ESMP development timeline

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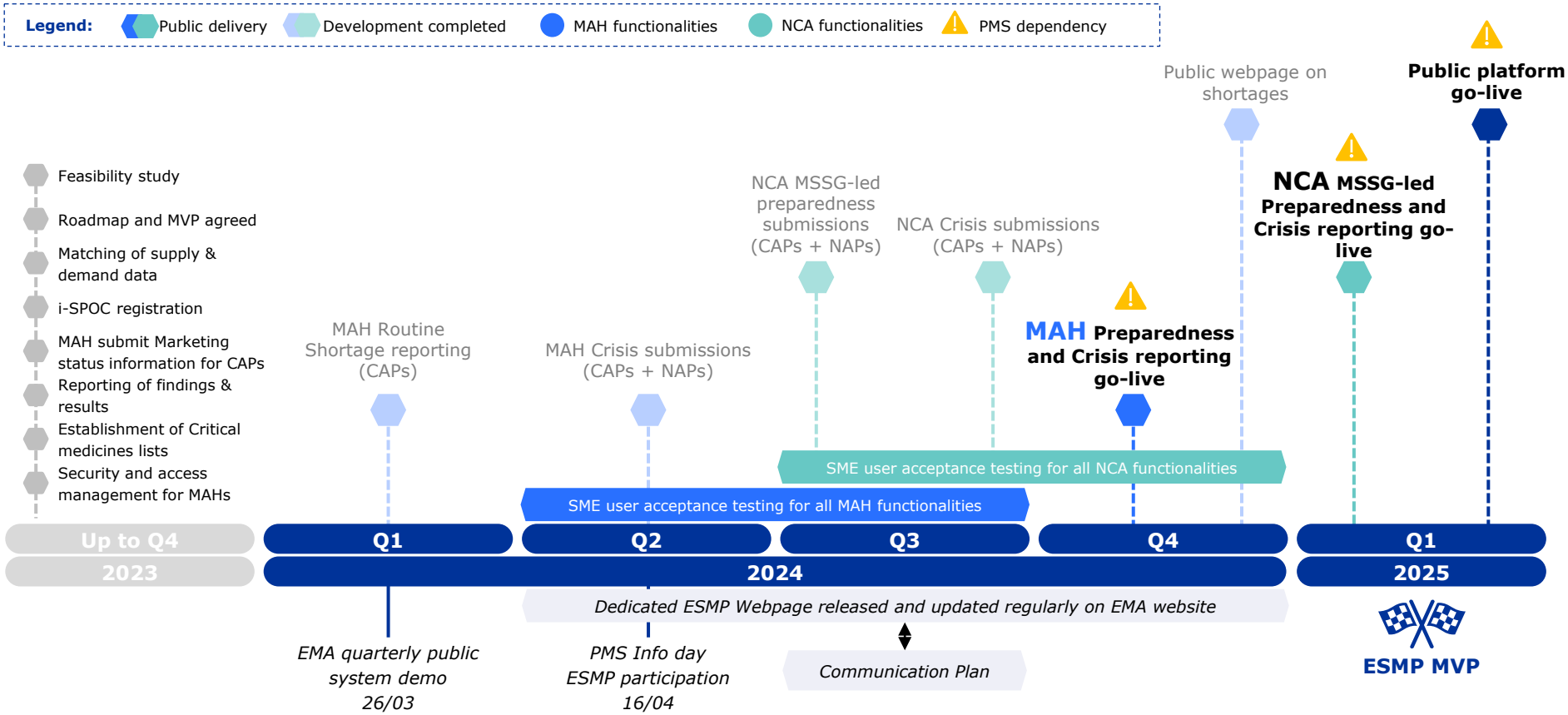

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PMS dependencies and required actions for ESMP

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1. Data on CAPs is already available to the PMS, imported through IRIS and used by ESMP

2. Data on NAPs is available in xEVMPD and migration is ongoing to PMS. This data, once migrated, will need to be ingested by IRIS in order to be used by ESMP. Performance risk identified in the ingestion step by IRIS team.

3. Actions on MAHs required for data enrichment in xEVMPD/PMS for NAPs

MAH SUBMISSION:
NAPs data at PACK SIZE in XEVMPD

The insertion of data on pack sizes of NAPs to be populated by MAHs in phases:

- **Union list of critical medicines** to be enriched via xEVMPD/Art57 **as soon as possible**, deadline Feb 2025
- **Crisis-specific lists and MSSG-led preparedness**, MAHs enrich data in XEVMPD/Art 57 **within 2 weeks** after crisis is declared

MAH SUBMISSION:
NAPs MANUFACTURING SITES in PMS PUI

- **Union list of critical medicines** to be enriched via PMS Product User Interface from Feb to Dec 2025

4. ESMP Interoperability with National Databases: Dependency on NAPs data being available in PMS so that NCAs can map the data to their systems. NAPs data will be available in PMS API (Q2 2024) and in Product UI (Q3 2024).

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How to stay informed on PMS work

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ESMP Key Drivers

- PMS dependencies and required actions for ESMP
- Industry actions on PMS/XEVMPD to prepare for ESMP

PMS Info-Day *(16 April 2024)*

This event aims to offer further insights into the **implications of PMS for key stakeholders** and present the **connection of PMS to other EMA digital solutions** (i.e. eAF, SPOR, ESMP, ePI, etc.)

The event will be available **online for live broadcast** on the dedicated **web page** and **EMA YouTube Channel**.
Details are published soon on EMA Website.

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Implementation timeline and Stakeholders' readiness

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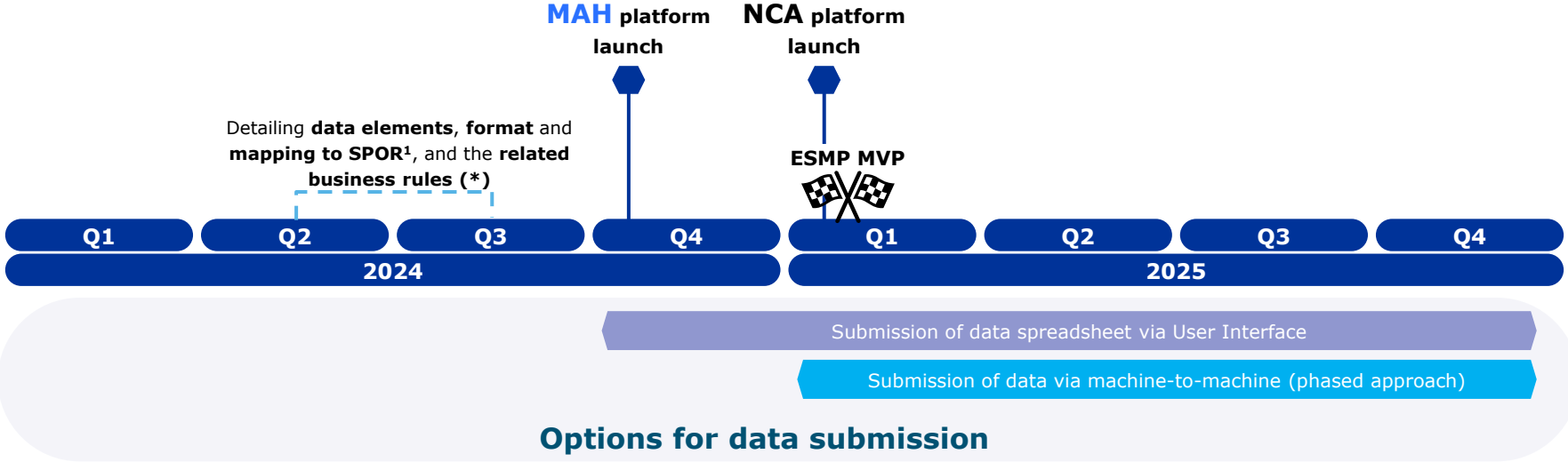
Important : To prepare for ESMP launch, ensure readiness to report and favour interoperability with national and industry systems, MAHs and NCAs should:

- **Review business and technical specifications** of datasets in scope of reporting requirements (*);
- **Collect relevant data** from internal source system(s);
- **Align data** in scope of reporting requirements with dataset specifications;
- Plan and **develop possible changes** in internal business processes and IT systems.



Note: As an example, the use of SPOR implies that your MAH and NCA reconcile the relevant product information with the corresponding product in PMS.

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Interoperability communication timeline

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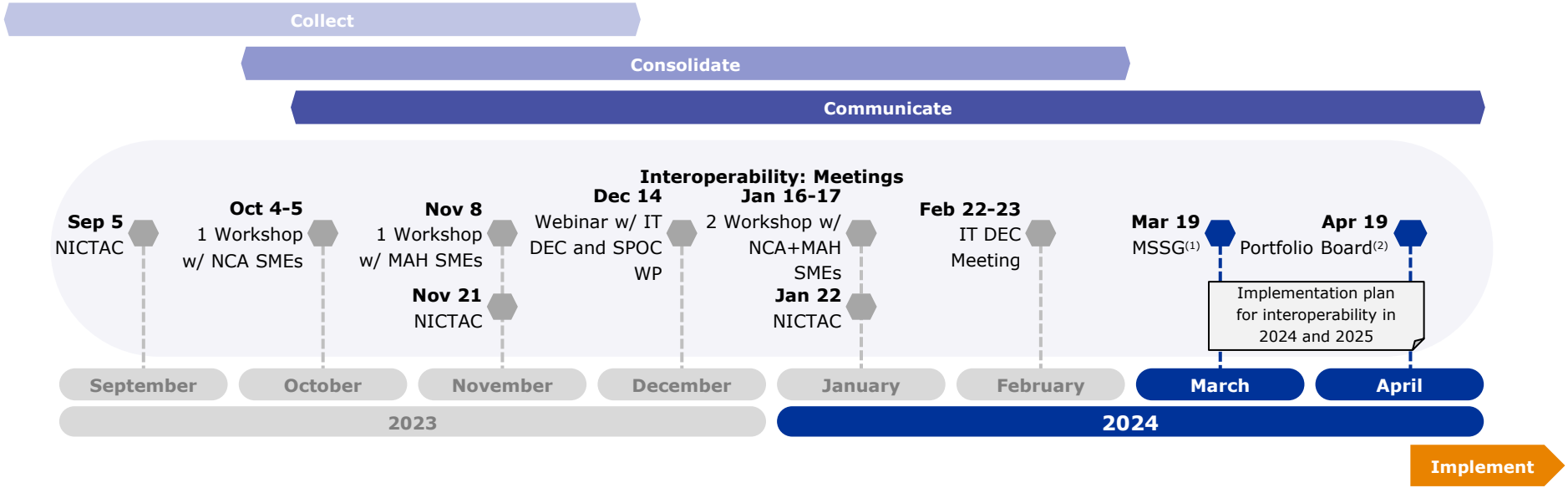
Work Plan on ESMP interoperability options for MAHs and NCAs



Please note: each meeting with stakeholders was followed by post-mailing in which outcomes and relevant materials are shared

(1) MSSG endorses the Interoperability approach
(2) Portfolio Boards endorses the Business Case

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Any questions?

Further information

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Interoperability in the European interoperability framework

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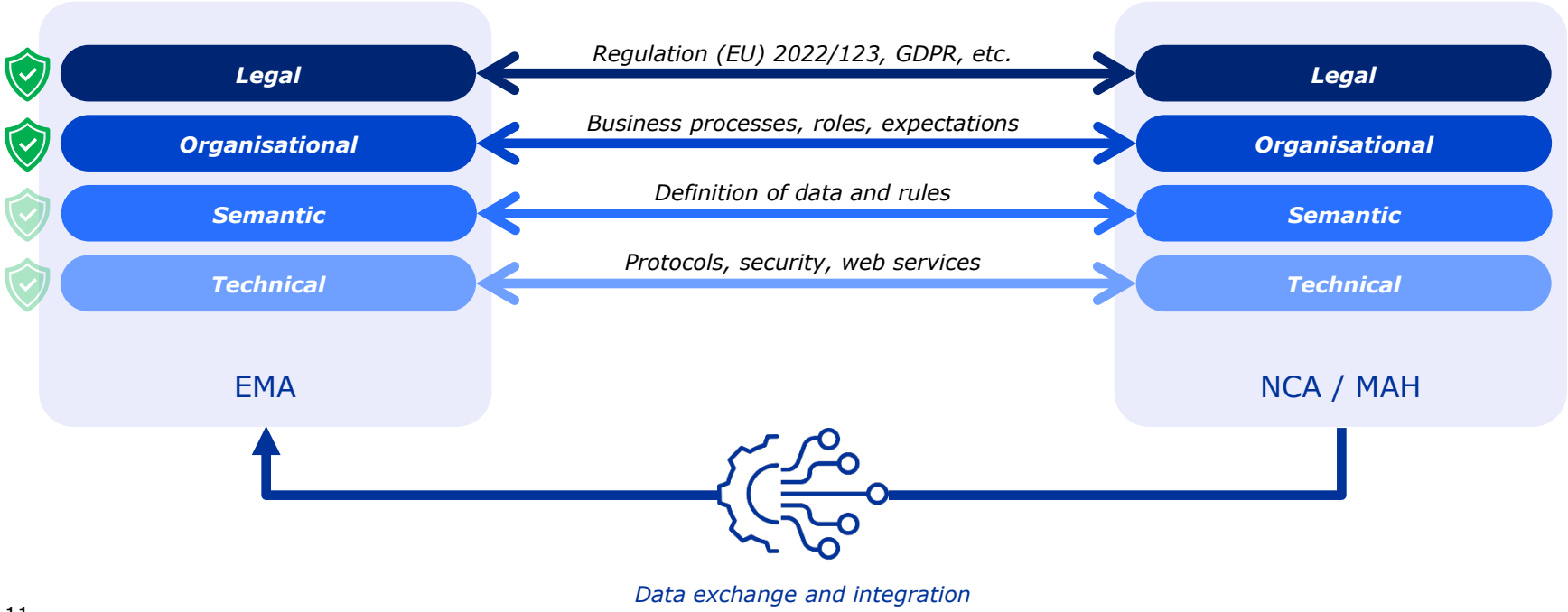
Interoperability is defined as the **ability of organisations to interact towards mutually beneficial goals**, involving the **sharing of information and knowledge** between these organisations, through the business processes they support, by means of the exchange of data between their ICT systems.



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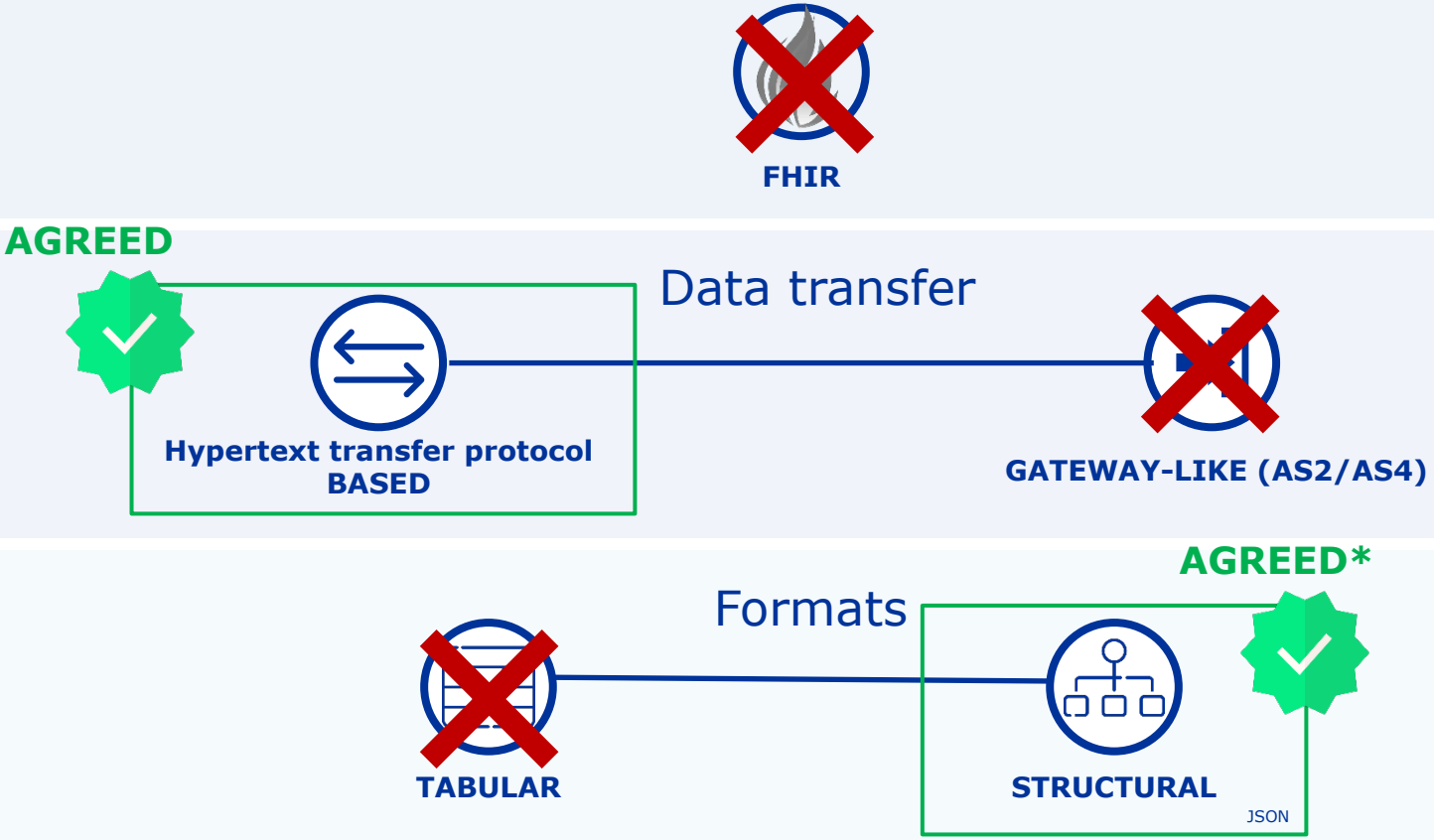

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Dependencies on PMS

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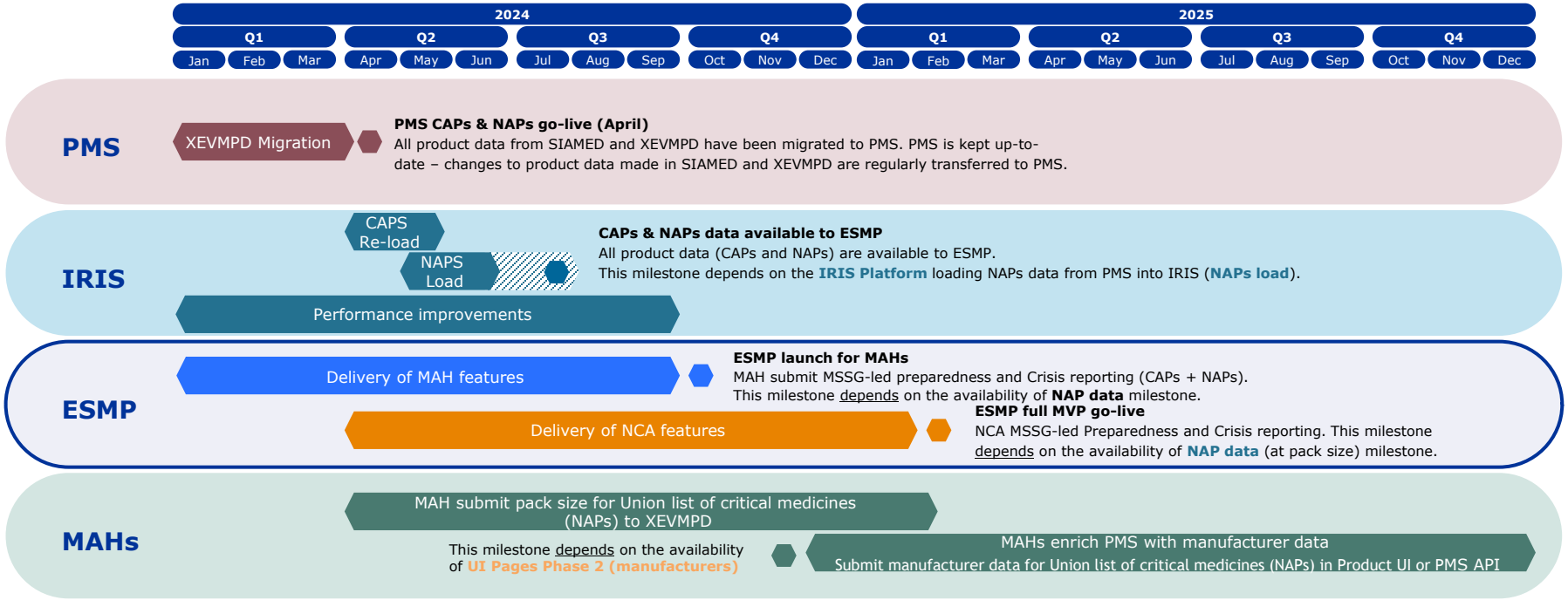

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