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SCIENCE MEDICINES HEALTH

Update on electronic submissions and eAF

Approach towards eCTD v4.0 implementation and next steps for eAF (DADI)

Presented by: **Karl Hamilton**, Product Lifecycle Management Value Stream Owner
and **Kristiina Puusaari**, eSubmissions Programme Manager / eAF Product Owner

Digital Business Transformation Task Force

Agenda

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1	**Context of eCTD v4.0 and eAF (DADI) in the Product Lifecycle Management Value Stream**	***Karl Hamilton*** *Product Lifecycle Management Value Stream Owner*
2	**Roadmap for eCTD v4.0 implementation in EU**	***Kristiina Puusaari*** *eSubmissions Programme Manager / eAF Product Owner*
3	**Next steps in eAF transformation (formerly DADI)**	***Kristiina Puusaari*** *eSubmissions Programme Manager / eAF Product Owner*
4	**Q&A session**	***All***

Context of eCTD v4.0 and eAF (DADI) in the Product Lifecycle Management Value Stream

Presented by: **Karl Hamilton**, Product Lifecycle Management Value Stream Owner

Overview

The creation of a **Product Lifecycle Management Value Stream (PLM)** has brought together **eSubmissions, eCTD v4.0, electronic Application Forms (eAF), electronic Product Information (ePI)** and **SPOR (Product Management Service)** to strengthen how they are developed, integrated and rolled out to maximise benefits

Target state sees full **integration and automation**, where possible, with a **target architecture design** until all components are fully developed.

Change Management has been put in place across the Value Stream products to **improve stakeholder engagement and coordination of Subject Matter Expert input** and other key roles.

The **Product Lifecycle Management portal** will bring these products together, including a **new user interface in 2023 for product data viewing, correction and enrichment**.

Vision

EMA's aim is to **transform and optimise regulatory procedure management across the product lifecycle**, unlocking more value together with our partners and stakeholders, for the benefit of public and animal health in the EU

Product Lifecycle Management Value Stream in context

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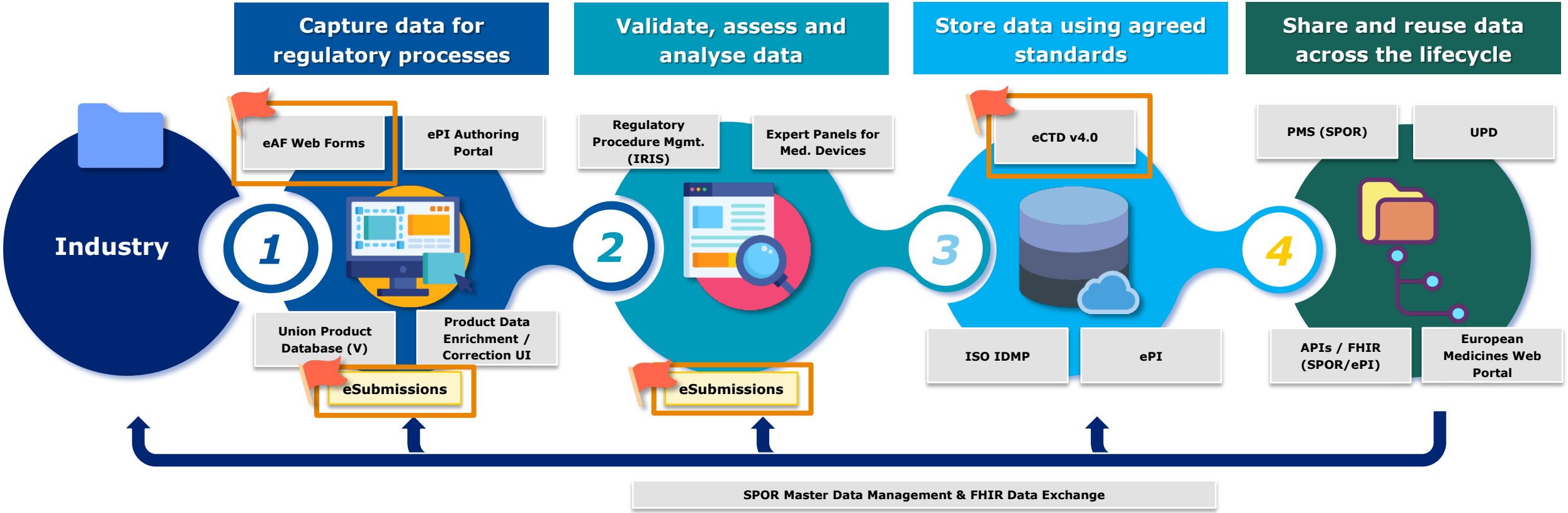

Customer Centricity

- Industry
- Citizens
- EMA and National Regulators
- Healthcare Providers

Recap of ceremonies and means of addressing bugs/issues

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With the move to Agile ceremonies, our aim is to ensure the right audience is around the table for the discussions that concern them most.

Please continue to raise technical issues or questions via EMA Service Desk, at System Demos, etc.

Key vehicles to collaborate

Formal engagement

Strategic and operational through Subject Matter Experts & ceremonies (e.g. Quarterly strategic portfolio review, system demos)
Industry Stakeholder Platform meeting *

Additional meetings

Meetings, webinars and workshops will be set up on topics as required: engagement in a structured way, but not *structural*

Subject Matters Experts' contribution

Structural Subject Matter Expert participation (content contribution)

Supported by consistent outreach and communications on prioritisation and roadmaps

**** While not an Agile ceremony, this forum has a role in discussing specific topics of relevance***

PLM Value Stream Calls for Expression of Interest

The Product Lifecycle Management (PLM) Value stream launched a series of **calls for expression of interest for Agile roles** (i.e., *Network Product Owner (PO), Network Subject Matter Experts (SMES) and Industry SMEs*)

Product	Role	# of people	Opening date	Closing date
UPD	Industry SME	3	31/10	14/11
	Network PO	1	31/10	16/01
	Network SME	3	31/10	16/01
Regulatory Procedure Management (IRIS) for Human & Veterinary domains	Industry SME	3-4	08/11	29/11
	Network SME	2-3	08/11	29/11
PMS	Industry SME	4	15/09	04/11
	Network SME	4	15/09	04/11
	Network PO	1	07/11	16/01

Legend:

- Closed
- Open

Lessons learned and further improvements

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1

Web eAF (formerly DADI) was the first major Agile release for PLM. Initial feedback shows increased investment in stakeholder engagement and Change Management is beneficial.

2

Feedback on what went well and room for improvement very welcome and is being addressed by the team.

3

Frequent **awareness sessions, demos, Q&A sessions and UAT sessions** were positively received - acknowledgement that late adjustments to timing was not ideal for participants.

4

Feedback on shorter release times for recordings and **more information on what to expect from UAT product features**.

5

Parallel **transition of EMA Service Desk tool and change of product name from DADI to eAF** recognised as not ideal and will be taken into account in future.

6

Commitment to **communicating as early and as transparently as possible on future UATs and releases**, critically for mandatory use.

Optimising PLM product development and integration

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Work on mapping and **improving the user journey across PLM and related Value Stream products** starting early 2023, including regulatory procedure management (IRIS), ePI, eAF, PMS

The goal is to make the **user journey smoother** and **optimise how products integrate in future**

Change Management investment significantly increased to **improve stakeholder experience**

Roadmap for implementation of eCTD v4.0 in EU region

Presented by: **Kristiina Puusaari**, eSubmissions Programme Manager / eAF Product Owner

Electronic submissions (eSubmissions)

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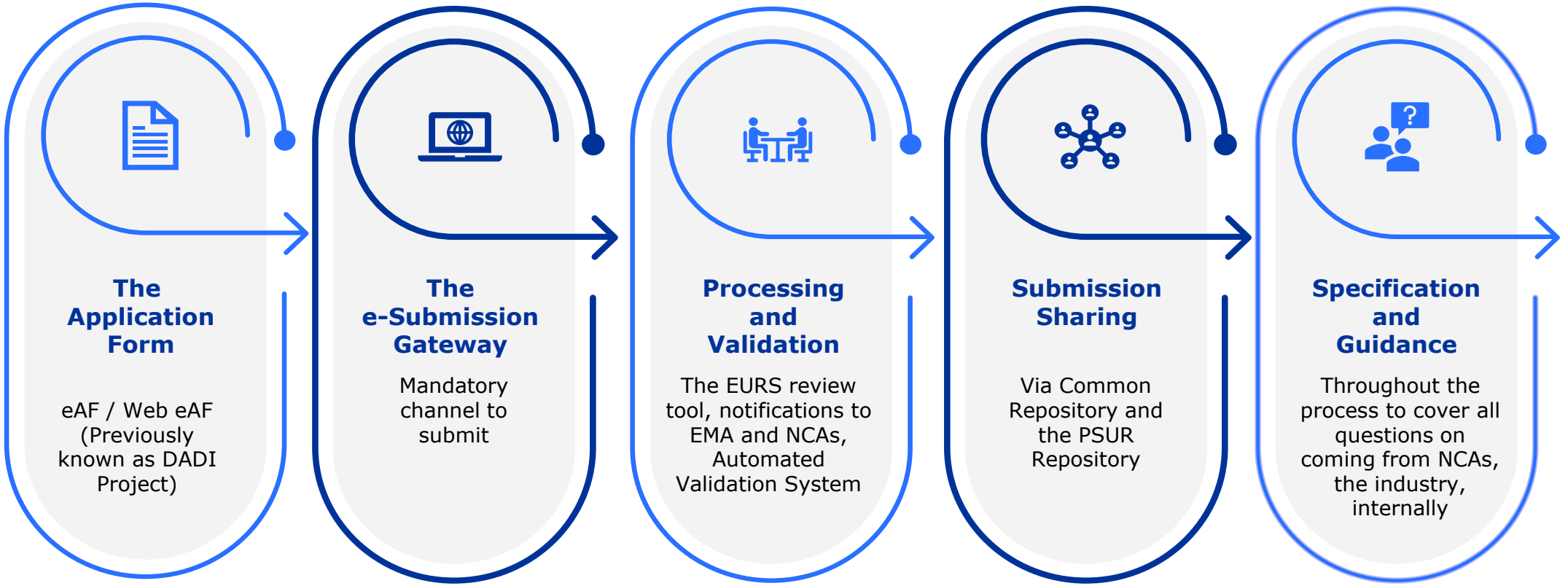
- With **eSubmissions** we create, enable, maintain and improve the **submission tools and processes**
- eSubmissions support the **EMAs core business and the whole EU Network**
- **Implementation of eCTD v4.0** requires changes to business processes and systems and will be carried out incrementally



Journey from NeeS to eCTD v4.0

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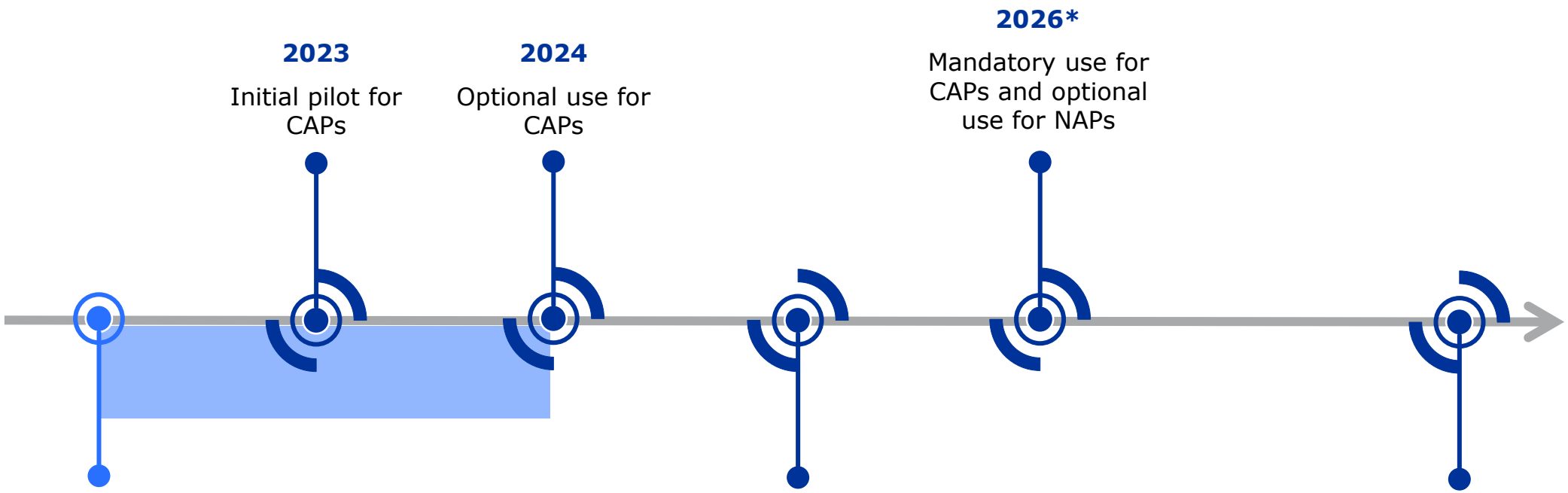
The initial introduction of **mandatory use of eCTD** in the EU started with **Centralised Procedures** and progressively extended to all European procedure types (including MRP/DCP/NP).
The **impact of eCTD v4.0 is wide**.

We have launched a project (transitioning to epic) to implement **eCTD v4.0 in the EU**. The stepwise implementation will start with a **pilot for CP** and then extending to all other procedure types.

In 2023, we will review the specification and implementation guide, rollout an **eCTD v4.0 compliant review tool at EMA and analyse business process and system changes** required to support eCTD v4.0

EMA is currently reviewing the **Common Repository tool** to ensure that NCAs are able to read/review eCTD v4.0 format submissions.

Proposed Roadmap for eCTD v4.0 implementation in the EU



Other regions plan mandatory use between 2026 - 2028

- Timelines are indicative and subject to iterative change.
- Engagement with Industry and Network on eCTD v4.0 will increase in 2023 and Subject Matter Expert calls will be issued (timing to be confirmed).

Next steps for eAF (formerly DADI)

Presented by: **Kristiina Puusaari**, eSubmissions Programme Manager / eAF Product Owner

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Key updates

Q4 2022

- The **first eAF for human CAP variations** was launched on the **Product Lifecycle Management Portal** on **4 November 2022**
- **Hypercare period is in progress** to address urgent bugs and ensure stability of the system
- eAF Team is preparing for the features for **NAP integration** to be ready for **UAT and second major launch expected in 2023**
- Analysis and preparation work are progressing on **Initial Marketing Authorisation forms for the Human and Veterinary Domains**

2023

- The **UAT** and **launch window** for the **NAP capabilities** will not take place in Q1 2023 as originally announced – the specific timeline for both will be communicated at least **two months in advance**
- Launch of **eAF for CAPs and NAPs with sufficient functionalities** to replace the current pdf eAF will trigger start of the **6 month transition period**
- **Product User Interface on PLM Portal** will be developed to integrate with eAF features for consistency of user experience and re-use

Questions and feedback

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