EMA
EUROPEAN MEDICINES AGENCY

PLM portal and process of ePI

Gravitate Health's Open E2E ePI Community

6 June 2025

Presented by:
Elizabeth Scanlan
ePI Product Owner, European Medicines Agency

EMA-HMA-EC: progress of ePI initiative

Key Principles

2020: ePI is authorised summary of product characteristics, package leaflet and labelling created using the EU ePI Common Standard. ePI optimises dissemination via the web, e-platforms and print.
Benefits of up-to-date timely information

EU ePI Common Standard

2021: Harmonisation using EU ePI Common Standard based on FHIR: a set of XML (and/or JSON) health data resources,
plus a REST API
for accessing them

FHIR

ePI at PLM Portal

Creation and management by companies & regulators, storage in FHIR repository

Pilot

2023-2024: Creation of **ePI in real procedures** by EMA, AEMPS, DKMA, MEB and MPA

Successful pilot paves the way for implementation of ePI

16 December 2024

Report outlines recommendations and next steps

News · Human · Product information

agencia española de medicamentos y productos sanitarios

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Inspectie Gezondheidszorg en Jeugd
Ministerie van Volksgezondheid, Welzijn en Sport

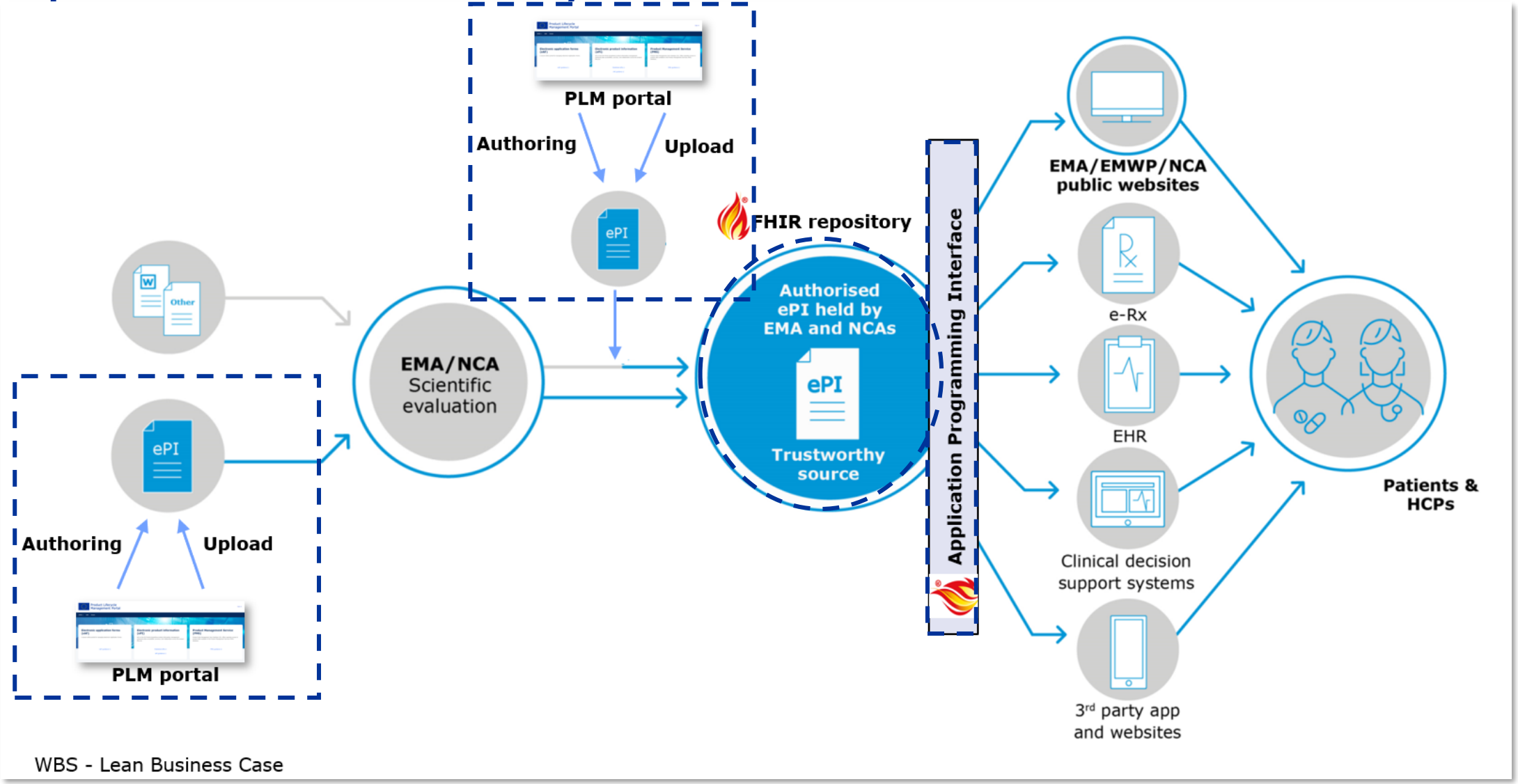
LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Developed with funding by the European Union

EMA

Classified as internal/staff & contractors by the European Medicines Agency

ePI product and ecosystem



WBS - Lean Business Case

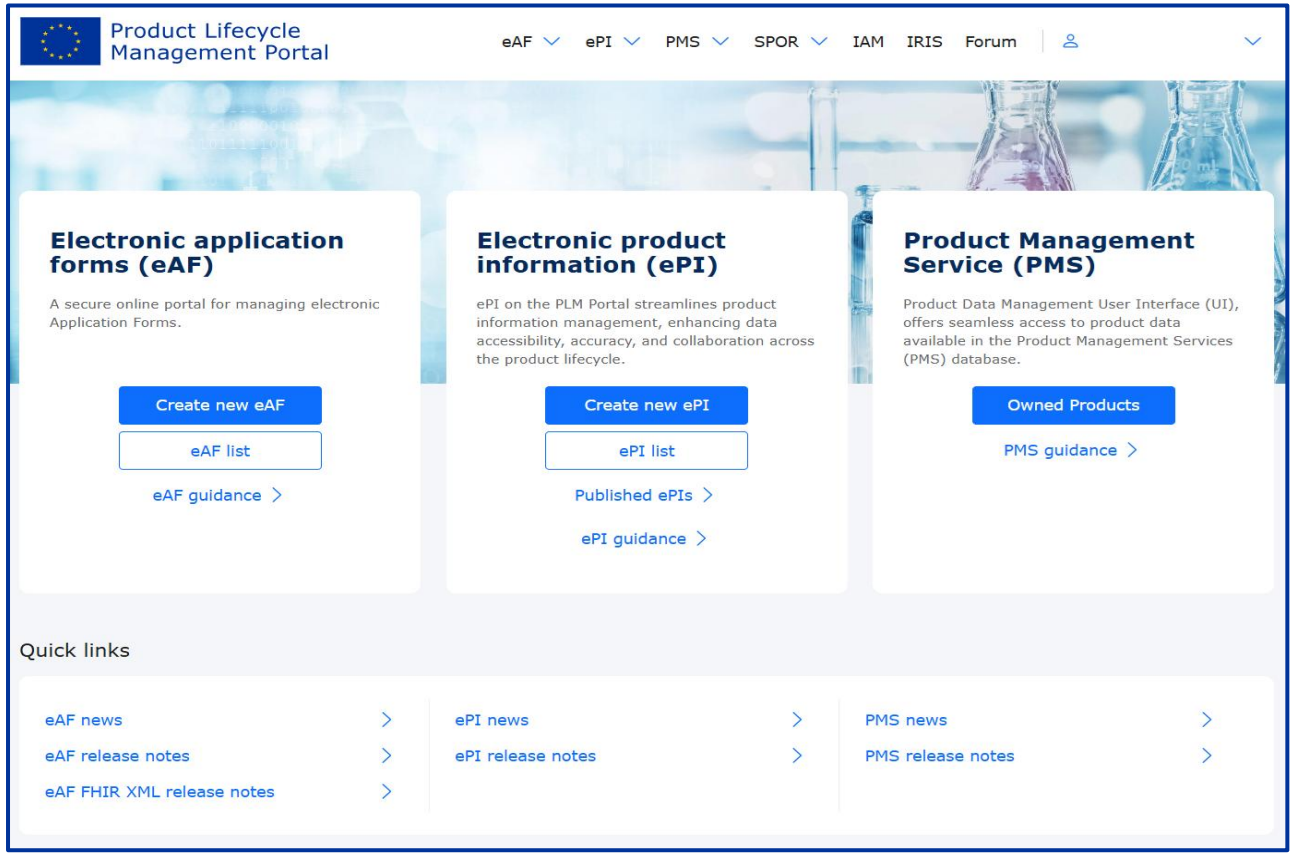
Classified as internal/staff & contractors by the European Medicines Agency

ePI at the Product Lifecycle Management portal

From the same portal, applicants can manage ePI, electronic application forms and product data.

ePI features:

- ePI authoring & management
- Rich-text editing
- ePI export to FHIR/Word
- Repository & API



Classified as internal/staff & contractors by the European Medicines Agency

ePI pilot outcomes

All 23 companies and 5 regulators **successfully created and published** ePI in real regulatory procedures with no blocks

KPIs on ePI creation, management and portal usability met

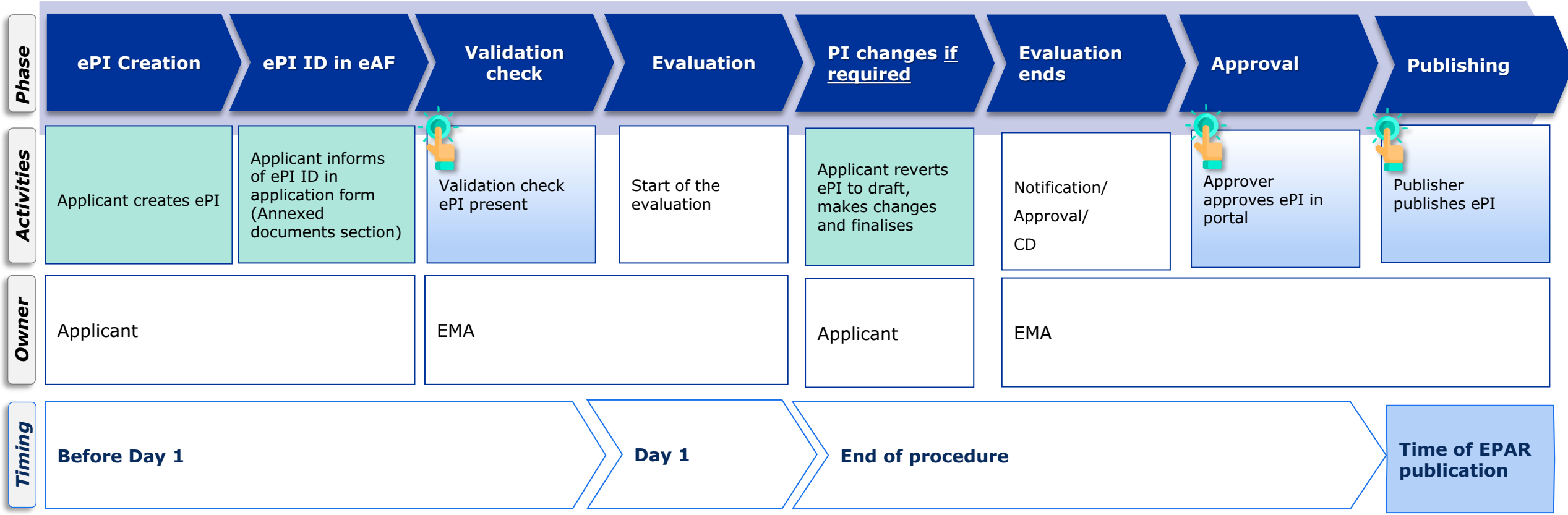
Recommendations made in categories:
Guidelines, Business Process and PLM Portal

Plan to go live for EMA CAPs first, then early adopter NCAs

EMA

Classified as internal/staff & contractors by the European Medicines Agency

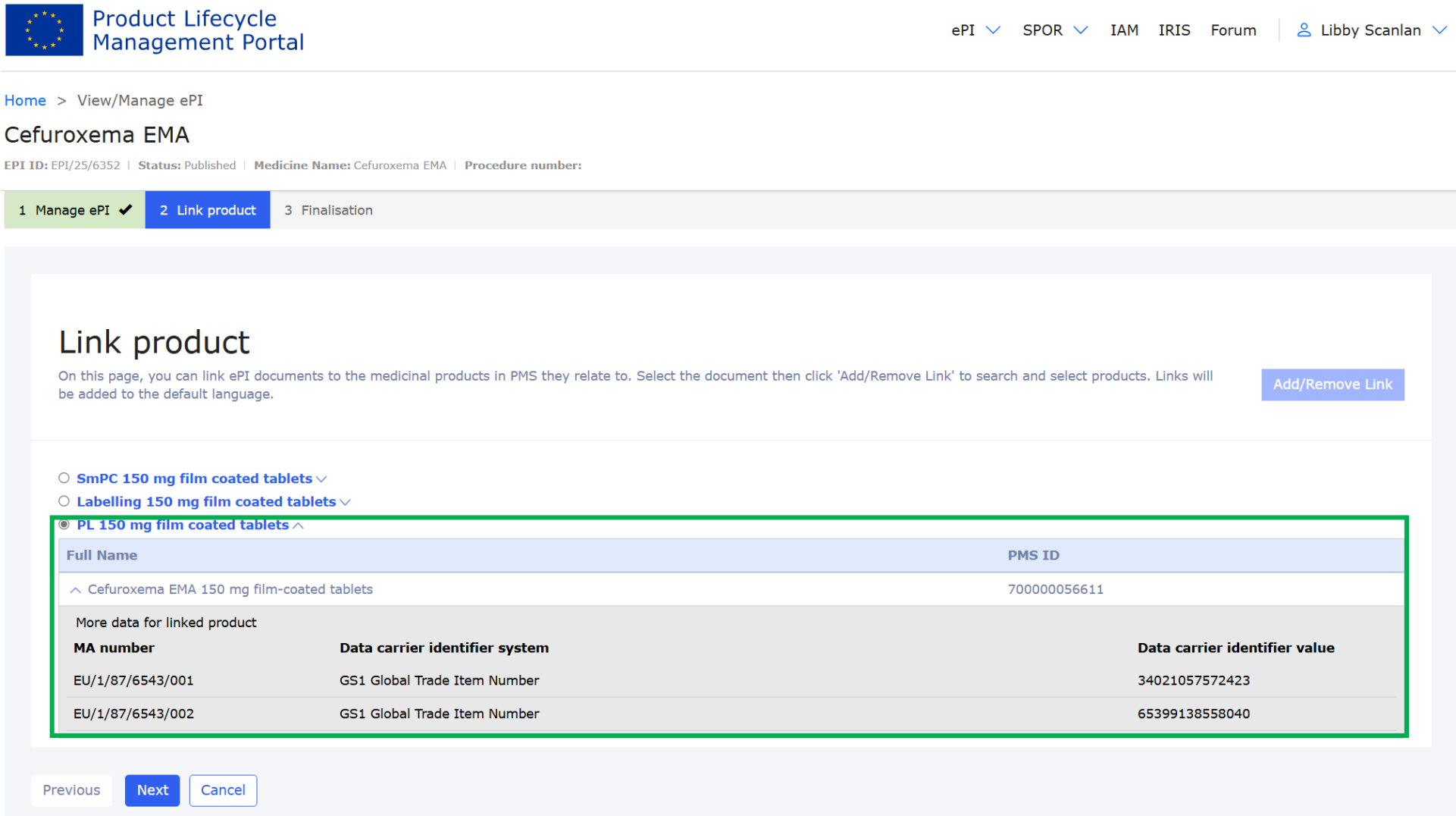
Business process for initial MAA, Art 61.3, IA, IB



- eCTD Pdf and Word PI submitted business as usual
- Future digitalisation of entire workflow

Classified as internal/staff & contractors by the European Medicines Agency

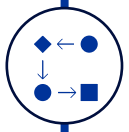
Linking ePI to PMS structured product data at PLM portal



Classified as internal/staff & contractors by the European Medicines Agency

Pre-implementation work

Ongoing epic



Developing and adapting **business process**

Guidance development

Stabilisation and **performance** optimisation

User Acceptance Testing

Additional **PLM Portal development**

IRIS-eAF integration

Classified as internal/staff & contractors by the European Medicines Agency

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

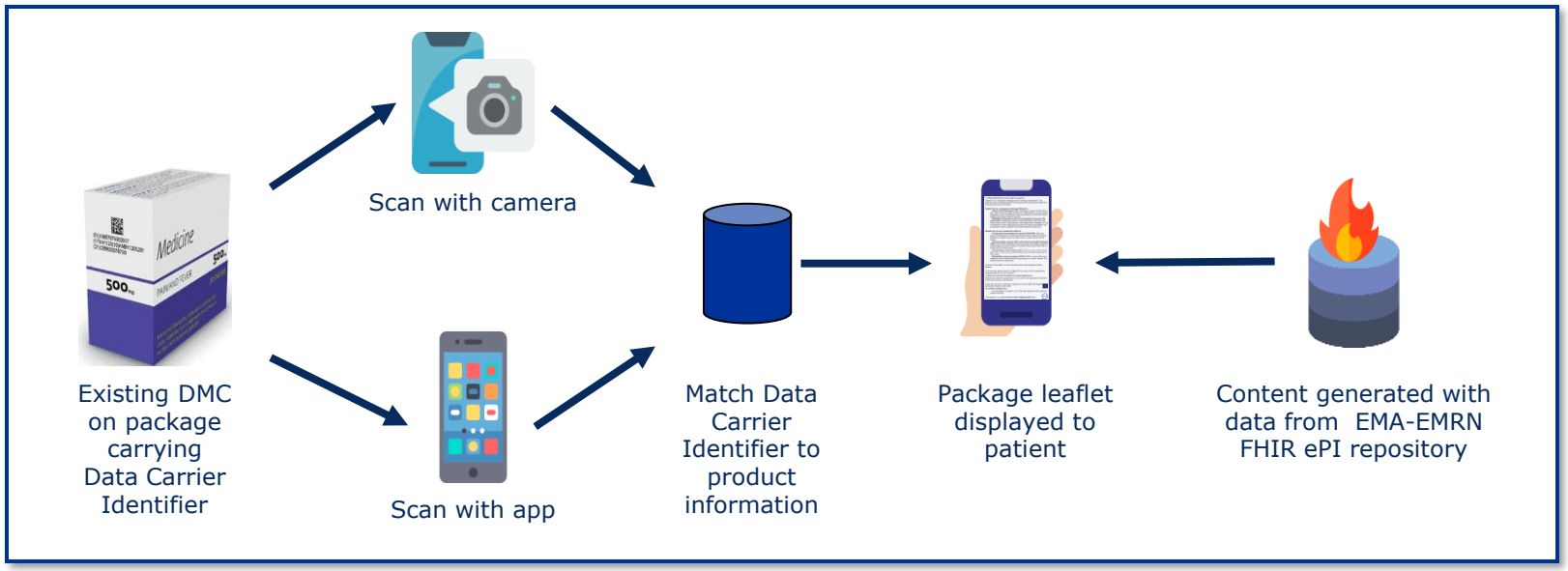
Thank you

ePI@ema.europa.eu

Follow us

Classified as internal/staff & contractors by the European Medicines Agency

Digital format easily accessible to all patients



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 31 March 2025
2 EMA/95076/2025
3 European Medicines Agency

4 **Reflection paper on linking to electronic product information (ePI) from EU medicine packages**
5
6 Draft

Start of public consultation	31 March 2025
End of consultation (deadline for comments)	30 June 2025

7

Comments should be provided using this EUSurvey form. For any technical issues with the form, please contact the EUSurvey Support.

8

Keywords	Electronic product information, ePI, summary of product characteristics, package leaflet, DataMatrix, data carrier identifier, patients, healthcare professionals

- **Data matrix code** (already on the box and used for anti-falsification) preferred to adding **additional QR code**
- **EU wide solution** to access ePI requiring **cross-industry collaboration**

Classified as internal/staff & contractors by the European Medicines Agency