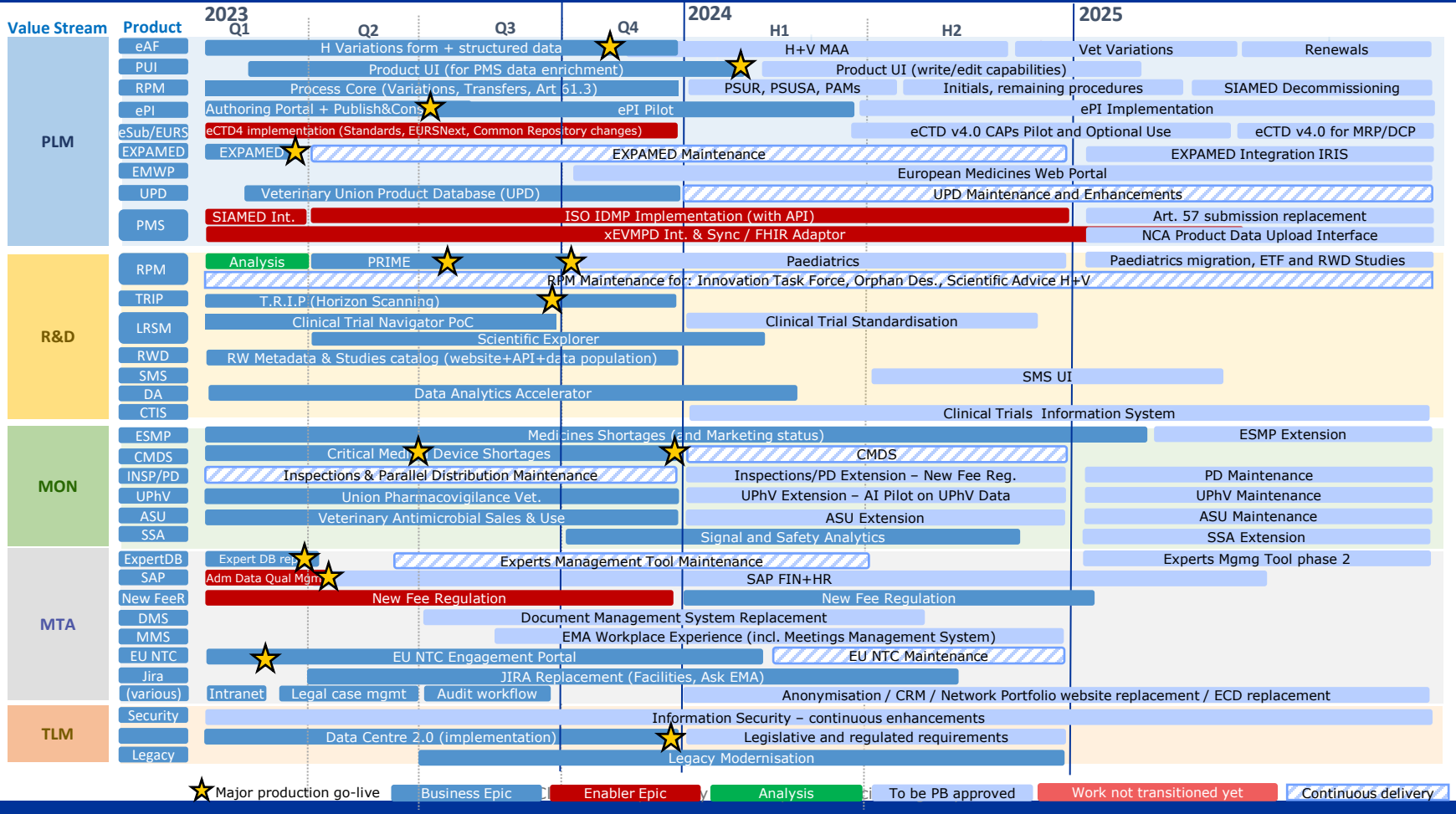
Portfolio Roadmap 2023-2025

Updated 5 September 2023

2023 and beyond: Network portfolio roadmap

EUROPEAN MEDICINES AGENCY



Glossary

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Acronym	Name
API	Application Programming Interface
ACT EU	Accelerating Clinical Trials in the EU
Art. 57	Article 57 of Regulation (EU) 726/2004, which requires marketing authorisation holders to electronically submit to the Agency information on all medicinal products for human use authorised in the EU
ASU	Antimicrobials Sales and Use (veterinary products)
AWS	Amazon Web Services
Business Epic	Business epics are large initiatives that deliver Solutions needed by the business/customers
CAP	Centrally Authorised Product
CMDS	Critical Medical Devices Shortages
CTIS	Clinical Trials Information System
DA	Data Analytics
DADI	Digital Application Dataset Integration
DARWIN	Data Analysis and Real-World Interrogation Network (DARWIN EU)
DC 2.0	Data Centre 2.0 (cloud-based data centre)
DCP	De-centralised Procedure
DIGIT	DG DIGIT, European Commission Directorate General for Informatics
DREAM	Documents and Records Management System used at EMA

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Acronym	Name
eAF	Electronic Application Form
eCTD	Common Technical Document in electronic format
ePI	Electronic Product Information
EMRN	European Medicines Regulatory Network
EMWP	European Medicines Web Portal
Enabler Epic	Enabler epics are pieces of work that extend the architectural infrastructure of the solution under development or improve the performance of the value stream
Epic	An epic is a container with one common objective, for a development initiative large enough to require analysis, definition of a minimal viable product (MVP) and financial approval before implementation. An epic usually takes more than one Programme Increment to complete and is broken into multiple Features.
ESMP	European Medicines Shortages Monitoring Platform
ESMDP	European Medicinal Devices Shortages Monitoring Platform
ETF	Emergency Task Force
EURS	European Review System for eCTDs
EU NTC	EU Network Training Centre
EU-SRS	European Substance Reference System
EVVet3	Eudra Vigilance Veterinary version 3 *(see UPhV)*
EXPAMED	Expert Panels on Medical Devices and In Vitro Diagnostic Devices

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Acronym	Name
FHIR	Fast Healthcare Interoperability Resources
IDMP	The ISO IDMP standards specify the use of standardised definitions for the identification and description of medicinal products for human use
HERA	Emergency Preparedness and Response Authority
HMA	Heads of Medicines Agencies
IAM	Identity and Access Management
IRIS	A secure online platform for handling product-related scientific and regulatory procedures with EMA (iris.ema.europa.eu)
iSPOC	Industry Single Point of Contact
ITF	Innovation Task Force
Jira	Service desk ticketing system used at EMA
LRSM	(Data) Lifecycle Regulatory Submissions Metadata
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MD	Medical Devices
MON VS	Monitoring Value Stream
MRP	Mutual Recognition Procedure
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
MTA VS	Managing the Agency Value Stream
MVP	Minimal Viable Product

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Acronym	Name
NAP	Nationally Authorised Product
NCA	National Competent Authority
NICTAC	Network ICT Advisory Committee represents the network IT community
NPAG	Network Portfolio Advisory Group represents the Management Board and HMAs
NTC	Network Training Centre
P3i	Waterfall project management methodology, used at EMA prior to SAFe Agile
PAM	Post-authorisation Measure
PB	Portfolio Board
PD	Parallel Distribution
PHE / ME	Public Health Emergency / Major Events
PI	Programme Increment, a three-month period of work
PI Planning ceremony	A quarterly event to plan work for the entire Value Stream in the next quarter, ensuring that teams and stakeholders have a shared mission and vision
PLM VS	Product Lifecycle Management Value Stream
PMS	Product (Data) Management Service
PPMT	Public Procurement Management Tool
PRIME	PRIority MEdicines
PO	Product Owner (PO) is the Agile team member primarily responsible for maximizing the value delivered by the team by ensuring that the team backlog is aligned with customer and stakeholder needs.
PSUSA	PSUR single assessment procedure
PSUR	Periodic Safety Update Report

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Acronym	Name
R&D VS	Research & Development Value Stream
RPM	Regulatory Procedure Management
RW Metadata	Real-World Metadata
SA	Scientific Advice
SAM	Serverless Application Model
SAFe	Scaled Agile Framework
SIAMED	An Information System for the management of regulatory procedure for centrally authorised products
SOC	Security Operations Centre
SPOR	Substance, Product, Organisation and Referential
SSA	Signal and Safety Analytics
T.R.I.P.	The acronym stands for: Identify Topics from screening relevant external and internal data sources, express Relationships between topics, associate them with relevant Information, and accumulate Perspectives from subject matter experts
TLM VS	Technology Lifecycle Management & Information Security Value Stream
UPD	Union Product Database (for veterinary products)
UPhV	Union Pharmacovigilance Database (for veterinary products, formerly known as EVVet3)
Value Stream	Value Streams represent the series of steps that an organization uses to implement Solutions that provide a continuous flow of value to the Business/Customer
VSM	EMA Value Stream Manager (VSM) is a “Servant Leader and Coach” for the Value Stream teams
VSO	EMA Value Stream Owner (VSO) has the primary responsibility for the business outcomes, including the delivery of business outcomes, in their Value Stream
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary