Direktoratet for
medisinske produkter

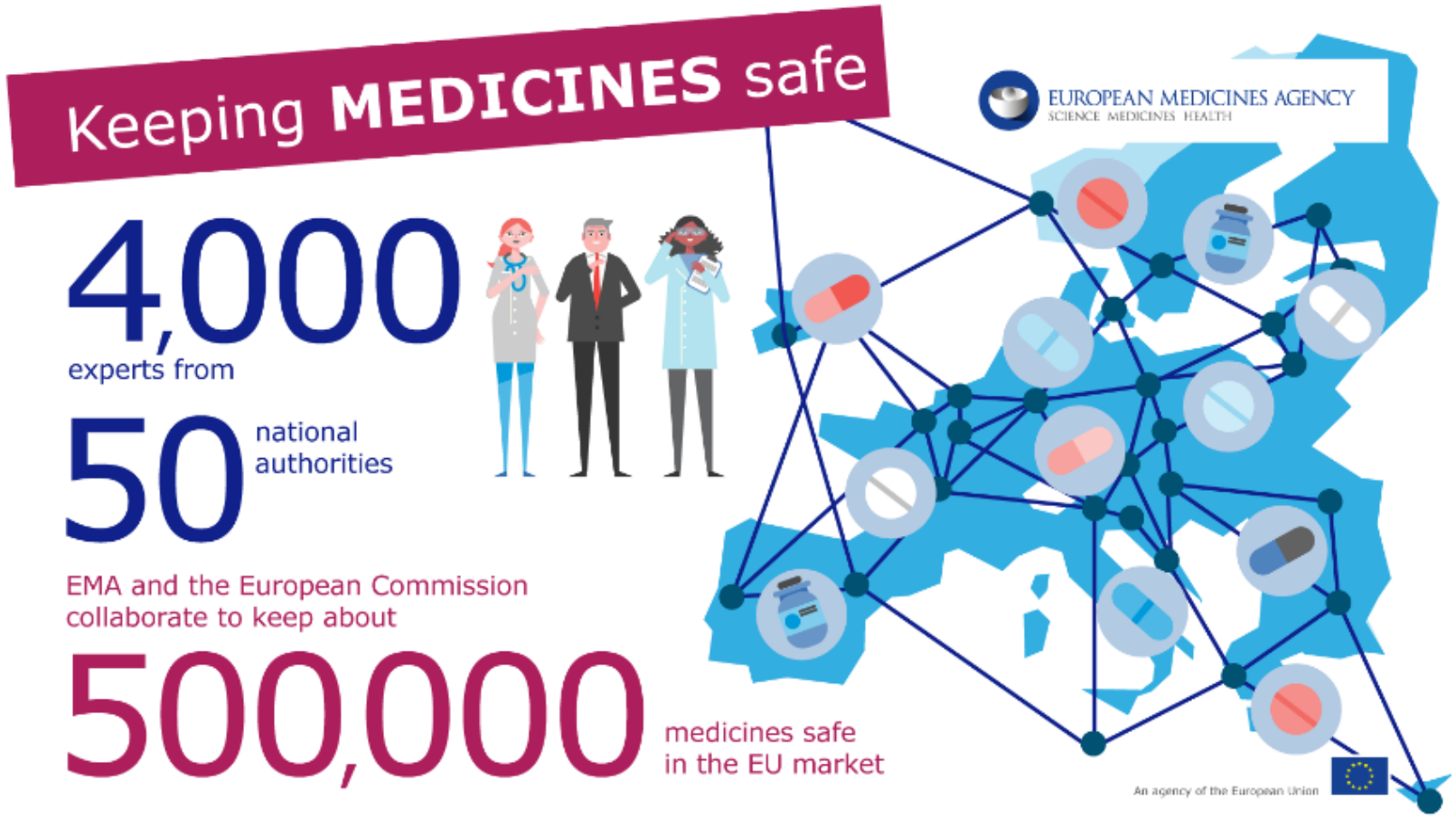
ISO IDMP og SPOR

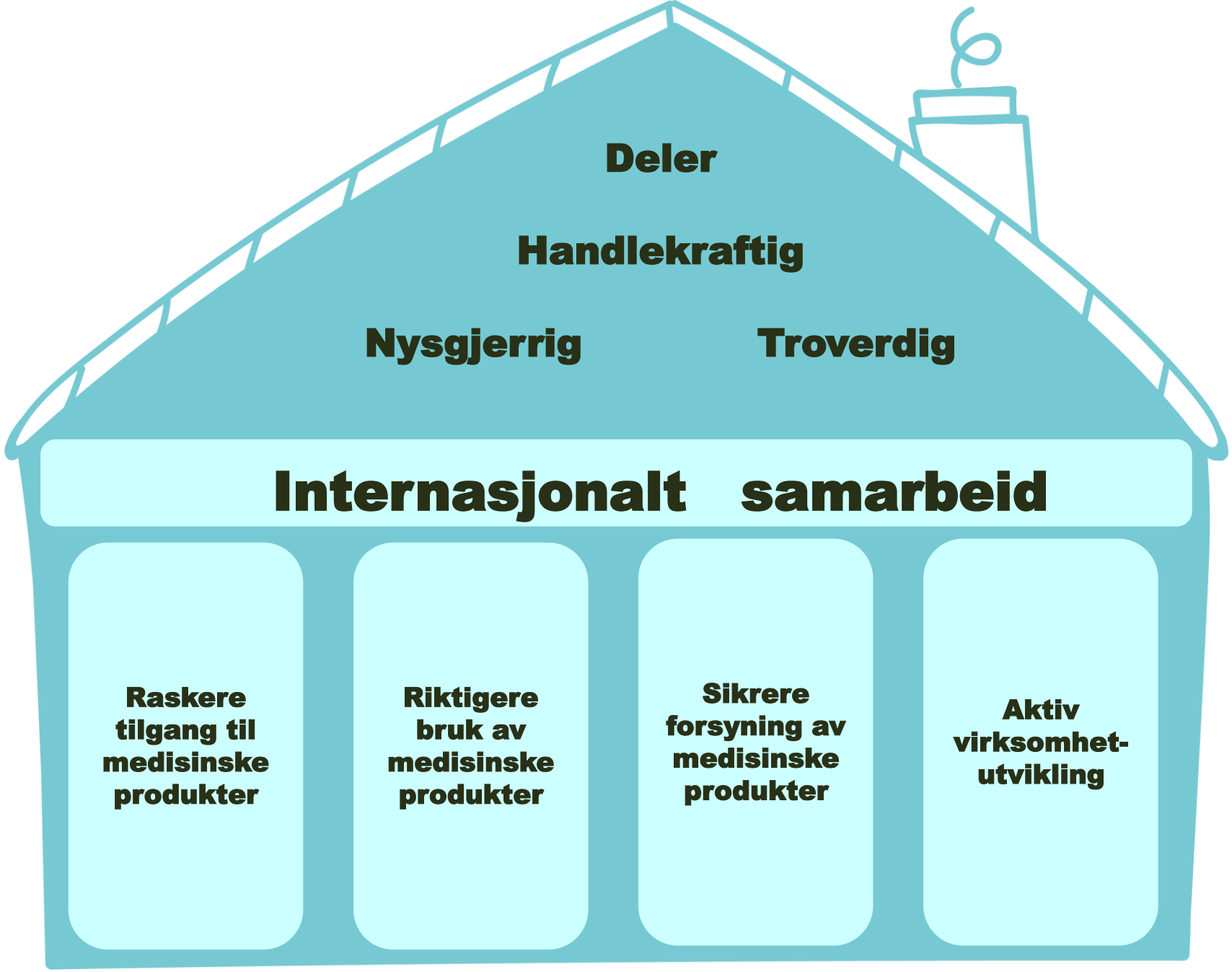
- en forutsetning for internasjonalt samarbeid

Regulatorisk industrimøte 06.02.2024

Kristine Aasen
Virksomhetsarkitekt, DMP

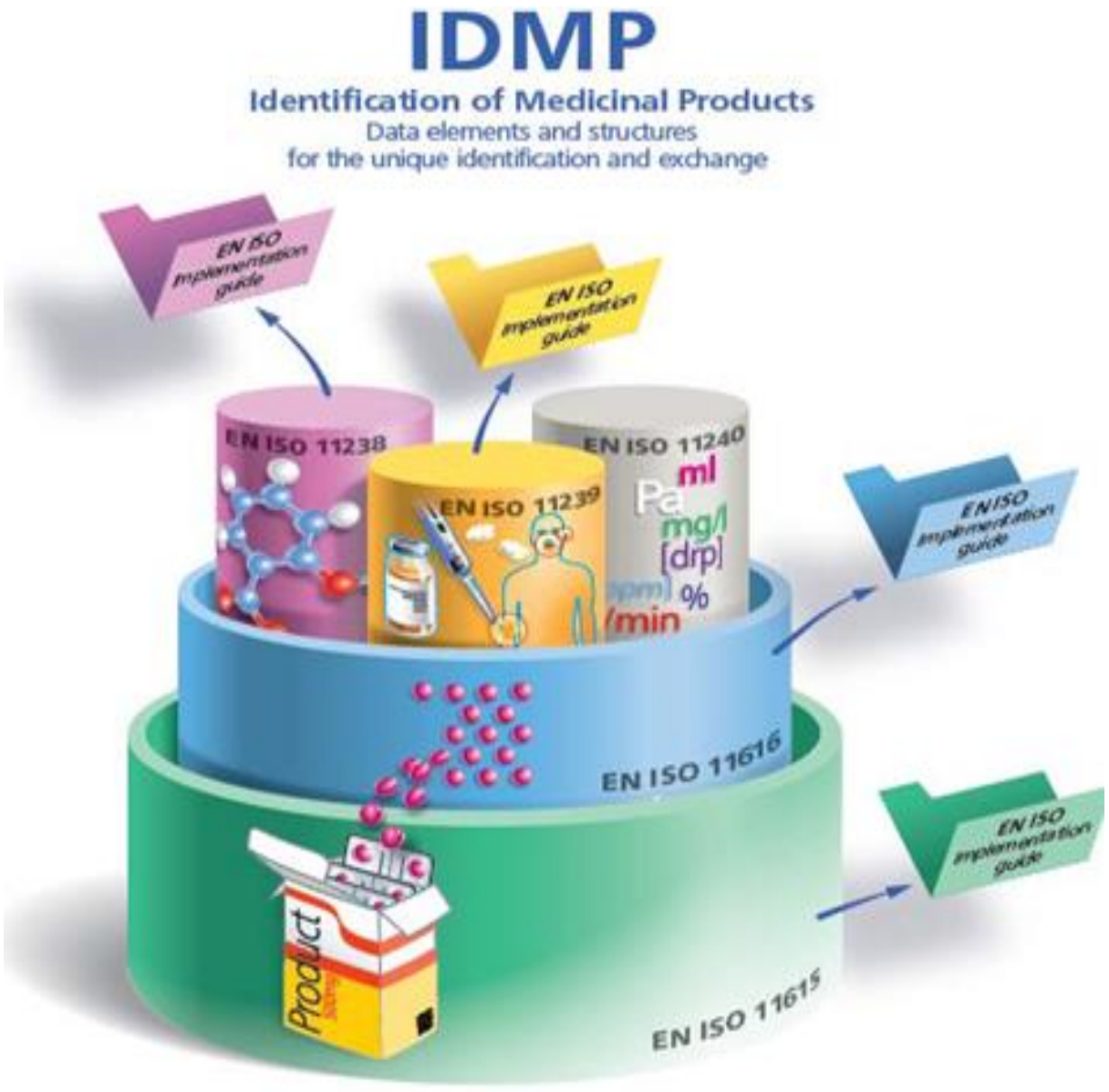
Det europeiske regulatoriske nettverket




Deler
Handlekraftig
Nysgjerrig
Troverdig
Internasjonalt samarbeid
Raskere tilgang til medisinske produkter
Riktigere bruk av medisinske produkter
Sikrere forsyning av medisinske produkter
Aktiv virksomhet-utvikling

UNICOM

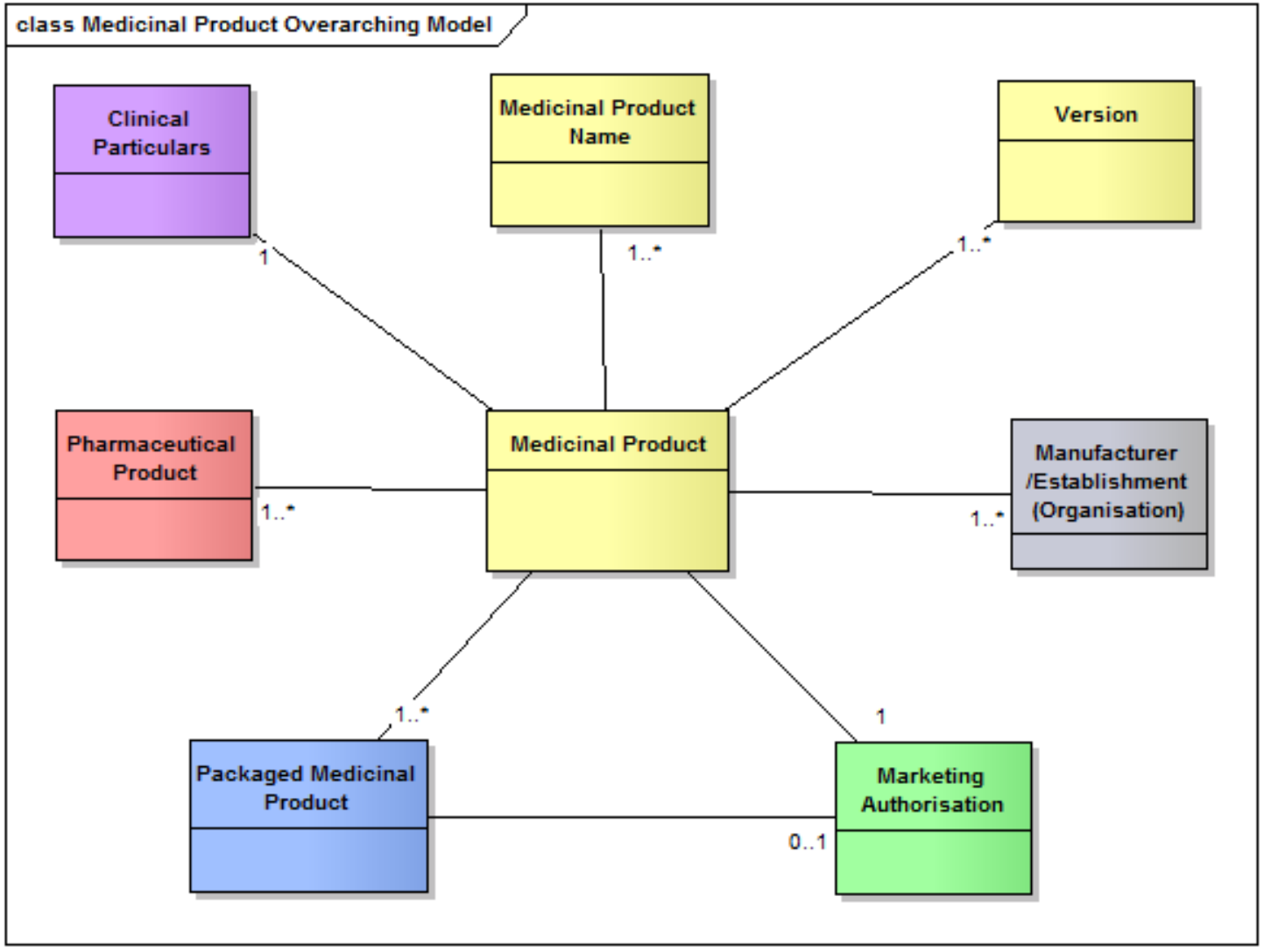
Up-scaling the global univocal identification of medicines



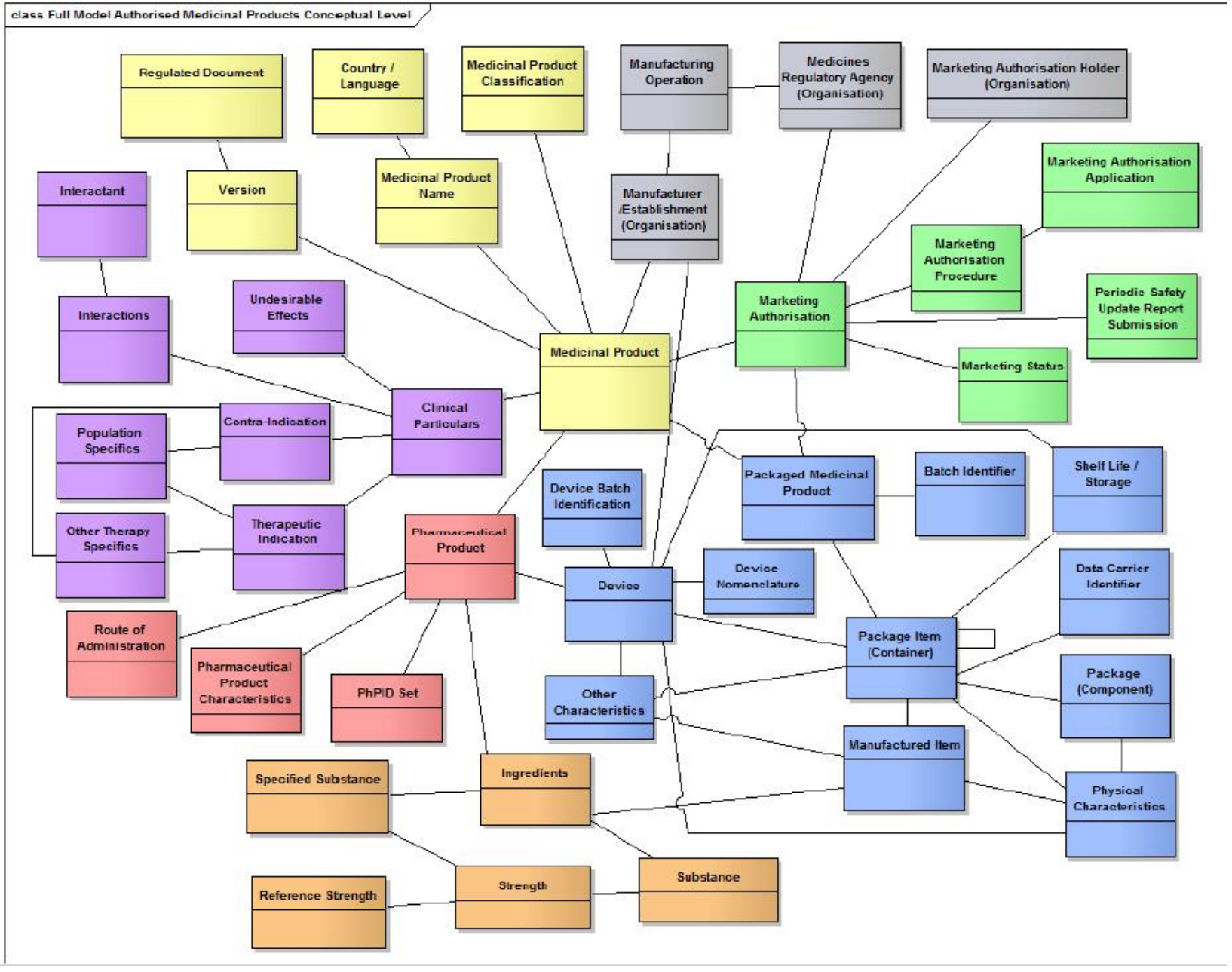
UNICOM Supports IDMP Use cases across the medicinal product lifecycle

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299

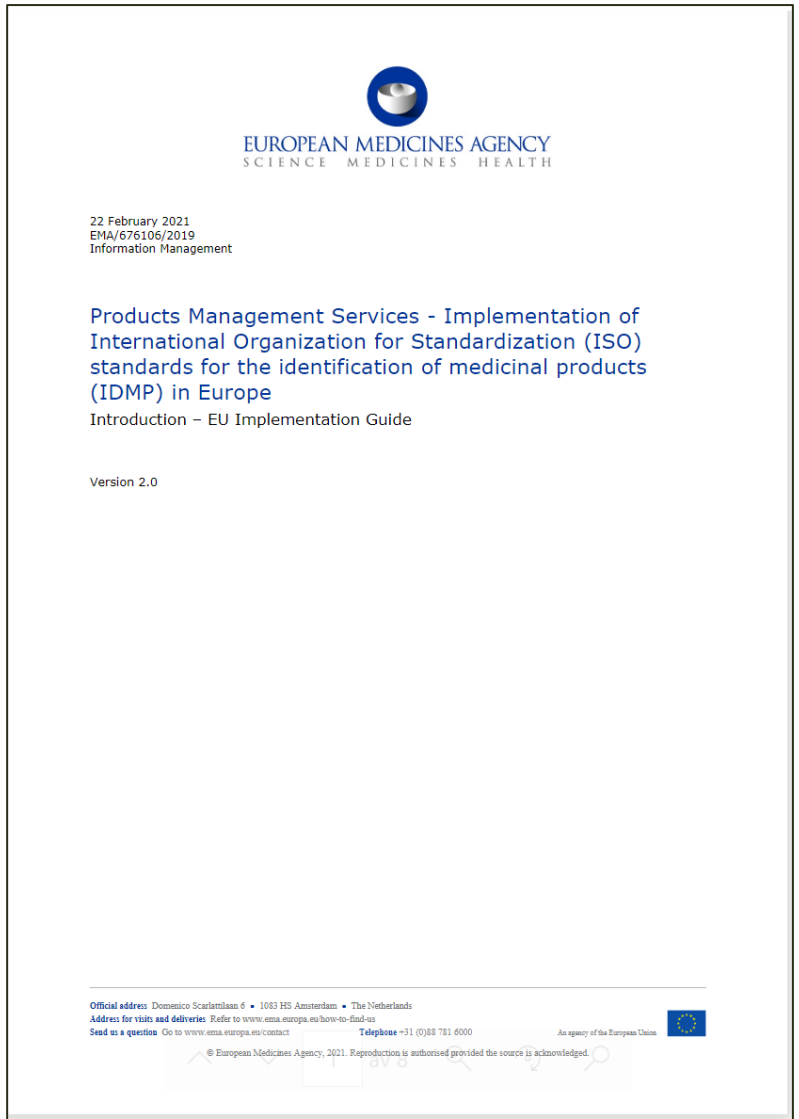
ISO IDMPs klassemodell



ISO IDMPs datamodell



EU implementeringsveiledere



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

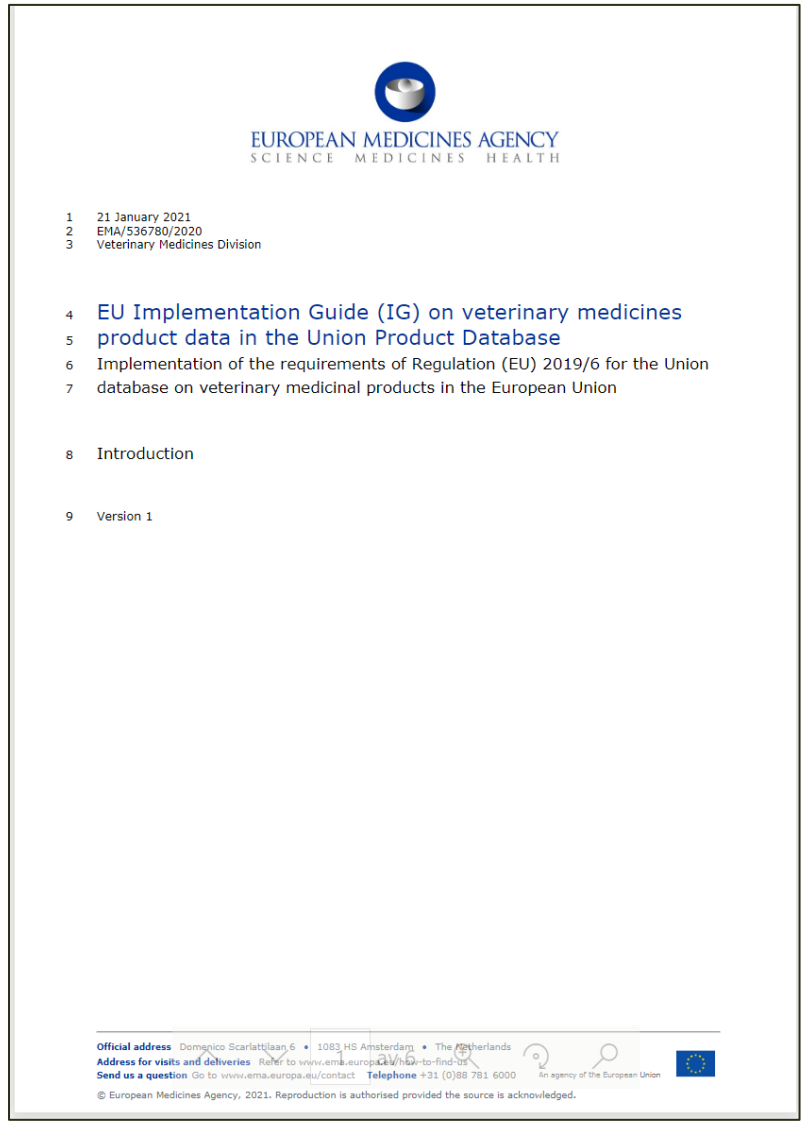
22 February 2021
EMA/676106/2019
Information Management

Products Management Services - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe

Introduction – EU Implementation Guide

Version 2.0

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 21 January 2021
2 EMA/536780/2020
3 Veterinary Medicines Division

4 EU Implementation Guide (IG) on veterinary medicines 5 product data in the Union Product Database

6 Implementation of the requirements of Regulation (EU) 2019/6 for the Union
7 database on veterinary medicinal products in the European Union

8 Introduction

9 Version 1

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EU implementeringsveilederen datakatalog

2.10.5.2. Regulatory application type

Tag	Description
User Guidance	The type of regulatory application shall be described using a term ID. • The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. • In case of grouping of variations, the application submission type with the highest ranking of variation shall be selected. This value is an attribute within the Regulatory application procedure Identifier/Number.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000155688
Value(s)	As listed in the Application Submission Type RMS list
ISO Element Name	Application Type
ISO Path	/MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationProcedure/MarketingAuthorisationApplication/ApplicationType
FHIR Element Name	Type
FHIR Path	RegulatedAuthorization.case.application.type

Fast Healthcare Interoperability Resources

FHIR

- Er en standard for utveksling av data i helsesektoren
- Beskriver dataformater og dataelementer (ressurser)
- Er et API (Application Programming Interface) for utveksling av data

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SPOR

Login

Substances | Products | Organisations | Referentials | Help

SPOR data management services

Delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities.

The four SPOR data management services are:

- Substance Management Services (SMS)
- Product Management Services (PMS)
- Organisation Management Services (OMS)
- Referentials Management Services (RMS)

OMS and RMS are the first services to go live and they provide the data foundations for PMS and SMS.

SMS and PMS are not currently activated. More information on the implementation of SPOR data management services is available on the EMA corporate website.

The SPOR portal provides users with the following data management services:

- view, search, export SPOR data;
- request new and updated SPOR data;
- translate SPOR data;
- browse relevant SPOR documentation.

Data management and data quality processes drive the SPOR data management services to ensure that the highest quality of data is available to support EU regulatory processes.

Access to SPOR

Use the links in the navigation panel above to access OMS and RMS.

Please use the menus in the navigation panel to navigate RMS and OMS with 'read-only' access to SPOR.

You will need an EMA account with SPOR user roles to conduct additional tasks, such as requesting changes to data, translating data or managing user preferences.

If you already have an active account for any EMA-hosted website or online application, you should use the same credentials to log in.

If you do not already have an EMA account, you need to create an EMA account and request the specific SPOR user roles you require.

Please check if you are able to log in before registering as a new user with SPOR.

Create EMA Account

Registered users can log in using the button at the top of the page.

Using SPOR

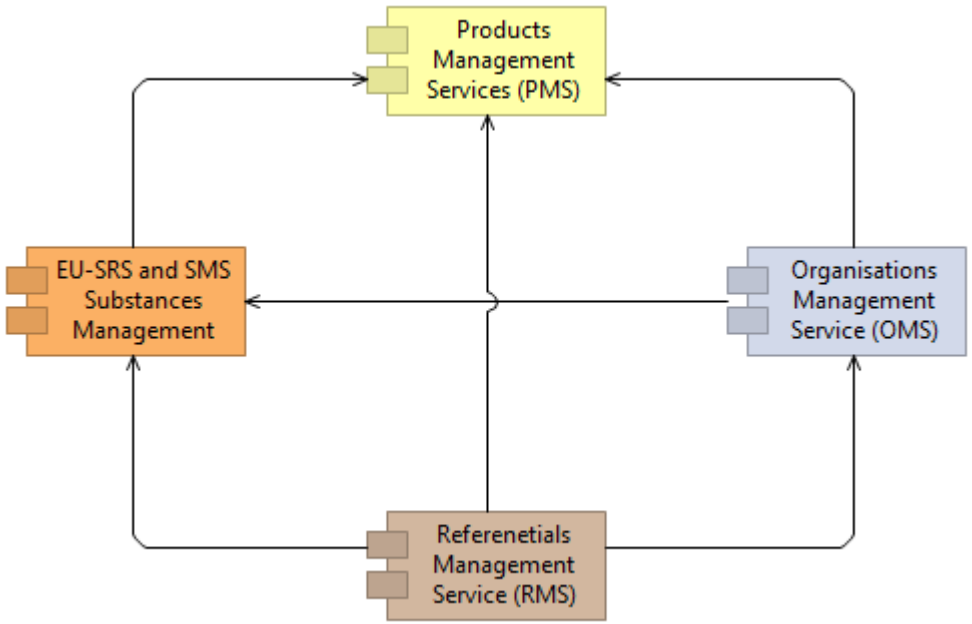
For more information about using SPOR see "About SPOR data management services". This document provides details on:

- SPOR projects;
- access policy and user roles;
- customer support;
- data content;
- copyright;
- data protection.

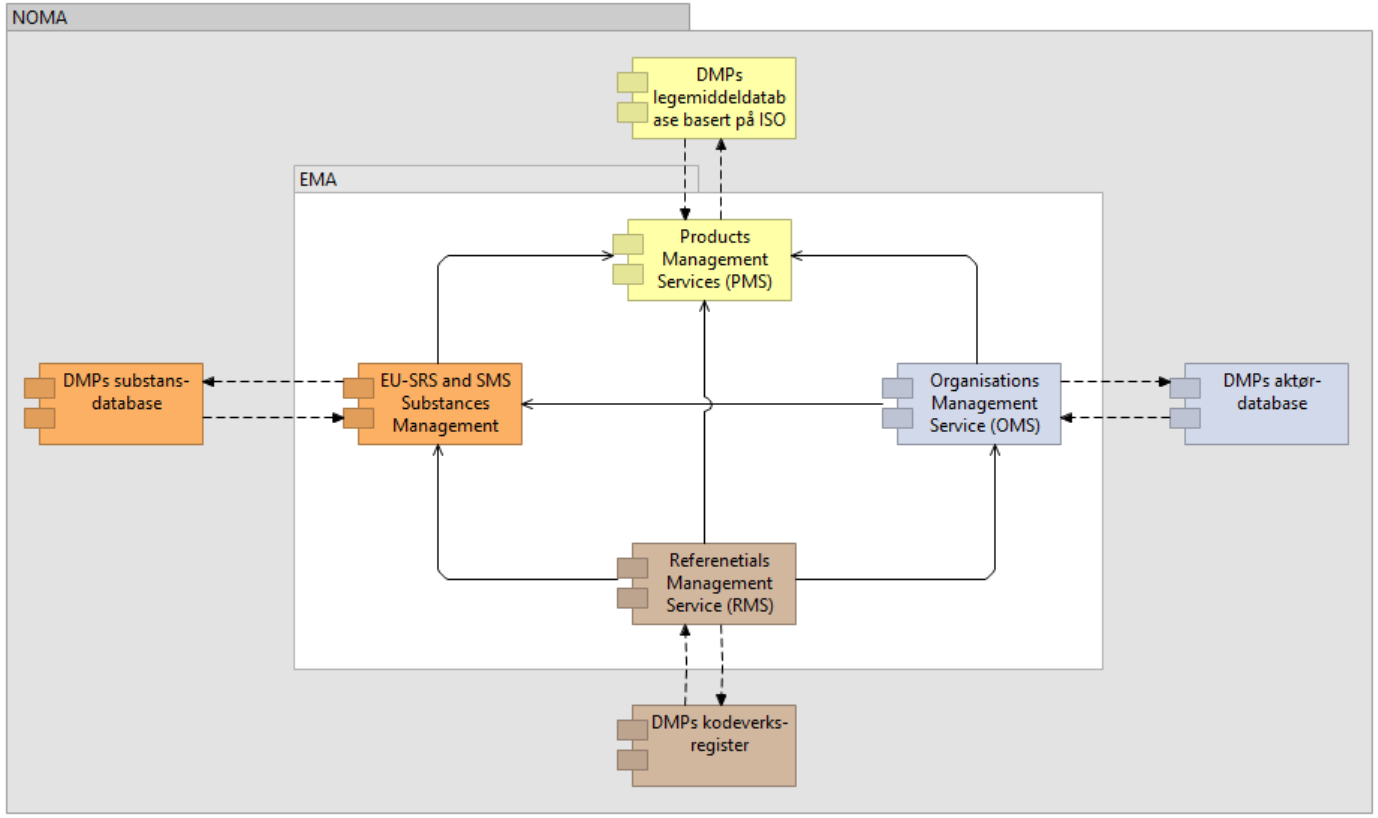
Related information

For further information about EMA's implementation of SPOR and the ISO IDMP standards, please see the EMA corporate website. This also includes key

SPOR-prosjektet implementerer ISO IDMP i EMA



DMPs mål er å integrere mot EMAs SPOR-databaser



Welcome to PLM Portal

A secure online portal for managing electronic Application Forms, electronic Product Information (ePI) and authorised product data (PMS) in the European Union, in collaboration with the European Medicines Regulatory Network.

Sign In >

Quick links

Public Register & List

Access further information

Guidance & Support

Reference additional material to support your work

News

Stay up-to-date with the latest news and information related to the PLM Portal.

Application Forms Avaliable

Marketing Authorisation Applications

Apply for Initial Marketing Authorisation or an extension of a Marketing Authorisation

- Human MAA CAP >
- Human MAA NAP >

Variations

Apply for a variation

- Human Variation CAP >
- Human Variation NAP >

Renewals

Apply for renewal of Marketing Authorisation

- Human Renewal CAP >
- Human Renewal NAP >

PMS Art. 57 Submission

Portal to provide an update of the product data in accordance with the Art. 57 requirement

- Data Submission Art.57 >

Product Lifecycle Management – Connecting the Value Stream

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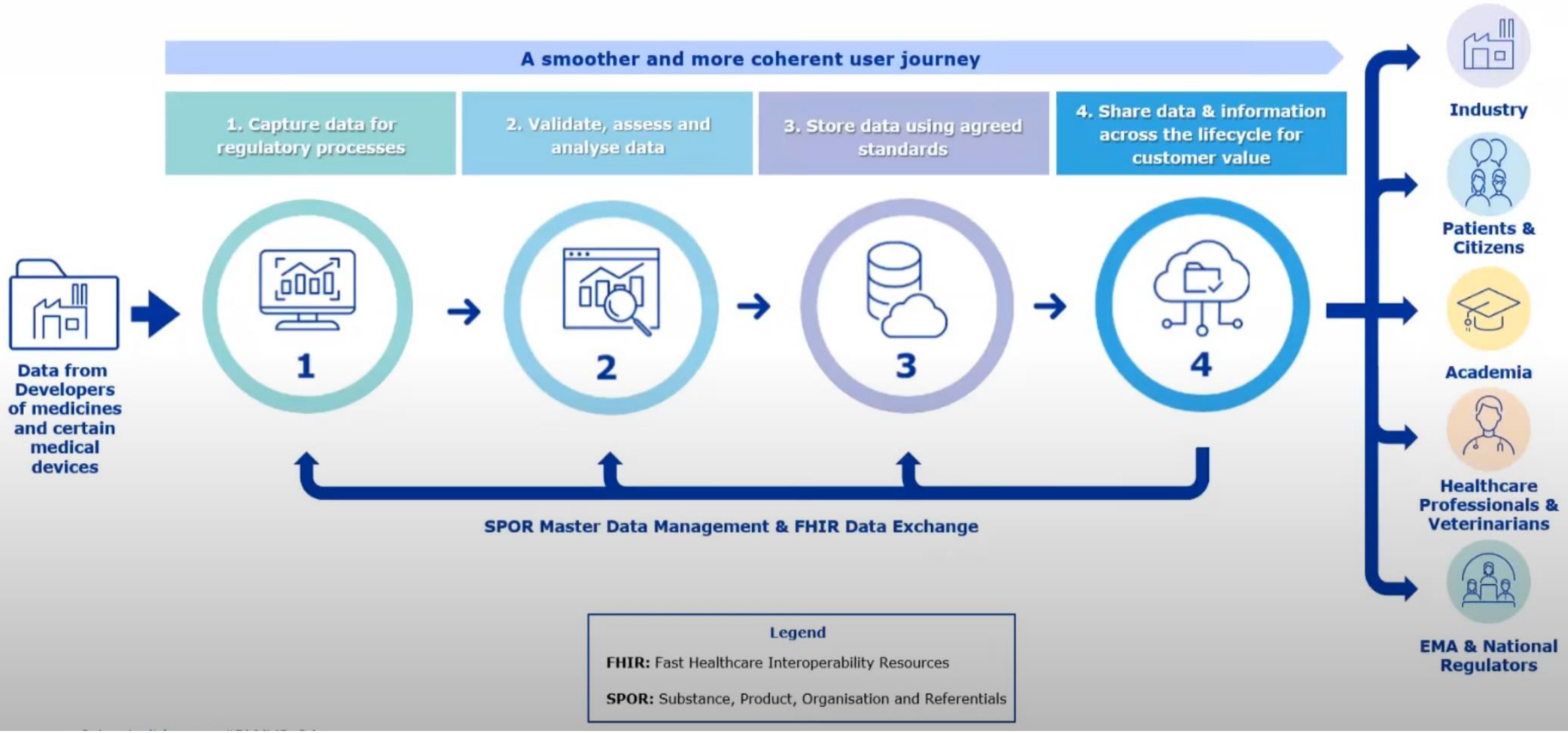

Overview of Product Lifecycle Management activities

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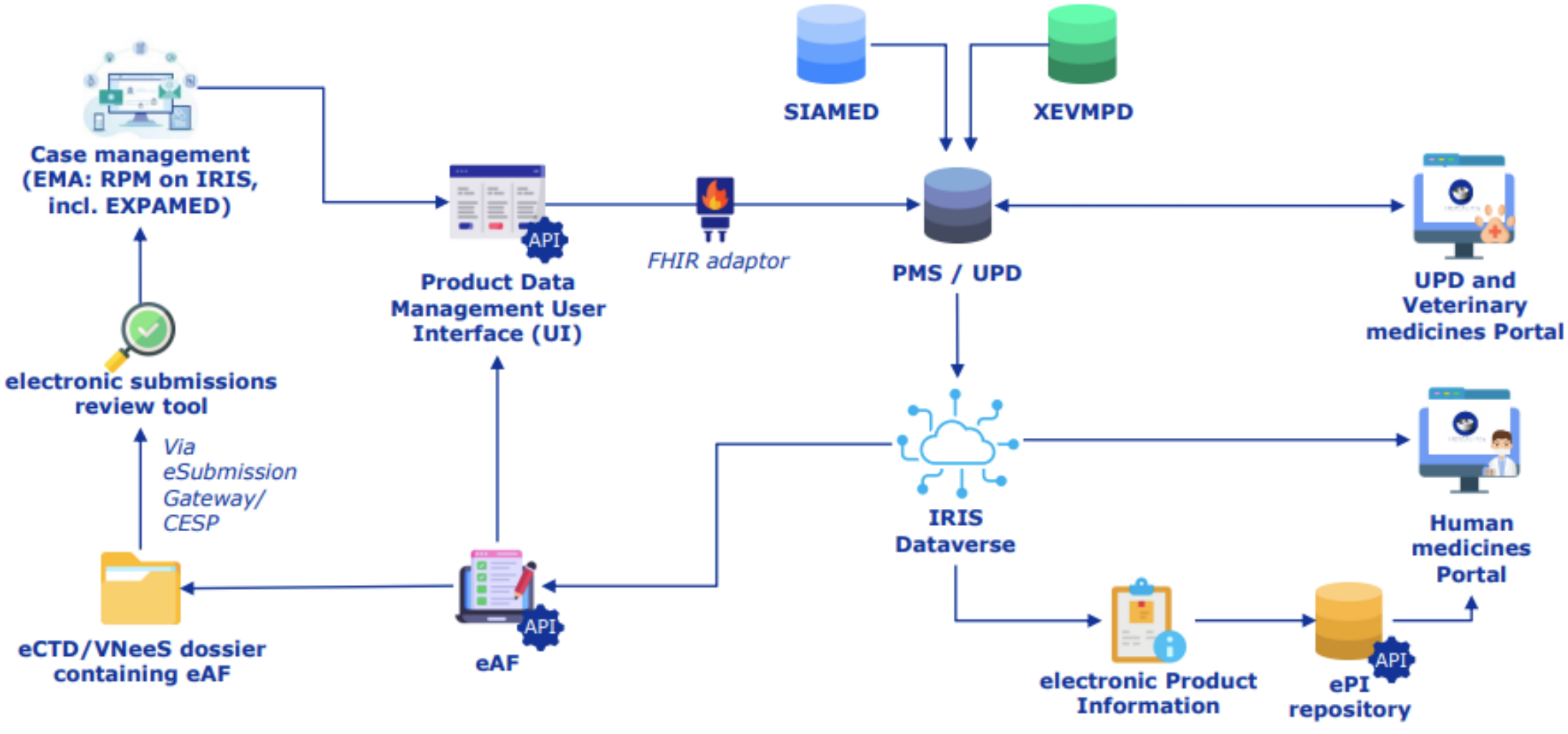

Sequencing of epics

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Human Variations eAF (CAPs)

Work completed

Human Variations eAF (CAPs + NAPs)

Ongoing work

Human MAA eAFs

Vet MAA eAFs

eAF API

Future work *(What's next?)*

Renewals eAF

Vet Variations eAF

Future work *(What's later?)*

Acronyms

API: Application Programming Interface

CAPs: Centrally Authorised Products

NAPs: Nationally Authorised Products

MAA: Marketing Authorisation Applications

IMPORTANT: this slide **DOES NOT represent timelines or sequencing of release** but pieces of work or events to be delivered and the impact on users.

Referanser

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https://lovdata.no/forskrift/2009-12-18-1839/§10-12 https://unicom-project.eu/wp-content/uploads/2021/10/UNICOM-handboek_A4_04.pdf

https://spor.ema.europa.eu/sporwi/

https://www.hl7.org/fhir/

https://www.ema.europa.eu/en/human-regulatory/overview/data-medicines-iso-idmp-standards-overview

Home · PLM (europa.eu)

Product Lifecycle Management (PLM) Value Stream Deep-Dive Webinar (youtube.com)

dmp.no

helsenorge.no

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