UNICOM

Up-scaling the global univocal identification of medicines

Overview, Objectives, Results @DGRA

Georg Neuwirther

Head of IT AGES Medizinmarktaufsicht,
Strategy Board Member UNICOM, WP 3 Lead

This project has received funding from the European Union's
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Disclaimer

The information provided represents the knowledge and status at the time of its preparation. It does not necessarily represent the view of the regulatory authority to which the presenter belongs. Do not use this information for decision making, but instead always refer to official documents, relevant regulations and regulatory guidelines.

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Medicinal product data contained in many systems

Article 57 (XEVMPD)

European Medicines Verification System (EMVS)

100+ Pharma logistic systems

100+ pharmacy systems

- High effort to build up and maintain information about medicinal products
- Every data system has it‘s own specifications and dialects
- Exchanging data across systems impossible or a massive burden …

1000+ MAH Databases (RIMs)

27+ NCA Databases

27+ Social Insurance System

Health Service Provider Tool (e.g. Medication)

Medicinal product dictionaries

SPOR Product Management Service
European Shortage Monitoring Plattform (ESMP)
Union Product Database*

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Many initiatives are ongoing

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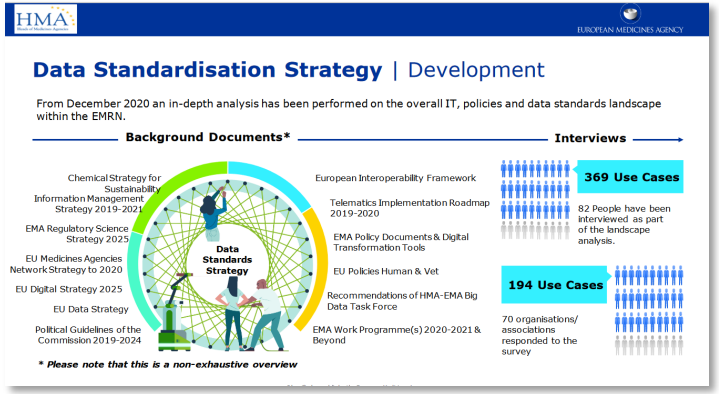
SPOR

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

Link

Link



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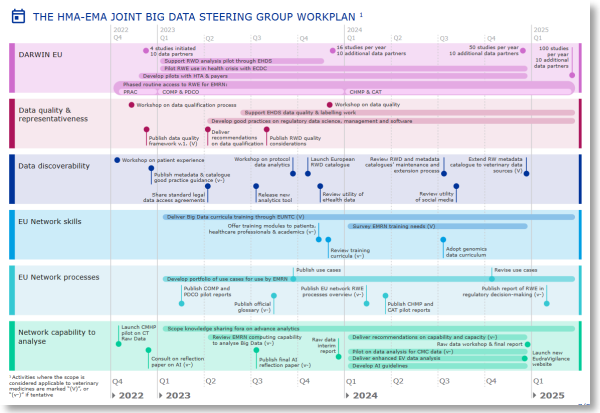
BIG Data



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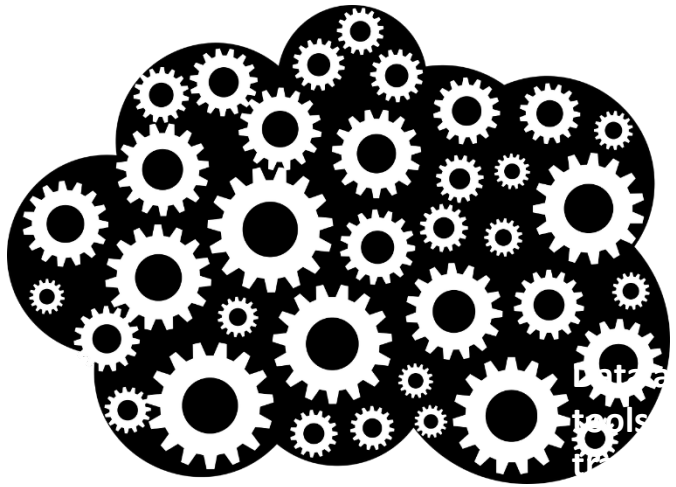

e.g. Raw data pilot CHMP

Link

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First conclusions

We put a lot of effort into data related strategies, business processes and IT systems but still have challenges to make sure that

- Data can easily be exchanged across IT-systems
- Medicinal products and it‘s “composition” can be easily identified
- Medicinal product data can easily be re-used in paper-like representations and eHealth initiatives
  - Patient Summaries, electronic products information, dossiers
- …

In this presentation, we will get an overview of the UNICOM goals that address these topics.

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What is UNICOM?

UNICOM is a project consortium that received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299. Further detail can be found here: https://unicom-project.eu/ or on LinkedIn

" …. This innovation action is expected to support two goals:

*(i) the **cross-border mobility** of European patients by offering safer eDispensations across borders,*

*(ii) the implementation of the **IDMP standards** in Member States drug databases (including a possible linkage to the EU SPOR - Substance, Product, Organisation and Referential master data database) allowing the identification of locally available medicinal products which are equivalent to the one identified in a foreign prescription. …"*

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Vision & Mission

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UNICOM Objectives

By accelerating **the diffusion of ISO IDMP standards**, UNICOM supports

- Regulatory processes of National Medicines Authorities (NMAs) & the European Medicines Agency (EMA)
- Cross-border digital health services (ePrescription, Patient Summary)
- Global pharmacovigilance
- Better healthcare, public health, medical research (e.g. through Big Data Analytics, Artificial Intelligence applications)

As an Innovation Action*, UNICOM is about implementation: Realising a seamless, semantically interoperable Data Value Chain enabling data sharing across the full life cycle of medicines, and across all actors involved in handling such information*

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Consortium Members

Fully committed consortium of 41 members:

- 26 National Drug Agencies and eHealth Authorities
- Standard Development Organisations (SDOs)
- Providers of cross-border ePrescription services
- Clinicians
- Industry, SMEs, research
- Two USA partners
- 18 countries are represented

Formal and informal co-operation with international organisations

- EMA
- WHO Uppsala Monitoring Centre (UMC)
- WHO Collaborating Centre for Drug Statistics Methodology, Oslo
- FDA
- SDOs (MedDRA, EDQM, CDISC, Observational Health Data Science & Informatics group [OHDSI]…)
- Close co-op and integration with EU-wide activities
- eHealth Network (eHN): MSs & EC co-operate on Digital Health policies
- MyHealth@EU eHDSI services (PS, eP): Realisation

Collaboration MoU with IMI Project - Gravitate Health

Duration: Dec. 2019-May 2024 (4,5 years)

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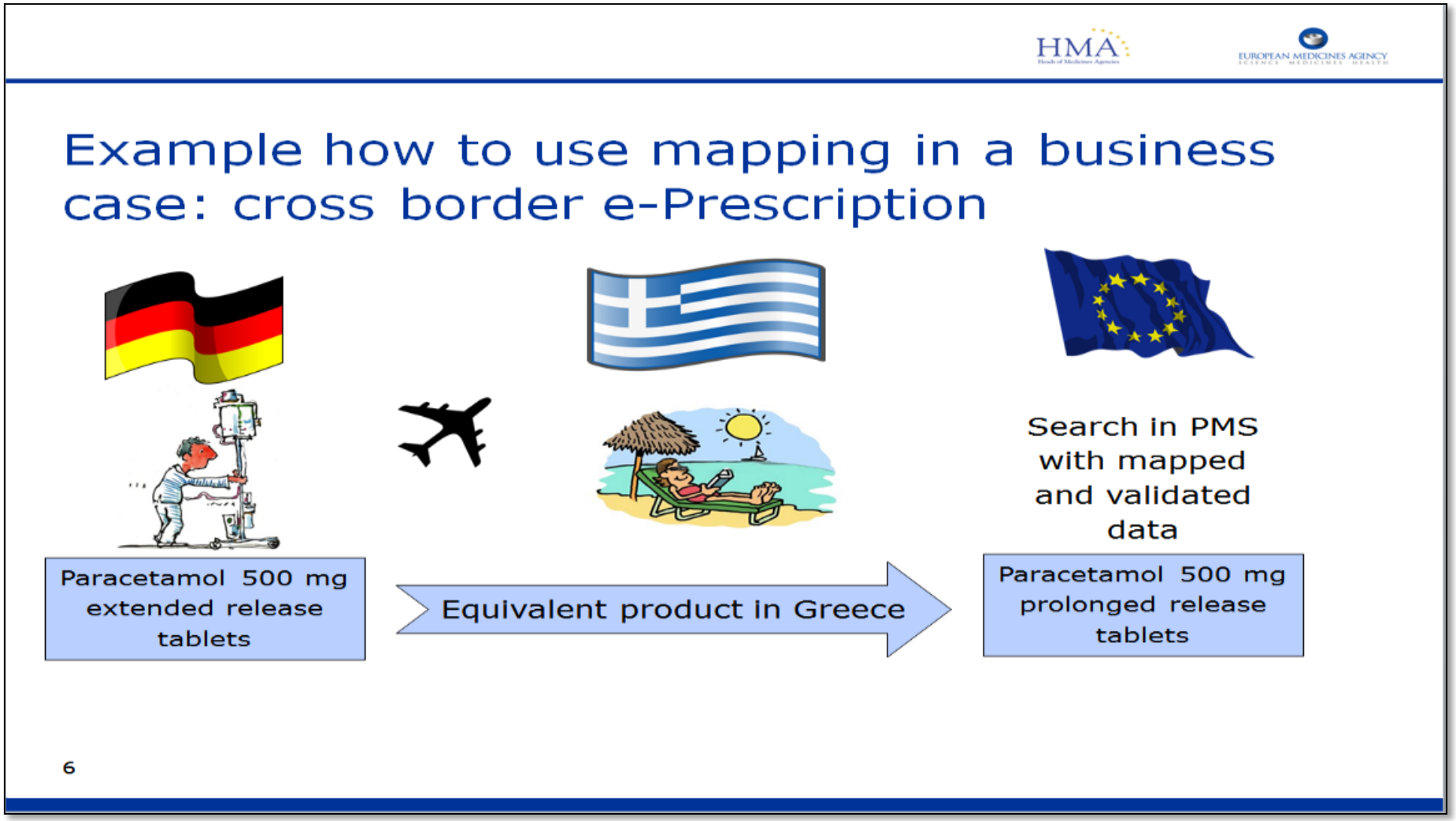
Use-Case eHealth: Cross-Border ePrescription



Source: EMA

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Use Case: Harmonizing data representation

ATC code	Active ingredients in English	Name of the medicinal product	Dose Form	Strength	MAH	Country	MA procedure	EU Procedure Number	
D06AX01	Fusidic acid	**FUCIDIN 20 mg/g kreem**	cream	20mg 1 g			NAP		
D06AX01	Fusidic acid	**FUCIDIN 20 mg/g salv**	ointment	20mg 1 g			NAP		
D06AX01	fusidic acid (anhydrous)	**Fucidin®**	Cream	2 %			NAP		
D06AX01	sodium fusidate	**Fucidin®**	Ointment	2 %			NAP		
D06AX01	SODIUM FUSIDATE	**Fucidin - Salbe**	Ointment				NAP		
D06AX01	Fusidic acid	**Fucidin**	Cream	2 % and 20 mg/g*			NAP		
D06AX01	fusidic acid (anhydrous)	**Fucidine 20 mg/g Salbe**	Cream	20mg 1 g			NAP		

- How does medicinal product data look like in your systems?
- Are you satisfied with data consistency and harmonisation across your company departments? (regulatory, vigilance, manufacturing, ..)

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Improving the situation needs that …

- We speak - at least - we understand the same language
- We align on semantics - “ ..what do we mean with an information element ..”
- We agree on business rules
- We create appropriate business processes and technical tools supporting those

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UNICOM members are implementing new ISO-standards

The **ISO IDMP standards** establish definitions and concepts and describe data elements and their structural relationships.

Source: EMA

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Scope of ISO IDMP

Source: EMA

In scope of ISO IDMP (excerpt*)

- Substances
- Manufactured product
- Packaged Product
- Administered product

List of values

* clinical particulars not showing

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ISO IDMP –set of standards documents

Source: EMA

- **Medicinal product information (MPID/PCID) - ISO 11615**
- **Pharmaceutical product information (PHPID) - ISO 11616**
- **Substances (Substance ID) - ISO 11238**
- **Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239**
- **Units of measurement (UCUM) - ISO 11240**

- **plus EU Implementation Guides organised by EMA**
- **plus** FHIR® that will be the technical background to exchange IDMP compatible data across Europa

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UNICOM Work Packages

- UNICOM partners are working on 12 work packages covering the objectives of this innovation action

- Today we will focus on **three** of the UNICOM workpackages
  - WP2: EU-SRS Substance Management
  - WP3: Fostering the usage of IDMP data in regulatory processes
  - WP4: Implementing new standards at the level pf regulators

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WP 2 - EU SRS - Substance Management in Europe

- **The scientific substance database EU- SRS went live Jan 24th, 2023**
  - Currently used by the Substances Validation Group
  - Maintenance and hosting transferred from BfArM to EMA

Go-live ceremony held at EMA on January 24, 2023

- **The HMA Substances Validation Group is live**
  - Continuing to enrich records in EU-SRS
  - "Guardians of substance data quality"
  - Collaboration with SMS team on sustances data
  - Substances management processes are being finalized

- **Cleansed substances data represent > 80% of the European MP (approx. 500.000)**

→ A great international achievement based on collaboration of UNICOM, HMA, EMA , FDA

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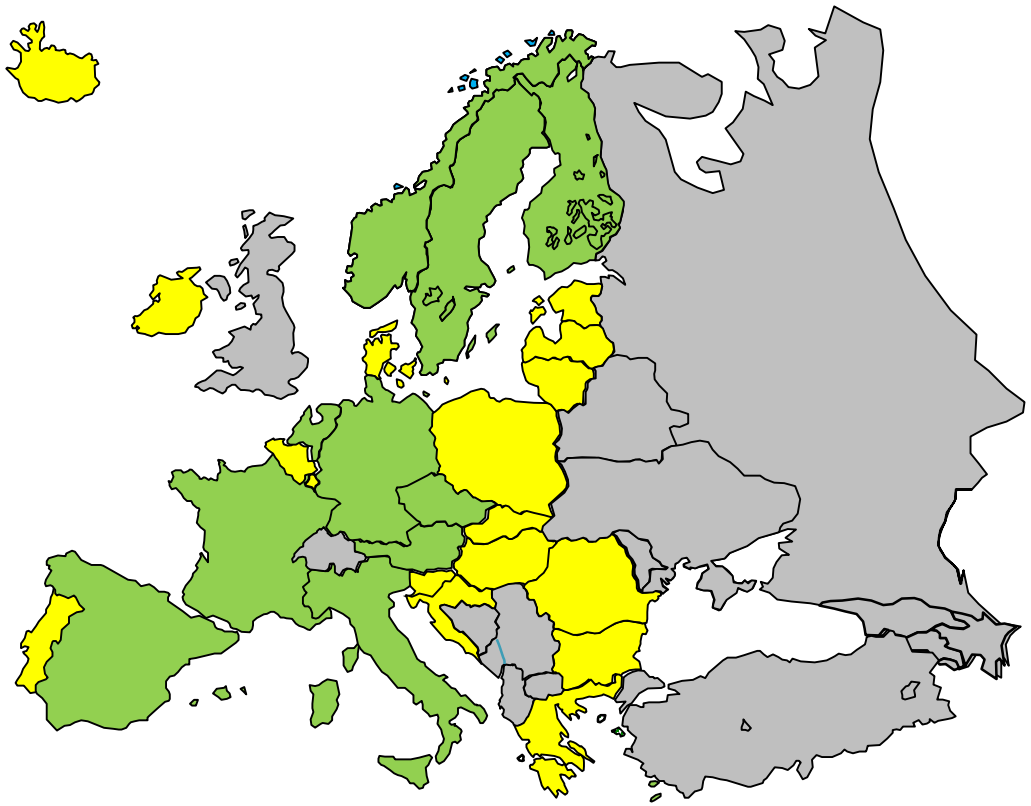
Involvement EEA members in SVG



EEA member involved in SVG

EEA member not yet involved in SVG

Facts & Figures - SVG

- 12 NCA's + WHO UMC
- 20 SVG members

Facts & figures on substances:

- 61.000 substances in EU-SRS
- Many cleansed & enriched, not all
- SMS data cleansed, representing 80% of products

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WP 3: Introducing ISO-IDMP compliant application forms

- At the moment neither application forms nor the tools for initial authorisations, variations and renewals are compliant to the ISO-IDMP standards.
- Thus, it is currently not possible to start, automate and feed regulatory processes with IDMP compliant/structured data and easily re-use the data in EU-wide eHealth services.

The aim of this UNICOM work package is to adapt the application forms and required tools towards the ISO-IDMP / FHIR standards and to increase the usage of EMA's SPOR. It will therefore *deliver web-based application forms compatible with IDMP standards and relevant European Guidance (like EMA IDMP EU IG)*

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AS-IS: Electronic Application Forms for Medicinal Products

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WP 3

Applicants

PDF-based forms including a <u>PDF-proprietary Data Exchange Format</u>

Initial Applications

Lifecycle Management

Regulators

Substance Terms, Organisations, Controlled Dictionary (EMA, providing master data from EUTCT, RMS, OMS)

Regulatory IT-Systems

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TO-BE and status of development

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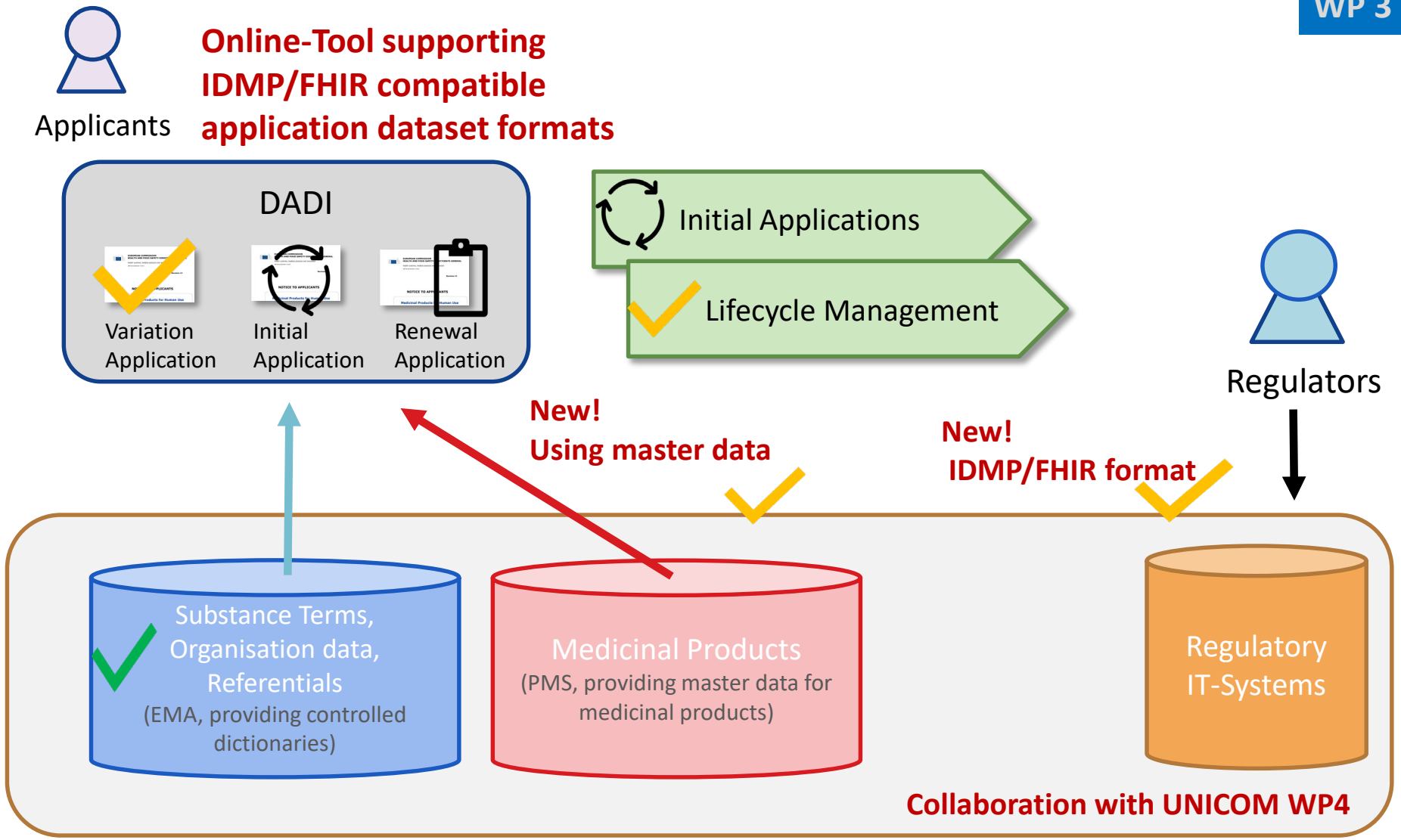
WP 3

UAT partly achieved, **first Variation Application From release in production since 04/11/2022**

In progress

pending



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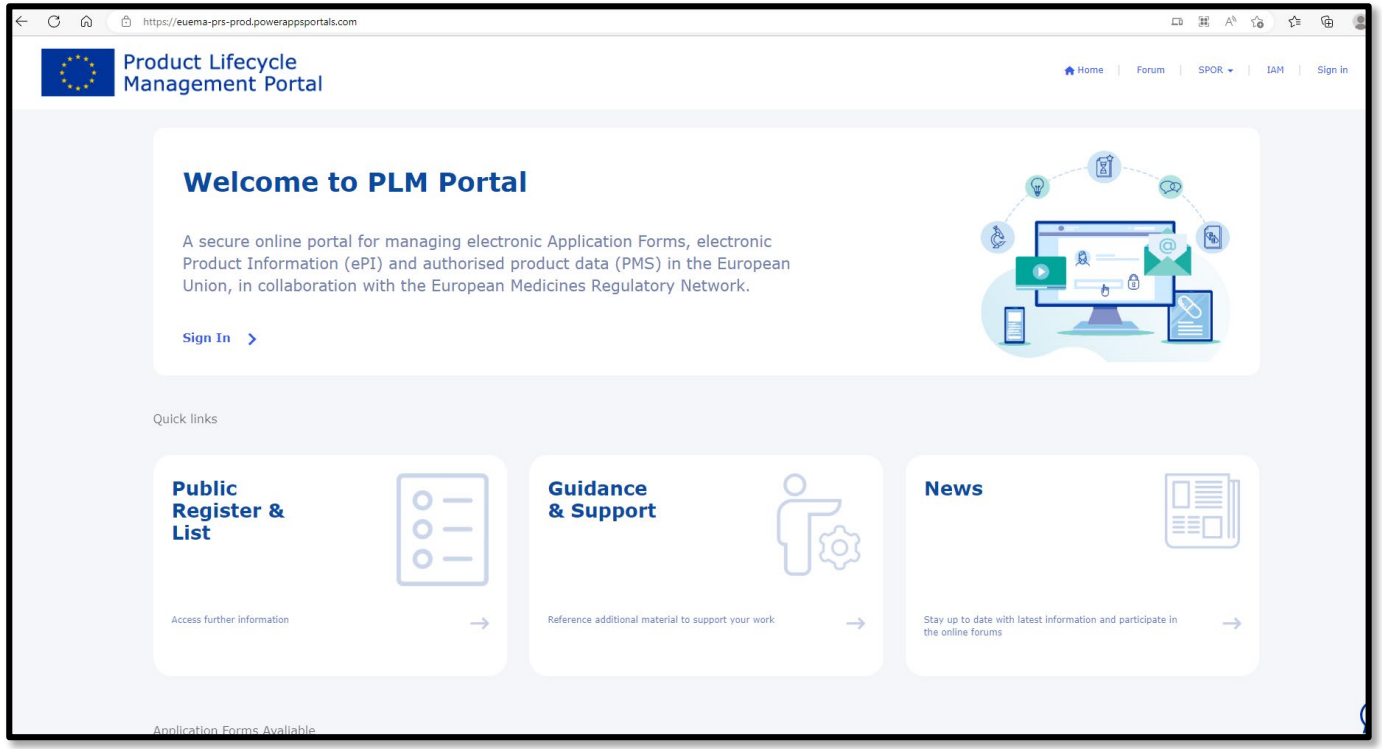
First Go-Live Release

WP 3

- The first release of Variation Application Forms is successfully online since 04.11.2022
  - This version covers variations of centrally authorised medicinal products



Link: Home · PLM (powerappsportals.com)

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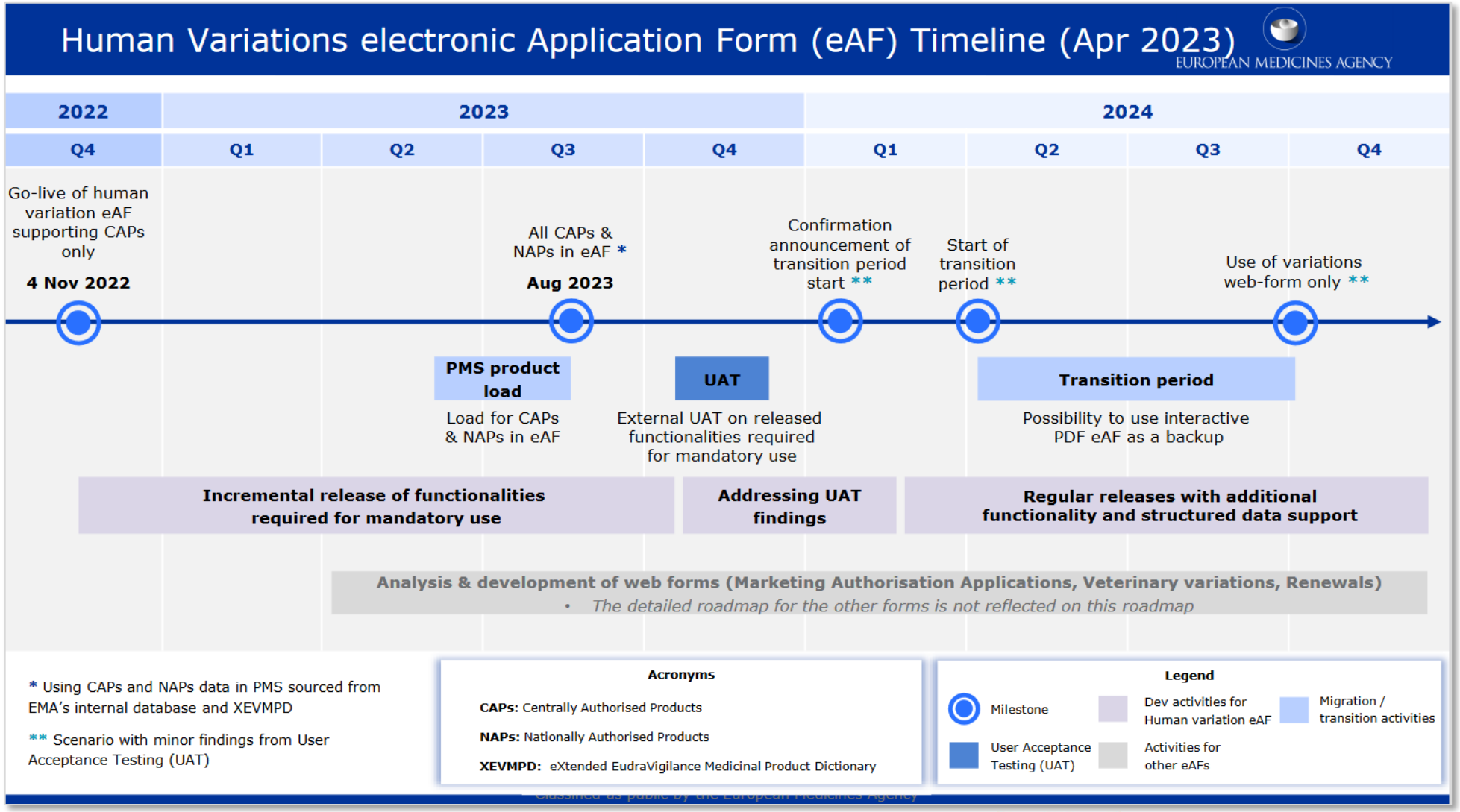
Updated timeline



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WP4: IDMP implementation at National Drug Agencies

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11 national implementation projects - refactoring or building new databases/systems and getting ready to:

- Map legacy data to controlled terminology
  (SPOR RMS, SPOR SMS, SPOR OMS)
- Migrate legacy data
- Refactor databases and user interfaces
- eAF data import to consume
  - IDMP compliant data with minimized manual typing effort
- Some NCAs provide prototypes for eHealth organisations and cross-border-prescription

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It’s also about knowledge sharing!

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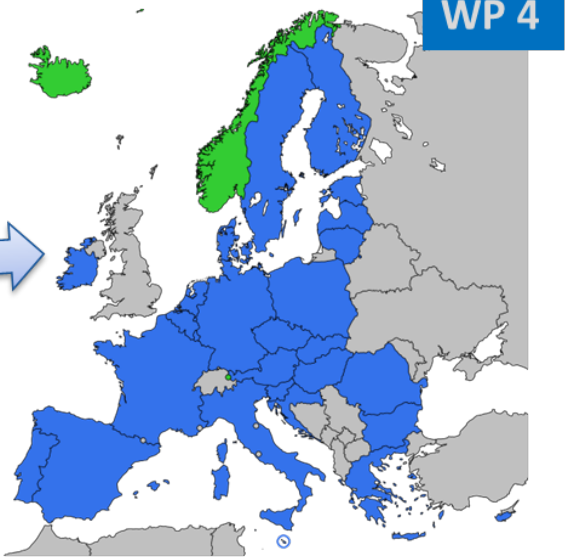
WP 4

Trainings



Guidelines

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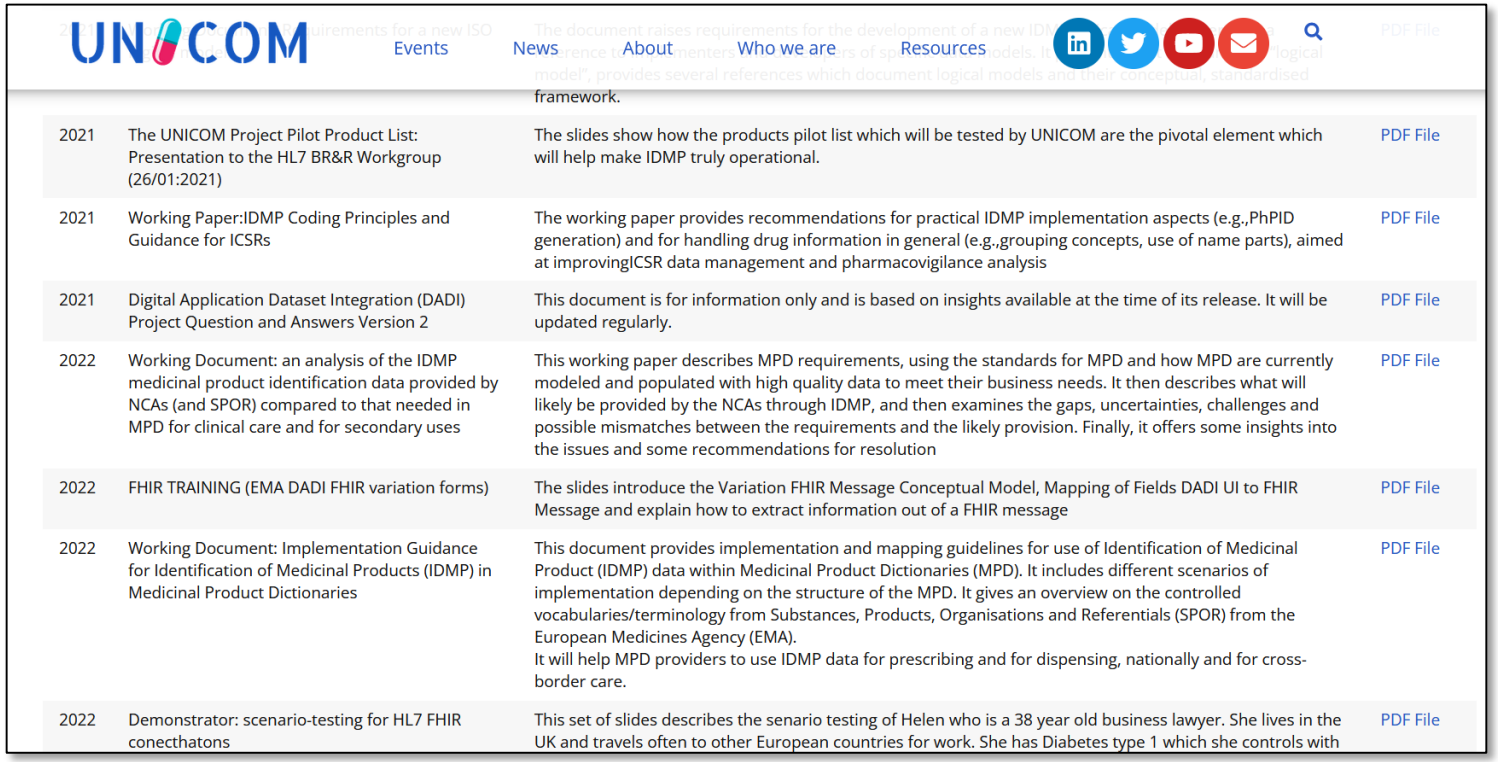
UNICOM Resources

- Please follow the link for further resources: https://unicom-project.eu/resources/project-resources/



		framework.	
2021	The UNICOM Project Pilot Product List: Presentation to the HL7 BR&R Workgroup (26/01:2021)	The slides show how the products pilot list which will be tested by UNICOM are the pivotal element which will help make IDMP truly operational.	PDF File
2021	Working Paper:IDMP Coding Principles and Guidance for ICSRs	The working paper provides recommendations for practical IDMP implementation aspects (e.g.,PhPID generation) and for handling drug information in general (e.g.,grouping concepts, use of name parts), aimed at improvingICSR data management and pharmacovigilance analysis	PDF File
2021	Digital Application Dataset Integration (DADI) Project Question and Answers Version 2	This document is for information only and is based on insights available at the time of its release. It will be updated regularly.	PDF File
2022	Working Document: an analysis of the IDMP medicinal product identification data provided by NCAs (and SPOR) compared to that needed in MPD for clinical care and for secondary uses	This working paper describes MPD requirements, using the standards for MPD and how MPD are currently modeled and populated with high quality data to meet their business needs. It then describes what will likely be provided by the NCAs through IDMP, and then examines the gaps, uncertainties, challenges and possible mismatches between the requirements and the likely provision. Finally, it offers some insights into the issues and some recommendations for resolution	PDF File
2022	FHIR TRAINING (EMA DADI FHIR variation forms)	The slides introduce the Variation FHIR Message Conceptual Model, Mapping of Fields DADI UI to FHIR Message and explain how to extract information out of a FHIR message	PDF File
2022	Working Document: Implementation Guidance for Identification of Medicinal Products (IDMP) in Medicinal Product Dictionaries	This document provides implementation and mapping guidelines for use of Identification of Medicinal Product (IDMP) data within Medicinal Product Dictionaries (MPD). It includes different scenarios of implementation depending on the structure of the MPD. It gives an overview on the controlled vocabularies/terminology from Substances, Products, Organisations and Referentials (SPOR) from the European Medicines Agency (EMA). It will help MPD providers to use IDMP data for prescribing and for dispensing, nationally and for cross-border care.	PDF File
2022	Demonstrator: scenario-testing for HL7 FHIR conecthatons	This set of slides describes the senario testing of Helen who is a 38 year old business lawyer. She lives in the UK and travels often to other European countries for work. She has Diabetes type 1 which she controls with	PDF File

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Further work packages ..

- WP5 – IDMP adoption by eHealth Services
- WP7 - eHDSI cross-border national eHealth services piloting
- WP 8 - Clinical Care, Patients, Pharmacies, Research, Pharmacovigilance
- WP9 – Medicinal Product Dictionaries and Clinical systems
- WP10 Socio-economic impact, legal and governance aspects

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Summary and next steps

- UNICOM supports the standardization of the content presentation of medicinal product and the cooperation in this regard in Europe. Through transatlantic cooperation, international aspects are also included.

- In addition to technical successes, it has been possible to establish a joint knowledge platform with committed partners from a wide range of disciplines.

- Our next step is to try to help more NCAs implement ISO-IDMP and evaluate funding options to do so.

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Thank you! Georg Neuwirther

Head of IT AGES Medizinmarktaufsicht,
Strategy Board Member UNICOM, WP 3 Lead
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