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Up-scaling the global univocal identification of medicines

Global patient safety through semantic interoperability - the univocal identification of medicinal products

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PUBLIC HEALTH & HEALTHCARE IN THE MOVE
Opportunities and Challenges in Research, Practice and Policy

Tallinn 2020, October 28-30

TALLINN HEALTH CARE COLLEGE

Improving Patient Safety – a Never Ending Story

Patient Harm: a Global Disease Burden

► **About one in ten patients is harmed during their treatments**

► **Patient harm is the 14th leading cause of the global disease burden**

► **Over 37 000 people in the EU die as a result of a healthcare-associated infections p.a.**

► **About 15% of hospital expenditures in OECD countries can be attributed to treating safety failures**

► **Cost of safety failure includes loss of trust in the health systems, governments, and social institutions**

(Source: Health First Europe. Patient Safety Policy Indicators. 15 November 2018

A Key Patient Safety Issue: Adverse Drug Reactions (ADRs)

Estimates for Europe (p.a.; 2000 - 2014)

► ADR rate at *hospital* admission 3.6 % of all hospitalizations (median; mean 4.6 %; > 3 m patients)

► ADR rate during *hospitalization* 10 % or > 8 m patients (median; mean 17.0 %)

► ADR prevalence in *outpatient* settings lower than 1 % (But: "80 % of the total economic burden of ADRs in Europe.")

► Fatal in-hospital ADRs: 42,000 to 419,000 deaths (EMA: around 200,000)

(Source: Jacoline C. Bouvy et al., Drug Saf (2015) 38:437–453)

Societal economic burden in EU (p.a.; 2007)

► Estimated at €79 billion

(Source: COMMISSION STAFF WORKING DOCUMENT EC SEC(2008) 2670 - pharmacovigilance)

Estimates for USA

► > 700,000 outpatients are treated in emergency departments p.a. for ADRs; 120,000 require hospitalization

(Budnitz et al. JAMA, October 18, 2006—Vol 296, No. 15)

► "Among 222 novel therapeutics approved by the FDA from 2001 through 2010, 32% were affected by a postmarket safety event"

(Source: Nicholas S. Downing et al., JAMA. 2017;317(18):1854-1863)

Barriers to the Free Flow of Safe Drug Information

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► **Only national markets for medicinal products**

► **Marketing strategies of pharmaceutical industry**

► **Data quality/legacy data for (older) medicines**

► **Absence of 'fit-for purpose', globally agreed standards (concepts, data models, resources), coding systems, and implementation guidelines to ensure high quality data at all levels of use and for core/all actors**

Data on medicines are probably the most widely used ones of any type of patient and health data, with the largest number of actors involved

European Innovation Action – Vision & Mission

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The UNICOM project is helping to ensure that any medicine and what it contains can be accurately identified anywhere in the world. We are working to improve patient safety and enable better healthcare for all.

https://unicom-project.eu/

Mission

The Challenge

► **A central issue in medicine-related events is the univocal identification of drugs**

► **It hinders the fast and reliable reporting, and integration of pharmacovigilance events**

► **"Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem"**

Mission

www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance-overview

► **Enabling the univocal identification of medicinal products by supporting and accelerating the**

  ➢ **further development,**
  ➢ **implementation, and**
  ➢ **diffusion of ISO IDMP standards (IDentification of Medicinal and pharmaceutical Products)**

► **across European health systems, to**

► **facilitate the free flow of semantically coded interoperable drug information**

► **Across all data users, covering the full life cycle of a medicine**

Key Identification Challenges (I)

➢ **Across health systems, the *same* medicinal product (MP) may have *different names***

➢ **Across countries, the *same* name may identify a *different* product** (with a different *active* substance)

➢ **Across EU Member States, the number and kind of MPs authorised for national marketing differ very considerably** (due to marketing strategies of producers, plus three different marketing authorisation procedures at EU and national levels)

Key Identification Challenges (II)

➢ **National databases of authorised drugs contain between 10,000 to 20,000 (> 50,000 in DE) medicinal products, whereas the EMA database records > 500,000 for the EU**

➢ **E.g., in cross-border ePrescription (eP) services this necessitates *substitution* in many, if not the majority of instances**

➢ **Substitution is only possible if the pharmacist can safely identify the medicine specified in the foreign prescription**

➢ **Similar challenges apply to the electronic recording of MPs in *other healthcare contexts***

The missing univocal identification of medicines hampers timely global *pharmacovigilance* reporting and warnings

Conceptual Solution: Semantic Interoperability Across Data Users

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Defining Semantic Interoperability for Health

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Health system interoperability

facilitates the recording, sharing, understanding and acting on patient and other health information among linguistically disparate medical professionals, patients and other actors within and across health systems in a collaborative manner

Barriers:

Absence of 'fit-for purpose', globally agreed **standards** (concepts, data models, resources), **coding systems** and **implementation guidelines**

Towards a seamless MP Data Value Chain

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Semantic interoperability will **facilitate data sharing across the full life cycle and all actors involved in handling MP information**

- **Pharmaceutical companies**
- **National Medicinal Products Regulatory Authorities (NMAs)**
- **Pharmacovigilance Systems (patient safety)**
- **Providers of medicinal product dictionaries**
- **Clinical software producers (EHR, Hospital Information, CDS, CPOE, PS, ePrescribing systems**
- **Healthcare professionals using these systems**
- **Pharmacy Systems (Order Systems, Supply Chain/Logistics/Stock Management Systems)**
- **eProduct Information/Patients/Intelligent apps for patient empowerment**
- **National ePrecription Systems**
- **xBorder digital health services**
- **Clinical trials/medical research**
- **Health systems & Public Health**

and across **different languages, alphabets, health cultures**

Concrete Solution: ISO IDMP Standards & Medicinal Products Data Model
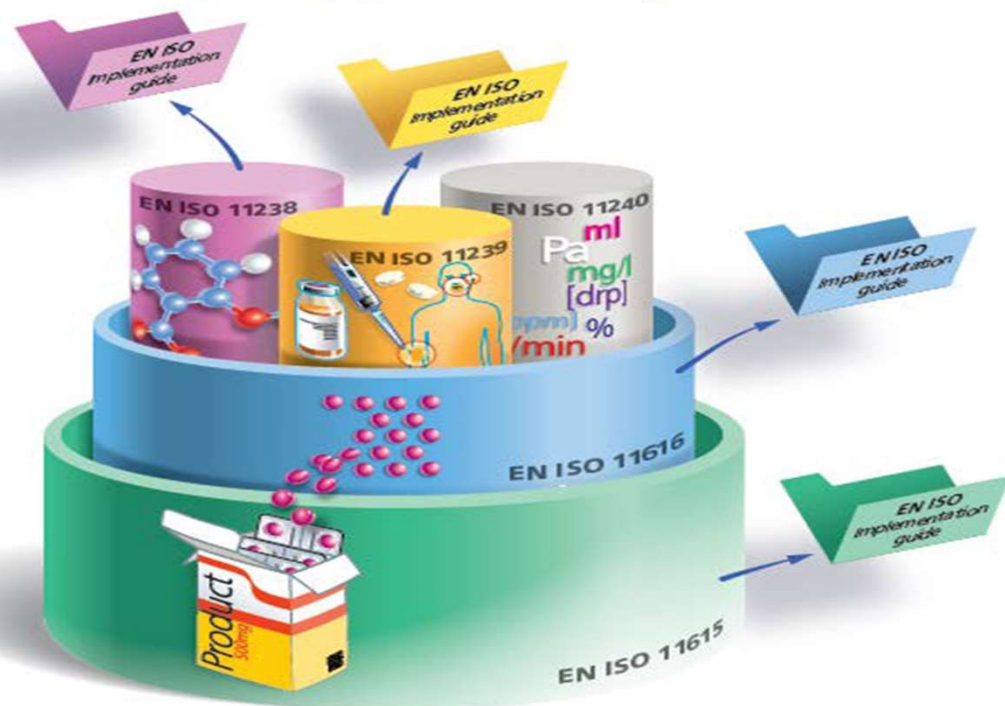
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International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP) Suite of Standards

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IDMP
Identification of Medicinal Products
Data elements and structures
for the unique identification and exchange

EN ISO implementation guide

EN ISO 11238
EN ISO 11239
EN ISO 11240
Pa ml
mg/l
[drp] %
/min

EN ISO implementation guide

EN ISO 11616

Product 500mg

EN ISO 11615

EN ISO implementation guide

The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships that are required for the unique identification of:

➢ *Medicinal* **Products** (MPID) and **Packages** (PCID) - ISO 11615

➢ *Pharmaceutical* **Products** (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

ISO IDMP standards apply to both authorised and developmental medicinal products for *human* use

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Overarching conceptual data model for MPs

Defining Medicinal & Pharmaceutical Products
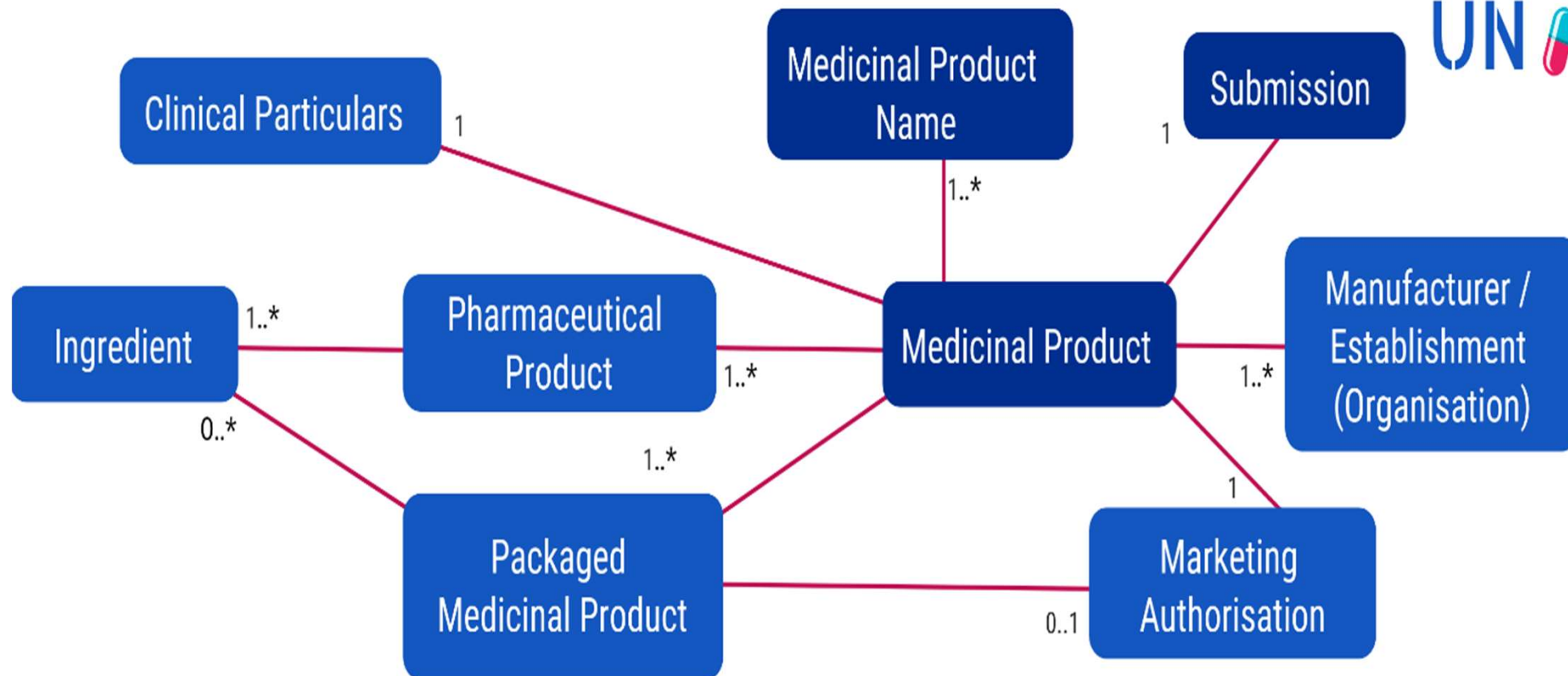
► **Medicinal Product (MP):**

"Any substance or combination of substances that may be administered to human beings (or animals) for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions"

► **Pharmaceutical Product (PhP):**

"The qualitative and quantitative composition of a Medicinal Product in the dose form approved for administration in line with the regulated product information. ... A Medicinal Product can contain one or more pharmaceutical products"

► Notes:

➢ **A prescription usually specifies a specific *package* or the quantity of a *medicinal* product**

➢ **Different medicinal products with distinct (brand) names (generics) may all contain the same pharmaceutical product**

➢ **If a single package contains, e.g., two types of tablets with different active ingredients, this single medicinal product contains two different pharmaceutical products**

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Core Medicinal (MP) and Pharmaceutical Products' (PhP) Attributes

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► **Active Substance(s)**

Codes for active substance(s)/specified substance(s) ID(s) will be based on the EU-Substance Registration System (EU-SRS), from which the European Medicines Agency will provide a Substance Management System (SMS) replacing for certain usages, e.g., INN or ATC terms/codes

► **Strength(s)**

Strength unit (unit of measurement and/or unit of presentation) codes will be based on UCUM codes (Unified Code for Units of Measure - Regenstrief Institute, USA)

► **Administrable dose form**

is the "general method by which a pharmaceutical product is intended to be administered to the patient." Codes are provided by the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe

Standard Developing Organisations (SDOs) involved

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11 Standard Development Organisations (SDOs) and related organisations, which have a transversal impact on UNICOM and IDMP

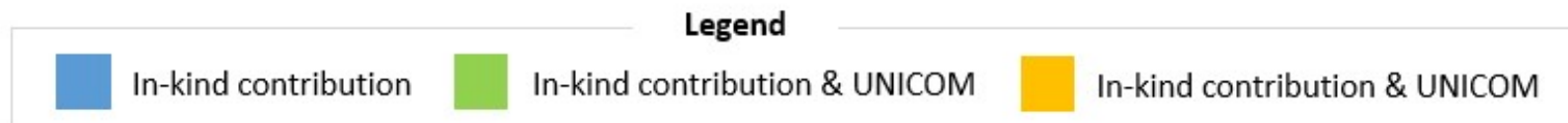# European Innovation Action – Objectives, Actions, Partners

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Objectives

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By accelerating the further development and 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. Big Data Analytics, Artificial Intelligence applications)

As an Innovation Action, UNICOM is focusing on implementation: its long-term goal is to realise 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

Implementing an EU Substance Management System

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HMA Endorsement EU-SRS PoC	Evaluate PoC & create roadmap	HMA Endorsement EU-SRS implementation	Go-live EU-SRS	Report to HMA	Report to HMA

Execution EU-SRS Proof of Concept | **Phase 1 execution EU-SRS implementation** | **Interim evaluation & report** | **Phase 2 execution EU-SRS implementation** | **Hand-over to EMA**

Feb 2019 · Dec 2019 · Mar 2020 · Mar 2021 · Jun 2021 · Mid 2022

Legend

- In-kind contribution
- In-kind contribution & UNICOM
- In-kind contribution & UNICOM

Common EU Submission Platform (CESP)

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► **Applications for authorisation of medicinal products & management of their life cycles**

► **Electronic forms & tools compliant with IDMP for**

 ▷ **Initial application**

 ▷ **Variation**

 ▷ **Renewal activities**

► **Replacement of legacy PDF-technology based forms with web-based CESP Dataset Module**

► **Integration with EMA's SPOR (Substances, Products, Organisations, Referentials) DB services**

► **Ensuring well-structured IDMP compliant interoperable drug information for all further processes and actors**

Cooperation of National Medicines Authorities

11 National Competent Authorities are working together to implement IDMP in their medicinal products related IT systems

Vision: With compatible IT systems and regulatory processess to ensure data of high quality we will be able to provide IDMP-compatible data and enable various use cases throughout Europe for several stakeholder groups (e.g. eHealth scenarios)
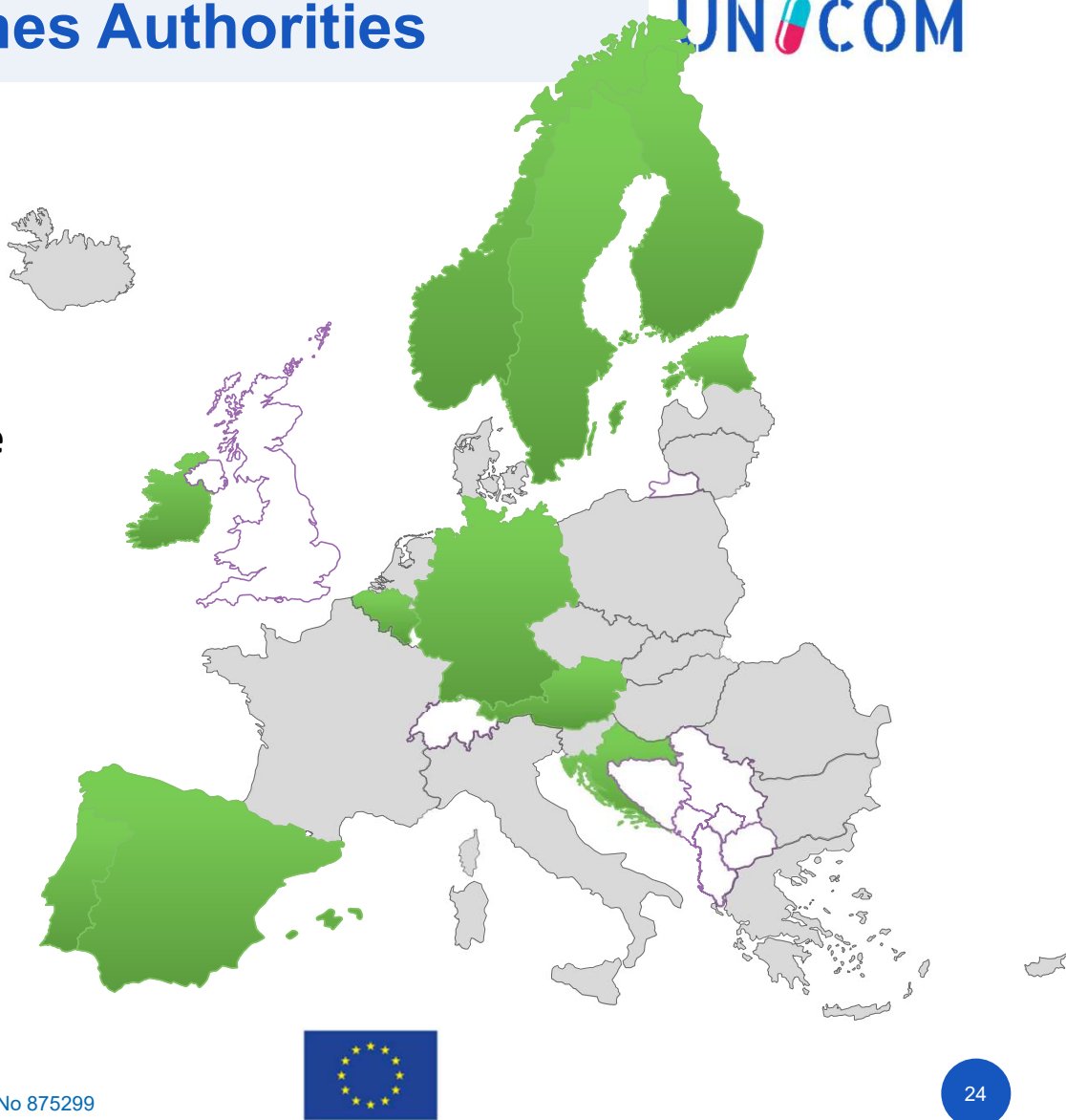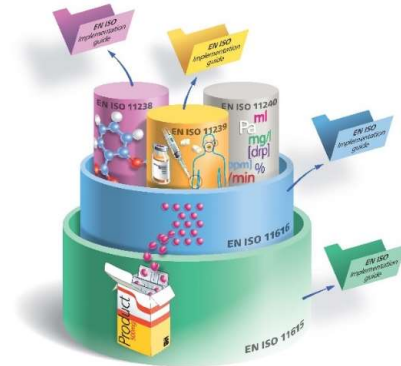
Exploration of Improvements for Health Systems

Ultimately, IDMP implementation & diffusion will support

► **Patients**

► **Health professionals**

► **Healthcare provider organisations**

► **Public Health services**

to improve the quality and efficiency of health systems

Health System Application Fields – IDMP coded Data in Multi-Country Settings

Patient facing apps: empowerment through access to health data with more accurate, fully integrated medicines and safety information across health systems

✓ **Understandable medicines information/medication record in cross-border settings (semantic interoperability)**
✓ **Safety alerts**
✓ **Individual decision support**

Health professionals: Medication review and safe eDispensation through multilingual drug class terminology

✓ **Reliable, fully understandable medicines information**
✓ **More consistent implementations of clinical decision support systems (Order entry; dispensation/substitution…)**

Pharmacovigilance: global seamless, interoperable electronic information flows

✓ **Enabling the use of IDMP identifiers in individual case safety report (ICSR) messages**
✓ **Improving ICSR - clinical system connectivity for faster evidence gathering, integration, and reporting**

Clinical research and Big Data Real World Evidence (RWE)

✓ **Enable quality assessment of EHR and patient summary problem lists and risk assessments using IDMP**
✓ **Enhance the research value of Big Data leveraging IDMP implementation in drug utilization, safety, effectiveness and outcomes studies**

Consortium Partners

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► **Core IDMP data value chain actors are consortium partners (26 National Drug and eHealth Authorities, Standard Development Organisations (SDOs), providers of cross-border ePrescription services, clinicians, patients, and many others)**

► **Further stakeholders are involved through their associations or as experts (via an Advisory Board, expert workshops, meetings & conferences etc.)**

► **Estonia: RAVIMIAMET (Estonian State Agency of Medicines - EESAM), TARTU**

Other Actor and Stakeholder Participation

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▶ Through **other formal and informal relationships** and channels, various consortium partners are cooperating with other IDMP-relevant actors (like EMA IDMP Task Force; USA FDA)

▶ Informally **EMA, WHO Uppsala Monitoring Centre (UMC) for pharmaco-vigilance, WHO Collaborating Centre for Drug Statistics Methodology, EDQM, SDOs and others** participate and contribute to selected WPs and meetings

▶ **Global Outreach:**
  ➢ **EU (15 countries)**
  ➢ **UK, Norway**
  ➢ **USA**
  ➢ **Trans-Atlantic cooperation**
  ➢ **… and beyond**

Facts

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Duration: Dec. 2019 – Nov. 2023 (4 years)

Budget: € 21 m; European Commission funding is € 19 m

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Benefits and Outlook

Semantic Interoperability along the medicine data value chain will

► **enable the seamless exchange and sharing of health data related to medicines across all actors and stakeholders involved in handling or consuming such data**

► **facilitate faster and better pharmacovigilance reporting**

► **create economic efficiency gains for industry and service providers**

► **facilitate the use case of ePrescription/eDispensation in a cross-border setting**

► **improve reliable recording of medicinal product information in clinical documents (e.g. Patient Summary)**

► **enable better communication towards patients**

► **improve reuse of medication related data for Public Health and medical research**

► **create synergies across regulatory, healthcare, public health and scientific domains**

Semantic Interoperability along the medicine data value chain will require

► **Close cooperation across various health Standards Developing Organisations**

► **The full commitment of National Medicines Authorities and other governmental actors, as well as of the European Medicines Agency (EMA)**

► **Considerable investments by many actor groups**

► **Involvement, exchange and cooperation across the full data value chain**

► **Long-term maintenance of standards, coding systems, implementation support**

Acknowledgements

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We are most grateful to colleagues at the participating organisations as well as external experts who contribute and critically review project work.

Thank you!

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Further Information on UNICOM

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