



Up-scaling the global univocal identification of medicines

UNICOM Project: Improve medicinal product data along their life cycle

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Agenda

- ▶ Positioning the challenge
- ▶ What is ISO IDMP
- ▶ UNICOM what it is and which are the stakeholders
- ▶ UNICOM achievements so far
- ▶ UNICOM and IHE?
- ▶ The way forward



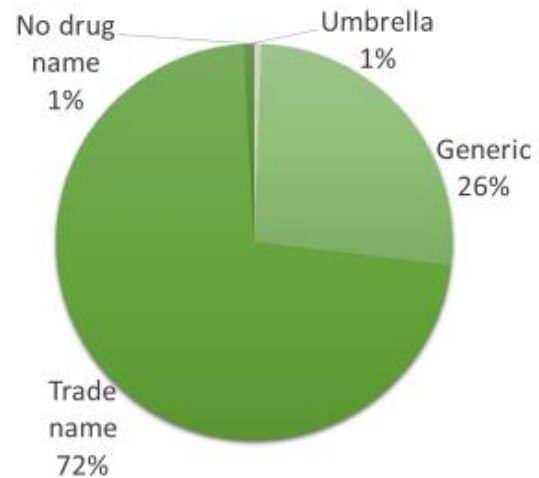
Positioning the challenge

UN  COM

- ▶ **Pharmacovigilance**
 - **Same medicinal product**
 - ✓ Different name, expression of dosage, pharmaceutical dose form, route of administration
 - **Same medicinal product?**
 - ✓ What about substance(s)?
- ▶ **Cross border prescriptions**
 - How to identify medicinal products un-ambiguously?
 - How to decide which medicinal product is identical to another?
- ▶ **Decision support**
 - Decision support systems based on local product master data?
 - How to develop multimarket systems?
- ▶ **Shortage**
 - How to aggregate medicinal products which seem to be identical/different?

Identification of drug on ICSRs

Drug names on VigiBase ICSRs



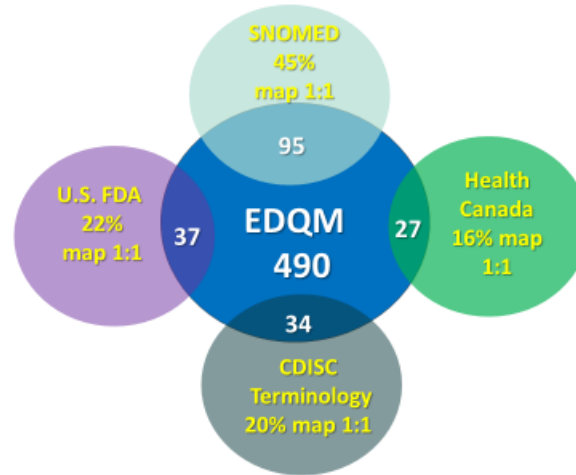
Identification of drug on ICSR

	All VigiBase	Reports 2012-2017
Batch number	18%	22%
No batch number	82%	78%

Region-to-Region Dose form Terminology

Various regions are using their own set of terminologies for dose form, which show different levels of granularity

→ One-to-one mapping between regional terminologies and a centrally controlled vocabulary of low quality



¹ <https://standardterms.edam.eu/>
² <https://evs.nci.nih.gov/fp3/FDA/SPL/About.html>
³ <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database/what-data-extract-drug-product-database.html>
⁴ <https://ncim.nci.nih.gov/ncimbrowser/>
⁵ <https://www.cdisc.org/standards/terminology>
(Note: In 2018, HC dosage form datasets for active products was downloaded and analyzed by FDA to determine the extent of 1:1 mapping)



Findings

Dose Form Challenge

❖ Dose Form expression variations (e.g. Pfizer Covid-19 vaccine)

- EMA – **Dispersion** for Injection
- FDA – **Suspension** for Injection
- UK – **Solution** for Injection



Pharmaceutical Dose Form	Release Characteristics	Intended Site	Administration Method	Basic Admin. Dose Form
Dispersion for Injection	Conventional (0047)	Parenteral (0033)	Injection (0012)	Dispersion (0079)
Suspension for injection	Conventional (0047)	Parenteral (0033)	Injection (0012)	Suspension (0085)
Solution for injection	Conventional (0047)	Parenteral (0033)	Injection (0012)	Solution (0083)

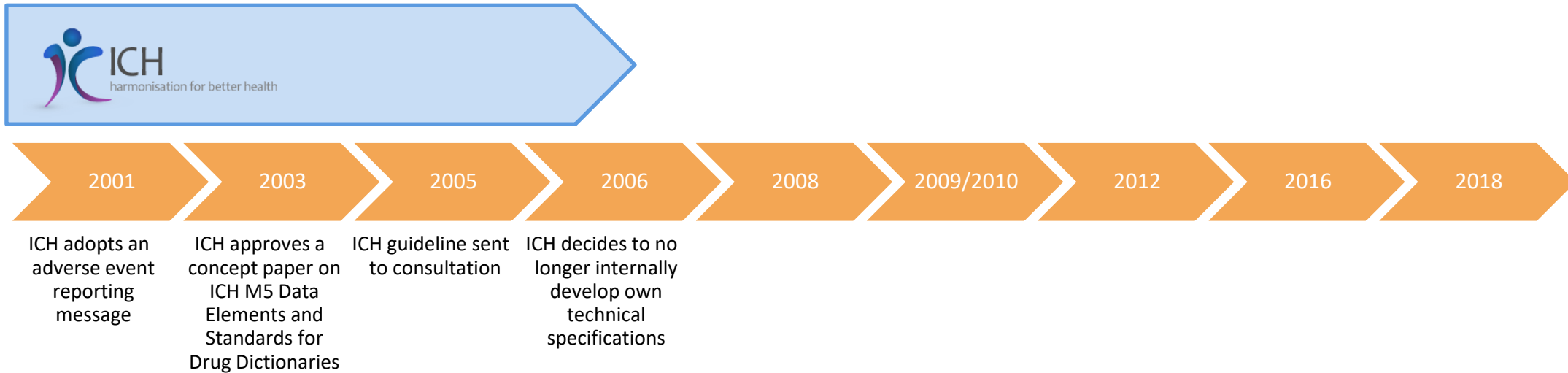


What is IDMP?

IDMP – the origin



Recognise the need to improve adverse event management.

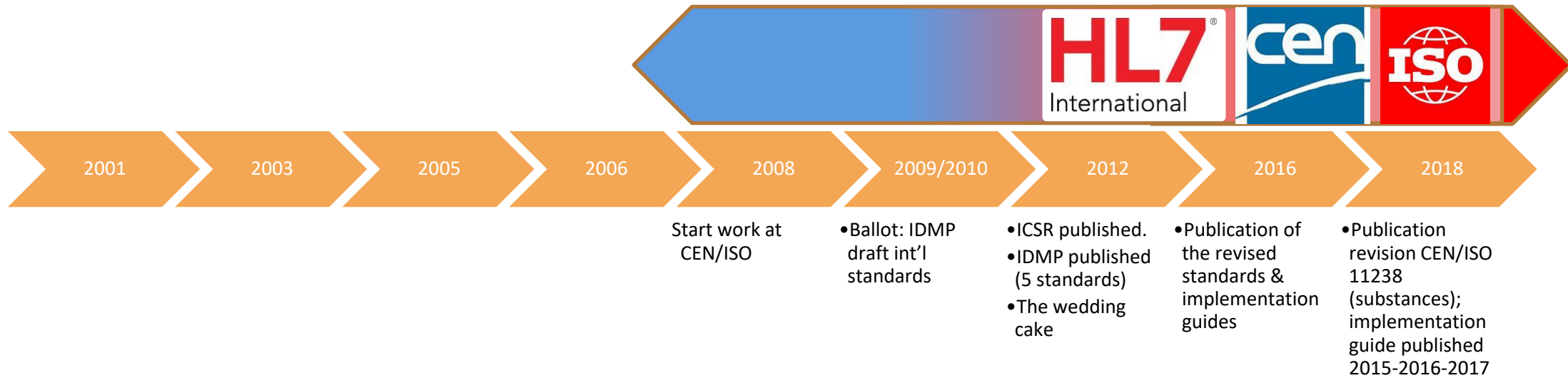


Source: Dr Andrew Marr

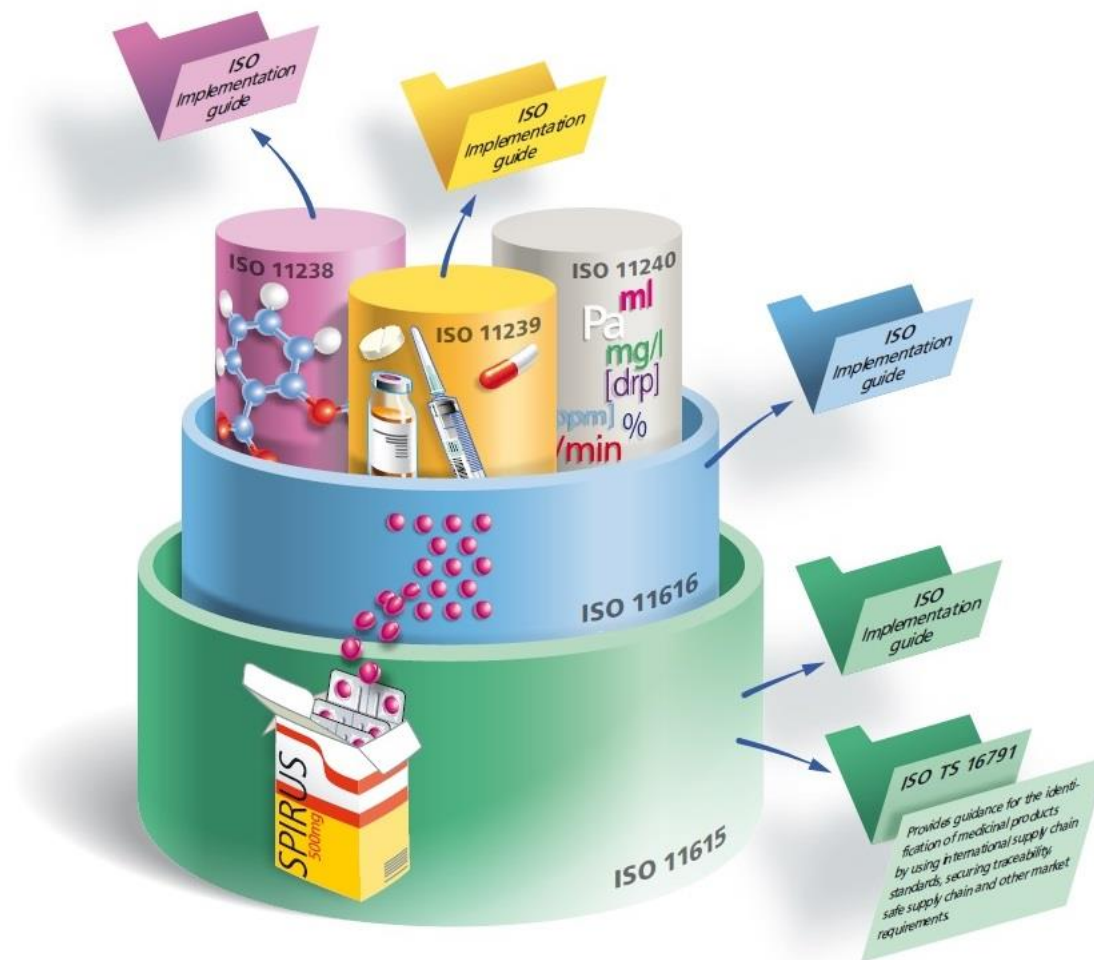
IDMP – the origin



Recognise the need to improve adverse event management.

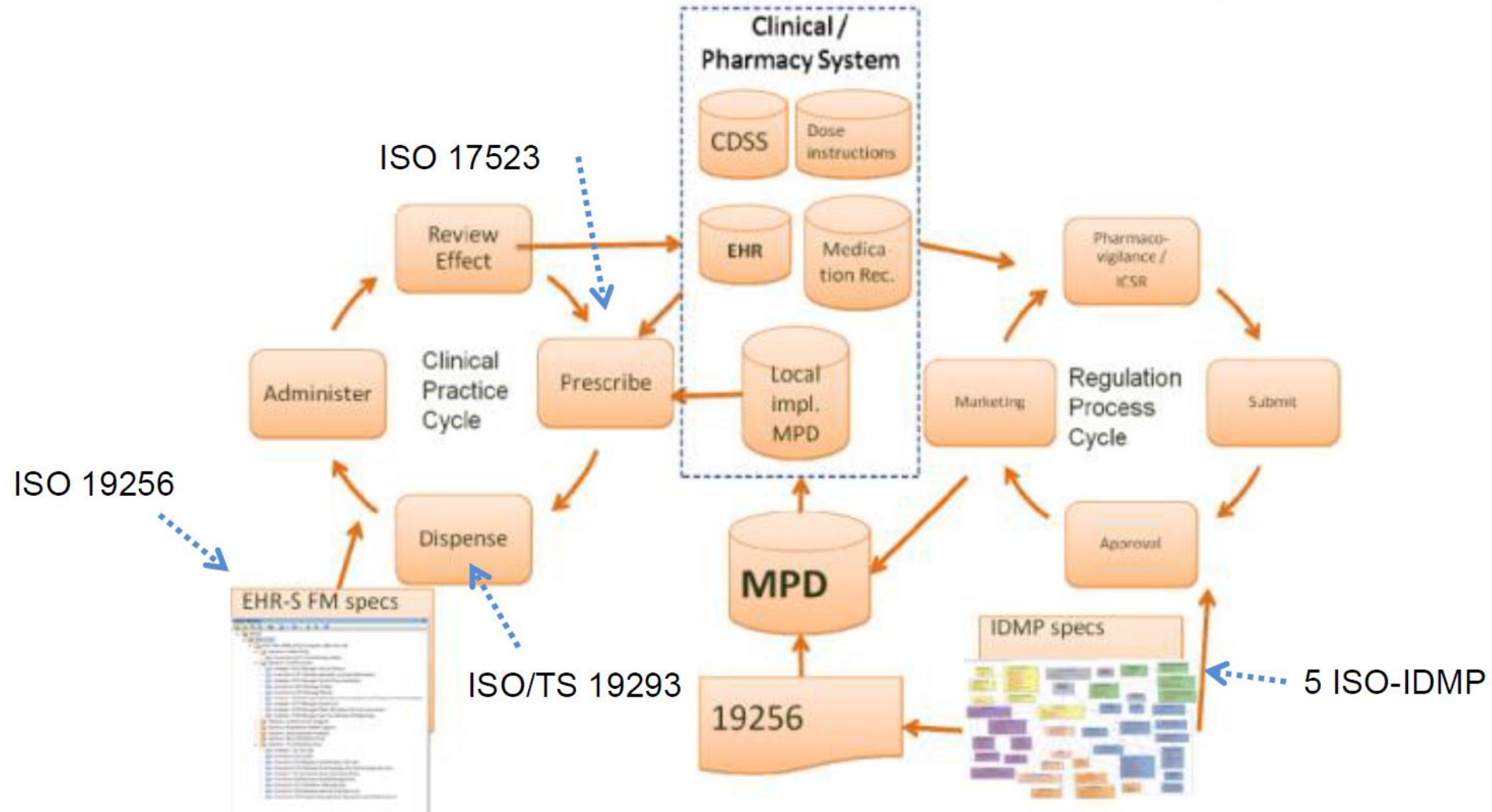


5 Standards, 4 + 1 Specifications, 1 Technical report



The «wedding cake»

Several relevant ISO standards that point to IDMP



UNICOM what it is and which are the stakeholders



The life-cycle of a medicinal product

► Covered by UNICOM and its 13 Work Packages



UNICOM, 13 Work Packages (WP)

- WP01 IDMP-related standards and terminologies
Robert Stegwee - Christian Hay (NICTIZ, Netherlands)
- WP02 Implementation of IDMP – Substance Management in Europe
Joris Kampmeijer Annet Rozema (CBG, Netherlands)
- WP03 Pan-European IDMP-compliant application forms
Georg Neuwirth Noel Diamant (AGES, Austria)
- WP04 IDMP implementation at National Drug Agencies
Pelle Persson (MAP, Sweden), Georg Neuwirth (AEGES, Austria)
- WP05 IDMP adoption by eHealth Services
Diogo Martins Anderson Carmo (Portugal)
- WP06 Software and extensions for CEF eHDSI
Alexander Berler, Kostis Kaggelides, Fotis Gonidis (Greece)
- WP07 eHDSI cross-border / national eHealth services piloting **Marcello Melgara** (Italy)
- WP08 Clinical care, Patients, Pharmacies, Research and Pharmacovigilance **Dipak Kalra**, Robert Vander Stichele (I~HD), Lucia Comnes (DATAWIZARD)
- WP09 Medicinal Product Dictionaries and Clinical System Software **Julie James**, Dipak Kalra (I~HD), Ursula Tschorn (IDMP1)
- WP10 Socio-economic Impact & Sustainable Legal and Governance Aspects **Rainer Thiel**, Veli Stroetmann, Petra Wilson (Empirica)
- WP11 Project management **Farah Diehl-Fahim**, Veli Stroetmann (Empirica)
- WP12 Overall scientific coordination and dissemination **Veli Stroetmann**, Farah Diehl-Fahim (Empirica)
- WP13 Ethics requirements **Veli Stroetmann**, Petra Wilson (Empirica)

- Database Providers(2)
 - Vidal, Z-Index
- eHealthDSI (7)
 - Aria, Elga, Nictiz, ...
- Health Authorities (4)
 - Ireland, Lombardia, Portugal, ...
- Industry (5)
 - Datawizard, IDMP1, ...
- National Competent Authorities for Medicinal Products (13)
 - Spain, Germany, Austria, Sweden...
- Networking (3)
 - COCIR, CTADHL, ETHEL
- Research (5)
 - I~HD, Universities in Italy & US, ...
- Standard Development Organisations (10)
 - ISO, HL7, SNOMED...



UNICOM achievements so far : a few examples



91

Deliverables
listed on EC
portal

158

Deliverables to
submit
including
iterations

32

Deliverables
including
Iterations
approved in
First Periodic
reporting Sep
2021

30

Deliverables
submitted
including
iterations

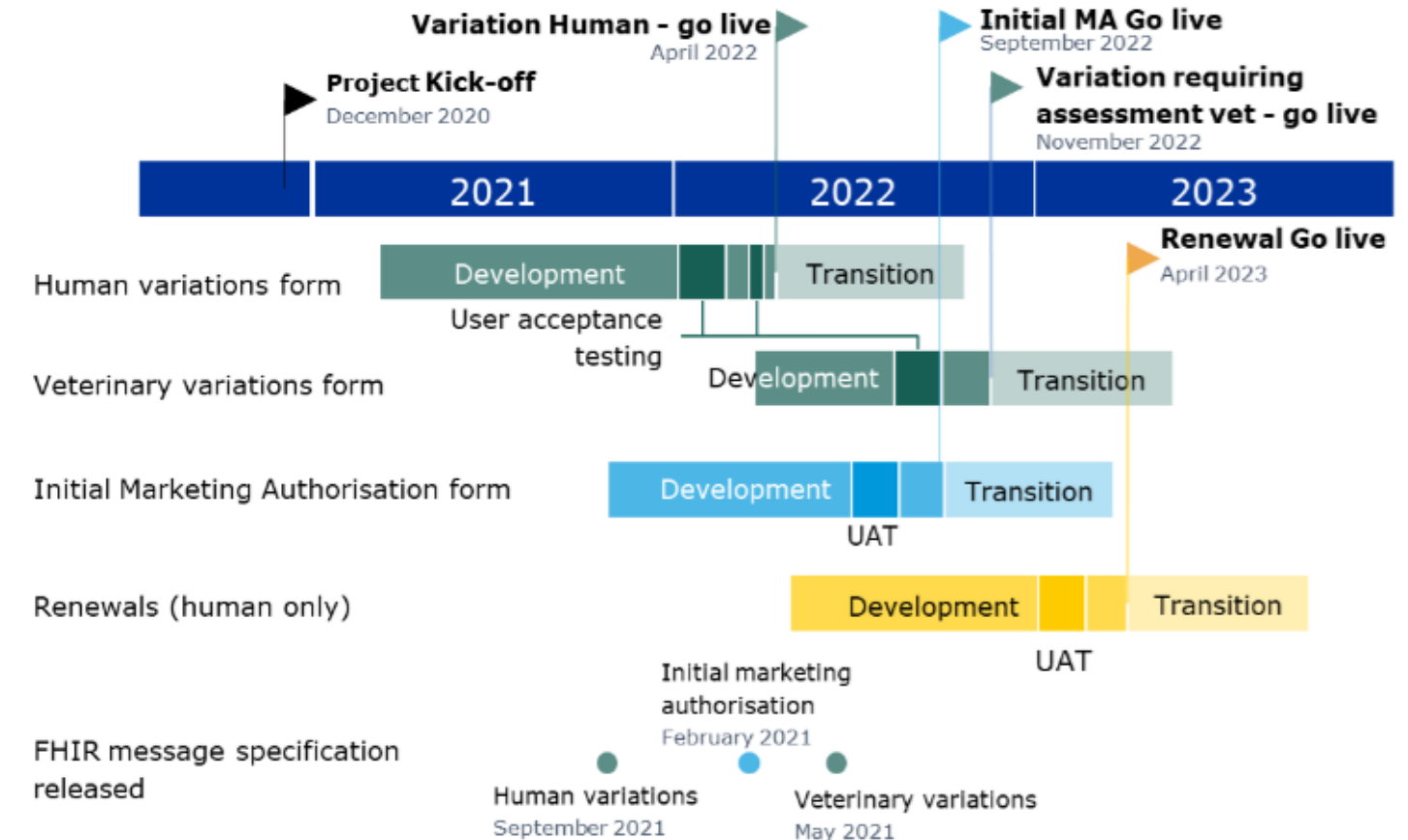
WP3 – Pan- European IDMP compliant application forms

Main Achievements:

Gap and requirements analysis for IDMP compatible application forms

DADI Roadmap and Objectives. Going live in October 2022

Diagram 1 – DADI Project Timeline (version August 2021)



- ▶ Co-create with eP cluster the CP-066 – Prepare eHDSI Requirements Catalogue for ISO IDMP
- ▶ Contribution on the revision of eHN eP guidelines (v0.3)

Main Achievements:

- Business Requirement Specifications
- Guidelines for IDMP-based Cross-Border eP eD PS
- Guidelines for cross-border semantic interoperability
- Semantic Specifications
- Technical specifications for cross-border services
- Guidelines to implement IDMP in National eHealth Services
- Liaison with EC, MSs and stakeholders annual report

Main Achievements:

- Jointly develop Wave 6 Assets, released on 6/2022, implementing CP-63 (enhanced packed medicinal product description) and CP-66 (Adoption of IDMP attributes)
- WP6 co-operating with eHDSI Solution Provider to implement the enriched eP/eD – PS display tool and the component to support smart substitution

WP7 eHDSI cross-border national eHealth services piloting

eHDSI Wave 6 timing and actions

- ▶ June 30th, 2022: IDMP enabled assets adopted
- ▶ September 2022: prepare Wave 7 Change Proposals with eP Cluster & Semantic TF
- ▶ October-November 2022: Preparatory Pre-Production Testing for eP/eD & PS
 - ▷ Member States must perform test with eHDSI Reference Test Data
- ▶ February-March 2023: Formal Pre-Production Testing for eP/eD & PS
 - ▷ Member States must perform test with eHDSI Reference Test Data, to be authorised to go in **Routine Operation**
 - **UFIS can be used by MSs**
- ▶ Since Autumn 2023: Routine Operation eP/eD & PS IDMP enabled
 - ▷ MSs must use Certified Medicinal Products Databases
 - ▷ MSs without Certified Product Databases, may continue using Pre-Production Environment and PPL/UFIS

Main Achievements:

- ✓ Co-operated with eHN SG on Semantic on the released eHN Guidelines on ePrescription and Patient Summary (Release 3), to include IDMP related requirements and Data Elements
- ✓ eHDSI eP Cluster, Semantic Task Force and UNICOM submitted (September 2021) the Change Proposals to enrich medications description with IDMP attributes & Identifiers (CP-66) and improve complex packages description (CP-63)
- ✓ June 2022: Released eHDSI Wave 6 IDMP enriched assets released, with UNCOM support
- ✓ Working with EC DG Santé and Member States to prepare October eHDSI Pre-Production Testing

Main Achievements:

- 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
- Implementation Guidance for Identification of Medicinal Products (IDMP) in Medicinal Product Dictionaries

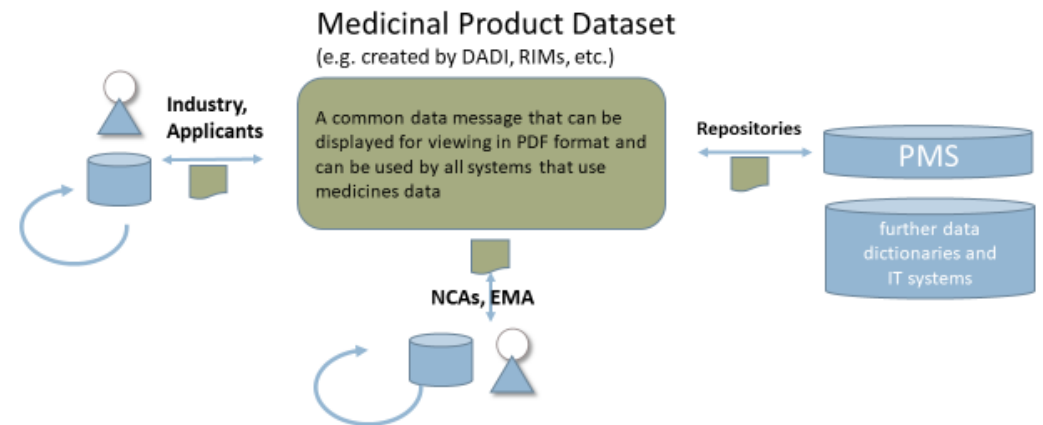


UNICOM and IHE?



- ▶ Raise awareness in the regulatory authorities community
- ▶ ...and in the pharmaceutical companies
 - ... learn how to test systems' conformity to IHE Profiles by using validators and the interoperability between systems or simulators
 - ... learn how to test interoperability of software products in a neutral, structured and rigorous environment with peer users

Opportunities of a shared „Product Dataset“



- ▶ Well defined shared semantic and technical format used for data exchange across the network
- ▶ Utilising identical datasets ensures **data consistency** between participating IT systems
- ▶ No separate dataset formats might be needed to read and populate data repositories

07/09/2022

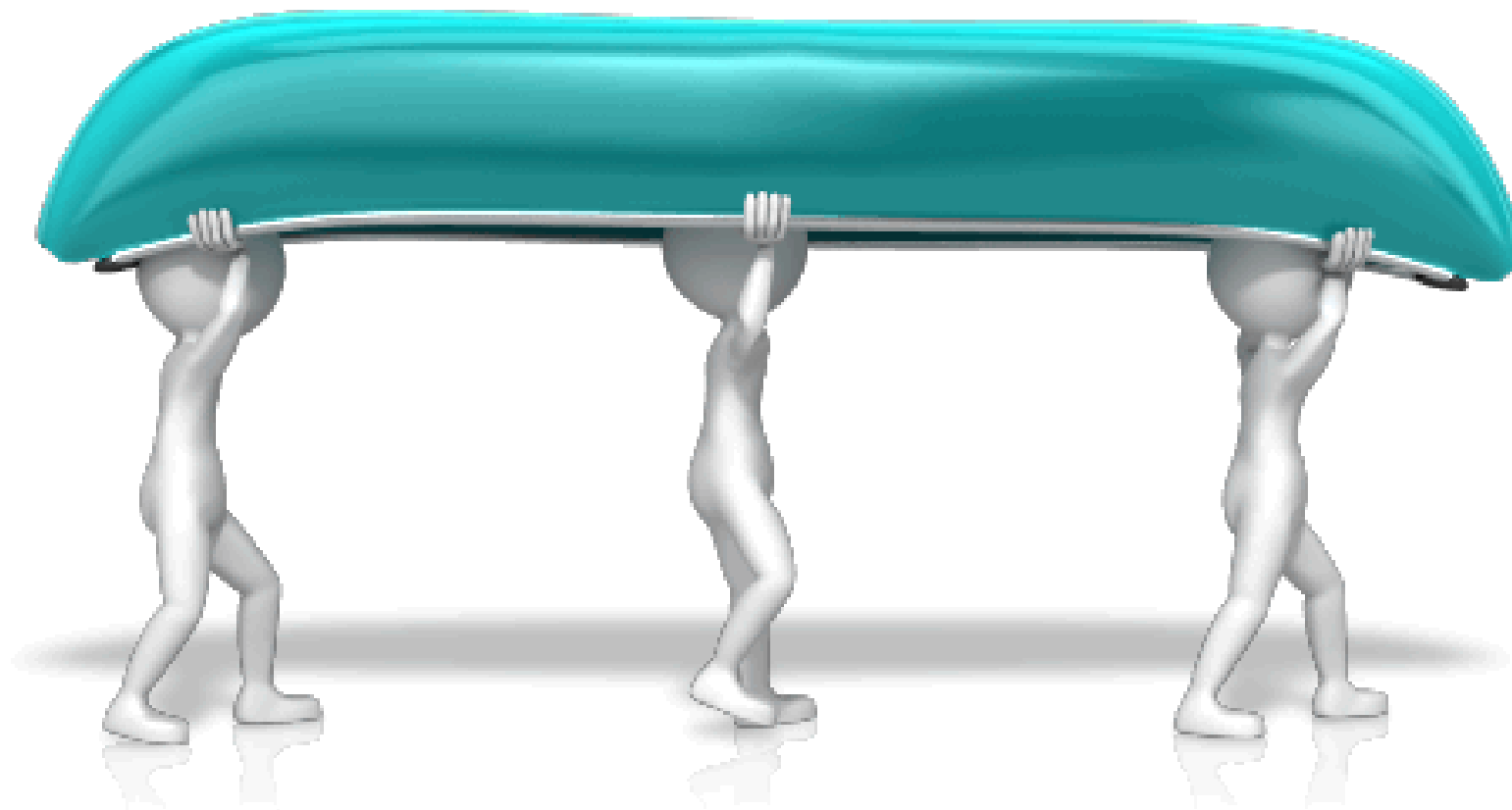
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The way forward

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We are mid-term. Still lot to deliver





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