Up-scaling the global univocal identification of medicines

UNICOM Project: Improve medicinal product data along their life cycle

Christian Hay, Sr. Consultant Healthcare, GS1 Global Office

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

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

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

Positioning the challenge

Inconsistencies

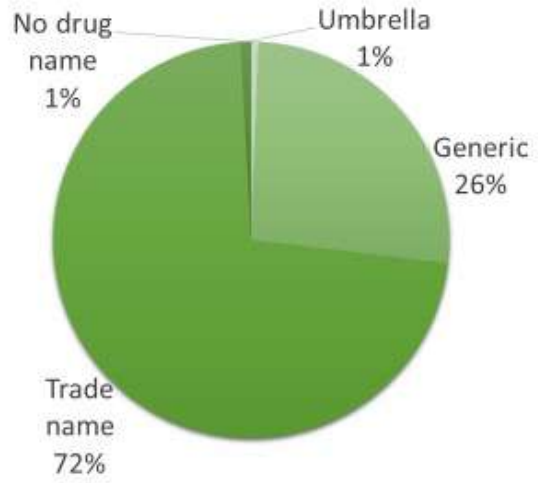
- Pharmacovigilance
  - Same medicinal product
    - ✓ Different name, expression of dosage, pharmaceutical dose form, route of administration
  - Same medicinal product?
    - ✓ What about substance(s)?
- Cross border prescriptions
  - How to identify medicinal products un-ambiguously?
  - How to decide 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?

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

Pharmacovigilance

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%

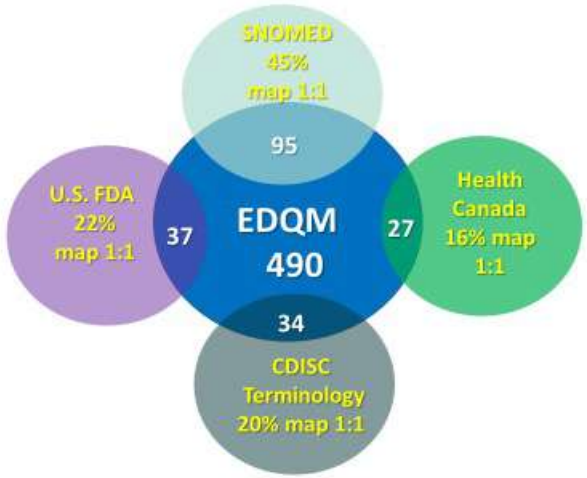
This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Pharmaceutical dose form

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.edqm.eu/).
[2] https://evs.nci.nih.gov/ftp1/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 dataset 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

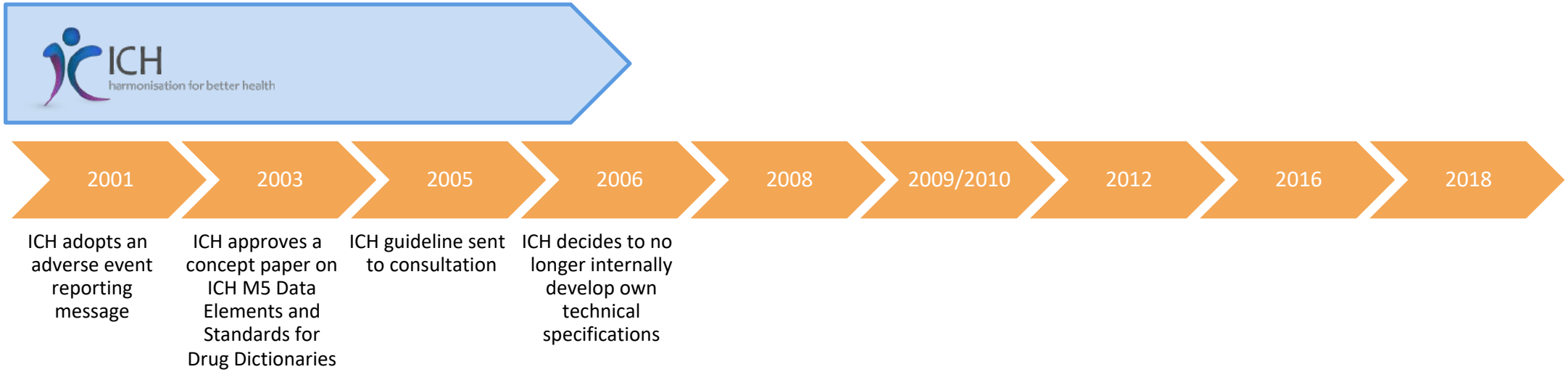
Pharmaceutical Dose Form	Release Characteristics	Intended Site	Administration Method	Basic Admin. Dose Form
Dispersion for Injection	Conventional (0047)	Parenteral (0033)	Injection (0012)	**Dispersion** (0079)
Suspension for injection	Conventional (0047)	Parenteral (0033)	Injection (0012)	**Suspension**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

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

What is IDMP?

IDMP – the origin

Recognise the need to improve adverse event management.

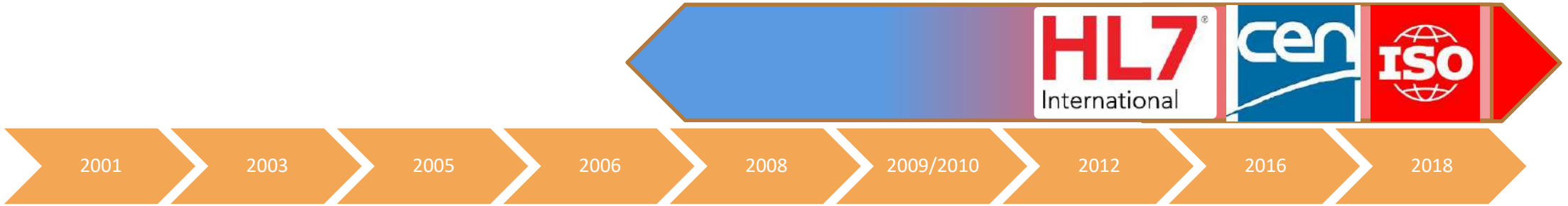


Source: Dr Andrew Marr

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

IDMP – the origin

Recognise the need to improve adverse event management.



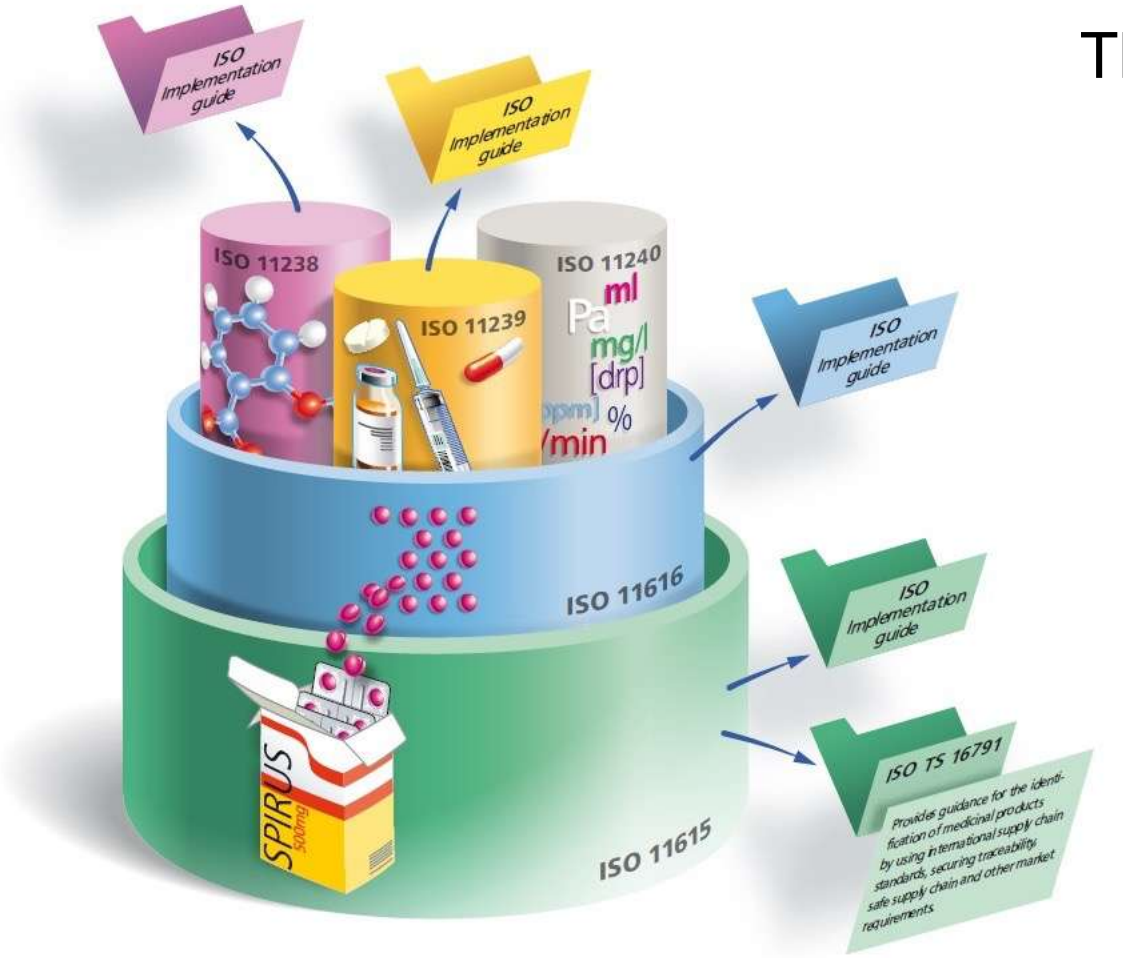
Start work at CEN/ISO

- Ballot: IDMP draft int'l standards
- ICSR published.
- IDMP published (5 standards)
- The wedding cake
- Publication of the revised standards & implementation guides
- Publication revision CEN/ISO 11238 (substances); implementation guide published 2015-2016-2017

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

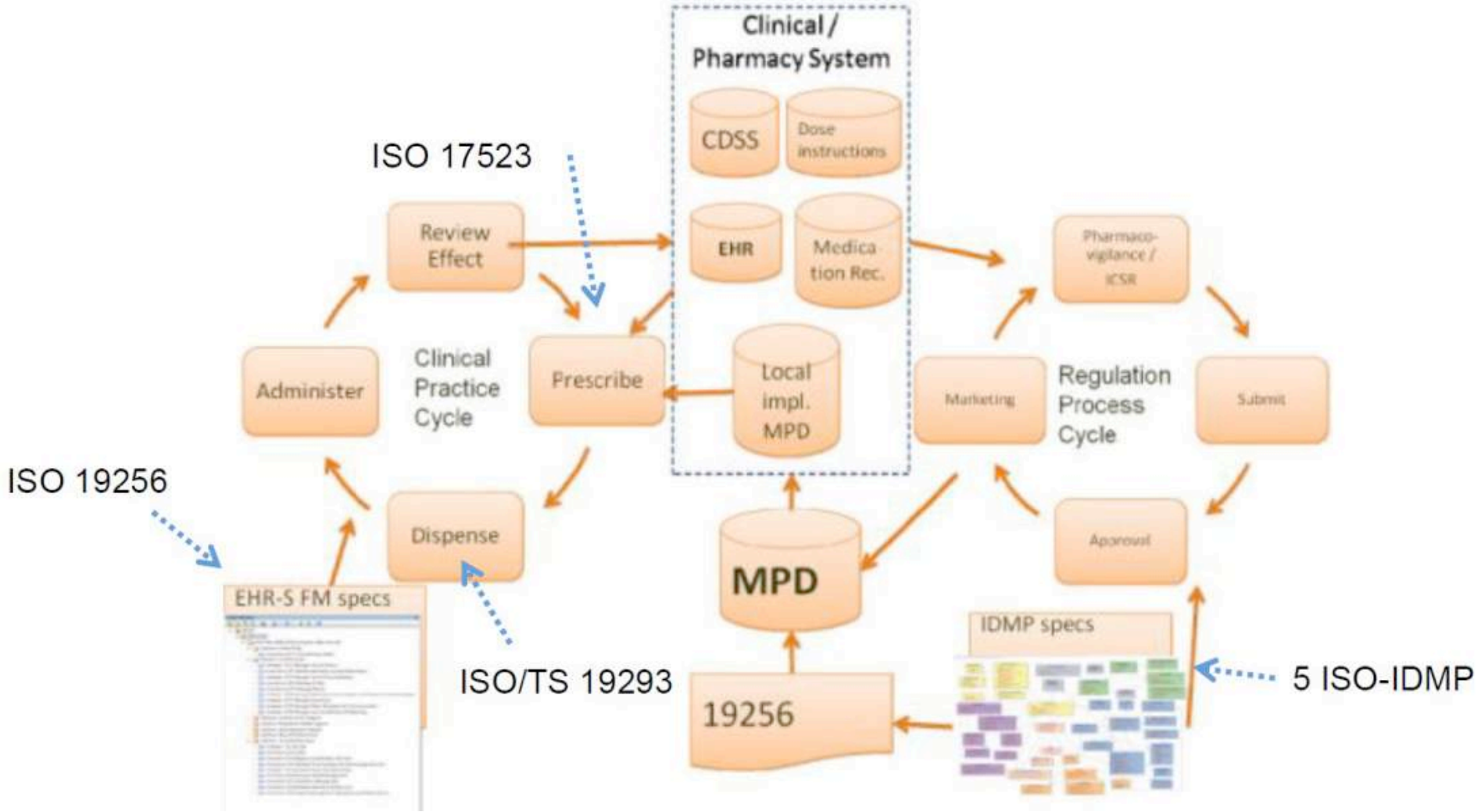
5 Standards, 4 + 1 Specifications, 1 Technical report

The «*wedding cake*»



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

Several relevant ISO standards that point to IDMP



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

UNICOM what it is and which are the stakeholders

The life-cycle of a medicinal product

- Covered by UNICOM and its 13 Work Packages

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

UNICOM, 13 Work Packages (WP)

- WP01 IDMP-related standards and terminologies
  Robert Stegwee - Christian Hay
- WP02 Implementation of IDMP – Substance Management in Europe
  Joris Kampmeijer Annet Rozema (CBG)
- WP03 Pan-European IDMP-compliant application forms
  Georg Neuwirther Noel Diamant (AGES)
- WP04 IDMP implementation at National Drug Agencies
  Pelle Persson (MAP, Sweden), Georg Neuwirther
- 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,** Lucia Comnes, Robert Vander Stichele
- WP09 Medicinal Product Dictionaries and Clinical System Software **Julie James,**
  Dipak Kalra, Ursula Tschorn
- WP10 Socio-economic Impact & Sustainable Legal and Governance Aspects **Rainer Thiel,** Veli Stroetmann, Petra Wilson (Legal)
- WP11 Project management **Arturs Mietulis,** Farah Diehl-Fahim, Veli Stroetmann
- WP12 Overall scientific coordination and dissemination **Veli Stroetmann,** Arturs Mietulis
- WP13 Ethics requirements **Veli Stroetmann,** Petra Wilson

49 Stakeholders

- 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…

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

UNICOM achievements so far : a few examples

Deliverables in UNICOM

91
Deliverables listed on EC portal

158
Deliverables to submit including iterations

32
Deliverables including Iterations approved in First Periodic reporting Sep 2021

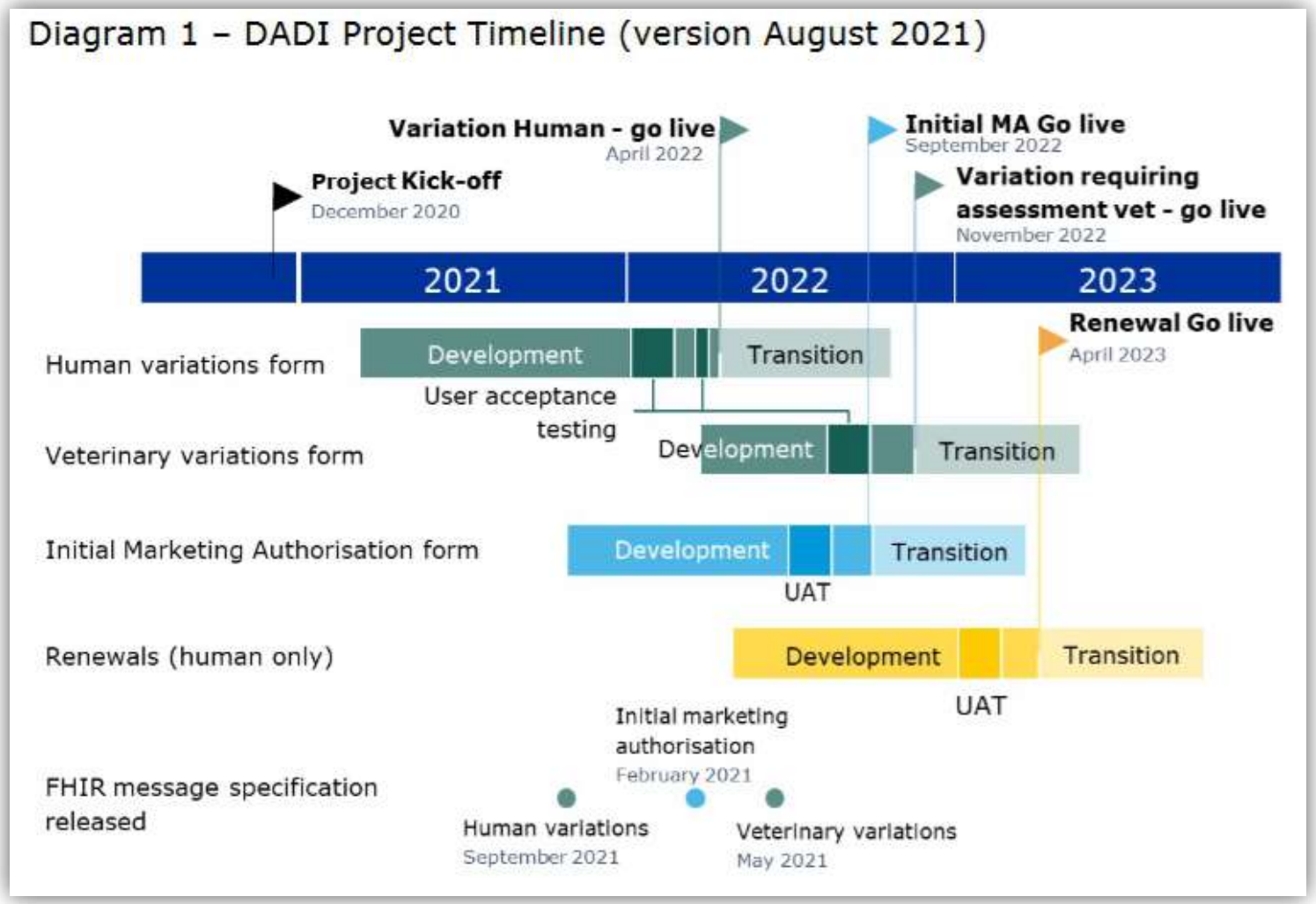
30
Deliverables submitted including iterations

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

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



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

WP5 – IDMP adoption by eHealth Services

- 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

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

WP6 Software and extensions for CEF eHDSI

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

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

WP7 eHDSI cross-border national eHealth services piloting

UNICOM

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

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

WP9 – Medicinal Product Dictionaries and Clinical systems

Main Achievements:

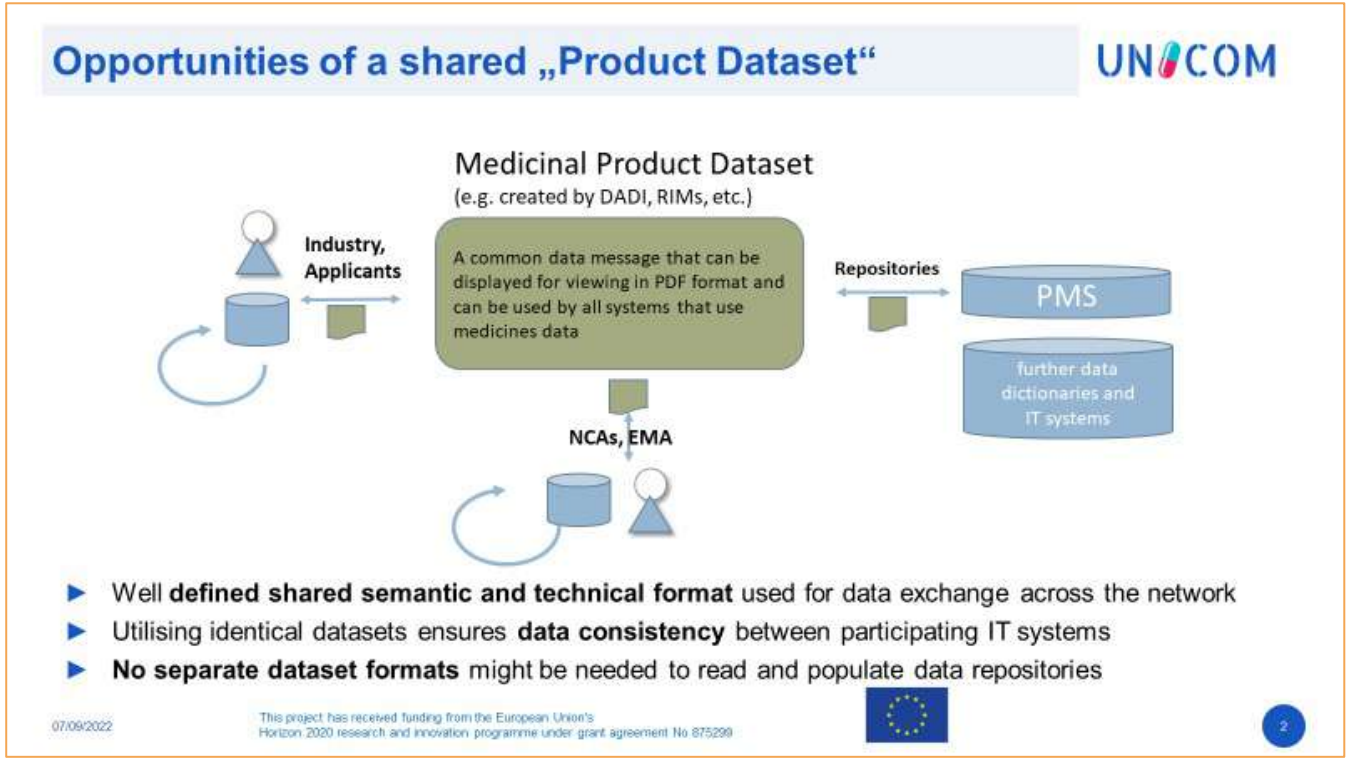
- An analysis of the IDMP medicinal product identification data provided by NCAs (and SPOR) compared to that needed in MPD for clinical care and for secondary uses
- Implementation Guidance for Identification of Medicinal Products (IDMP) in Medicinal Product Dictionaries

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

UNICOM and IHE?

UNICOM @ IHE day: 14 September 2022

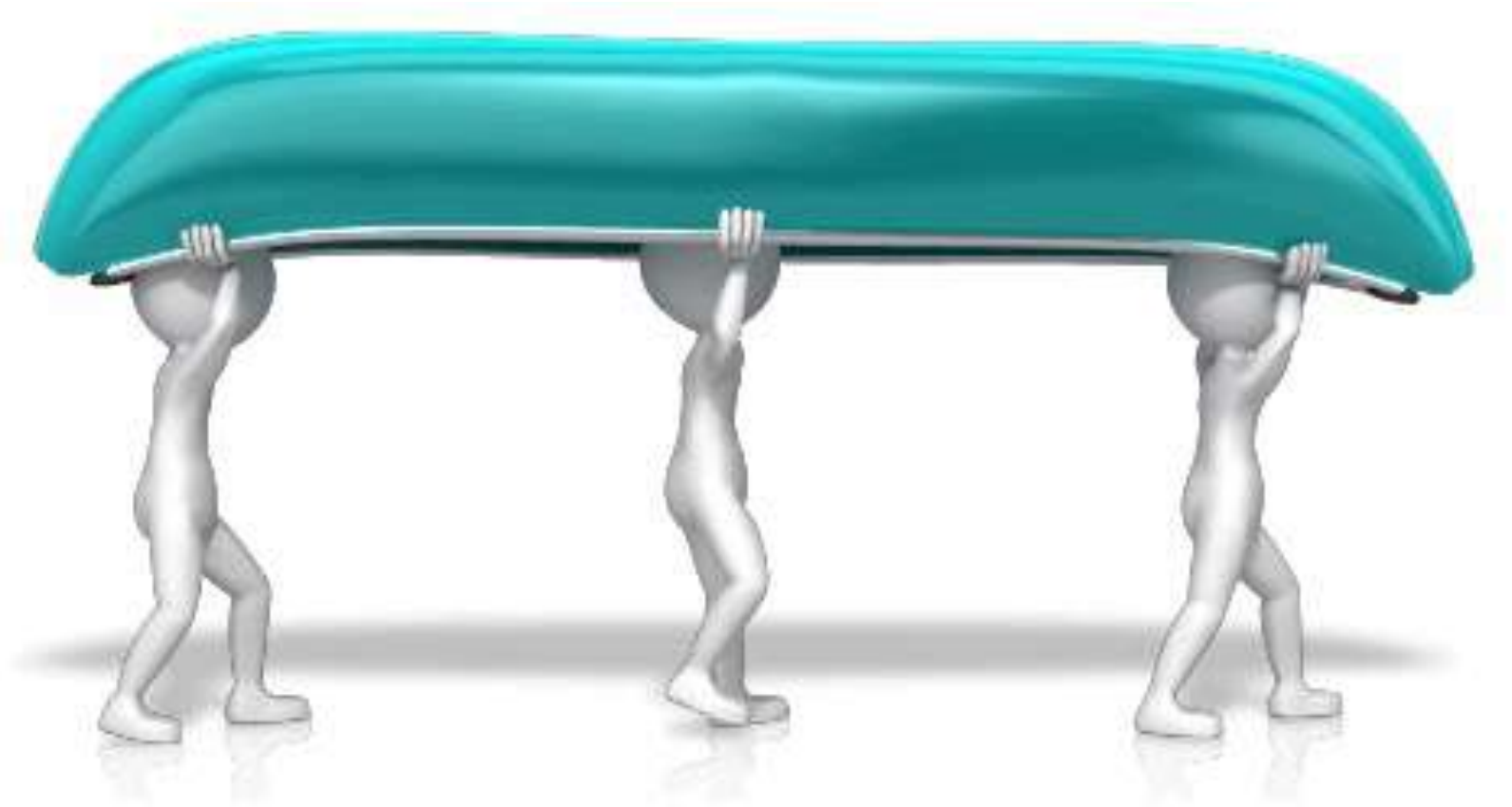
- Raise awareness in the regulatory authorities community
- …and in the pharmaceutical companies
  - … learn how to test systems' conformity to IHE Profiles by using validators and the interoperability between systems or simulators
  - … learn how to test interoperability of software products in a neutral,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



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

The way forward

We are mid-term. Still lot to deliver



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

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

Contact

- www.gs1.org

Christian Hay,
Sr Consultant Healthcare
E: christian.hay@gs1.org
M: +41 76 3691054

GS1 Global Office
Avenue Louise 326
1050 Brussels
Belgium

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