Overview - UNICOM and some of the various associated work packages
International Pharmaceutical Regulators Programme

Christian Hay, February 2021
Who am I?

- Master in Laws, University of Geneva
- Board Swiss Medical Informatics Association
- Teaching Univ. Applied Sciences Bern
- With GS1 since 1991
- Convenor ISO TC 215, WG 6 since 2012
- Deputy lead, UNICOM WP 1
GS1 is a Standards Development Organisation working with others
UNICOM WP 1
IDMP related standards and terminologies

Nictiz

Health Informatics TC251

SNOMED International

EN Heritage

MedDRA

edQM

HL7

IHE Europe

WHO

Uppsala Monitoring Centre

WHO Collaborating Centre for Drug Statistics Methodology
## List of deliverables and tasks responsible

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Understanding where IDMP play
WP 1 : Gap analysis
Gap Analysis about existing and new standards and profiles

- Chapter 6 – Analysis is structured according to 5 implementation domains

Number of gaps and issues:
- Development and Production: 7
- Regulation and Authorization: 18
- Dissemination and Information: 14
- Prescription and Dispensation: 11
- Utilization and Outcome Assessment: 13
Overall process to handle identified gaps

WP-1 to help identify the gaps, analyse their causes and possible solutions

WP-1 to coordinate gap analysis across use cases and implementation domains

WP-1 to hand over to the relevant SDO’s to address an interim and final solution

SDO’s to discuss the identified gaps, with help from WP-1 and other informed experts

SDO’s to formulate a response, including estimated timeline for final resolution

WP-1 to disseminate this response an possible interim solutions within UNICOM

WP-1 to inform and discuss with the Community of Expertise where appropriate
What is expected from the gap-analysis

Deliverable 1.1 Gap analysis is about existing and new standards and profiles structured according 5 implementation domains.
WP 1 : IDMP Logical Model
Need for IDMP Logical Model?

• Was discussed at ISO TC 215 WG 6 in 2017
  - Was premature?
• Current IDMP standards and IG:
  - Conceptual Model or Logical Model?
  - Sufficient for univocal implementation?
  - Appropriate when technology changes (HL7 v3 → HL7 FHIR)?
• What about implementations which are on-going?
  - Logical Model to take this into account (provided information is shared)
• IDMP Logical Model mandatory?
  - As an ISO Technical Specification, to be considered as a reference
How does the logical model relate to conceptual and physical models?

**Conceptual Model** (concepts and relationships)

What data means
Defined concepts and relationships that are used in the real world / universe of discourse
Example: “Patient Identifier: unique value that identifies a single patient or subject of care”

Represented as

**Logical Model** (data elements and relations)

How data is modelled
Structures for how data is modelled, with data elements, groups, relations, cardinality, data types, etc.
Example: Patient.PatientID: 0..1: string

Implemented as

**Physical** (technical specification)

How data is implemented
An actual implementation in a physical system, e.g. a database or a field in a file
Examples: “Patient_ID: VARCHAR(25)”
UNICOM WP 1 deliverable

- «Requirements for a new IDMP Logical Model»
- Requirement to provide the glue between detailed logical models
- Not framed to regulatory processes
IDMP logical model
more detailed logical models
WP 1: Communication
Community of Expertise

- Once a month
- Open to public participation
- Around 100 participants each time – from Japan to Brazil
- Explain:
  - Pilot Product List
  - Gap Analysis
  - Logical Model
  - PhPID calculation
  - IDMP and COVID-19 vaccines
  - 23 March: EU IG v2.0 (SPOR implementation at EMA)
- Recordings on youtube (UNICOM-Europe)
IDMP Handbook

- In preparation
- Target audience: non-specialist reader
- 3 stories
- Quiz for self evaluation
- UNICOM formatting for submission
  - Transposed in a reader-friendly format by Mai 2021
Training - information

- UNICOM does not provide training neither education
- Outside UNICOM, one not-for-profit organisation has been taking the need for training/education into consideration: CTADHL (www.ctadhl.org/training)
Pilot Product List

(transversal)
Requirements (March 2020)

• “Sufficient quantity” of products to support
  - The cross border dispensing pilot of WP7
  - Products “commonly used in primary care” – a small (100-200 set of PhP1s cover roughly 80% of primary care prescriptions – but there will be variations in that set across countries (e.g. which is the statin of choice in a jurisdiction)
  - Examples for the Implementation Guidance for mapping (WP9 D9.4 & D9.5)
• Examples of more challenging products
  - Multi-ingredient products, modified release dose forms etc.
• Cross border dispensing pilot
Substances in the PPL (January 2021)

• Identifying (therapeutically active) substances is one of the cornerstones of identifying medicinal products
• The “list” has been chosen on the basis of
  - The principles of ISO 11238
  - Substances that are very commonly used in patient care (e.g. a statin)
  - Substances that experience has shown are “challenging” (e.g. substances available with a variety modified release dose forms (e.g. an opioid), substances modifications that affect potency – a corticosteroid)
  - Substances that will provide a range of products for the PPL
• Provides identifiers from EU-SRS, EU-TCT, SNOMED CT, UNII, CAS
• Substances have been “cleaned” by the WP2 Substances experts in UNICOM/EU
• Will be worked on in three “batches”
UNICOM PhPID pilot

First phase completed fall 2020

- PhPID for 6 prioritised substances from PPL completed for products from Belgium

Next phase spring 2021

- Remaining 31 substances for products from x countries
Identified data validation issues

Substance

• Hydrates information varies depending on source

Dose form

• Variations in dosage form depending on source: tablet versus coated tablet

Strength

• Some strength hard to define e.g. patches and powder for solution for injection/infusion

• Collaboration with EU IDMP IG v2.0 for defining patterns that express strength for different product types. To be tested in next phase of the pilot, also recalculate some of ID from first phase
Global vaccine process

EU marketed vaccines

US marketed vaccines

Covid-19 vaccines

Global non-confidential data:
- Assigned Global ID and mapping to
  - UNII
  - EUTCT

Assignment solved

Global experts:
- EMA/FDA

Validation

non-confidential data export

Assign Global unique ID without issue

Issue

EMA and FDA expert team
WP 3/4 : National Competent 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 processes 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)
WP 8 : Clinical care, Patients, Pharmacies, Research, Pharmacovigilance
Demonstrators

https://youtu.be/9l54fb4y1FA
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