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
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?
Pharmacovigilance

Identification of drug on ICSRs

Drug names on VigiBase ICSRs

- No drug name: 1%
- Trade name: 72%
- Generic: 26%
- Umbrella: 1%

Identification of drug on ICSR

<table>
<thead>
<tr>
<th></th>
<th>All VigiBase</th>
<th>Reports 2012-2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batch number</td>
<td>18%</td>
<td>22%</td>
</tr>
<tr>
<td>No batch number</td>
<td>82%</td>
<td>78%</td>
</tr>
</tbody>
</table>
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

Findings

Dose Form Challenge

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

<table>
<thead>
<tr>
<th>Pharmaceutical Dose Release Form</th>
<th>Characteristics</th>
<th>Intended Site</th>
<th>Administration Method</th>
<th>Basic Admin. Dose Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispersion for Injection</td>
<td>Conventional (0047)</td>
<td>Parenteral (0033)</td>
<td>Injection (0012)</td>
<td>Dispersion (0079)</td>
</tr>
<tr>
<td>Suspension for Injection</td>
<td>Conventional (0047)</td>
<td>Parenteral (0033)</td>
<td>Injection (0012)</td>
<td>Suspension (0085)</td>
</tr>
<tr>
<td>Solution for Injection</td>
<td>Conventional (0047)</td>
<td>Parenteral (0033)</td>
<td>Injection (0012)</td>
<td>Solution (0083)</td>
</tr>
</tbody>
</table>

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What is IDMP?
Recognise the need to improve adverse event management.

- **2001**: ICH adopts an adverse event reporting message
- **2003**: ICH approves a concept paper on ICH M5 Data Elements and Standards for Drug Dictionaries
- **2005**: ICH guideline sent to consultation
- **2006**: ICH decides to no longer internally develop own technical specifications
- **2008**: ICH guideline sent to consultation
- **2009/2010**: ICH decides to no longer internally develop own technical specifications
- **2012**: ICH decides to no longer internally develop own technical specifications
- **2016**: ICH decides to no longer internally develop own technical specifications
- **2018**: ICH decides to no longer internally develop own technical specifications

Source: Dr Andrew Marr

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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
The «wedding cake»
Several relevant ISO standards that point to IDMP

ISO 17523
ISO 19256
ISO/TS 19293
5 ISO-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 Neuwirther** Noel Diamant (AGES, Austria)
- WP04  IDMP implementation at National Drug Agencies  
  **Pelle Persson** (MAP, Sweden), Georg Neuwirther (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)
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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…
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
Main Achievements:
Gap and requirements analysis for IDMP compatible application forms

DADI Roadmap and Objectives. Going live in October 2022
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
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

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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

Making IDMP real... for patients, clinicians and their systems
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
The way forward
We are mid-term. Still lot to deliver
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