Implementing IDMP to improve patient safety and facilitate better healthcare for all

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WP1 – IDMP related standards and terminologies
Implementing IDMP to improve patient safety and facilitate better healthcare for all

**Agenda for today**

- Problems to be solved
- UNICOM at a glance
- UNICOM aim and objectives
- IDMP Standards and related terminologies
- Landscape of standards use
- Role of SNOMED CT in all of this
- Information about resources available to engage with the project and the outcomes of implementation tests

**Some key terms and abbreviations:**

- IDMP – IDentification of Medicinal Products
  - A set of five interrelated ISO International Standards with four dedicated implementation guides
- ICSR – Individual Case Safety Report
  - An HL7 based reporting standard, including references to IDMP and other terminologies
- ePrescription / eDispensation
  - Current scenarios in the Cross Border eHealth Digital Service Infrastructure (eHDSI) based on IHE profiles and HL7 standards
  - Making use of a Master Value Sets Catalogue to enable safe and automatic translation of clinical terms across borders
Problem to be solved: A simple use case on drug-drug interactions

IF

V-Activ
P单纯力

THEN

MONOCINQUE RETARD

+ + ?

IMDUR 30 mg

EXPRESS BLUE

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
A case of reported side-effects

IF

IS REPORTED TO CAUSE DEPRESSION

WOULD THE SAME PRECAUTION HOLD FOR

?
Or the well-known case of drug substitution

**IF**

**IMIGRAN RECOVERY**

**50 mg tablets sumatriptan**

**ACTS ON THE ROOT CAUSE OF MIGRAINE**

**IS NOT AVAILABLE AT THIS TIME**

**COULD THIS BE SUBSTITUTED BY**

**SUMOXEN**

**50 mg**

**85/500 mg**

**For the treatment of migraine**

**OR**
UNICOM at a glance – an EC supported Innovation Action on the implementation of IDMP standards

- A broad consortium of partners
  - 14 National Competent Authorities for Medicinal Products – including support from the European Medicines Agency
  - 7 National eHealth Competence Centers / National eHealth Contact Points
  - 5 Industry Partners (Health IT)
  - 5 Research Organisations
  - 2 Medicinal Database Providers
  - 8 Standards Developing Organizations

- 4 year program: 2020-2023
- 13 work packages
- 21 M€ total budget

- National implementations in:
  Austria, Belgium, Croatia, Estonia, Finland, Germany, Ireland, Norway, Portugal, Spain, Sweden, The Netherlands
UNICOM aims:

► to break down barriers hindering
► the free flow of
  ▶ detailed
  ▶ semantically coded
  ▶ interoperable
► drug information
► across the globe

UNICOM objectives:

► Implementation of IDMP for Marketing Authorization in EU countries and at EU level
► Adaptation of Member States’ cross-border digital health services to include IDMP (ePrescribing, Patient Summary)
► Exploration and implementation of IDMP in clinical practice:
  ▶ pharmacovigilance reporting
  ▶ medicinal product dictionaries
  ▶ digital health services
The IDMP standards are at the core of the standards and terminologies needed to achieve the objectives.

EN ISO 11238: identification and exchange of regulated information on substances

EN ISO 11239: pharmaceutical dose forms, units of presentation, routes of administration and packaging

EN ISO 11240: identification and exchange of units of measurement

EN ISO 11616 regulated pharmaceutical product information

EN ISO 11615 regulated medicinal product information
The relationship between IDMP and SNOMED CT

Jane Millar, SNOMED International
The use of standards varies across 3 Application fields and 5 Implementation domains.
Use cases requiring interoperability are found at the cross-roads of applications and implementations.
All Standards Developing Organizations will support the use of common identifiers for different purposes.
SNOMED CT can help implement the various IDMP standards with specific parts of the terminology.

There is an Expo session detailing alignment between SNOMED CT and IDMP – 9 October, 1400-1430 UTC.
The SNOMED CT Drug Model is closely related with IDMP
<table>
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<th>Overview of SNOMED CT and IDMP compatibility</th>
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**SNOMED CT**
- Real Clinical Drug (National extension model)
- Real packaged clinical drug (National extension)
- Clinical drug ‘containing precisely’
- Pharmaceutical Dose Form
- Medicinal Product ‘containing only’
- Medicinal Product Form ‘containing only’

**IDMP compatibility**
- Medicinal product – EN ISO 11615
- Packaged product – EN ISO 11615
- Manufactured item – EN ISO 11615
  - Or PhP Level 4 – EN ISO 11616
- Model compatible with EN ISO 11239:2012
- PhP Level 1 – EN ISO 11616
- PhP Level 3 – EN ISO 11616
The involvement of SNOMED International with UNICOM

- WP 1 – focusing on use of IDMP, its implementation with other standards and identification of any work needed on any of the standards to facilitate implementation in the agreed use cases
- WP 8 – contribution to ‘Clinical applications of IDMP’ and ‘IDMP and Pharmacovigilance’
- WP 9 – Medicinal Product Dictionaries and Clinical System Software. Potential areas of SNOMED CT content work and mapping, as the linkage between EHRs and regulation are explored
- Working with SNOMED International member countries who are participating in testing/piloting to facilitate linkage and also inform members globally who are considering implementation of IDMP
- Bringing to the project the maps SNOMED CT to MedDRA and MedDRA to SNOMED CT for reporting of adverse events created as part of the WEB-RADR 2 project.
- Exploring other areas where SNOMED International experience of maintaining, updating and distributing a terminology and its derivatives might facilitate the implementation of IDMP in its link to clinical and the different perspectives as they combine
From a standards point of view an initial Gap Analysis has been published

- Response from a series of workshops and initial appraisals by the users in the various work packages
- Living document, identifying gaps and the way forward to address these through the SDO’s, throughout the project
- Engage with SNOMED International and/or your National Release Centre to get involved

Website unicom-project.eu
Introductory webinars and videos
Educational offerings (in development)
Community of Expertise on IDMP related standards and terminologies – meeting monthly
- Specified topic with introductory speaker(s)
- Open forum for all issues brought forward
- Understanding of (parts of) the standards and terminologies involved is expected

Many more to come ...
- Follow the UNICOM Project on LinkedIn and Twitter

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