WP-1 / 26th community of expertise  
Standards for Safe Medication Data  

8 March 2024  
Moderation:  
Esther Peelen, NICTIZ  
Zain Ishfaq, NICTIZ
SOME RULES FOR THE VIRTUAL MEETINGS
Everybody is on mute
Please post your question in the Q&A facility
Be concise when speaking
You may show your approval!

Question / comment may be shared with Q&A
Participants invited to provide inputs via Mentimeter
Asking a question or making a comment: please use the Q&A facility

1. Move the mouse on the screen to have the options bar appearing

2. You then select «Q&A» and write your question
Showing support and providing a comment on a question or answer

You can support a question by clicking the «thumbs up» which moves it up on the list for the presenters.

You can comment on a question or answer to engage in a conversation.

Typing and sending a new question does not retain the context of your comment.
Security

- Security is our priority
- This session is password protected

Recording of this session is made available on UNICOM’s youtube channel [https://www.youtube.com/c/UNICOM-IDMP](https://www.youtube.com/c/UNICOM-IDMP)

At the end of the virtual session, a questionnaire will be sent to the participants, to help us understand participant’s reactions and needs.
Standards for Safe Medication Data

Community of Expertise, 8 March 2025, 15:00-16:30

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
Introductions to our esteemed colleagues and today's speakers...

Esther Peelen  Robert Stegwee  Christian Hay  Zain Ishfaq

...and panellist: you all!
The nature of WP 1 IDMP related standards and terminologies
Work Package 1 is grouping Standards Development Organisations (SDO) and related organisations, which have a transversal impact on the UNICOM project.

Our main task: to facilitate the implementation of IDMP Data Exchange

- Nearly 100 different standards define, use or should use IDMP in data exchange
- Liaising with all other WPs, to support their needs and provide inputs about standards
Overview of tasks and deliverables in WP 1

Task 1.1 IDMP data exchange (Nictiz/ISO/CEN)

Task 1.2 Activities related to adverse events (SNOMED)

Task 1.3 Activities related to eHealth (HL7 Europe)

Task 1.4 Education and certification (Nictiz/ISO/CEN)

Task 1.5 Testing and assessment (IHE Europe)

Task 1.6 Visibility for standards (Nictiz/ISO/CEN)

D1.1: M6
D1.2: M12
D1.1v2: M18
D1.3: M28
D1.4: M52
D1.5: M18
D1.6: M31
D1.7: M53

Gap analysis
Reqs for Logical Model
Gap analysis
Education
Test Lab
IDMP in a capsule
Demonstrator
Business Plan
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
Our way of working in WP 1

► Everyone at the table

► Share knowledge and experience

► Identify gaps and work towards a resolution within the relevant SDO

► Align within UNICOM/Work Packages

► Implement resolutions in specifications and products across and beyond UNICOM

► Provide a forum for discussion and dissemination
  ▶ IDMP in a capsule,
  ▶ Communities of Expertise
  ▶ UNICOM demonstrator
The essential role of the Gap Analysis
The essential role of the Gap Analysis

- 2020 – before UNICOM kick-off, stakeholders revealed un-clarities and possible misunderstanding about IDMP standards and related terminologies

- Very first task for Work Package 1 to present a gap-analysis engaging all SDOs and Work Packages

- Objective of the Gap-Analysis
  - Document gaps as raised by stakeholders
  - Trigger SDO work to address the gaps
  - Document what SDOs have done in the course of the UNICOM project
Defining a methodology to collect gaps

Adopting the five stages of Medicinal Product life cycle

*With simplicity in mind, the WP 1 team distinguishes five implementation domains:*
Gap analysis was as well fed by a series of 7 virtual workshops (replacing a 3 days meeting cancelled due to COVID)
The highlights of our achievements across the landscape
The landscape extends the five implementation domains with three application fields.
Ensure that any medicine and what it contains can be identified across the landscape

Substance, Dose Form, and Strength and the IDMP Logical Model
Requirements for the IDMP logical model: links to more detailed logical models
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299

IDMP implementation in National Competent Authorities and advancing their connectivity

Substance, Dose Form, and Strength and the IDMP Logical Model

FHIR for submissions

Exchange setup for NCA to MPD and to NCPeH

Clarification of Manufactured Product
Transforming regulatory medication definition data to clinical medication data
Substance, Dose Form, and Strength and the IDMP Logical Model

Ensure that any medicine and what it contains can be identified across borders
Substitution demo developed as part of the UNICOM Test Lab
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299

Supporting safe Dispensing

- Where should the substitution “engine” reside and how will it be governed?
- How should national substitution rules be codified?

Get substitution list:
- Provider fetches list of Dispensation options

Substitution Logic “Engine”... running locally or in a shared service.
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
Ensure that any medicine and what it contains can be identified anywhere in the world

Substance, Dose Form, and Strength and the IDMP Logical Model

- FHIR for submissions
- Cross Border identification in PS and eP/eD
- Exchange setup for NCA to MPD and to NCPeH
- Substitution demo
- Clarification of Manufactured Product
- MPID/PhPID Lookup Function
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
Medication Safety through better information for and from patients

Substance, Dose Form, and Strength and the IDMP Logical Model

- FHIR for submissions
- Exchange setup for NCA to MPD and to NCPeH
- Clarification of Manufactured Product
- Cross Border identification in PS and eP/eD
- Substitution demo
- MPID/PhPID Lookup Function
- Improved ADE Reporting
- ePI in local language through Gravitate Lens

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
Improved ADE Reporting to MHRA using the SNOMED to MedDRA mapping and vice versa

First release April 2021

Development of the maps
MHRA worked alongside SNOMED and the MSSO to help develop the 2 maps.

SNOMED → MedDRA
MedDRA → SNOMED

The maps were developed using the most commonly used terms.

Benefits of the mapping
• Reduced inconsistencies
• Better quality of data
• Streamlined process
• Continual updates

Report documentation:
• Adverse Drug Events (ADEs)
• Medical History
• Lab tests
Highlights of our achievements across the landscape of IDMP

- Substance, Dose Form, and Strength and the IDMP Logical Model

- Development and Production
- Regulation and Authorization
- Dissemination and Information
- Prescription and Dispensation
- Utilization and Outcome Assessment

- FHIR for submissions
- Cross Border identification in PS and eP/eD
- Improved ADE Reporting
- ePI in local language through Gravitate Lens

- Exchange setup for NCA to MPD and to NCPeH
- Substitution demo
- MPID/PhPID Lookup Function

- Clarification of Manufactured Product

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
Moving forward – an Institute for Safe Medication Data (ISMD)
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299

Gap analysis as a pivot between looking back and looking forward

Identification
Based on user experience and expert input
We’ve identified and analysed issues

Resolution
We’ve developed resolutions with users’ advice
Some issues still need resolution

Implementation
Some resolutions have been demonstrated
Some resolutions are implemented in systems

Follow-up
Some resolutions need standards revision
New issues will come up
Who's going to continue the work of WP 1 – setting up a Business Plan

► Working Title: **Institute for Safe Medication Data**

► A way to continue the work of UNICOM Work Package 1 around IDMP related standards and terminologies

► Suggested tasks:

  ▶ Support a Community of Expertise around Medication Data Standards
  ▶ Coordination of ongoing development of Medication Data Standards across SDOs
  ▶ Coordination of issues and resolutions around Medication Data Standards and their use
  ▶ Education on Medication Data Standards and their use in practice
  ▶ Arbitration in cases of disputes on the interpretation and implementation of Medication Data Standards
  ▶ Certification of both products and services, as well as people and organisations
  ▶ Monitoring of adoption and maturity of Medication Data Standards in practice
  ▶ Provide tooling for the tasks above, as well as for the support of implementers of Medication Data Standards
  ▶ ...

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
Input for discussions on the tasks and scope of an ISMD

www.menti.com  2363 3097
Further discussion on an Institute for Safe Medication Data (ISMD)

The tasks and scope of an ISMD
Input for discussion on the structure of an ISMD

www.menti.com 2363 3097
The structure of an ISMD
You are invited!

- 26th April Closing UNICOM meeting in Brussels and Online
Thank you for your participation in this last UNICOM CoE

Please don’t forget to fill out our short evaluation form on Google