Putting resources developed by UNICOM to the test - to your benefit

The conference starts at 09:30

UNICOM Day

Rennes
28 September 2023
Agenda for this Webinar

► Welcome & Introduction

► What is the value proposition of IHE in the context of IDMP + testing tools

► Teams presentations & Open discussion about the use cases and opportunities/challenges about IDMP

► UNICOM Test lab
  ▶ Submission of variations – Robert Stegwee *
  ▶ Updates to the MPD – Zain Ishfaq
  ▶ NCA to NCPeH – Robert Vander Stichele
  ▶ Including substitution in eDispensation – Angela Ferrara
  ▶ Product lookup for patient facing apps – Nicole Veggiotti

► Discussion
Welcome

Alexander and Esther (representing WP1 and WP6)
How the UNICOM Test Lab works

► Scope: work on specific use cases to advance and demonstrate the practical use of the Unicom Assets

► Each use case has been served by one or more teams
  ▶ Each team self organised and worked together to demonstrate and test the use case

► UNICOM Test Lab organisation
  ▶ WP6 provided a technical Helpdesk
  ▶ Each team has (if needed) a dedicated space in Github
  ▶ Each team has been comprised with UNICOM Partners and associated entities (third parties)

► Still open:
  ▶ Other use cases relevant to UNICOM and Third Parties are allowed and welcomed.
  ▶ Collaboration with other projects would be beneficial, e.g. Gravitate Health?
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299

UNICOM Test Lab is about Collaboration and Co-creation

- Monthly Plenary meetings
  - Align tasks: Organize material, Keep track of the progress
  - Additional material required?: Educational material

- Bi-Weekly technical meetings
  - FHIR IG – T6.1 / Substitution Component: What is it? How to use?
  - What is IHE? AOB from plenary: Awareness, Methodology/ test tools

- Ask Anything sessions
  - Interaction with participants: Pool of questions where some are answered in a live session?
  - Live examples?: Tooling or component processes

- Weekly mentorship to teams
  - Support & Guidance: Follow ups
  - Discussion: Questions/needed material

UNICOM TEST LAB Webinar(s)
Roadmap so far

► WP1-WP6-WP12 coordination calls at least once per month
► Plenary Meetings – all participants
  ▶ June 20, 2pm CEST – Kick off organisation
  ▶ July 18, 2pm CEST – Team Goals
  ▶ August 22, 2pm CEST – Progress and open issues
  ▶ September 19, 20m CEST – Progress and open issues -> UNICOM Day

► Educational Sessions on IHE and UNICOM Assets
  ▶ Proposed topics IHE
    ▶ IHE Methodology – how does IHE works?
      • IHE Testing processes – what can we test and how in the next IHE Connectathon in May/June 2024?
      • IHE Pharmacy - how and what to integrate from UNICOM into IHE Profiles

  ▶ Proposed Topics UNICOM
      • UNICOM FHIR IG
      • UNICOM IDMP DB and API
      • UNICOM Test tools
      • GitHub session

► W6 Helpdesk supported teams at any moment with ad hoc teleconferences
WP6 - Helpdesk use – Task 6.6

- Update software artifacts and tools in GitHub
- Track issues and document processes
  - Use Github features for open issues tracking and tasks
- Test lab teams management & support
  - Mentoring Sessions
- Support contact points via email (IHE, DW, GNOMON, ARIA) - WP6 Task Leaders
- Better documentation on the software where required
- **Align** with IHE Pharmacy (UNICOM Profiles/transactions?)
- Align with eHDSI Testing and Waves (WP7)
- Align with Dissemination activities (WP12)
Key messages for today

► Testing the UNICOM resources across the landscape
  ▶ Often N:M testing scenarios – multiple systems need to be interoperable with multiple other systems

► What are we looking for in testing
  ▶ Testing needs across the UNICOM work packages, as coordinated by WP1
  ▶ Coordinating testing tools and methodology, as provided by WP6
  ▶ Testing interoperability scenarios between UNICOM resources and the systems they need to talk to
  ▶ Testing conformance to IDMP and related standards and terminologies
  ▶ Define what could be tested in a future Connectathon --> 2024
  ▶ Define what need to be adopted by IHE Pharmacy

► What comes next?
  ▶ Ghent meeting
  ▶ 2024?
What is the value of IHE in the context of IDMP + testing tools

Derek Ritz
Agenda for this section

► Unpacking: “What is the value of IHE in the context of IDMP + testing tools”
  ▶ What does IHE “do”?
  ▶ What are the component workflows to adopting IDMP in Europe?
  ▶ How will an IHE-supported collaborative lab add value?
► Brief overview of IHE’s role in the digital health standards ecosystem
► Brief overview of the IHE Methodology and its resulting artefacts
► High level “superset” list of our UNICOM use case participants
► Connecting the use cases into a UNICOM data pipeline
► Implications for the Test Lab and its value proposition
► Q&A
What role does IHE play in the digital health SDO ecosystem?
What role does IHE play in the digital health SDO ecosystem?
How does IHE play this role?

Domain Committees
Radiology
IT Infrastructure
Pharmacy
Quality, Research & Public Health
Cardiology
Devices
Eye Care
Dental
Pathology and Laboratory Medicine
Radiation Oncology
Patient Care Coordination
Dental

Deployment Committees

Create engineering artefacts.


boring
What is the **value proposition** in creating **boredom**?

**Scale** is the innovation.
Maybe we at IHE should change its marketing “tag line”…

Taking all the fun out of digital health for over 20 years.
What is the IHE Methodology and how does it help?
There are **three** key pillars to the Methodology.

1. **IHE Profiles** (implementable actor-transaction specifications)
2. **IHE reference models** (technical frameworks defined in Gazelle)
3. **IHE conformance assessment** (testing events)
IHE Profiles follow a prescriptive format and governance process.
In Volume-1, the **use case** is described in simple terms.
In Volume-2, **actor-transactions** are unambiguously defined.
In Volume-3, **data content definitions** are normatively documented.
It is possible to have a **content-only** IHE Profile.
Volume-4 contains *regional* or *national* constraints on the *global* spec.
Pillar 2 is **reference models**. These are built from the **IHE Profiles**.
The **models** can be thought of as **assemblies** of Lego® blocks.
Their *boringly* engineered dimple patterns means blocks **fit** together.
The reference models are described in IHE Gazelle.
Software solutions operationalize one or more building blocks.
Engineering events can be leveraged to **iterate** the reference models.

**Gazelle** as an instrument of *innovation*.
Pillar 3 takes these events a further step – to **conformance** testing.

**Gazelle** as an instrument of **governance**.
Products that pass the tests “fit” with the framework.

**Gazelle** as an instrument of governance.
Products that are **non-conformant** are identified and told what to **fix**.

**Gazelle** as an instrument of **governance**.
This process ensures conformant solutions **plug-and-play**.

**Gazelle** as an instrument of **governance**.
Key takeaways

IHE’s mature processes give us a way to take IDMP to **scale** in Europe.

IHE does **not** define new standards. The IHE Methodology is employed to describe how a portfolio of standards are **implemented** to support **interoperability**.
What are our component IDMP workflows and how do they “connect”? 
We leveraged a “template” to help us define IHE Volume-1 content.
We explicitly reference supporting or complementary UNICOM artefacts in our use case descriptions.

Sequence diagrams leverage a consistent participant list, so we can see how our use cases “fit together”.

A checklist of relevant content created consistency across use cases.

<table>
<thead>
<tr>
<th>Section</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Name of the UNICOM use case</td>
</tr>
<tr>
<td>Title description</td>
<td>1-sentence description of the UNICOM use case</td>
</tr>
<tr>
<td>Title version # and date</td>
<td>Update these for each iteration of the document</td>
</tr>
<tr>
<td>Profile Introduction</td>
<td>Fill in the use case name (highlighted in yellow)</td>
</tr>
<tr>
<td>Vol-1 : Introduction</td>
<td>One or two sentences to describe the UNICOM use case workflows; similar to title description.</td>
</tr>
<tr>
<td>Vol-1 : Overview : Concepts</td>
<td>Leverage content developed in the Antilope form to populate a description of the use case context and its business importance.</td>
</tr>
<tr>
<td>Vol-1 : Overview : Participants</td>
<td>List and describe the relevant participants in the use case. NOTE: these should correspond to the participants in any use case sequence diagrams.</td>
</tr>
<tr>
<td>Vol-1 : Overview : Content</td>
<td>List and describe artefacts / documents exchanged by the workflow participants.</td>
</tr>
<tr>
<td>Vol-1 : Overview: References</td>
<td>List complementary or supporting UNICOM documents, deliverables, and/or artefacts</td>
</tr>
<tr>
<td>Vol-1 : Use Case : UC-#</td>
<td>Number and name each use case</td>
</tr>
<tr>
<td>Vol-1 : Use Case : UC-# : Introduction</td>
<td>Briefly introduce the use case</td>
</tr>
<tr>
<td>Vol-1 : Use Case : UC-# : Sequence diagram</td>
<td>Use a diagramming tool to illustrate the use case as a sequence diagram; the participants should coincide with those already described.</td>
</tr>
<tr>
<td>Vol-1 : Use Case : UC-# : Narrative description</td>
<td>Describe the use case diagram; include important notes related to pre- and post-conditions.</td>
</tr>
<tr>
<td>Test Plan : Introduction</td>
<td>Use the gherkin syntax to describe a set of normative, testable scenarios based on the defined use case(s).</td>
</tr>
</tbody>
</table>
Across **all** our UNICOM use cases, **who are the participants?**
Across **all** our UNICOM use cases, **who are the participants?**

We want to list the **systems**... and we need to know **who are the relevant **humans**.**
Across **all** our UNICOM use cases, **who are the participants?**

**Pan-European humans**
- Pharmaceutical Company
- EMA

**Humans in Country-A**
- Patient (*domiciled in Country-A*)
- Provider of care
- National digital health agency*
- MPD governance authority*
- National Competent Authority

**Humans in Country-B**
- Provider of care
- National digital health agency*
- MPD governance authority*
- National Competent Authority

**Pan-European Systems**
- Pharma Company's database
- SPOR

**Systems in Country-A**
- Patient's app
- Provider's app
- National EHR*
- NCPeH (eHDSI gateway)
- MPD
- NCA's database*

**Systems in Country-B**
- Provider's app
- National EHR*
- NCPeH (eHDSI gateway)
- MPD
- NCA's database*
What are the governance relationships between systems and humans?

- **MPD governance and scope** seem to differ from MS to MS.
- Sometimes the MPD is governed under the auspices of the NCA, sometimes under the **national digital health agency**, and sometimes there is a separate MPD entity.
- Also... sometimes the MPD is a library, used to regularly update provider applications... and sometimes it is a real-time OLTP service that includes medicines substitution logic.
5 UNICOM use cases

Submission of variations
NCA-MPD
Cross-border eP/eD
Patient-facing apps
NCA-NCPeH
5 UNICOM use cases

Submission of variations

NCA-MPD

“Setup” Activities

NCA-NCPeH

“Runtime” Activities

Cross-border eP/eD

Patient-facing apps
If we connect our use cases, we start to see our **UNICOM data pipeline**.
There is a predecessor-successor relationship between our use cases. Elements of our “data pipeline” must be set up before our care delivery (“runtime”) use cases are doable.
To mitigate risk, we’ve been working to create test data to support use cases that rely on a pipeline that is **not yet in place** (UNICOM T6.1).
What does this tell us about our Lab’s value proposition?
The Lab’s value chain starts well *in advance* of conformance testing.

- **Innovation**
- **Implementability**
- **Governance**
The Lab’s value chain starts well *in advance* of conformance testing.

- **Innovation**
- **Implementability**
- **Governance**

We want to **collaborate** with the relevant stakeholders as early in the process as possible so that the **use case definitions** are correct.

We want to **prototype**, where we can, to ensure we “**want the right things**” from our technology solutions. We’re actively doing this, for example with **FHIR** community members.
The Lab’s value chain starts well *in advance* of conformance testing.

**Innovation**
**Implementability**
**Governance**

*Scale* is the innovation.

We need to involve *industry players* *early on* to ensure our normative IDMP specifications can be widely adopted and deployed.
The Lab’s value chain starts well *in advance* of conformance testing.

When the time comes, we will leverage the lab to *conformance-test* digital health solutions.

Member states can reference test result evidence as a requirement in solution *procurement* documents.
Test lab use cases

High level
Submit an application

Updates to the MPD

NCA to NCPEH

Substitution in eDispensation

Patient-Facing Apps
Company A disposes of Marketing Autorisation for «Sweetdreams», a medicinal product sold in country A. An excipient has to be replaced by another. This information is communicated to the local NCA with a structured electronic message (HL7 FHIR). Local NCA acknowledge receipt of the information with a structured electronic message (HL7 FHIR).
The use case consists in:

- Company generates FHIR message with right information (right data regarding substance ID).
  • NCA received and manages incoming structured message without alteration

  • NCA sends acknowledgment structured FHIR message to Company

  - Company receives and manages incoming message without alteration
NCA in country A publishes updates on authorized medicinal products to all MPD providers in country A. Newly authorized medicinal products need to be added, canceled authorizations need to be removed. The current authorized list of medicinal products for country A need to be integrated in the MPDs across the country. The NCA provides the detailed updates to the MPD providers in an electronic format (FHIR). MPD providers each acknowledge receipt and processing of these updates with an electronic message (FHIR).

For consideration:
MPD provider needs to propagate the changes in the authorized medicinal products to the clinical systems - Pharmacy Information Systems, Electronic Health Record Systems, Medication Management Systems, etc.
The use case consists of:

- NCA compiles the changes to be communicated in a FHIR bundle (fully updated and identified medicinal products)
- MPD receives FHIR bundle without further alteration
- MPD processes the changes and flags any inconsistencies in e.g. product identification in its own database
- MPD provides feedback to NCA on receipt and processing of the updates provided in a FHIR bundle
- NCA receives acknowledgement and processes the feedback provided

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
This use case is about aligning the work done in NCAs with the subset of IDMP attributes needed for the cross border eP/eD.

The idea is to analyse and propose a approach to automate this process as the MALeH will evolve between different waves of the MyHealth@EU services.

The assets provided for this use case are:
- The semantic assets defined in D6.4
- The IDMP database and database API provided in D6.1

The scope of this use case is to synchronise the medication list used in cross border with the NCA list with the use of IDPM.
Use case: Substitution in eDispensation

What if:
a Greek patient shows up in a Belgian Pharmacy and requests to be dispensed for αμλοδιπίνη Κάψουλα σκληρή 10mg

By identifying the IDMP data on the box, the pharmacist realizes that this about amlodipine,
and more specifically:
amlodipine besilate capsule, hard 10mg

In Belgium available as: Amlor 10 mg (Upjohn), and in generics by a number of companies but as tablets
Use case: Substitution in eDispensation

The use case consists of:

- Two countries participating in eHDSI
- Cross-border exchange of enhanced ePrescription with ISO IDMP attributes (MALeH)
- Country B, country of eDispensation, applies the substitution rules and national rules if required
- Country B, sends back to Country A the updated CDA of eDispensation

- Teams created for this use case to take into consideration the testing strategy and testing processes of eHDSI (WP7)
Mario travelled to Greece for a trip and forgot to take his medication to treat hypertension with him. He uses a patient-facing app to manage his medication while communicating with a pharmacist in a foreign country.

The use case consists of:
• Usage of the Smart Substitution component
• Access through FHIR API to IDMP Database
• Mobile application interaction
Submission of variations

Robert Stegwee
Submission of variations

Purpose: to support the investigation of future interoperable use of the variations web-based electronic Application Form (eAF) for Human medicinal products in the EMA PLM Portal, as co-developed with UNICOM WP3 (former DADI project). The creation of the variations eAF by applicants could reuse the already existing structured data in their internal systems. The processing of the variations eAF by receiving NCA's is being implemented (WP4) but could benefit from multi-stakeholder testing.

Context: MP Data in Europe

Process: regular CAP and NAP submission

Main contact: Robert Stegwee
Added benefits

► Future actions on the roadmap:
  ▶ Replace forms for initial marketing authorisations (human and veterinary), variations for veterinary medicinal products and renewal forms (human only) for CAPs and NAPs
  ▶ Support data cleansing in collaboration with PMS
  ▶ Explore further machine-to-machine solutions

► Re-use structured data to decrease re-keying and subsequent errors
  ▶ From applicant to create eAF, to be included in dossier
  ▶ From applicant to EMA in CAP submission
  ▶ From applicant to NCA in NAP submission

► Re-thinking the processes to eliminate and automate steps
  ▶ Enable streamlined and simplified processes, with automated data imports facilitating procedure handling by regulators
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
Further contact with the Pistoia Alliance on the creation of FHIR excerpts for submission based on the IDMP Ontology that they are creating

- The IDMP Ontology will enable industry partners to provide their internal data in an IDMP compliant format
- By creating FHIR excerpts for submission, based on the IDMP Ontology, industry is supported in the implementation of FHIR for IDMP
- IDMP Ontology group is looking into alignment with the UNICOM FHIR IG (linked to the IDMP Database in WP 6)

Future testing scenarios are likely to include:

- RIM electronic submission to NCA in HL7 FHIR format (RIM – Regulatory Information Management)
- RIM receives submission response from NCA in HL7 FHIR format
- IDMP Ontology is used to feed product and publishing data to RIM in HL7 FHIR format
- IDMP Ontology is used to make HL7 FHIR response available to internal (product and publishing) systems for checking
Questions and next steps
Update to the MPD

Zain Ishfaq and Esther Peelen
Purpose, benefits and involved stakeholders

► **Purpose**: to support the accurate and efficient sharing of medicinal product data via the National Competent Authority to the Medicinal Product Dictionary for further distribution in clinical systems by using IDMP

► **Benefits**: reuse of high-quality data including IDMP-identifiers. Results in less (manual) updating: more efficiency and more accuracy.

► **Role of IHE**: based on a harmonised process description, IHE-profiles can be drafted for testing the standardised process including standardised data for a seamless and automated dataflow

► **Process description set up in cooperation with Z-Index, CBG. Vidal**

► **And with the help of the material made by WP9, material shared by Rutt Lindström and the insights of the people involved with the UNICOM day.**

► **Main contact**: zain.ishfaq@nictiz.nl esther.peelen@nictiz.nl
Substance Management Services (SMS)

Product Management Services (PMS)

Organisation Management Services (OMS)

Referentials Management Services (RMS)
National Competent authorities

Definition:
medicines regulatory authority in a European Union member state that, according to the legal system of that member state, is responsible for the granting of marketing authorisations, clinical trial authorisations and manufacturing authorisations for medicinal products.
Definition:
System that is specifically designed to support the prescription, dispensing and administration of medications in healthcare based on an accurate listing, description and identification of medicinal products.
Example of a problem

Our crossborder nightmare

**OZEMPIC**: 1 pen of 3ml, 4 needles.

Pack size differs by country:

- Finland: 1 pen
- Estonia: 4 doses
- Portugal: 3 ml

*SmPC* text: One ml of solution contains 1.34 mg of semaglutide*. One pre-filled pen contains 4 mg semaglutide* in 3 ml solution. Each dose contains 1 mg of semaglutide in 0.74 ml solution.
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
Dataflow NCA to MPD
Data in NCA systems

1. Example 1: Losec Control 20mg gastro-resistant tablets

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
ISO IDMP on FHIR challenge
How to build a bridge from regulatory data to clinical?

Dataflow from regulatory to clinical data space
Update use case NCA to MPD – IHE volume 1 Use-case analysis

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

Question:
- Should we assume and take as a starting position that IDMP-compliant model
- Is there added benefits in making a content specification between NCA to MPD
- Or should MPD's be tasked with the capability to request the data needed
- Would the MPD's want the NCA's to have a certain terminology system
Delivery of validated data on national medicinal product packs, compliant with IDMP, from the National Competent Authority for Marketing Authorization to the National eHealth Contact Point

Robert Vander Stichele
USE CASE Purpose and Context

► Purpose:

▶ To test the willingness National Competent Authorities for Marketing Authorization to validate a minimal dataset of Medicinal Product Pack data, compatible with IDMP for the Minimal Attribute list

► Context:

▶ The EU is organising a massive infrastructure for cross-border services for ePrescription, eDispensation, and PatientSummary.

▶ This is coordinated by eHealth.

▶ The member states are invited to create National Contact Points for eHealth (NCPeH), able to send and receive prescriptions and patient summaries. A calendar has been established where each country indicates the timeframe for participating in this endeavour.

▶ In order to function well, these National Contact Points for eHealth must be in possession of validated information on the national medicinal products in IDMP-compliant format and compliant with the eHealth HL7 CDA Template adopted in MyHealth@EU.
Validation by NCA of the minimal data set, produced by MPD or eHealth, and centrally standardized to IDMP

- The National Competent Authority for Market Authorization (NCA) decides to participate with a collection of all medicinal product packs for 4 substances: amlodipine, carbamazepine, ibuprofen, simvastatin.

- This collection is provided by UNICOM, as the result of a collaboration with the local MPD or eHealth Organisation, and of Central standardization to IDMP.

- The NCA validates the available data from the UNICOM T6.1 database on the (selected) national medicinal product packs, with regard to compliance with IDMP for the Minimum Attribute List (MAL). (including report on procedures of validation).

- The resulting data set is analysed for quality of IDMP implementation and for correctness of codes (EDQM, ATC, SPOR, UCUM).
Implicated countries

► Italy

► Greece

► Belgium
Participants

► Lead
  ▶ Robert Vander Stichele

► Members core team
  ▶ Members from Italy, Greece, Belgium
  ▶ Members from HL7 and WP5

Interested persons from other countries can join, by writing an email to robert.vanderstichele@ugent.be
Minimal Data Sets for testing implementation of IDMP

Inititally focussed on 4 substances
(amlodipine, carbamazepine, ibuprofen, simvastatin)

Focussed on Minimal Attribute List (UNICOM D5.7)
Approx. 20 IDMP variables per National Medicinal Product Pack

Aimed to support:
Use cases in UNICOM TESTLAB;
Pilots in UNICOM;
Pre-testing Cross Border Services

To be extended gradually to:
The UNICOM Pilot Product List (35 substances)
The eHSDI Critical Test Data (additional 5 substances)
The WHO Essential Medicines List (300+ substances)
All Substances (3000+ substances)
Origin of the draft Minimal Data Set submitted to validation

- Internal draft by content experts of the NCA
- Export from the authentic source of medicines, Centrally standardised in UNICOM
- Export from a national Medicinal Product Dictionary, Centrally standardised in UNICOM
- Export from a Testfile, developed by eHealth, Centrally standardised in UNICOM

Draft sample of Standardised national Medicinal Products Packs
Draft sample of Standardised national Medicinal Products Packs

Internal Validation by NCA

Validated sample of IDMP-compliant National Medicinal Products Packs

EMA SPOR Terminology services

National Competent Authority for Marketing Authorisation
Director Business operations/
Director ICT/
Pharmaceutical expert
Integration with the IHE testing Process

- Starting to identify the relevant institutions and humans in the process of validation of IDMP implementation

- Get the minimal data sets ready

- Fill in the IHE Use Case Template
  - Complete Volume 1: Use Case Description
  - Complete the test plan
    - Choose the countries
    - Get the test data
    - Apply the data quality requirements
Conclusion of the initial phases of this use case

► This use case does not fit into the IHE approach to testing of semantic interoperability of transactions between actors.

► It is more a quality control process that needs to focus on content quality of data, produced within one organisation.

Working with the IHE testing methodology in its initial phases was considered very instrumental for the further development of this quality control program.
Renewed focus of this use case for assessing the quality of medicinal product data

a) Are all authorised and marketed medicinal products packs for the 4 substances present in the database?

b) Are all medicinal products correctly standardized to IDMP?
   a) Is the right substance modifier (if any) chosen for each product?
   b) Is the right EDQM administrable dose form chosen?
   c) Are the business rules for expressing strength correctly applied?

c) Are the correct EU-SRS, EDQM, UCUM, ATC codes used?

d) Are the correct SPOR codes present?

Can we formulate concrete requirements for each of these aspects of quality of data?
Renewed purpose of the use case

- Create a set of requirements for testing the quality of IDMP implementation
  
  ▶ For internal testing of data sets provided by third parties to NCAs
  
  ▶ For internal testing of data sets internally created by NCAs
  
  ▶ For external testing of trusted data provided by NCAs
Note: Perspectives on a further use case

Survey of the transfert process of validated Medicinal Product Data from NCA to NCPeH

- A survey will be sent to The National Competent Authority for Market Authorization (NCA), already participating in data transfert to the NCPeH, requesting information on:
  - Protocol of transfert process
  - Sample of data sent by NCA to NCPeH
  - Sample of data used by NCPeH as used in the cross border pilot services

- Sample of data used by NCPeH could be tested for Quality of IDMP implementation, Semantic Interoperability, and extent of coverage of medicinal products
Two methods for transferring “Trusted Data” on Medicinal products From the National Competent Authority for Marketing Authorisation (NCA) to the National Contact Point in eHealth (NCPeH)
**National Competent Authority for Marketing Authorisation**
Director Business operations/
Director ICT/
Pharmaceutical expert

**Draft sample of Standardised national Medicinal Products Packs**

**Validated sample of IDMP-compliant National Medicinal Products Packs**

**Validated sample of IDMP-compliant Medicinal Products Packs in HL7/CDA**

**National eHealth Contact Point**
ICT-expert in Semantic Interoperability

**Mechanism of transfer of trusted data**

**EMA SPOR Terminology services**

**eHSDI Master Value Set**

**Internal Validation by NCA**

**Integration of trusted data by NCPeH**
Questions and next steps
Cross-border / Including substitution in eDispensation

Marcello Melgara, Angela Ferrara & Luca Garbarino
Including substitution in eDispensation

Purpose

This use case aims to facilitate the exchange and Cross-border dispensing of ePrescriptions enhanced with IDMP attributes between two countries, Country A and Country B.

It seeks to facilitate patients' access to medications while adhering to substitution rules and national regulations in the country of dispensation.
Including substitution in eDispensation

Context:

The use case operates within the context of eHDSI, which entails healthcare collaboration across international borders among participating nations.

Non Technical Factors

- Legal
- Regulatory requirements
- Privacy and data protection

Country B

Substitution Rules

Main contact: angela.ferrara@intelleraconsulting.com

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
The functional process flow prerequisite is that Country B should have a complete list of IDMP compliant medicinal product packages for ePrescription medicines, so that the substitution module can work properly.
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
Participants and timeline
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299.

Including substitution in eDispensation

Participants

Use Case Subscribed

<table>
<thead>
<tr>
<th>Name</th>
<th>Surname</th>
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</thead>
<tbody>
<tr>
<td>Alexander</td>
<td>Berler</td>
<td>Gnomon Informatics</td>
</tr>
<tr>
<td>Kostas</td>
<td>Karkaletsis</td>
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<tr>
<td>Jose</td>
<td>Costa Teixeira</td>
<td>IHE</td>
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<td>Alexandros</td>
<td>Staridas</td>
<td>IDIKA S.A.</td>
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<td>Robert</td>
<td>Vander Stichele</td>
<td>I-hd</td>
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<tr>
<td>Haralampos</td>
<td>Karanikas</td>
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This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299

**Timeline**

- **END OF AUGUST**
  - Test labs
  - extended group meeting webinar

- **1° WEEK OF SEPTEMBER**
  - Foster participation and registrations to the use case

- **2° WEEK OF SEPTEMBER**
  - Send to participants the credentials for the Italian ePs generated, for pre-event testing purposes.

- **28 SEPTEMBER**
  - Discuss and show results
Cross-border/Including substitution in eDispensation Unicom
Assets & Results

Resources produced by UNICOM
Including substitution in eDispensation

Results

Poland
- 31/03 10:00 CET
- PL2IT(NCPNPH80A01H501K)

Cyprus
- 28/03 1:30 CET
- Crossed out
- Planned 07 Apr 2023
- CY2IT(NCPNPH80A01H501K)

Croatia
- 29/03
- Green check
- HR2IT(NCPNPH80A01H501K)

Ireland
- 31/03
- Green check
- IE2IT(NCPNPH80A01H501K)

Greece
- Green check
- For the drugs of eP test, eD in the Greek context

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<tr>
<th>eHDSI value set (MVC 6.1.0) + coding system</th>
<th>SPOR-RMS list name</th>
<th>EMA IG 2.1 attribute name (Preferred in RED)</th>
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<td>Authorised Pharmaceutical Form</td>
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<td>Manufactured Dose Form</td>
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<td>Administrable Dose Form</td>
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<td>Strength (Concentration single value or low limit)</td>
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<td>Routes and Methods of Administration</td>
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<td>Anatomical Therapeutic Chemical classification system – Human</td>
<td>ATC code(s)</td>
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<td>Substance</td>
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<td>Marketing Authorisation Holder (Organisation)</td>
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<td>Product Management Service Identifier (PMS ID)</td>
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<td>Packaged medicinal product identifier (PCID)</td>
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<td>Pharmaceutical Product identifier (PhPID)</td>
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</table>
Product lookup for Patient-Facing Apps
Use Case
Request to renew a medication on the Medication List from a patient from Country A in Country B

Nicole
Use case: Test Lab benefits and value propositions

- **Instrument of Innovation**
  Participants can share (or discover) important insights related to the practical aspects to realize IDMP-empowered digital health workflow
  Thanks to the developed applications
  Ground testing regarding digital health systems in Europe will inform the best directions to reach new solutions

- **Instrument of Implementability:**
  The work of the lab is to move from theory to practice
  For IDMP to go to scale, the change management and related specifications need to be practically implementable
  The lab adds value upstream of conformance testing and helps highlight interoperability specifications

- **Instrument of Governance**
  The lab will provide a trusted conformance-testing service
  Testing capacity enables EU Member States to exercise governance over digital health actors to ensure their ability to interact with each other in the service of patient care workflows that depend on shared health data
Use case: PFA & HCPA applications benefits for end-users

The solution provided by the UNICOM project can represent a useful and necessary tool to help and facilitate travelling citizens’ lives and protect their health, eliminating barriers and personal fears of forgetting their medication at home and discontinuing their therapies.

It presents benefits both for patients and healthcare providers.

Patient’s health is safeguarded, since they gain information on the medications they take, no matter where they are. Moreover, their new applications are demonstrably interoperable and meet national and EU specifications. HCPs in foreign countries can see all this information, and so they are put in a position to rationally and safely dispense the medication with awareness about the safety and health of foreign patients.
Use case: purpose and relevance

This use case represents a pilot within the UNICOM Project to test the usefulness of ISO/CEN IDMP standards for the univocal identification of medicinal product in a private sector real-world scenario.

This use case aims to demonstrate the possibility for patients from Country A who are abroad without their medicine to obtain a similar substitute medicine in Country B, in order to safeguard their health and ensure their adherence and continuity of treatment.
Application for users
Patient-Facing Apps (PFAs)

Three applications are provided to patients:
Pharmawizard4UNICOM, eHealthPass and InfoSAGE

All present the same functionality:

✓ Ability of **searching for medicine** to gain information about it
✓ Ability of **adding medicines** to patients’ Medication List
✓ Ability of selecting a medication from the Medication List to be refilled
✓ Ability of **creating a medicine data QR code** to be shown to the HCPs abroad to make them able to find a substitute drug
✓ Ability of **adding the identified substituted drug** to the Medication List via the QR code generated by the HCP app.
Patient-Facing Apps aim to **empower patients’ access to medicinal information** and **find substitute drugs abroad**, adding them to their Medication List.

An important purpose of these applications is to provide patients with information about the medications they are taking, put them on their personal medication list, and have a secure tool with them when travelling abroad to find the similar medications in a foreign country.

This is possible because the apps are integrated with the **IDMP Database**, developed in Task 6.1, and the **Substitution Component**, developed in Task 6.2.
Application for users
Patient-Facing Apps (PFAs) - Medication List

The apps carry the Medication List and minimal clinical data of the patient in the local language and with the local Medicinal Product Dictionary.

The Medication List is IDMP-compliant, so that can produce for each medicine on the list:

- ✓ the Pharmaceutical Product Identifier (label PhPID)
- ✓ the substance with the role of precise active ingredient
- ✓ the granular EDQM administrable dose form
- ✓ the normalized expression of strength
With the **Patient-Facing App** the user is able to:

- **Create a Medication List**
  - The patient saves Medicinal Products on his/her mobile device

- **Generate QR codes for the Healthcare Provider App**
  - To communicate with the pharmacist (dispenser) about the drug to be substituted

- **Add substitute drugs to the Medication List**
  - To record pharmacist’s chosen medication on the app
PFAs communication module

Welcome & onboarding

List of actions: Medication List, QR code reader

Medication List: add medications

Generate QR

Generated QR code

Healthcare provider app

Read QR

Cam opened with QR code reader

Add the new drug to the Medication List

Medication List: add medications

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
One interface is provided to healthcare professionals (physicians, pharmacists..), with the following functionalities:

- **Scanning** the Patient-Facing App generated QR code
- **Connecting to the Substitution Component of the UNICOM server** to get a list of equivalent or similar drugs from which to choose the most appropriate medication
- **Generating a new QR code** containing the substitute drug data and information to be sent back to the Patient-Facing App
Other interesting functionalities present in the interface are:

- Language settings (currently Italian and English)
- Font scaling and contrast management
- Substitution country settings

Application for users
Healthcare Provider App (HCPA)
Application for users
Healthcare Provider App (HCPA) - Software components and architecture

The HCPA is developed in Flutter and consists of two basic components:

A. **Substitution Manager**: an application module responsible for the integration of APIs with the Substitution Component.

B. **Filter Manager**: an internal component of the Substitution Manager making it possible to filter the results obtained by the Substitution Component

These two components combined with the UNICOM backend enable drug substitution between different countries.
With the **Healthcare provider app** the dispenser (or prescriber) is able to:

- **Scan FPA-generated QR codes**
  - To obtain a list of similar medications and their characteristics

- **View the medications the patient is currently taking**
  - Thanks to a Medication-IDMP Multilanguage Representation

- **Consult a list of potential substitute medications**
  - To select the best substitute medications for the patient

- **Generate a QR Code to be sent back to the PFA**
  - Improved results with search bar & filters
  - To inform the patient with the chosen medication’s characteristics
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299.
The system back-end architecture consists of two main systems

A. **FHIR server** exposes the APIs for:
   - ✓ the IDMP to get medicinal data
   - ✓ Medication suggestion component

B. **Substitution component module** to get data on substitutions of the identified drug for different countries
Use Case basic scenario

A. A patient from Country A, travelling to Country B can select a medication from the Medication List that needs refilling and present the corresponding QR code to the healthcare provider in Country B.

B. The HealthCare Provider Application (HCPA) can read the PFA-generated QR code, to send information via API to the UNICOM T6.1 database and receive back a list of similar medications available in Country B, applying the local substitution rules.

C. The healthcare provider makes an informed choice and provides the patient with the identifier of the chosen medication (and its labelling information) via an HCPA-generated QR code to be sent back to the PFA.

D. The patient from Country A can now gain information about the similar medication available in Country B.
Data represented via JSON (JavaScript Object Notation) format provide Patient-Facing and Healthcare Provider Applications with the ability to read or generate medication identification.

The medication key will correspond to the PhPID label of the user-selected medication.

The substitution key will correspond to the PhPID label of the substitute medication selected by the healthcare provider.
A. **Patient from Country A:** a user with the Patient-Facing Application (PFA) in need for a medication refill in Country B

B. **Healthcare provider (HCP) from Country B:** a dispenser (pharmacist) able to hand over the information of the equivalent medication to the patient and possibly dispense an OTC medication or a prescriber (physician) who can prescribe an equivalent medication, according to the local rules (Country B local rules)
Use Case basic scenario – patient's journey

A. Selection of the medicinal product for which a refill is needed
B. The PFA connects through an API with the IDMP database and retrieves the IDMP description of the national Medicinal Product from Country A.
C. PFA-generated QR code
D. Capture of the request for refill by the HealthCare Provider App (HCPA), which sends an API request to the FHIR server, requesting equivalent medicinal products from Country B
E. The FHIR server sends back the information to the HCPA
F. List of similar medicinal products, described both with national identifiers and labels and with international IDMP Ids and labels
G. After the selection of the best equivalent medication, the HCPA generates a QR code to be sent back to the PFA
H. PFA reads the HCPA-generated QR code and integrates the equivalent medicinal product to the existing Medication List
Our patient

The use case presented involves Haris

- Male
- 45 years old
- 90 kg
- 175 cm
- Hypertension

Patient medication list: 
Amlodipine 5mg 1DDD (Brand Zocor) to treat hypertension
During an unexpectedly extended stay in a foreign country, the patient is in need of a **refill** of **amlodipine**. He shows the pharmacist the **QR code** for the drug needed.
During an unexpectedly extended stay in a foreign country, the patient is in need of a refill of amlodipine. He shows the pharmacist the QR code for the drug needed.
The pharmacist recognizes that the medicine comes from a foreign country. Thanks to the HCPA, he/she can identify the similar medicine marketed in his/her country. He/she shows the patient the new drug.
The patient scans the pharmacist's QR code and add this drug to the Medication List.
The patient scans the pharmacist's QR code and adds this drug to the Medication List.
Questions and next steps

T8.3  
IDMP and Patient Empowerment Apps

25 PATIENTS

PILOT

4 ACTIVE INGREDIENTS

AMLODIPINE
CARBAMAZEPIN
IBUPROFEN
SIMVASTATIN

D8.6 DEMONSTRATION OF PATIENT EMPOWERMENT APPLICATION

D8.10 RESULTS OF PERSONALISED MEDICINE PILOT (T8.5) (FORTH)

T7.5
Pilot deployment and operation (ARIA)

Patient Empowerment Application validated with about 500 patients

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Questions and Answers – further discussion
Thank You!

And don't forget to register for the UNICOM Test Lab meetings and the UNICOM Day on 28 September 2023