The Global Language of Business

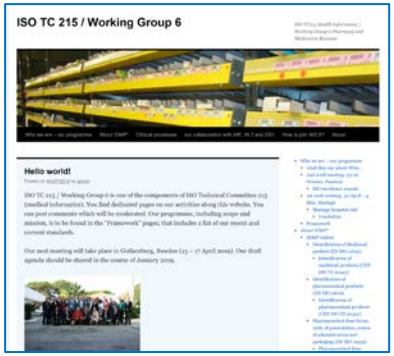
Overview - UNICOM and some of the various associated work packages

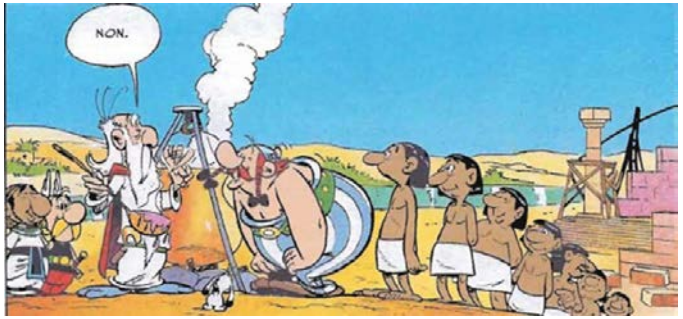
International Pharmaceutical Regulators Programme

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

List of deliverables and tasks responsible

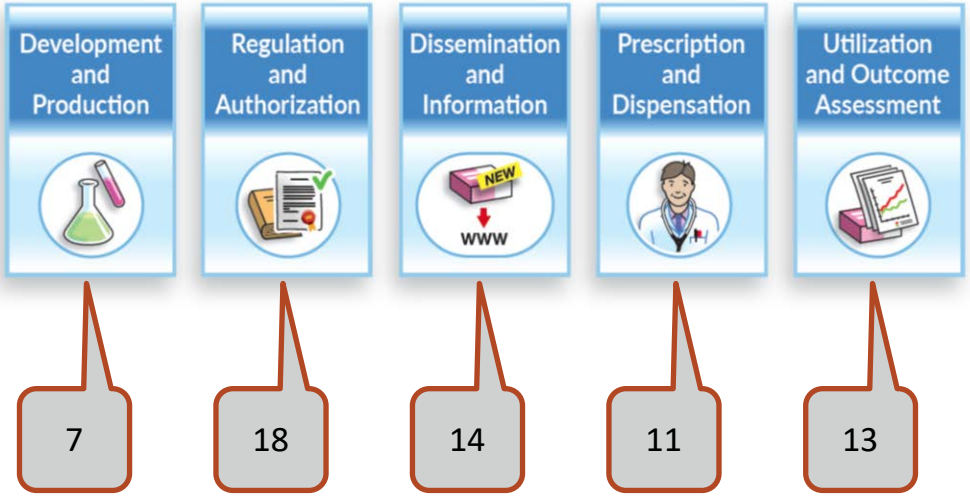
Deliverable Number	Deliverable Title	Lead beneficiary	Type & Dissemination level	Due Date (in months)	Task responsible
D1.1	Gap analysis about existing and new standards and profiles	NICTIZ	Report Public	6	NICTIZ/ISO
D1.2	Requirements for a new ISO logical model [platform independent]	NICTIZ	Report Public	12	NICTIZ/ISO
D1.3	Report on education and certification programs	NICTIZ	Report Public	16	NICTIZ/ISO
D1.4	Report on testing profiles, projectathons IDMP-rel. data exchange	IHE	Report Public	46	IHE
D1.5	ISO IDMP Handbook *for dummies*	NICTIZ	Report Public	18	NICTIZ/ISO
D1.6	Develop demonstrators, including videos	NICTIZ	Demonstrator Public	24	NICTIZ/ISO
D1.7	Business plan for IDMP Community of Expertise	NICTIZ	Report Confidential	36	NICTIZ/ISO

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



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

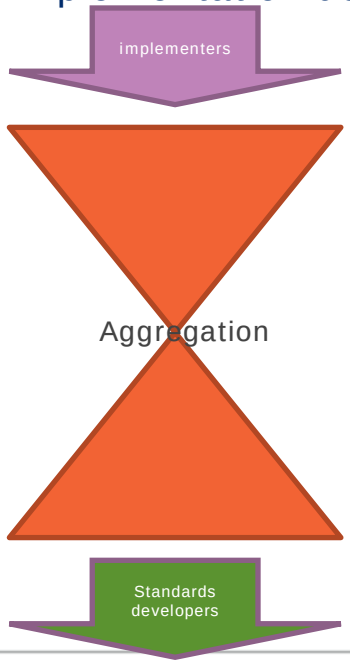
SDO's to formulate a response, including estimated timeline for final resolution

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



UNICOM Work Packages
Interactive sessions
webinars “community of expertise”

*SDO involvement
Inventory of standards
Link requirements to SDO(s)
Tentative to set priorities
Communicate Gap-Analysis to SDO / SDO working groups
Follow-up tasks

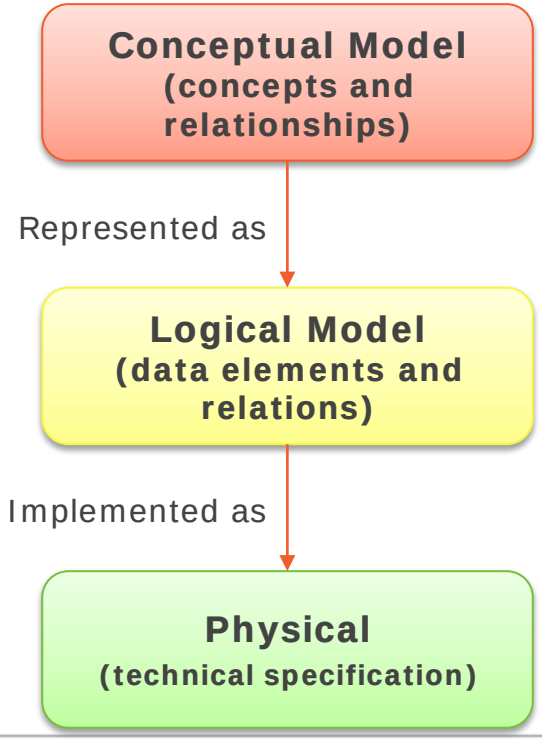
Receive input from Gap-Analysis
Discuss, (in-)validate
Feedback to UNICOM WP-1
Integrate into standards when appropriate

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?



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"

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

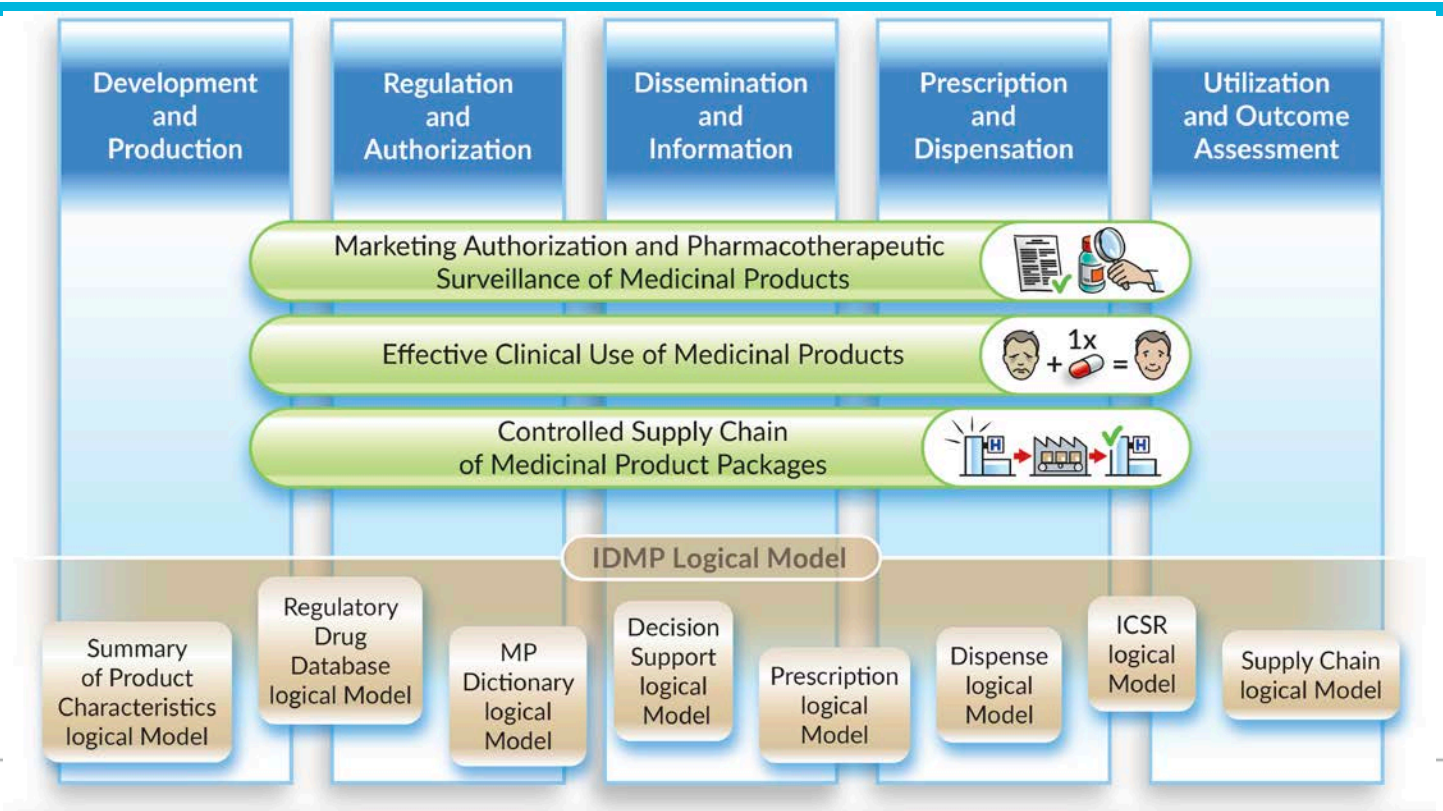
How data is implemented

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

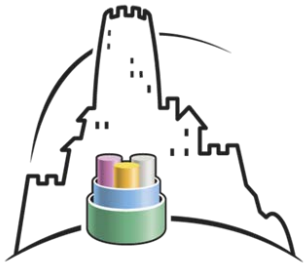
- Once a month
- Open to public participation
- Around 100 participants each time – from Japan to Brazil
- Explain:
  - Pilot Product List
  - Gap Analysis
  - Logical Model
  - PhPID calculation
  - IDMP and COVID-19 vaccines
  - 23 March: EU IG v2.0 (SPOR implementation at EMA)
- Recordings on youtube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

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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

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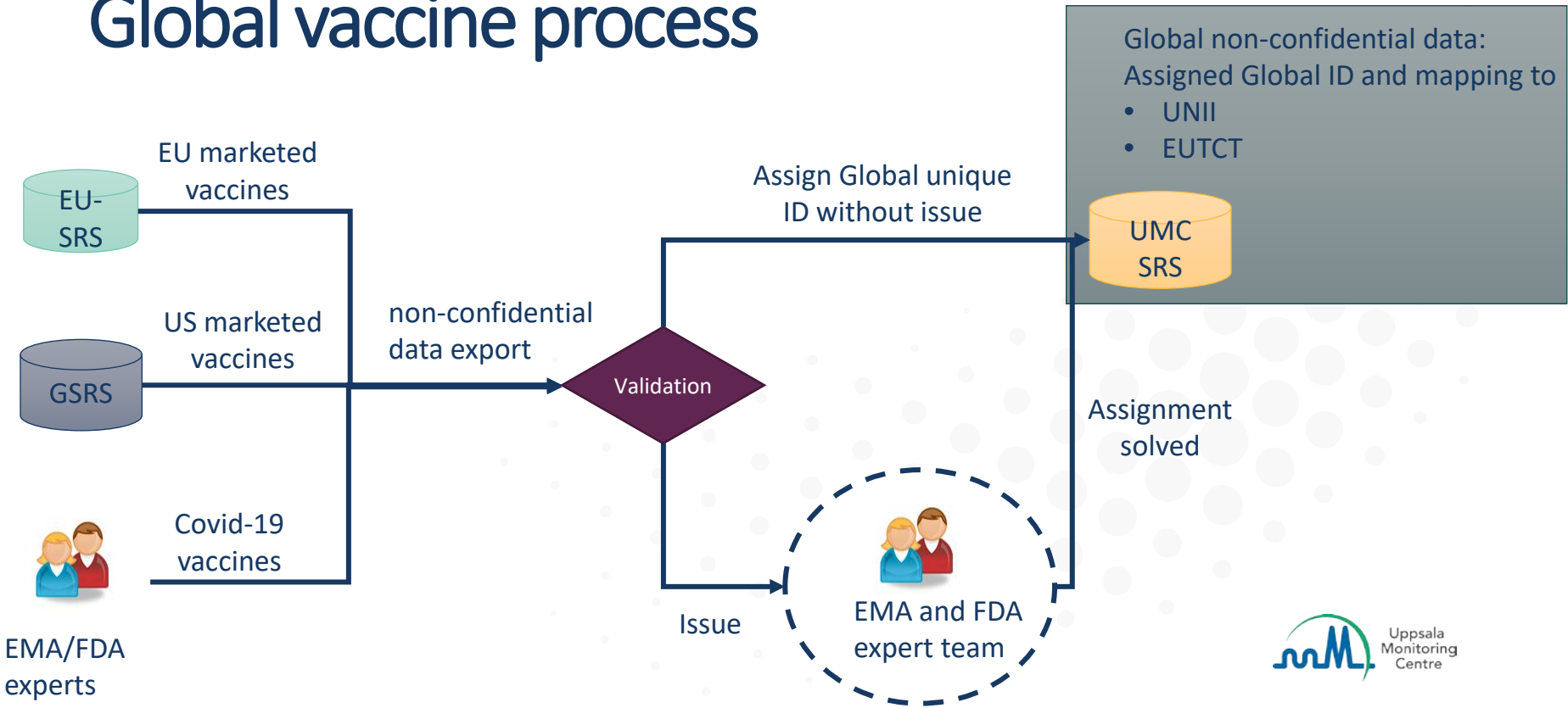
Global vaccine process



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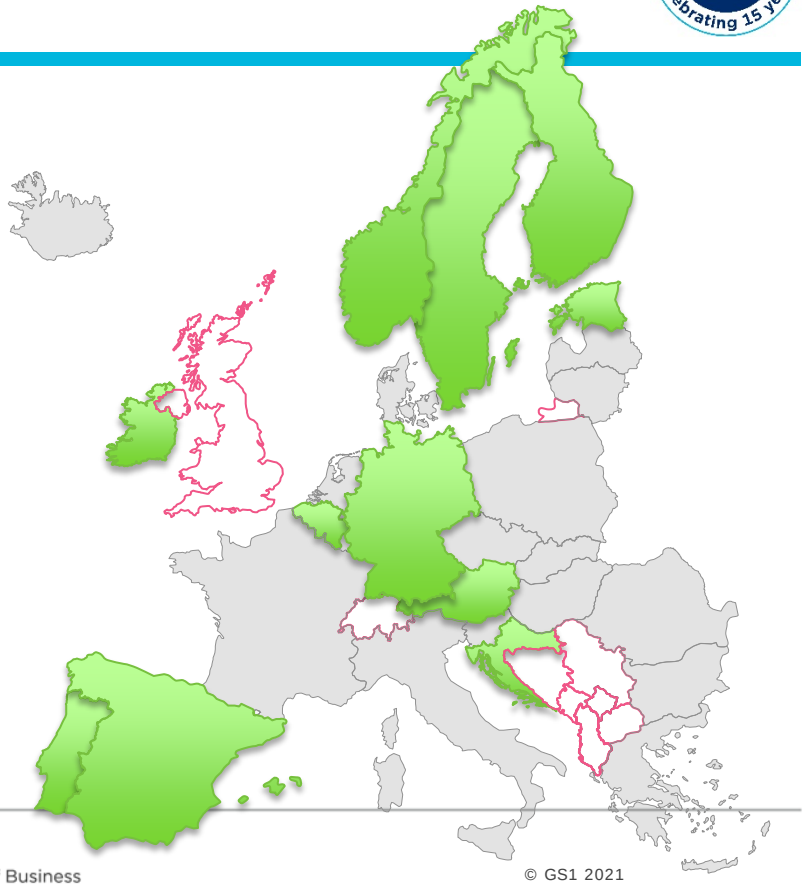
WP 3/4 : National Competent Authorities

Cooperation of National Medicines Authorities

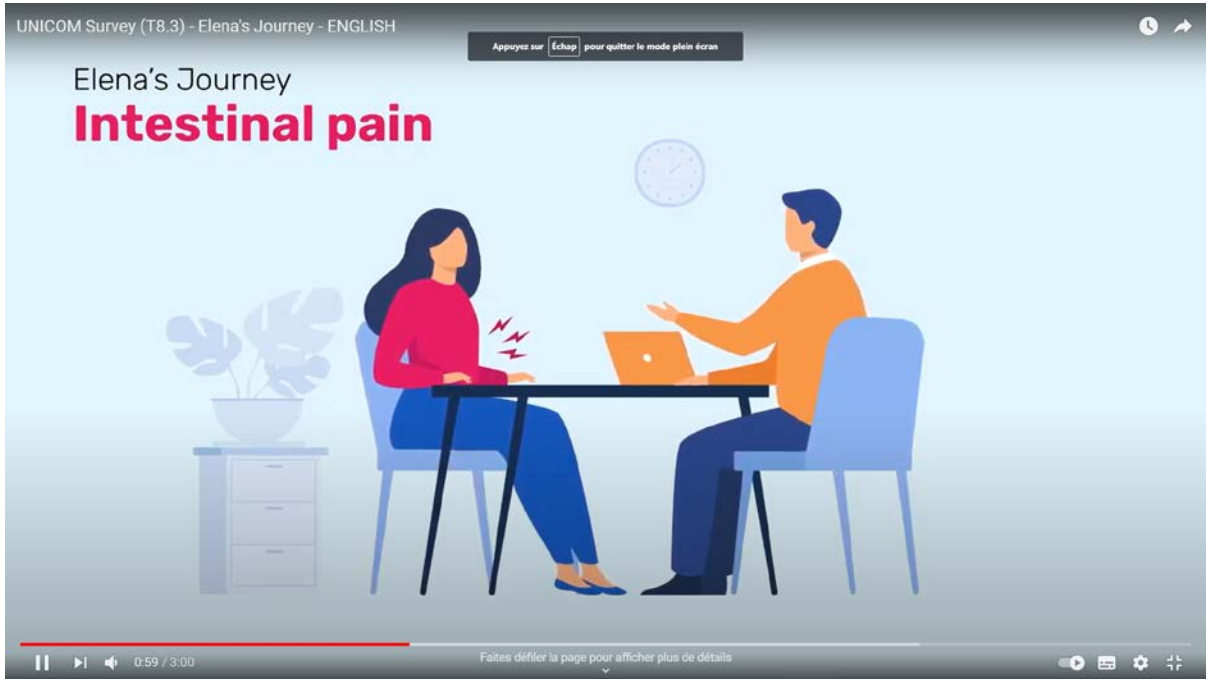
11 National Competent Authorities are working together to implement IDMP in their medicinal products related IT systems

Vision: With compatible IT systems and regulatory processess 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

Contact

Christian Hay,
Sr Consultant Healthcare
E: christian.hay@gs1.org
M: +41 76 3691054

GS1 Global Office
Avenue Louise 326
1050 Brussels
Belgium

www.gs1.org