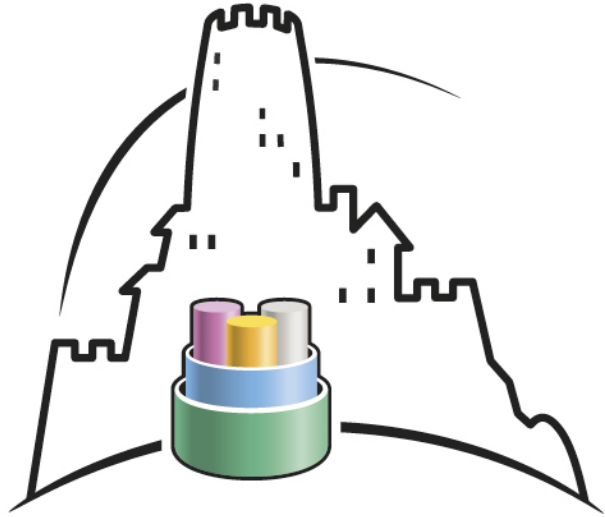


CTADHL (Citadel) Stakeholder meeting

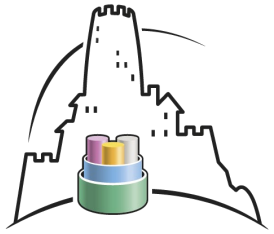
Call to Action – Delivering Data and Health Literacy

16th of November, 2021

Agenda

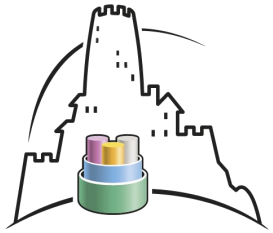
16th of November 2021, 15:00-17:30 PM, CEST	
Start	Topic
15.00-15.10	Welcome and opening remarks (Vada Perkins, Frits Stulp, Christian Hay)
15.10-17.25	Main discussion: - WP1: IDMP related standards and terminologies (Robert Stegwee & Christan Hay – UNICOM) - WP2: Implement IDMP, substance management in Europe (Annet Rozema, EU-SRS project manager, CBG-MEB) - WP3: Pan-European IDMP compliant application forms (Georg Neuwirther, Head of IT, Austrian medicines and medical devices agency) - WP4 : IDMP implementation at national drug agencies (Christer Backman, International & EU coordinator, Swedish Medical Products Agency) Open discussion
17.25-17.30	Closing remarks and final wrap up (Mary Ann Slack, Director US FDA)

UNICOM, 13 Work Packages (WP)



- WP01 IDMP-related standards and terminologies
  Robert Stegwee - Christian Hay
- WP02 Implementation of IDMP – Substance Management in Europe
  Joris Kampmeijer Annet Rozema (CBG)
- WP03 Pan-European IDMP-compliant application forms
  Georg Neuwirther Noel Diamant (AGES)
- WP04 IDMP implementation at National Drug Agencies
  Pelle Persson (MAP, Sweden), Georg Neuwirther
- 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,** Lucia Comnes, Robert Vander Stichele
- WP09 Medicinal Product Dictionaries and Clinical System Software **Julie James,**
  Dipak Kalra, Ursula Tschorn
- WP10 Socio-economic Impact & Sustainable Legal and Governance Aspects **Rainer Thiel,** Karl A. Stroetmann, Petra Wilson (Legal)
- WP11 Project management Shahan Tariq, **Farah Diehl-Fahim,** Karl A. Stroetmann
- WP12 Overall scientific coordination and dissemination **Karl A. Stroetmann,** Shahan Tariq
- WP13 Ethics requirements **Veli Stroetmann,** Petra Wilson



Welcome and opening remarks – Introduction CTADHL

CTADHL Mission

- Support global data and health literacy initiatives through trans-Atlantic collaboration and partnerships
- Strong advocate and expert of applicable international data standards
- Provide ISO-IDMP training to EU and US stakeholders who are involved in IDMP implementation or its decision making

CTADHL Board

Vada A. Perkins – President (CTADHL)

- Executive Director, Bayer Pharmaceuticals
- ISO TC215, Technical Advisory Group (TAG) Member
- Strong FDA and Industry experience on adoption of ISO IDMP

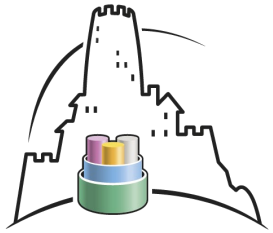
Frits Stulp – Chairman of the Board

- IDMP implementation SME in industry and regulator (Iperion)
- Promotor of ISO IDMP (IRISS IDMP Topic Group Leader)

Christian Hay – Executive Board Member

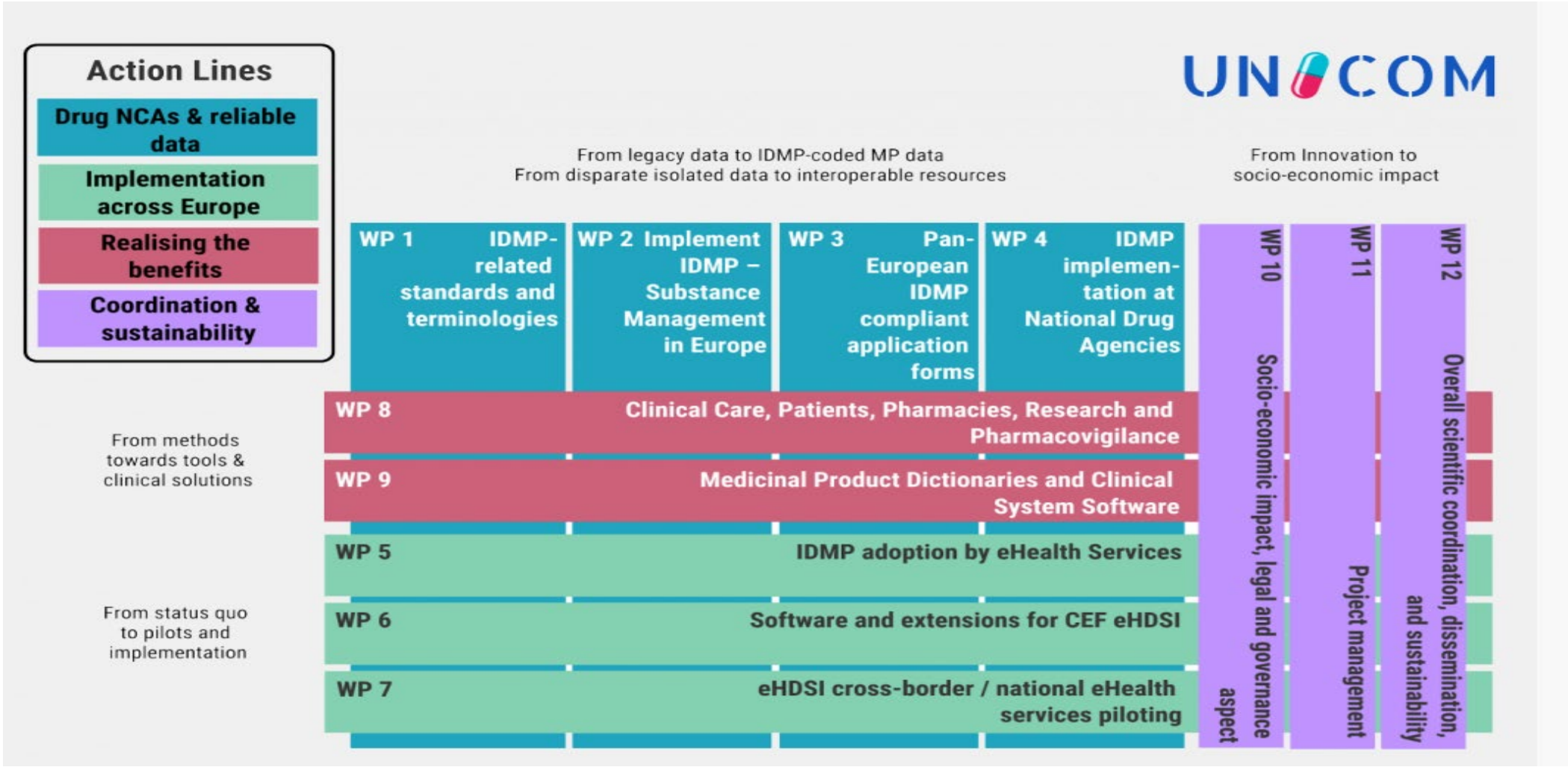
- Senior Consultant Healthcare (GS1, ISO TC 215)
- Strong contributor to the ISO IDMP standards globally

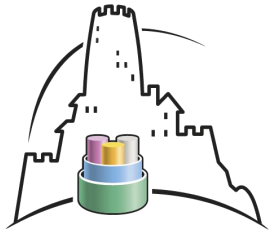
Our goal - execution



- Uniform adoption of the ISO IDMP standards in Europe, in alignment with trans-Atlantic initiatives and other regions as applicable
- Communication of use cases and value across all communities
- Communicate with key stakeholders to foster continued collaboration and engagement
- Promote and deliver training and education of ISO IDMP and related materials
- Create a network of professionals to contribute to the mission

UNICOM Action Lines





Main discussion

Work Package 1
IDMP-related standards and terminologies

Dr Robert A. Stegwee, Co-Lead of WP 1, Chair of CEN/TC 251 Health Informatics

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

- Work Package 1 is grouping Standard Development Organisations (SDOs) and related organisations, which have a transversal impact on UNICOM

- 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 gather their needs and provide inputs about standards

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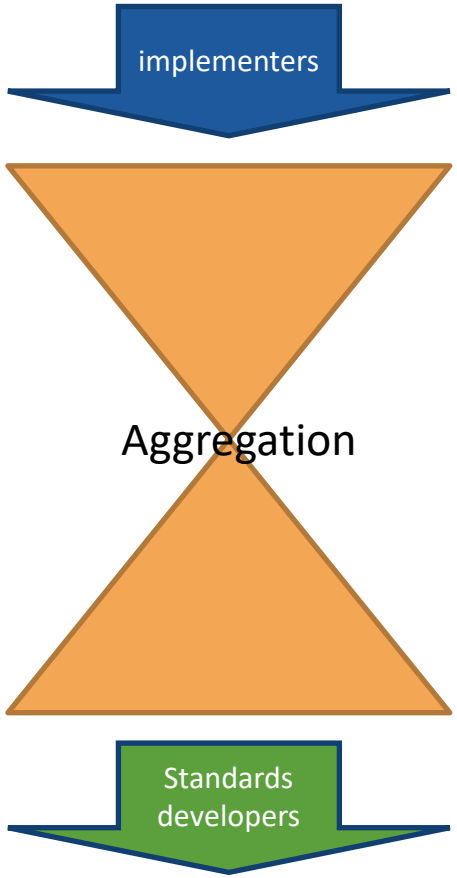
WP 1: IDMP-related standard and terminologies – our process

Source of information

Role for WP-1

Target audience



UNICOM Work Packages
Interactive sessions
“Community of Expertise” webinars

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

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

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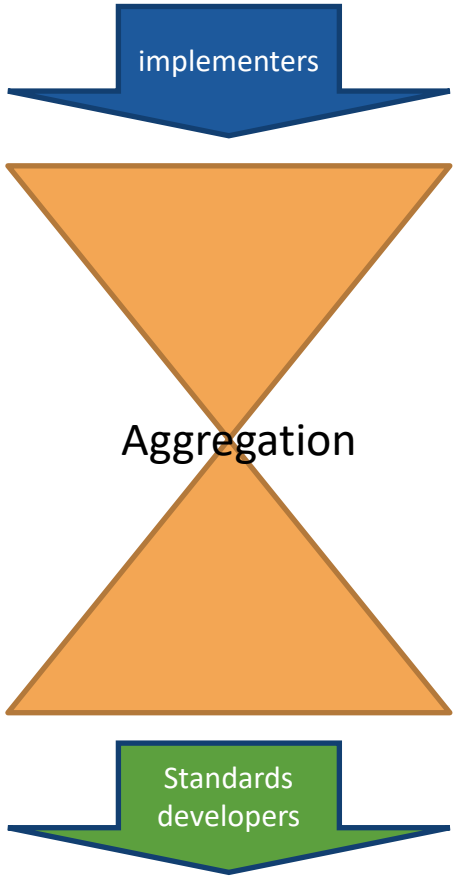
Horizon 2020 research and innovation programme under grant agreement No 875299

WP 1: IDMP-related standard and terminologies – an example

Source of information

Role for WP-1

Target audience



Pharmaceutical Dose Forms
Administrable Dose Forms
Expert inputs, Community of Expertise

Understand how changes in the Dose Form expression impacts existing standards

Support revision of EN ISO 11239 and CEN ISO TS 20440

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What does it mean for you?

- What is your role in the life-cycle of a medicinal product?

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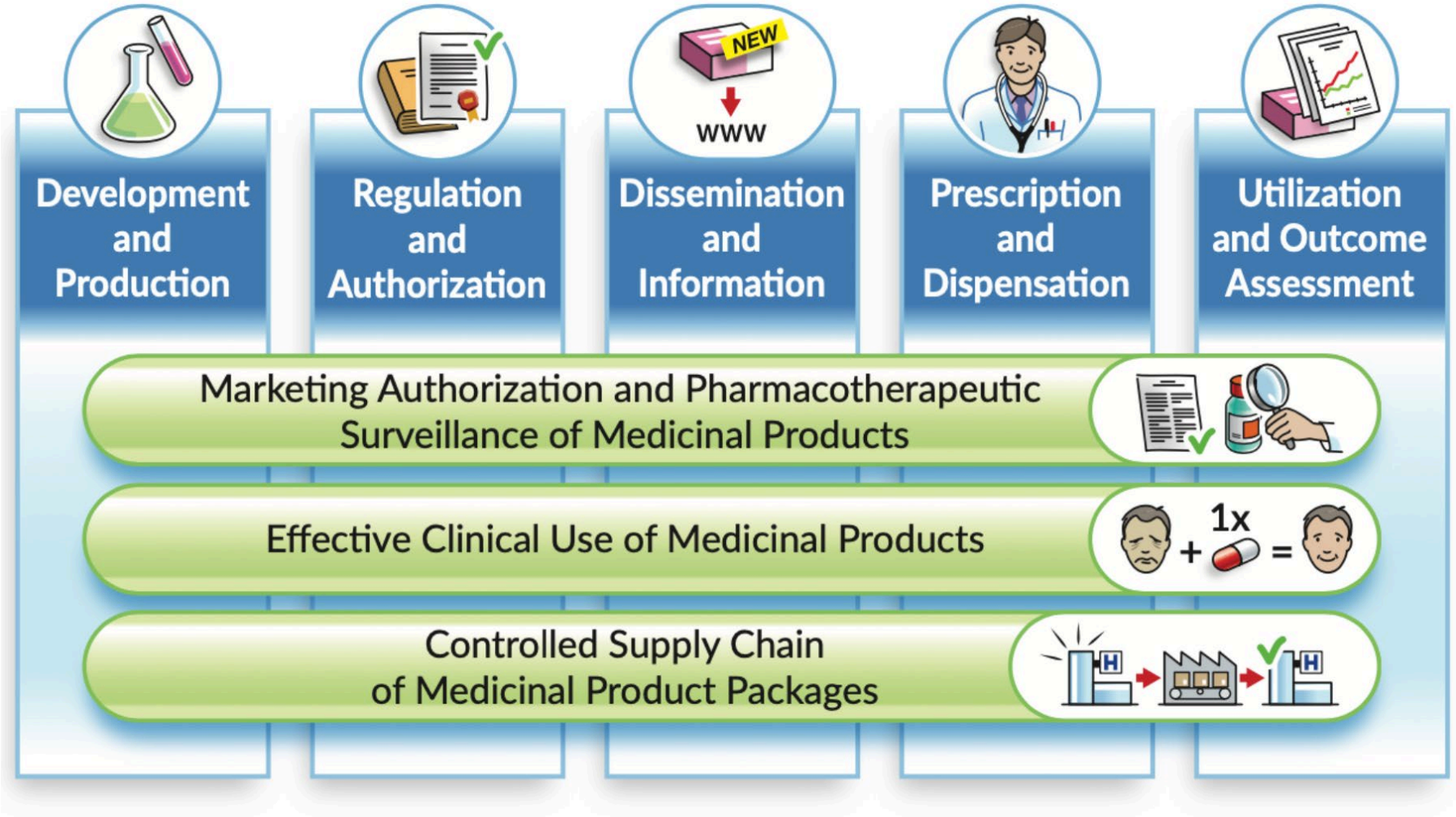
What does it mean for you?

- Which of the high-level processes are you engaged in?



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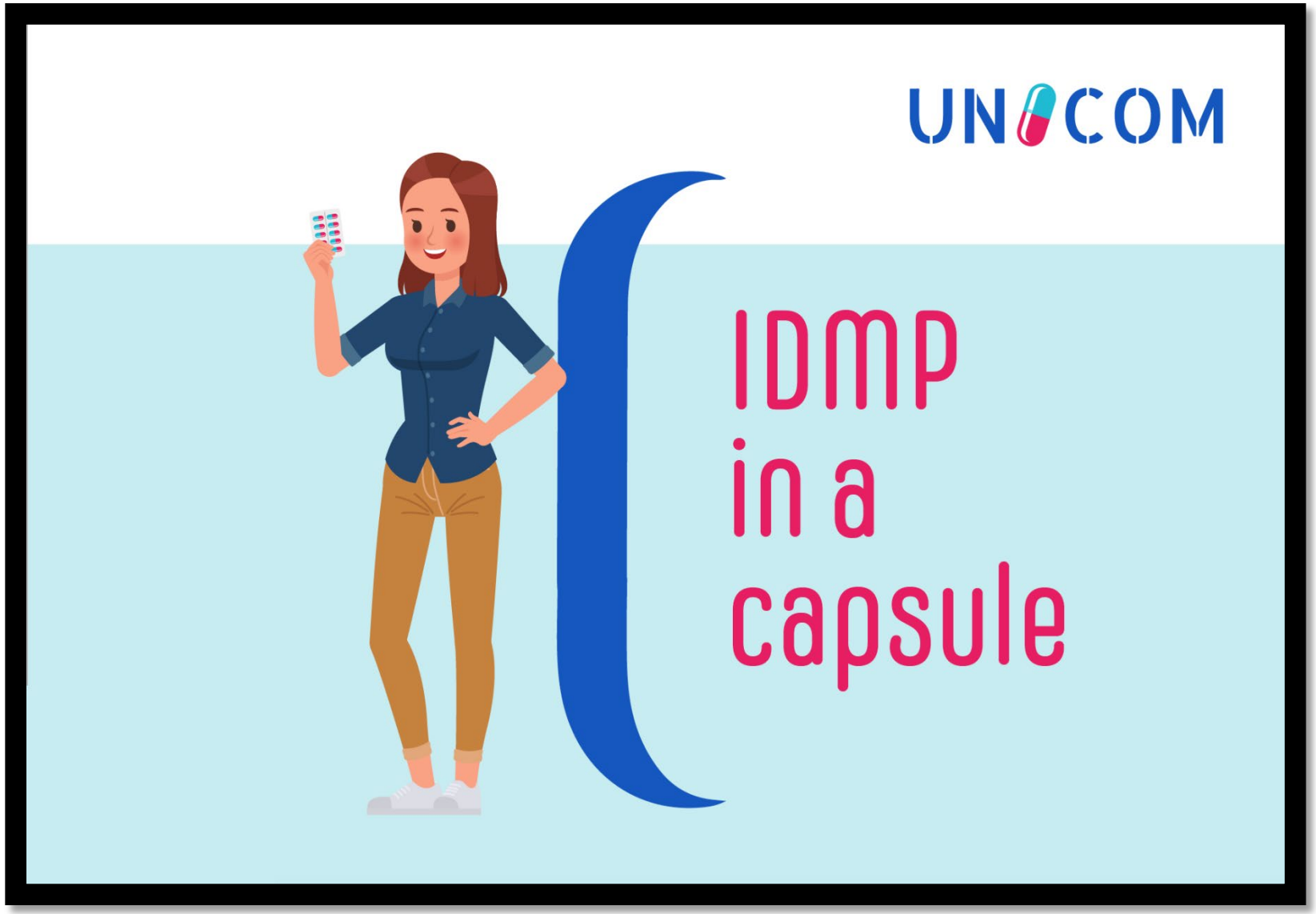
We just published IDMP in a capsule, which provides more details across the life-cycle



https://bit.ly/IDMP_in_a_capsule

Three themes:

1. The **story of Ingrid** – a person using medication and traveling abroad
2. The **theory of IDMP** explained in simple terms
3. The **story of SweetDreams** – a medicinal product marketed under different names in different countries

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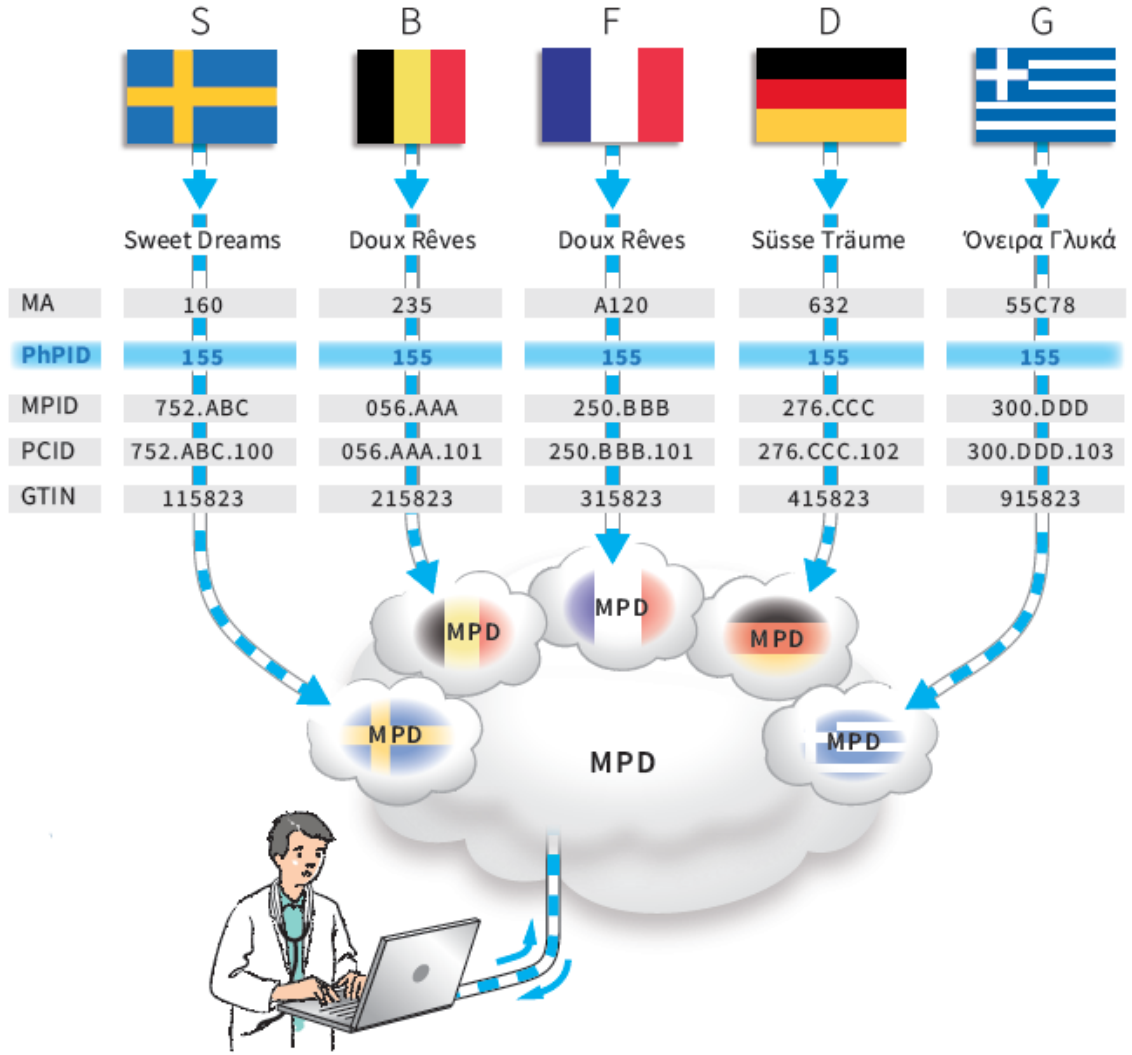
Focus on the role of IDMP Identifiers

- Illustrate how IDMP identifiers «bridge» the different processes:



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Call to Action from IDMP in a capsule

- Pharmaceutical companies and regulators shall take action to fully implement IDMP standards for medicinal products
- IDMP standards-enabled information shall then be collected and stored in medicinal product dictionaries (MPD) for easy access by doctors and pharmacists
- With the link between IDMP standards and the MPD, IT solution providers shall integrate this medicinal product information in their solutions
- Only then, will healthcare providers be able to safely prescribe and dispense the right medicinal products to the right patients, regardless of where they are
- Public health organisations can more easily and quickly aggregate worldwide information to address ADEs, recalls and important public health initiatives to ensure the world is a safer place for everyone.

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We're here to help implement the standards **and** to provide feedback to the SDOs

- Started with a series of workshops on specific issues with IDMP standards across UNICOM
- Published the Gap Analysis report, detailing what is missing or could be improved across the standards landscape
- Published the Requirements for a new ISO Logical Model, integrating the different life-cycle stages and separating out the stage-specific requirements for regulatory, for clinical use, for pharmacovigilance, etc.
- Identified work to be started on mapping EDQM to SNOMED-CT, to have access to correct pharmaceutical dose form information (both manufactured and administrable) in the clinical context
- Many more topics to promote the reuse of data across the life-cycle, rather than recoding, retyping, and maintaining the same information in each of the silo's / stages
- We're following through with the actions identified in the Gap Analysis report, through user interviews across the WPs
- We're reaching out to the broader audience through our monthly Community of Expertise meetings.

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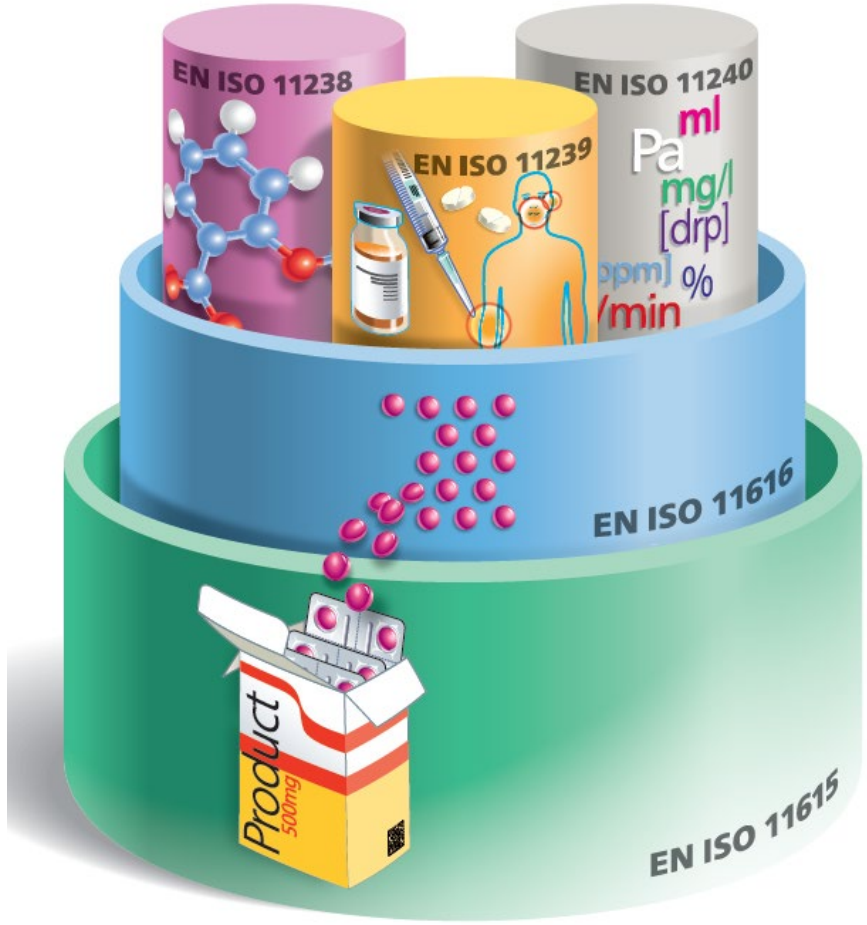
Contact

- www.unicom-project.eu

Dr Robert A. Stegwee
Transformational Consulting in eHealth
Spoorstraat 31
7471 BV Goor / The Netherlands

robert@trace-health.nl



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UNICOM

Up-scaling the global univocal identification of medicines

WP2: Technical review

Agenda

- Background of EU-SRS project
  - What is EU-SRS
  - EU-SRS Project
  - Collaboration with partners
  - The future of substance management
- Data cleansing activities
  - General update on cleansing
  - Chemicals cleansing results
  - Next phase
- System-related matters
- Globalization

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Background EU-SRS / WP2

WP2 – Implement IDMP Substance Management in Europe

What is EU-SRS?

- EU-SRS = **EU**ropean **S**ubstance **R**egistration **S**ystem
- EU-SRS will be connected to the EMA-SPOR Substance Management Service (SMS)
- EU-SRS will be maintained by a group of experts, *Substance Validation Group (SVG)* in cooperation with EMA data stewards

Why EU-SRS?

- There is no EU wide database with scientifically sound substance information of adequate quality for use in regulatory use cases, leading to errors in submissions, rework by assessors and duplication of substance expert work across the network.
- Successful support of the Product Management Service (PMS) as part of SPOR, is fully dependent upon the availability of a stable, reliable substances information, of adequate granularity.
- There is a legal obligation to implement the ISO IDMP standards: (EU) No 520/2012
- Many current business cases cannot be efficiently implemented without an EU substance database.
- NCA's will benefit of an EU substance database in the management of their own local substance database.

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WP2 – Key components of the activities

Substance Data

Cleansing EMA's SMS data
Building data in EU-SRS

- Chemicals
- Proteins
- Structurally Diverse /Vaccines
- Polymers
- Mixtures
- SSG1

EU-SRS System

Install & validate EU-SRS & Load substance data

- Validation Plan
- Test scenarios
- Prepare for interface with SMS
- Data load script
- Interim Hosting: BfArM (current)
- Final hosting: EMA (2022)

Documentation

Best practices
Maintenance processes

- Data cleansing guide (published)
- EU-SRS User manuals
- User training materials
- Interim process description
- Final process description
- Master Data Management Plan
- Signature Fields per Subst Class

Project oversight

Project Management
Stakeholders & Collaboration

Oversight, planning, risk mgt
Collaboration & Communication:

- EMA, NCA's, HMA,
- FDA/NATS, WHO-UMC
- Industry (Subst. Work Groups)
- Other WPs (esp WP1, WP3, WP4, WP8, WP9)

Parties directly involved

Unicom partners + other partners

- **EU Agencies**:
  - Unicom: AEMPS, AGES, BfArM, NoMA, SEMPA, FIMEA, CBG
  - Others: SUKL, PEI, JAZMP, ANSES, EMA
- **Others:** WHO-UMC, FDA/NCATS

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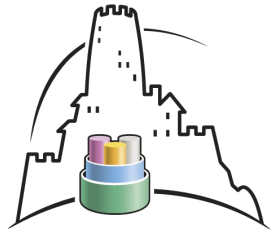
EU-SRS – Collaboration with Partners



LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Statens legemiddelverk
Norwegian Medicines Agency

AGES

CBG MEB

SÚKL

agencia española de medicamentos y productos sanitarios

Paul-Ehrlich-Institut

JAZMP

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail
Connaître, évaluer, protéger

fimea

Uppsala Monitoring Centre

Bundesinstitut für Arzneimittel und Medizinprodukte

FDA

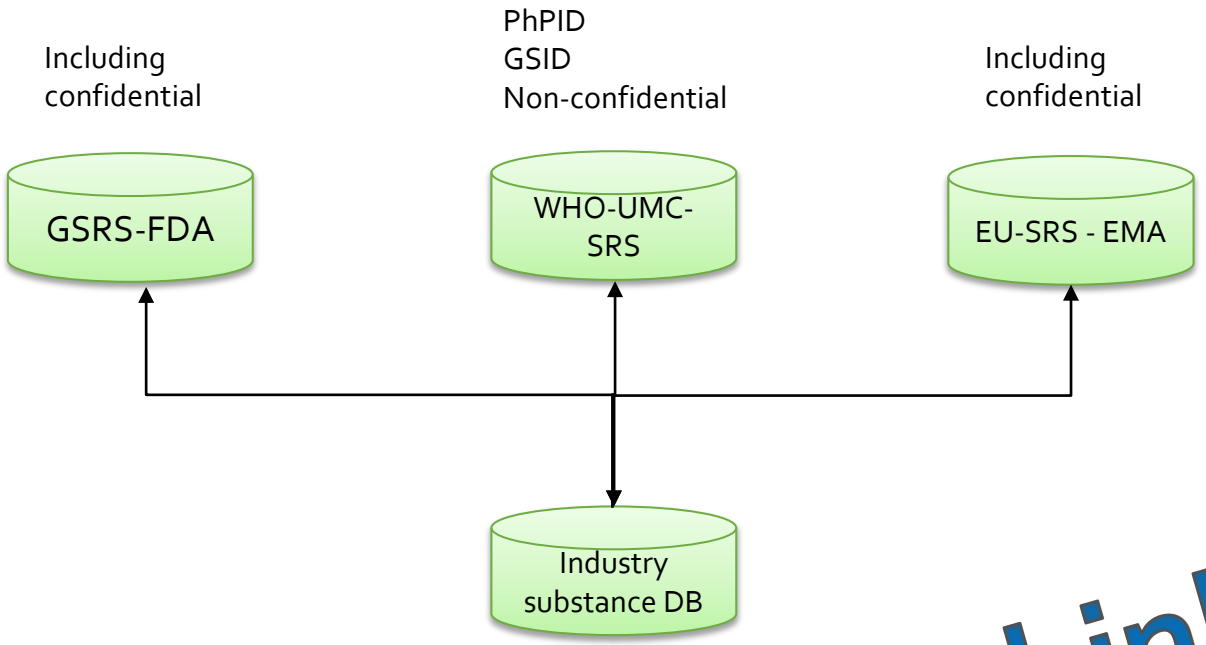
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

NIH National Center for Advancing Translational Sciences

- There is a close collaboration with EMA, NCA's, FDA/NCATS, and WHO-UMC
- The 22 SVG members come from a variety of NCA's. They are assessors and/or substance experts

EU-SRS

The future of substance management?



- Substance identifiers (UNII, EUTCT, GSID)
- Global approach, standards
- Same "signature fields" in each SRS
- Data exchange, staging area
- JSON file shared, validated, confirmed
- Share resources (agreed process)
- Scope differences between the instances
  - Early devt substances yes/no
  - Veterinary substances yes/no
  - Food, homeopathics

Current thinking

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Data Cleansing

General overview cleansing substances

Substance Class	# unique EUTCT codes	SVG cleansing names	SMS processing SVG advice	EU-SRS building records
Chemicals	17.000	Completed	Ongoing. Aim to complete 93% in 2021	Load into EU-SRS with script. Testing ongoing
Veterinary vaccines	1.036	Completed	Completed	Load script + some manual work. Preparation in finalization stage
Human vaccines	1.030	Ongoing, per organism type Bordetella, Influenza	Ongoing	Ongoing per organism type 5 / 55 organism groups built in EU-SRS
Proteins	2.000	Ongoing	Not yet started	Started, on hold. Current focus is on documenting the cleansing approach
Polymers	1.465	Ongoing, recently kicked-off	N/A	N/A
SSG1	>17.000	Ongoing, prioritization per type	N/A	N/A
Mixtures	1.856	To start in 2022	N/A	N/A

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Prioritization of data cleansing activities

- **17k unique chemical substances cleansed**
  - Confirm the preferred term
  - Match with FDA-UNII
  - Data load: make use of US public substances data from GSRS (pre-specified what fields to use)
  - Missing UNII's will be shared with FDA colleagues
    - Possibly increase the rate of matches
    - FDA confirmed the intention to load EUTCT codes into GSRS
  - Finalize documentation:
    - Master Data Management Manual for chemicals (will be shared with US colleagues
    - EU-SRS user guide
    - Process description

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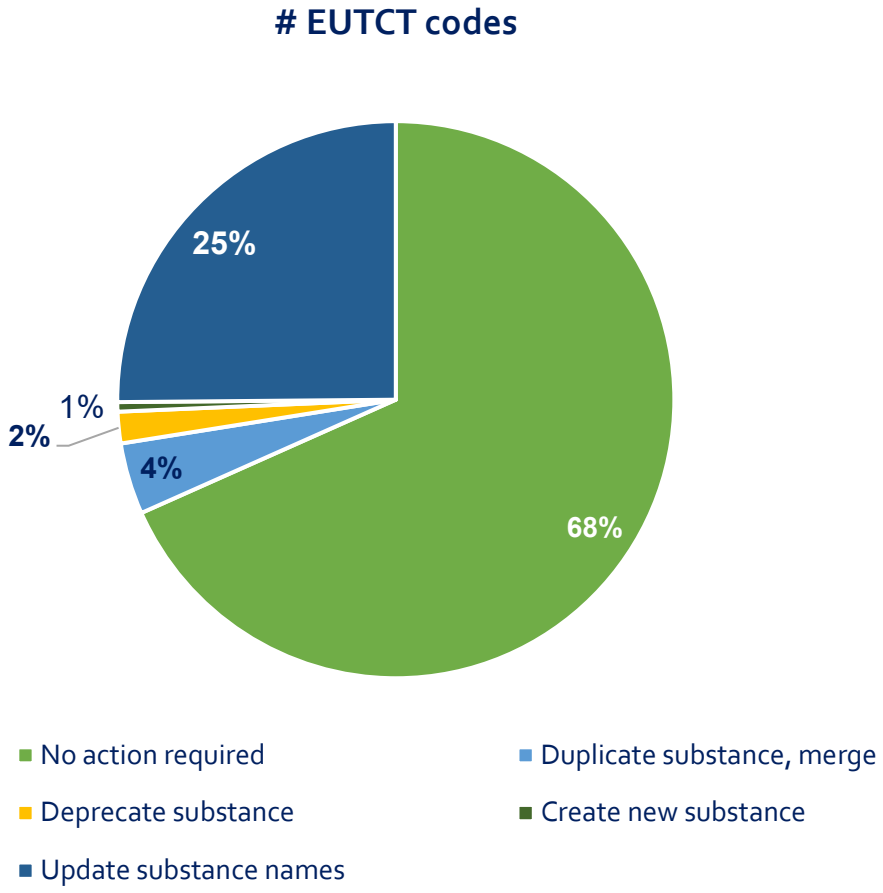
Pre-final results chemicals cleansing

Substance advice categories

1. No Action required for entire EUTCT id **n= ~11200**
2. Substance to be merged, duplicate **n= ~680**
3. Deprecate full EUTCT id **n= ~300**
4. Create new substance/new EUTCT id **n= ~90**
5. Update substance names* **n= ~4120**

n~17000 unique chemical substances

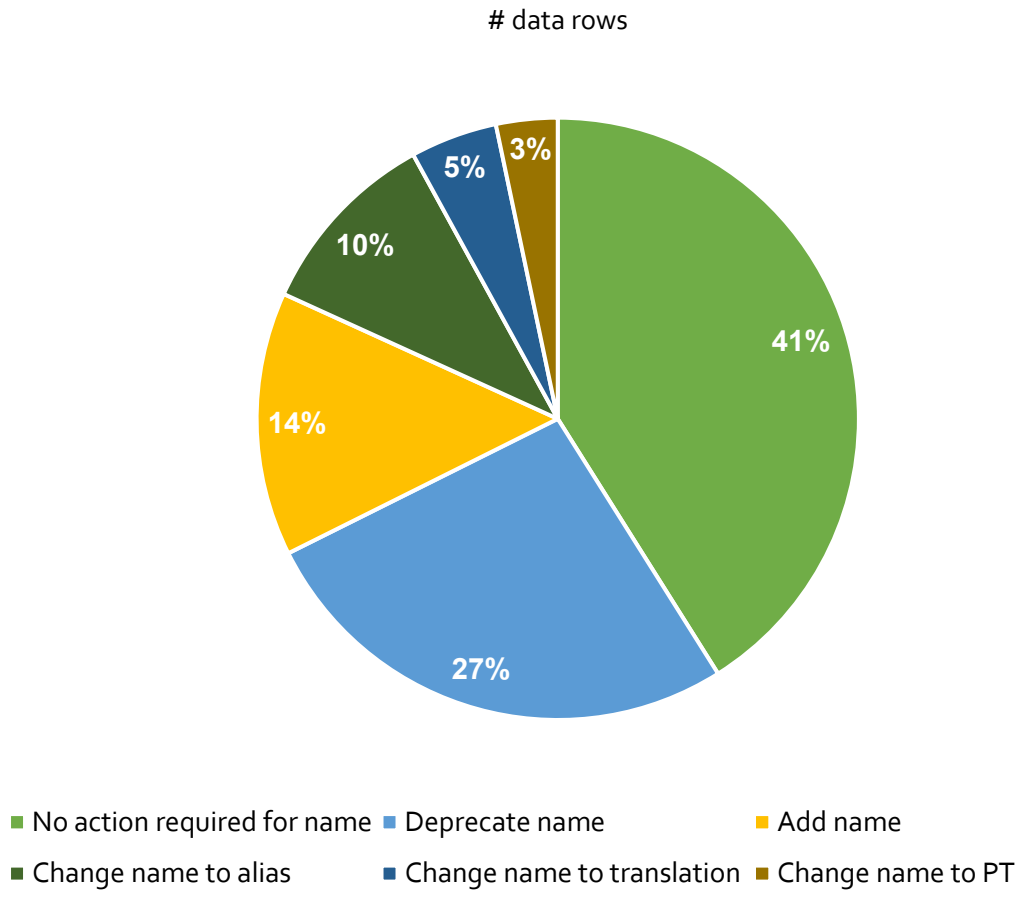


* Details further specified on next slide

Update of substances, continued

Update substance (# of rows)

1. No action required for name **n=~*5100***
2. Deprecate name **n= ~*3300***
3. Add name **n=~*1760***
4. Change name to alias **n=~*1270***
5. Change name to translation **n=~*580***
6. Change name to PT **n=~ *410***



Substance Data cleansing – next steps

- **Next: prioritization of data cleansing**
  - EMA provided file with product count per substance
  - Prioritize data cleansing based on product count
    - Authorized substances
    - Excipients + Active ingredients
  - Larger impact from cleansing expected in other substance classes, e.g.
    - Human vaccines
    - Proteins (e.g. insulins)
    - Polymers
    - SSG1

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EU-SRS system matters

System-related matters

- **EU-SRS at BfArM**
  - Current hosting by BfArM (GSRS software version 2.7)
  - Secured access SVG / EU-SRS steam through EurdraNet
  - Prepare for initial release at BfArM
    - GSRS software version 3.0 (software release expected in December 2021)
    - Validation of the software
    - Validation/confirmation of data load
- **Hand-over EU-SRS to EMA in 2022**
    - GSRS software version 3.x
    - System documentation
    - Validation documentation
- **EU-SRS / SMS interface**
  - Arranging the interface: the earlier the better
  - Specification of the interface to start soon
  - Field-by-field definitions, which system is in the lead?
  - Controlled vocabularies

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Technical collaboration

- **GSRS as open source software**
  - GSRS software developed by the NCATS team (specs FDA)
  - Custom code developed by BfArM (DE-SRS / EU-SRS)
  - Code submitted to the NCATS team
  - Several components of code implemented in the core software
- **EU-SRS decisions to be made**
  - Software version to use
  - Which custom code components to use (impact on validation)
  - Validation strategy
- **Collaboration with the US**
  - Regular meetings to discuss system-related matters
  - Input into GSRS software development roadmap
  - Support in testing efforts, user requirements specification
- **Future wish: exchange data**
  - Transatlantic/global alignment
  - Interest from industry to become involved
  - WHO-UMC to receive public data

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Globalization

Globalization

- Wish to take a global view on substance management
  - Global Vaccines Pilot (results available)
  - Global approach technically
  - Global approach in substance management
- GSRS software under investigation or (being) implemented:
  - GSRS
  - USP-SRS
  - DE-SRS
  - UMC-SRS
  - EU-SRS

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UNICOM

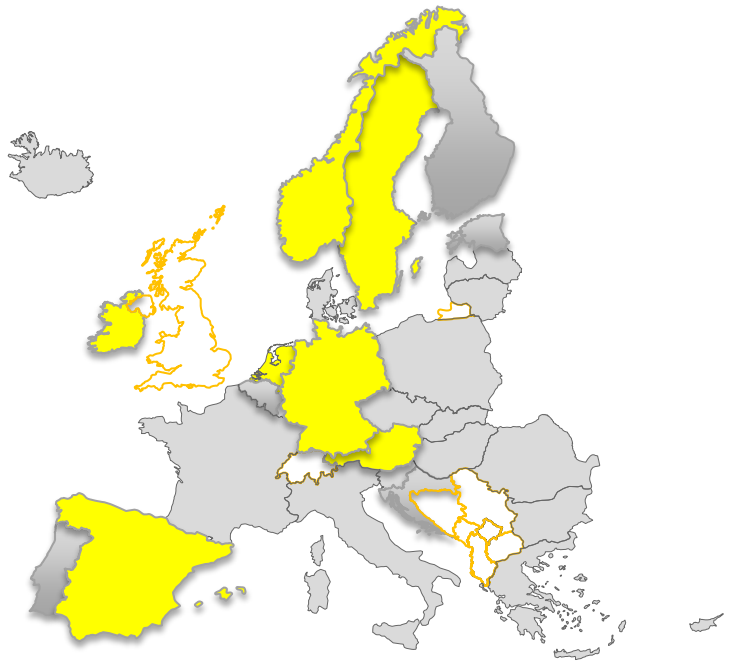
Up-scaling the global univocal identification of medicines

WP3: Pan-European IDMP compliant application forms

Georg Neuwirther, Noel Diamant
Austrian Medicines and Medical Devices Agency, 16.11.2021

UNICOM Consortium Workpackage 3 (WP3)

- **Engaged and fully committed consortium of 40 members**
  - core IDMP data value chain actors are consortium partners
  - 26 National Drug and eHealth Authorities, **7 partners are working in WP3**



WP3 members

NCAs
AEMPS – WP3
HALMED
CBG – WP3
BfArM – WP3
AFMPS
HPRA – WP3
INFARMED
FIMEA
SEMPA – WP3
AGES
EESAM
NOMA

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Objectives of the relevant Horizon 2020 call relevant for WP3

" …. *This innovation action is expected to support two goals:*

(i) the cross-border mobility of European patients by offering safer eDispensations across borders,

(ii) the implementation of the IDMP standards in Member States drug databases (including a possible linkage to the EU SPOR - Substance, Product, Organisation and Referential master data database) allowing the identification of locally available medicinal products which are equivalent to the one identified in a foreign prescription. …"

Focus for us - the EMRN - is item ii), ".. to foster the implementation of IDMP in Europe. .."

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Work package 3 - Overview

- Applying for authorisations for medicinal products and managing their life cycles is a regulated process supported by **electronic application forms** and **supporting electronic tools**.

- At the moment neither application forms nor the tools for initial authorisations, variations and renewals are **compliant** to the IDMP standards. Thus it is currently not possible to start, automate and feed regulatory processes with IDMP compliant/structured data and easily re-use the data in EU-wide eHealth services.

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Work package 3 – Key Objective

- The aim of this work package is to adapt the application forms and required tools towards the IDMP standards and to increase the usage of EMA's SPOR. It will therefore

Deliver web-based application forms compatible with IDMP standards

- **Differences between the current application data format and IDMP need to be identified;**
- **potential content related changes on the current application data format discussed with stakeholders, especially with Notice to Application (NtA) who is the owner of the application form**
- **UNICOM focus is on the human domain but synergies with the veterinary domain may be realized**

- □ procedures will be then alreasdy started with IDMP structured data!

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Horizon 2020 research and innovation programme under grant agreement No 875299

Current situation

Initial Applications (Authorisation)

PDF-based
with proprietary data backbone

Lifecycle Management
(Variations, Renewals)

PDF-based
with proprietary data backbone

proprietary data format
proprietary data format

Regulators (EMA, NCAs)
Case Management
& IT tools

SPOR-Services

- Substance Management Services (SMS)
- Organisation Management Services (OMS)
- Referentials Management Services (RMS)

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UNICOM WP3 will support data harmonisation via IDMP/FHIR compatible tools

Initial Applications (Authorisations)

Lifecycle Management (Variations, Renewals)

NEW: modern web tool supporting the creation of IDMP/FHIR compatible datasets Implemented by the EU project DADI

SPOR-Services

- Substance Management Services (SMS)
- Organisation Management Services (OMS)
- Referentials Management Services (RMS)

+ NEW

- Product Management Services (PMS)

NEW: IDMP/FHIR compliant data format

Regulators (EMA, NCAs)
Case Management
& IT tools

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Joint EU Telematics Project „DADI“

- A decision was made to align the technical framework to the EMA technology strategy.
  - UNICOM WP3 and EMA are now working together with EMA in the “DADI” project to replace the current PDF-forms
  - UNICOM WP3 contributes e.g. by acting as the product owner (joint with a second product owner from EMA)
  - The new tool will be implemented in EMA’s technical platform (Microsoft PowerApps) organised and executed by EMA

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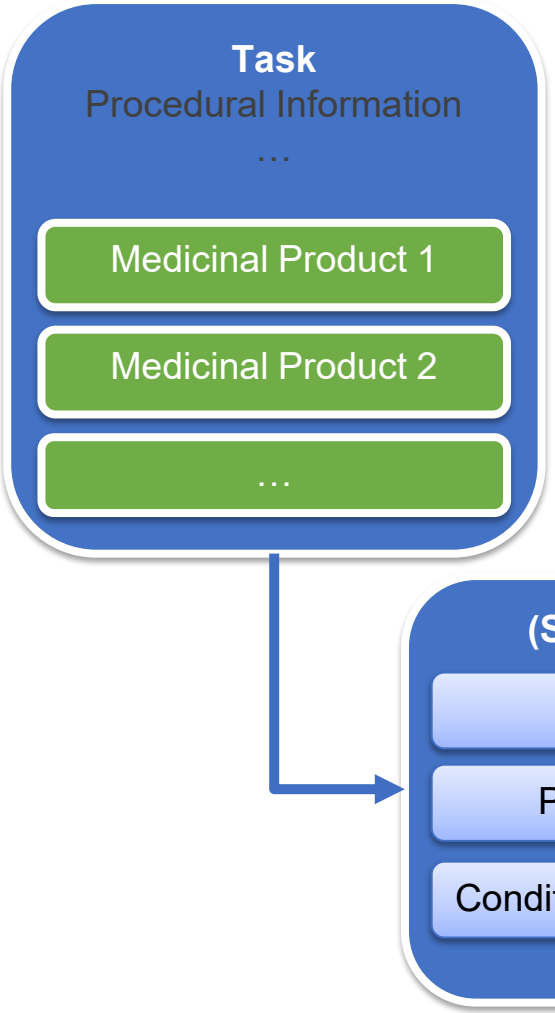
FHIR Backbone

Overview: Future FHIR message structure relevant in Variation Forms 1/2



Task = The Variation Application

- Procedural Information
  Procedure type summary, Type of Authorisation, Procedure numbers, Grouping, Worksharing,
- Annexed Documents, Declaration, Proof of Payment, Signatories
- List of medicinal products, list of changes (provenances)

Defines the scope(s), etc.

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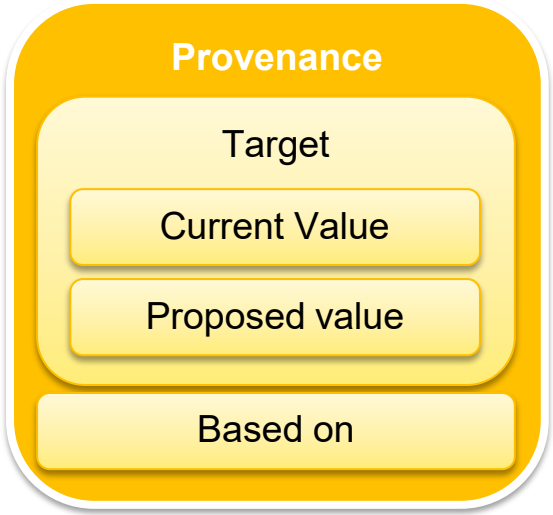
Overview: Future FHIR message structure relevant in Variation Forms 2/2

M:N A provenance can belong to many subtasks and vice versa



Target

- Which resources and elements are affected by the change. A list of links to the lowest point of the changed content. A link can always be followed to identify which medicinal product or packaged medicinal product is being changed.

Current Value

- Value and Type of the „old" data

Proposed Value

- A value and type or a link to a resource and an attribute within the product area

Based on

- The link to (Sub)Task showing that a specific change can belong to many variation classifications

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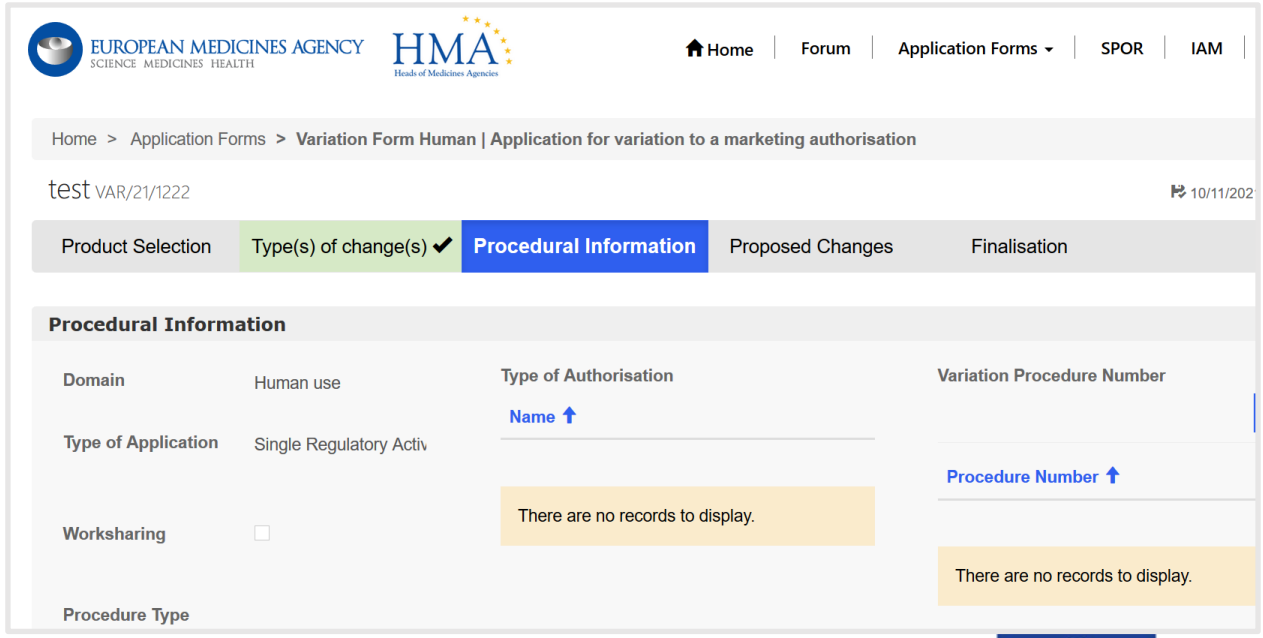
First impressions of the future UI

User Interface – Overview

Overview Application Form

Example: Variation Form Human

- **Product Selection**: Select from Nickname, PMS ID, active substance(s), EU Number, EMA Number, Marketing Authorisation Holder
- **Types of changes**: Select from Variation Classification
- **Procedural Information**: Mostly calculated fields
- **Proposed Changes**: structured product changes or unstructured dossier changes
- **Additional Information**: orphan, paediatric and market exclusivity



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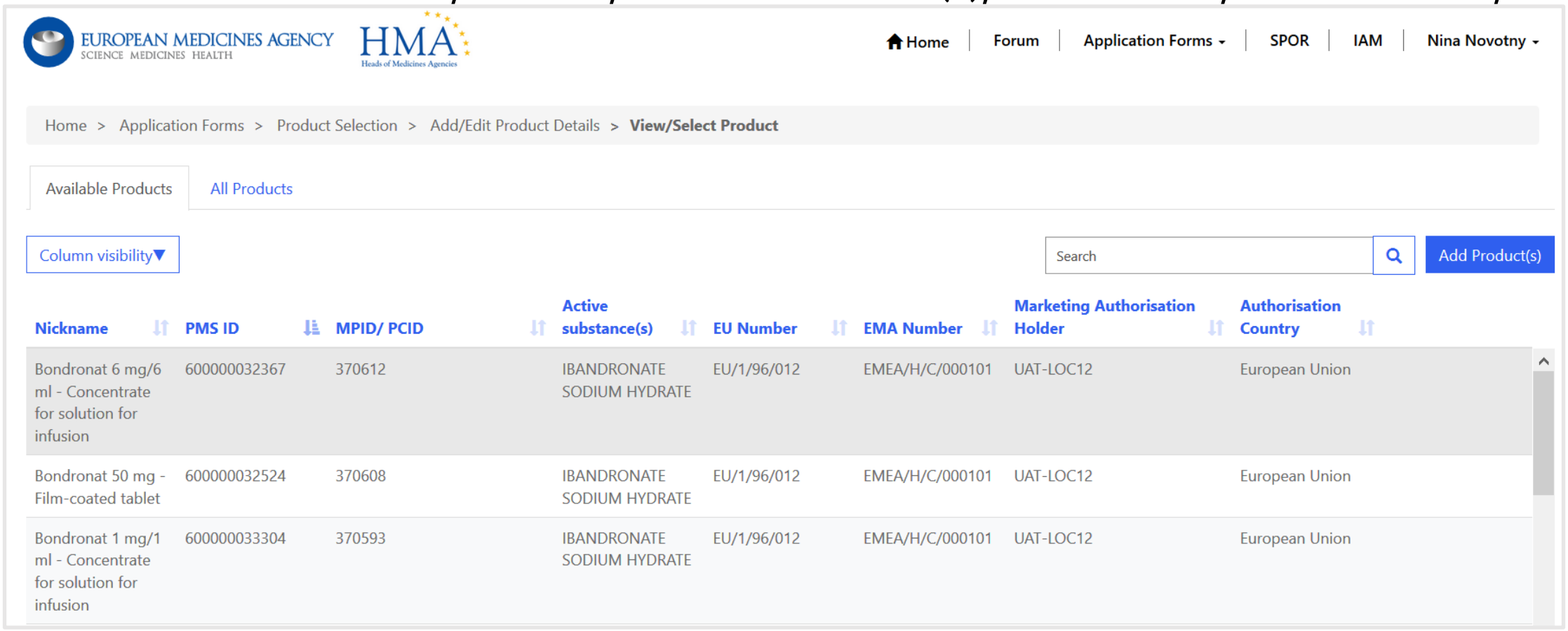
User Interface – Product Selection

Product Selection

- Select from Nickname, PMS ID, active substance(s), EU Number, EMA Number,



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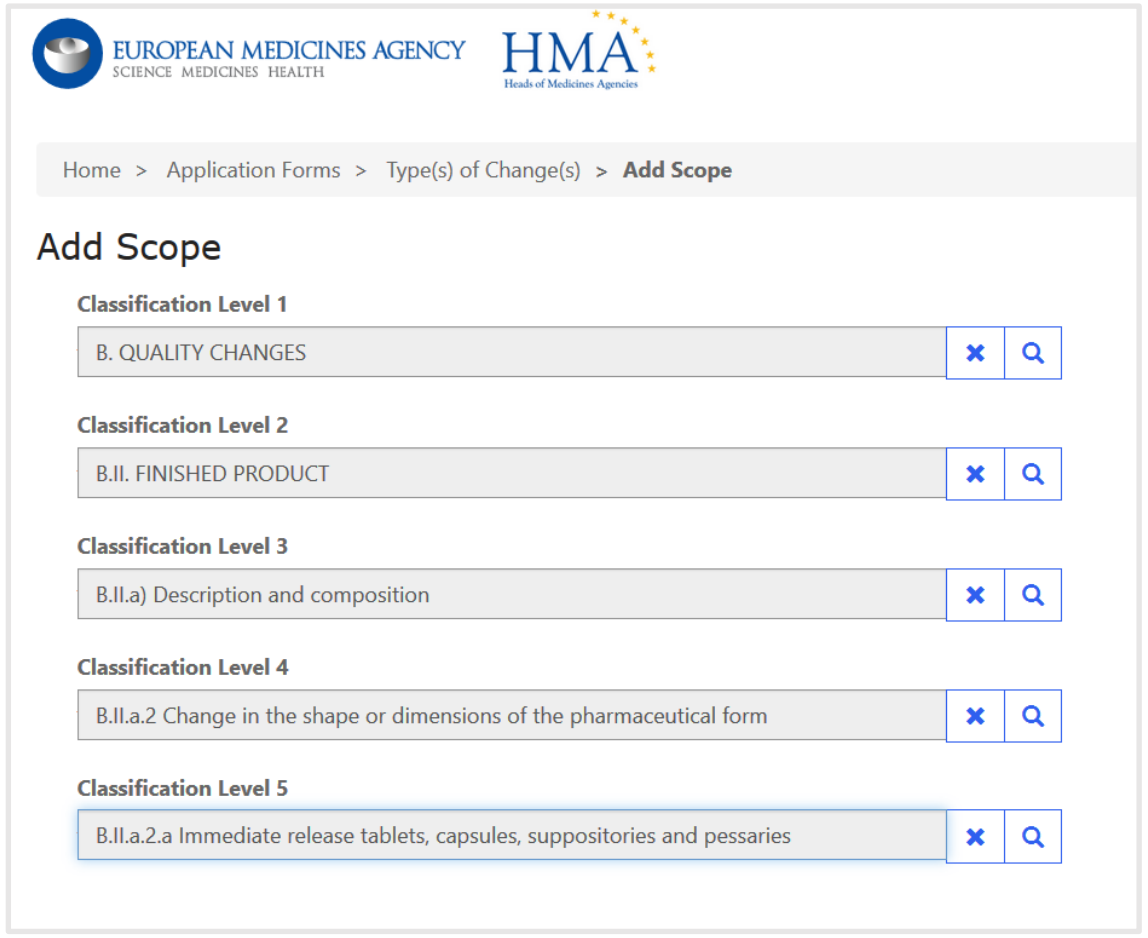
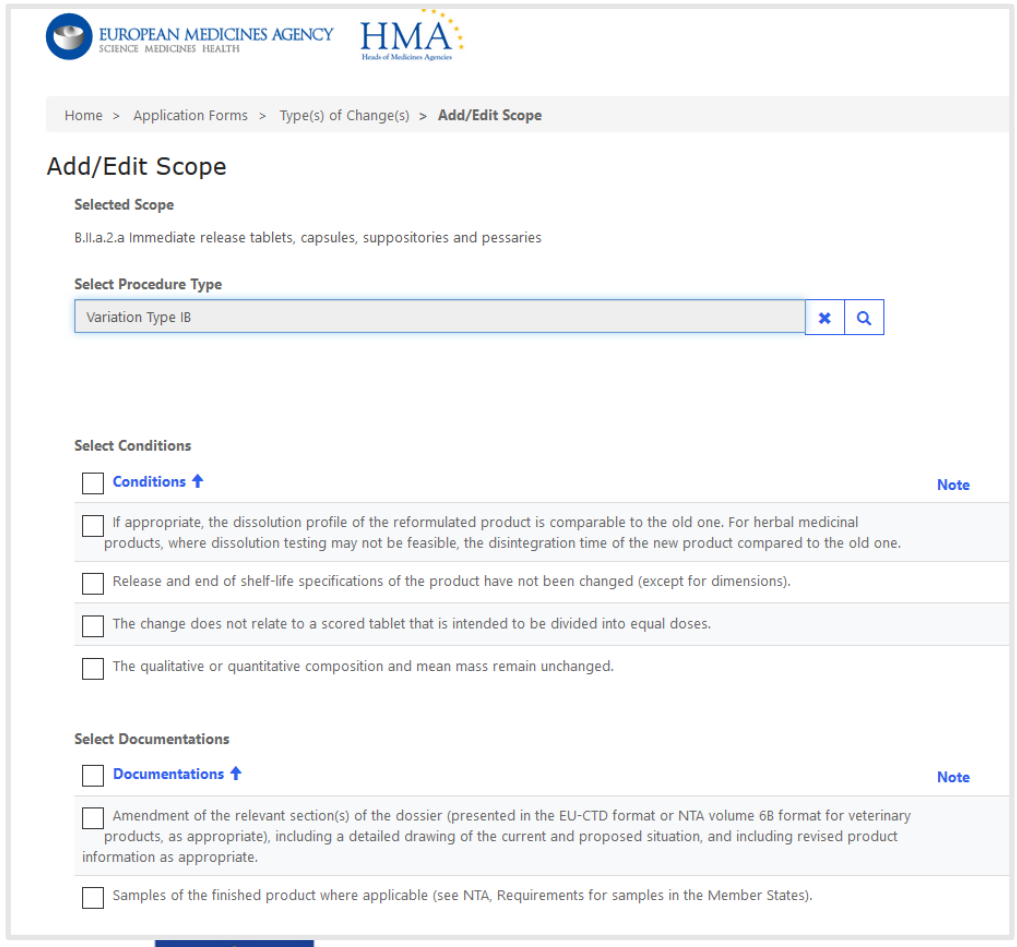
User Interface – Type (s) of changes

- Select from Variation Classification





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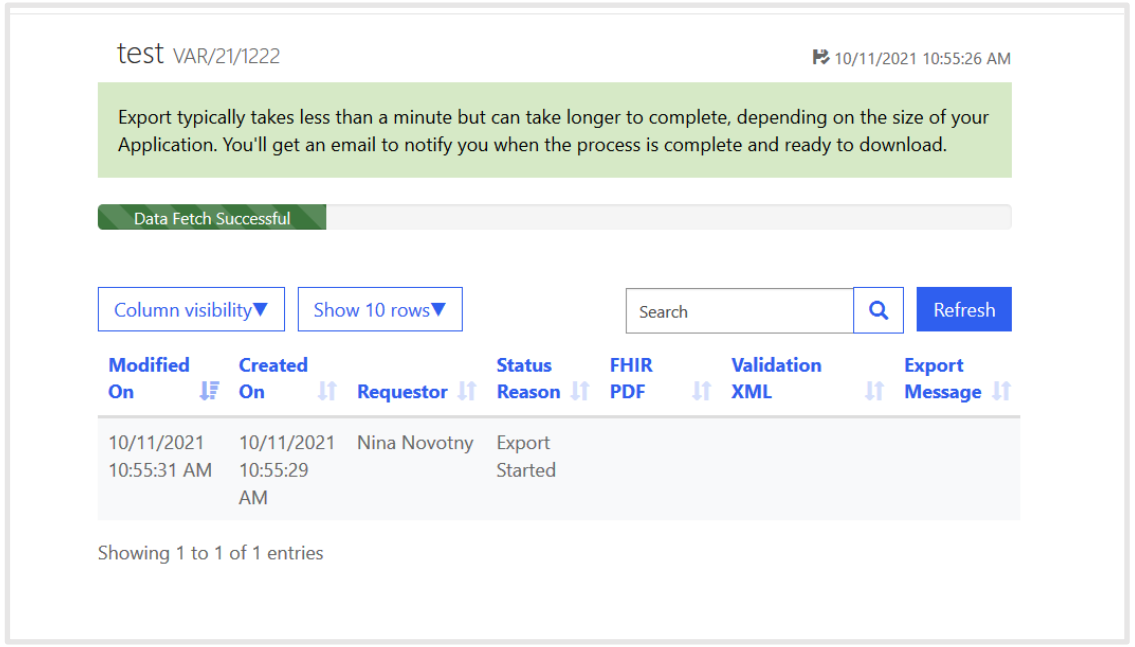
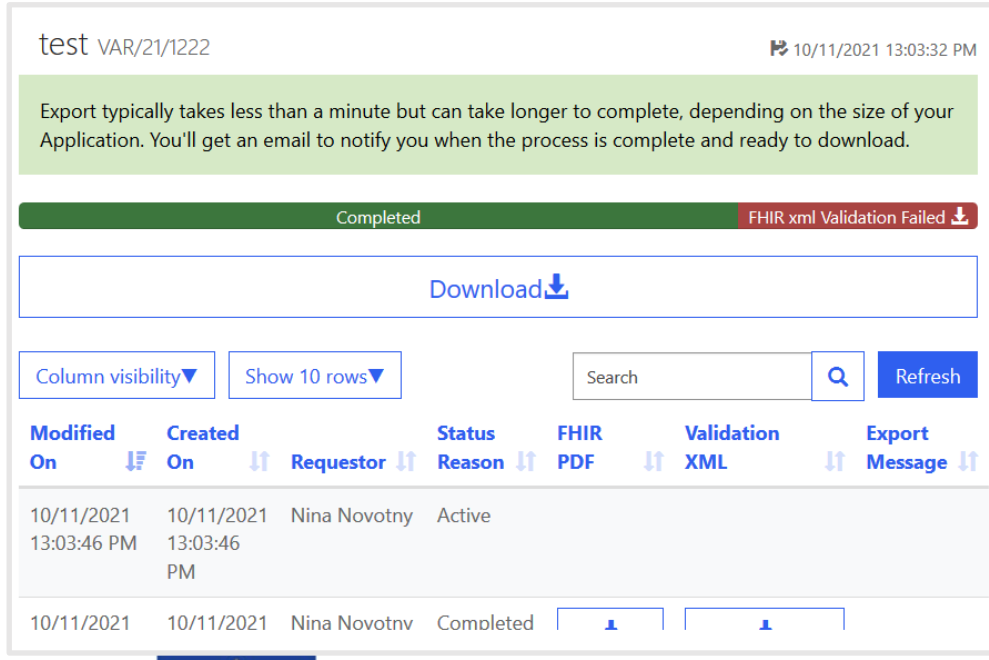
User Interface – Export Triggers

Export Triggers

- A product update in case there was a parallel variation
- A full data set validation
- A FHIR XML validation

Download: PDF with the FHIR XML attached





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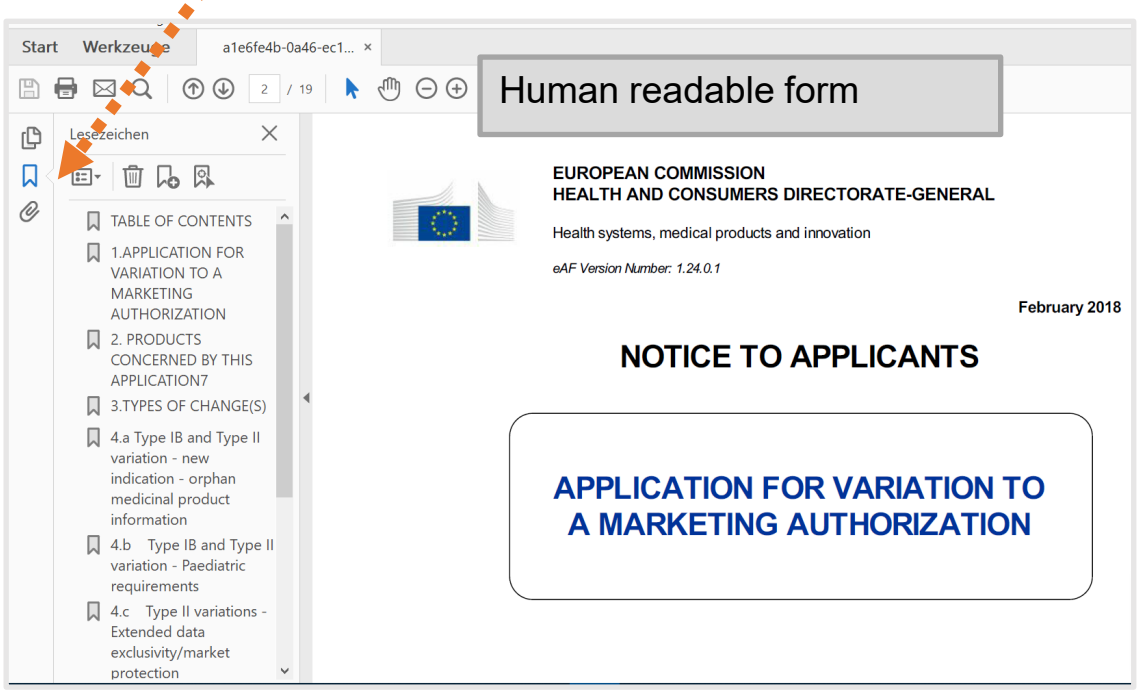
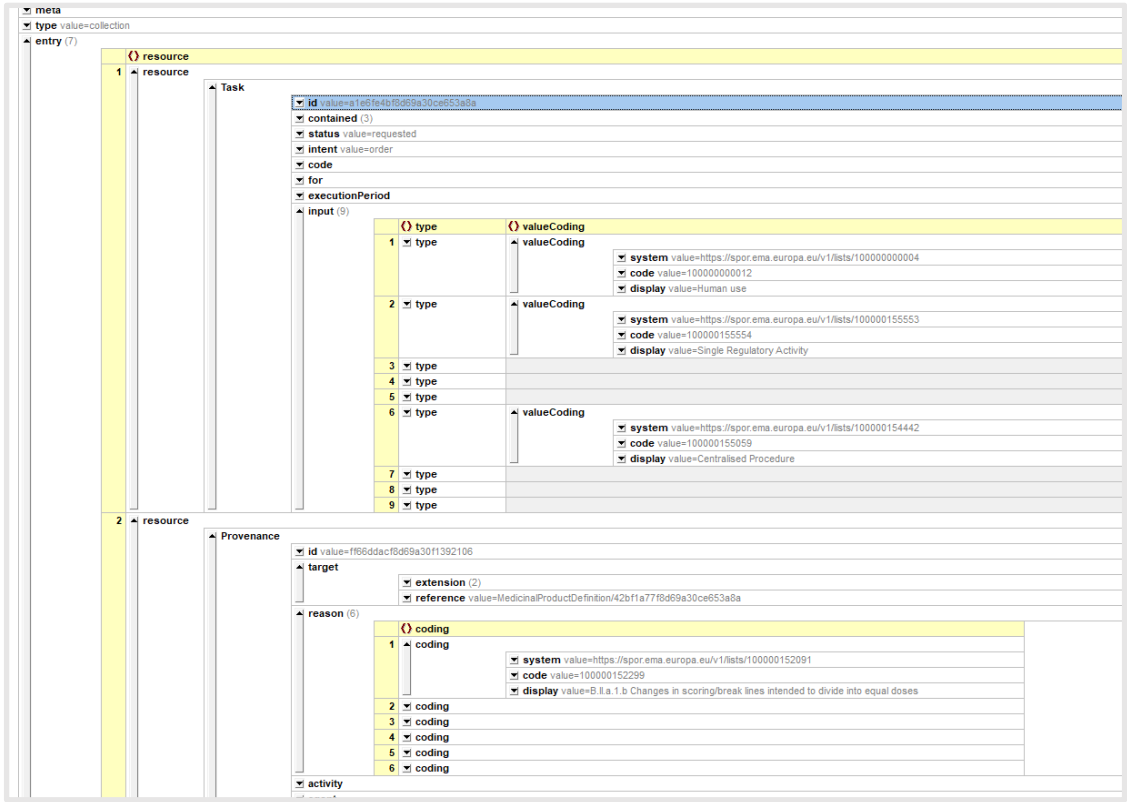
Example output

Attached FHIR XML data backbone

Human readable form



Concept of subtasks not shown here



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Thanks for your attention! For any questions, please contact us!

georg.neuwirther@ages.at
noel.diamant@ages.at

Thank you!

Pelle Persson, SEMPA

UNICOM

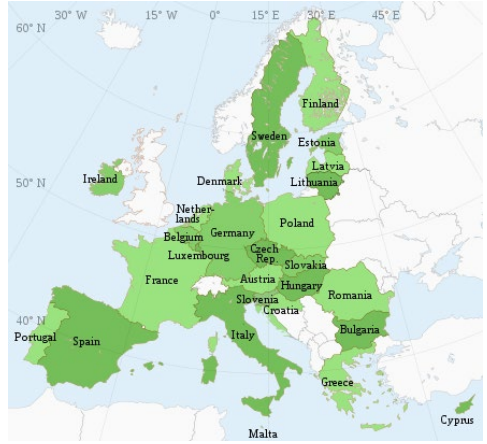
Up-scaling the global univocal identification of medicines

Transatlantic workshop 16 Nov 2021

WP4: IDMP implementation at NCAs

IDMP Implementation at National Medicines Authorities

- **11 national implementation projects**
- Austria, Belgium, Croatia, Estonia, Finland, Germany, Ireland, Norway, Portugal, Spain, Sweden
- **Development of guidelines, training and knowledge about IDMP**
- **Adaptation of the European Communication and Tracking System (CTS)**
  - Used for tracking and co-ordinating pre- and post-licensing regulatory processes
  - for human and veterinary medicinal products
  - authorised via mutual recognition and decentralised procedures



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IDMP Implementation at National Medicines Authorities

- Each NCA will **refactor** their old systems or **build new** medicinal product databases to make them IDMP compatible

- The systems will be connected to **EMA SPOR** services where applicable

- Competence is the key
  - ➢ Knowledge provision and best practice sharing on how to implement ISO IDMP at NCA level
  - ➢ European-wide guidance on how to standardise legacy data towards IDMP

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IDMP Implementation at National Medicines Authorities

- **Progress report** on refactoring or new build of national IT systems, migration of national data, and data interfaces to EMA's SPOR from all 11 NCA's
  - Monthly status reports from NCAs – orally and in writing
  - Bi-weekly meetings in WP4 lead
  - Monthly reports cross WPs (PEC)

  - **Mapping and cleansing data (SPOR) - priority**
    - Dependency on EMA
    - Delays occur – SPOR API, EU Implementation guides, Covid-19

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Lessons learnt

- **Best practice sharing and lessons learnt workshops**
  - All 11 NCAs shared during 2020 and 2021
  - Most lessons are related with the SPOR initiative organised by EMA/HMA, especially in conjunction with organisation data (OMS), substance terms (SMS), referentials (RMS).
    - Due to "moving targets" (FHIR standard versioning, interpretation of IDMP, EU IG vX) the project is more effort than expected.
    - Internal business experts' engagement is crucial for success of system development
    - Organization and responsibilities around eHealth are complex and projects in different agencies need to be in sync.
    - The ISO-IDMP standard does not specify which "**standard vocabulary**" should be used. Therefore, a database could be "ISO-IDMP compliant" but based on region wide – and not world –wide underlying terminology.

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Best practice

- Project SAFEST and FHIR implementation
- Best practice workshop on IDMP ingredient
- Telematics Forum on UNICOM and IDMP including a special topic on “Ingredients
- Best practice workshop on IDMP manufactured items and packaged medicinal product
- Best practice workshop on IDMP manufactured items andPharmaceutical product
- Best practice workshop on IDMP packages

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Deliverables not yet started

- Training through the Telematics Curriculum (EU NTC, training platform)
- Prototype presentation of ISO IDMP compliant datafeeds to eHealth consumers
- IDMP Gap-Analysis report on CTS (Communication and Tracking System

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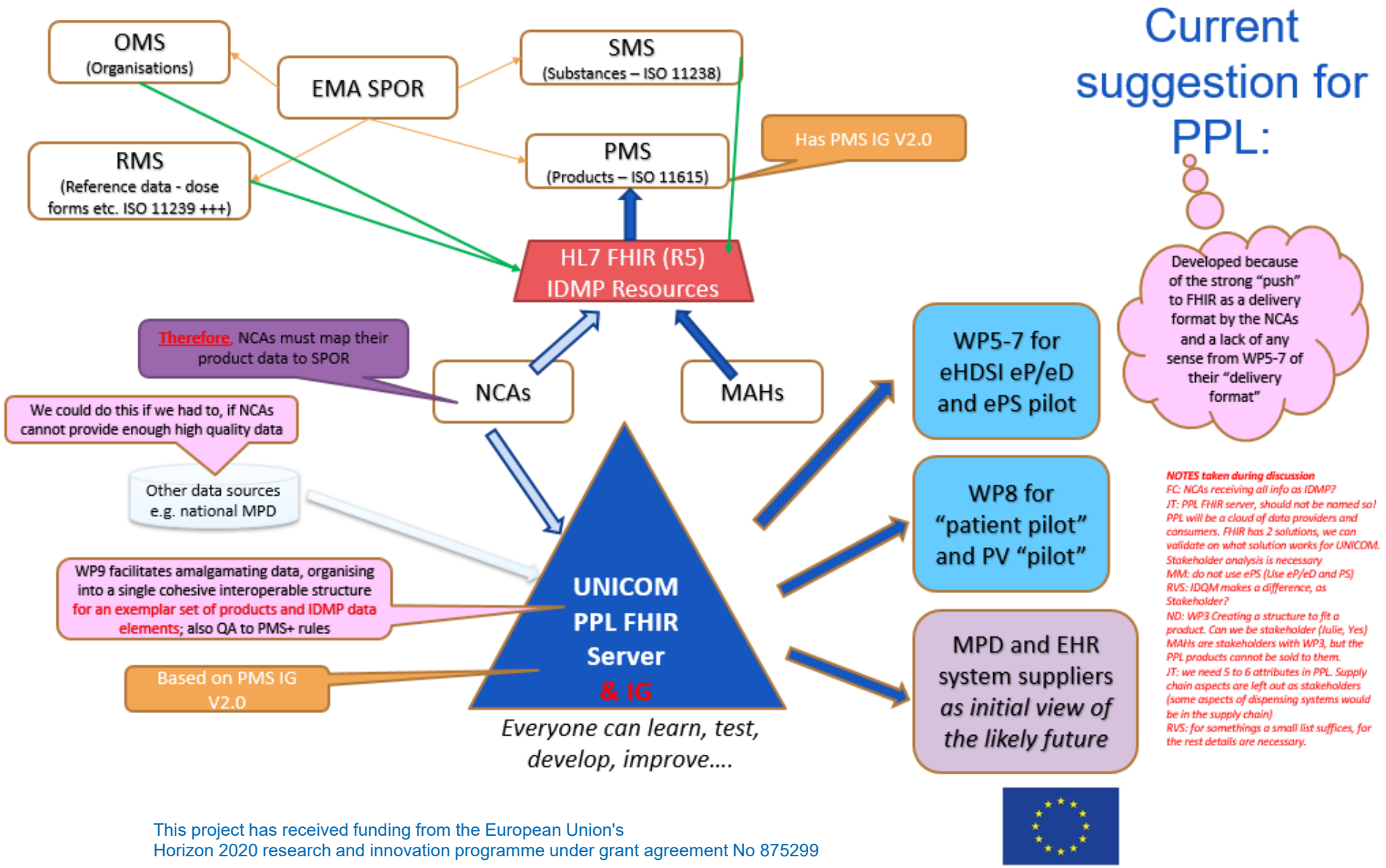
Delivery of selected ISO IDMP medicinal product data for cross-border pilots



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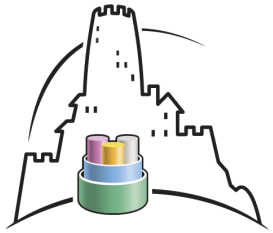
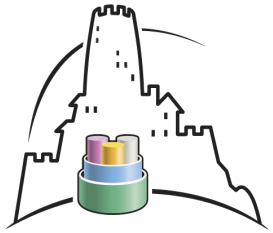
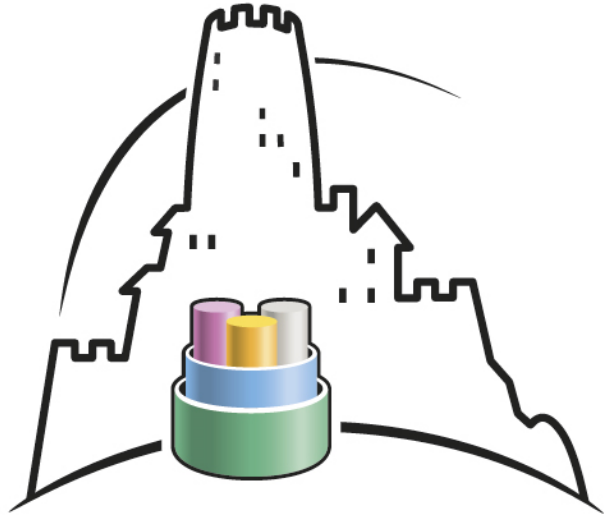
Thank you for your attention



Open discussion



Closing remarks



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