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**

<table>
<thead>
<tr>
<th>Start</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.00-15.10</td>
<td><strong>Welcome and opening remarks</strong> (Vada Perkins, Frits Stulp, Christian Hay)</td>
</tr>
</tbody>
</table>
| 15.10-17.25 | **Main discussion:**  
- WP1: IDMP related standards and terminologies (Robert Stegwee & Christian 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

- **Drug NCA's & reliable data**
- **Implementation across Europe**
- **Realising the benefits**
- **Coordination & sustainability**

Action Lines:

From methods towards tools & clinical solutions

From status quo to pilots and implementation

---

**WP 1**: IDMP-related standards and terminologies
**WP 2**: Implement IDMP - Substance Management in Europe
**WP 3**: Pan-European IDMP compliant application forms
**WP 4**: IDMP implementation at National Drug Agencies

From legacy data to IDMP-coded MP data
From disparate isolated data to interoperable resources

**WP 5**: IDMP adoption by eHealth Services
**WP 6**: Software and extensions for CEF eHDSI
**WP 7**: eHDSI cross-border / national eHealth services piloting

From Innovation to socio-economic impact

**WP 8**: Clinical Care, Patients, Pharmacies, Research and Pharmacovigilance
**WP 9**: Medicinal Product Dictionaries and Clinical System Software

---

**WP 10**: Socio-economic impact, legal and governance aspect
**WP 11**: Project management
**WP 12**: Overall scientific coordination, dissemination, and sustainability
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
WP 1: IDMP-related standard and terminologies

► 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
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
WP 1: IDMP-related standard and terminologies – an example

- **Source of information**: implementers
- **Role for WP-1**: Aggregation
- **Target audience**: Standards developers

**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**
What does it mean for you?

► What is your role in the life-cycle of a medicinal product?
What does it mean for you?

► Which of the high-level processes are you engaged in?
We just published IDMP in a capsule, which provides more details across the life-cycle.


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
Focus on the role of IDMP Identifiers

Illustrate how IDMP identifiers «bridge» the different processes:
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.
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.
www.unicom-project.eu

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

robert@trace-health.nl
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
Background EU-SRS / WP2
WP2 – Implement IDMP Substance Management in Europe

What is EU-SRS?

- EU-SRS = EUropean Substance Registration System
- 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.
### WP2 – Key components of the activities

<table>
<thead>
<tr>
<th>Substance Data</th>
<th>EU-SRS System</th>
<th>Documentation</th>
<th>Project oversight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleansing EMA's SMS data</td>
<td>Install &amp; validate EU-SRS &amp; Load substance data</td>
<td>Best practices Maintenance processes</td>
<td>Project Management Stakeholders &amp; Collaboration</td>
</tr>
<tr>
<td>Building data in EU-SRS</td>
<td>• Validation Plan</td>
<td>• Data cleansing guide (published)</td>
<td>Oversight, planning, risk mgt Collaboration &amp; Communication:</td>
</tr>
<tr>
<td></td>
<td>• Test scenarios</td>
<td>• EU-SRS User manuals</td>
<td>• EMA, NCA's, HMA,</td>
</tr>
<tr>
<td></td>
<td>• Prepare for interface with SMS</td>
<td>• User training materials</td>
<td>• FDA/NATS, WHO-UMC</td>
</tr>
<tr>
<td></td>
<td>• Data load script</td>
<td>• Interim process description</td>
<td>• Industry (Subst. Work Groups)</td>
</tr>
<tr>
<td></td>
<td>• Interim Hosting: BfArM (current)</td>
<td>• Final process description</td>
<td>• Other WPs (esp WP1, WP3, WP4, WP8, WP9)</td>
</tr>
<tr>
<td></td>
<td>• Final hosting: EMA (2022)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
• 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
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, homeopaths
Data Cleansing
# General overview cleansing substances

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

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
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
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 $n = \sim 5100$
2. Deprecate name $n = \sim 3300$
3. Add name $n = \sim 1760$
4. Change name to alias $n = \sim 1270$
5. Change name to translation $n = \sim 580$
6. Change name to PT $n = \sim 410$
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
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
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
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
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

<table>
<thead>
<tr>
<th>NCAs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>AEMPS – WP3</td>
<td></td>
</tr>
<tr>
<td>HALMED</td>
<td></td>
</tr>
<tr>
<td>CBG – WP3</td>
<td></td>
</tr>
<tr>
<td>BfArM – WP3</td>
<td></td>
</tr>
<tr>
<td>AFMPS</td>
<td></td>
</tr>
<tr>
<td>HPRA – WP3</td>
<td></td>
</tr>
<tr>
<td>INFARME</td>
<td></td>
</tr>
<tr>
<td>FIMEA</td>
<td></td>
</tr>
<tr>
<td>SEMPA – WP3</td>
<td></td>
</tr>
<tr>
<td>AGES</td>
<td></td>
</tr>
<tr>
<td>EESAM</td>
<td></td>
</tr>
<tr>
<td>NOMA</td>
<td></td>
</tr>
</tbody>
</table>
“.... 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. ..”
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.
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 already started with IDMP structured data!
Current situation

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

Initial Applications (Authorisation)

Lifecycle Management (Variations, Renewals)

Regulators (EMA, NCAs)
Case Management & IT tools

SPOR-Services

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

PDF-based with proprietary data backbone

proprietary data format

PDF-based with proprietary data backbone
UNICOM WP3 will support data harmonisation via IDMP/FHIR compatible tools

Initial Applications (Authorisations)

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)
- Referential Management Services (RMS)

+ NEW
- Product Management Services (PMS)

NEW: IDMP/FHIR compliant data format

Regulators (EMA, NCAs)
Case Management & IT tools

Lifecycle Management (Variations, Renewals)

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

(Sub)Task 1 to n

- Scope
- Procedure type
- Condition/Documentation

Defines the scope(s), etc.
Overview: Future FHIR message structure relevant in Variation Forms 2/2

Title:

Provenance

- 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

M:N A provenance can belong to many subtasks and vice versa
First impressions of the future UI
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
User Interface – Product Selection

Product Selection

- Select from Nickname, PMS ID, active substance(s), EU Number, EMA Number,
User Interface – Type(s) of changes

Select from Variation Classification

Add Scope

Classification Level 1
B. QUALITY CHANGES

Classification Level 2
B.II. FINISHED PRODUCT

Classification Level 3
B.II.a) Description and composition

Classification Level 4
B.II.a.2 Change in the shape or dimensions of the pharmaceutical form

Classification Level 5
B.II.a.2.a Immediate release tablets, capsules, suppositories and pessaries
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
Attached FHIR XML data backbone

Human readable form

NOTICE TO APPLICANTS

APPLICATION FOR VARIATION TO A MARKETING AUTHORIZATION

Concept of subtasks not shown here
Thanks for your attention! For any questions, please contact us!

georg.neuwirther@ages.at
noel.diamant@ages.at
Thank you!

Pelle Persson, SEMPA
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

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
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
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
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.
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 and Pharmaceutical product
- Best practice workshop on IDMP packages
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)
Delivery of selected ISO IDMP medicinal product data for cross-border pilots

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

Current suggestion for PPL:

- Developed because of the strong "push" to FHIR as a delivery format by the NCAs and a lack of any sense from WP5-7 on their "delivery format"

NOTES taken during discussion:
- NCAs recruiting of info on IDMP?
- CTL: FHIR server should not be named IDMP?
- PPL will be a collection of data providers and consumers, FHIR has 2 solutions, we can collaborate on what coalition works for UNICOM
- Watermark analysis is necessary
- MAH do not use FHIR (we of IDMP and WP5)
- UNICOM means a difference, as OHE/14?
- MG: FHIR creating a structure to fit a product? Can see it as a "heterochannel" (i.e., yes)
- MAHs and stakeholders with IDMP, but the PPL products cannot be such term
- (T) we need 3 to 6 distributors in PPL. Supply chain aspects are left out as stakeholders (some aspects of dispensing systems would be in the supply chain)
- (A) for something, we need less software, for the rest details are necessary.
Thank you for your attention
Open discussion
Closing remarks
CTADHL (Citadel)

www.ctadhl.com