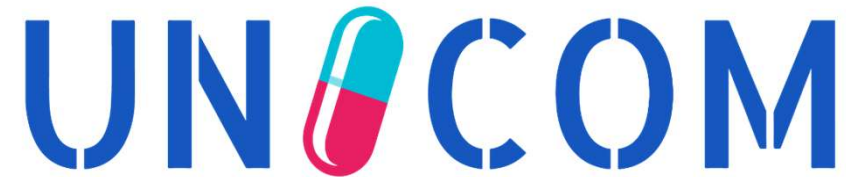




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Up-scaling the global univocal identification of medicines

U p d a t e

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The UNICOM project is helping to ensure that any medicine and what it contains can be accurately identified anywhere in the world. We are working to improve patient safety and enable better healthcare for all.

<https://unicom-project.eu/>



Progress Report on Selected WPs

- ▶ WP 1: **IDMP** improvements
- ▶ WP 2: Status of EU-SRS (**Substance Registration System**)
- ▶ WP 3: **European** Marketing Authorisation Application **submission system**
- ▶ Establishing an **IDMP** / HL7 FHIR **infrastructure** for testing and piloting
- ▶ **Outreach** to stakeholders and trans-Atlantic
- ▶ WP 5 - 7: **xBoder** IDMP implementation requirements
- ▶ Q&A



WP 1: IDMP improvements

- ▶ **Gap analysis about existing and new standards**
 - ▶ > 60 gaps identified across the UNICOM Work Packages and across the standards and terminologies required
 - ▶ Extending the initial IDMP scope from regulatory to include clinical use and pharmacovigilance
 - ▶ Ranging from ISO logical models to HL7 FHIR implementation guides and IHE profiles to test in connectathons

(Note: WP 1 does not develop its own specifications; UNICOM works together across 9 SDOs to address the gaps identified, track progress, and respond to new implementation challenges)

- ▶ **Requirements for a new ISO logical model for IDMP**
- ▶ **ISO IDMP Introduction - Handbook (for non-experts)**
- ▶ **UNICOM Community of Expertise – monthly webinars with a global audience:**
 - ▶ *August: Using ATC and INN in relation to IDMP*
 - ▶ *June: Evolving standards requirements for cross-border ePrescribing following IDMP implementation*
 - ▶ **May 28: Representation of clinical information related to medication using SNOMED CT and other standards**
 - ▶ **Apr. 29: Medicinal product dictionaries (MPDs), ATC, and the MelClass database**
 - ▶ **Mar. 23: EMA IDMP Implementation Guide v2.0**
 - ▶ **Feb. 19: IDMP Logical Model**
 - ▶ **Jan. 22: Pharmaceutical Dose Forms**





WP 2: EU-SRS (Substance Registration System)

► Substances data for IDMP

- IDMP implementation must be based on clean, consistent, high quality, scientifically sound substance data
- *UNICOM Pilot Substances List (PSL)* provides base for *UNICOM Pilot Products List (PPL)* to be used for testing and piloting IDMP implementation
- Trans-Atlantic cooperation of European Medicines Regulatory Network (European Medicines Agency, EU National Medicines Authorities), US Food and Drug Administration (FDA), US National Center for Advancing Translational Sciences (NCATS)
- EMA's substances data (Preferred Terms, Synonyms) are confirmed/cleansed, and substances such as (COVID) vaccines are built in directly into EU-SRS

► Pilot: global vaccines initiative

- Feasibility assessment of global alignment in managing vaccines substances, including antigens and adjuvants present in vaccine products (together with naming of substances and their IDs)
- By Sept. 2021, conclusions will be shared, including advice on next steps, e.g. possible data flow between EU-SRS, FDA and WHO, incl. suggestions for global collaboration on vaccines and other substances



WP 3: European Marketing Authorisation Application submission system

- ▶ Automatic feed into national and EMA regulatory processes of IDMP compliant medicinal product data over their full life cycle
- ▶ ISO-IDMP compliant forms for initial application, registration of variations, renewal activities
- ▶ Thereby enablement of easy re-use of data by any stakeholder, e.g., in EU-wide Digital Health (xBorder) services
- ▶ UNICOM & EMA signed an agreement to undertake together the **Digital Application Dataset Integration (DADI)** project to
 - Replace the current PDF-file based application forms
 - with new web based application forms compatible with
 - IDMP/FHIR
 - the EMA PMS/SPOR IDMP Implementation Guide (under development)



The need for an IDMP/HL7 FHIR infrastructure for testing and piloting

- ▶ **Final UNICOM goal**
 - Develop, test and pilot solutions that are scalable and compliant to IDMP and EMA's [Medicinal] Products Management Service (PMS)
 - as part of EMA SPOR (Substances, Products, Organisations, Referentials) EU master data system
- ▶ **Present deficiencies**
 - Not all SPOR services/master data are yet fully specified / not yet available
 - The EMA IDMP Implementation Guide (IG, presently v2) for PMS is still incomplete (e.g. Chapter 5 – Data access/export, or Chapter 9 - Process for submitting existing data on medicinal products are scheduled for inclusion in EU IG v3)
 - Various coding systems (e.g. EDQM - administrable dose form) are not yet fully fit-for-purpose of IDMP, or not yet EU-wide (globally) agreed upon
 - Some relevant HL7/FHIR profiles/resources are not yet available
- ▶ **Therefore, UNICOM needs an interim solution, *coordinated with EMA and key actors***



Establishing an UNICOM IDMP/HL7 FHIR infrastructure for testing and piloting

- ▶ **The UNICOM Pilot Product List (PPL) of IDMP-formatted and coded medicinal product data**
 - Based on about 35 common active substances (in co-op with WP 2 EU SRS)
 - Covers core IDMP attributes (up to about 50 items)
 - May lead to > 1,000 individual medicinal products / packages
 - Includes 'complex' MPs (several active substances, several manufactured items,...)
 - Input from 5+ National Medicines Authorities
- ▶ **The UNICOM HL7/FHIR infrastructure services/server**
 - Make IDMP MP data available for testing and piloting various functionalities
 - Stepwise approach, start small, learning by doing
 - Coordination across UNICOM, and with EMA/IDMP (Task Force; Regulatory Data Management Service), stakeholders, SDOs, ... needed
 - Perhaps: Proposals for an EU IDMP governance framework
- ▶ **Testing & piloting applications**
 - Handling of data (in/out; query; ...) by and among NCAs, and with external users like eHealth Agencies, providers of Medicinal Products Dictionaries (MPDs), perhaps others
 - UNICOM xBorder pilots
 - Patient Apps



Outreach to stakeholder groups and trans-Atlantic cooperation

- ▶ **UNICOM eHealth STAKEHOLDERS Outreach** (Webinar for nurses, doctors, pharmacists, patients) “Understand the issues at stake and make your voice heard”
 - To be offered also to other stakeholders
 - April, to be repeated in 6-12 month intervals
 - Around 100 participants, also available on UNICOM YouTube channel (<https://unicom-project.eu/unicom-youtube-channel/>)
- ▶ **Trans-Atlantic Cooperation**
 - Introductory workshop for key actors and stakeholders in North America
 - Participation of FDA, EMA, WHO and global SDO representatives
 - Ultimate purpose is harmonised, globally consistent IDMP implementation
 - Bi-monthly webinars targeting different stakeholders of the value chain - establishing a trans-Atlantic community of IDMP practice, learning from each-other

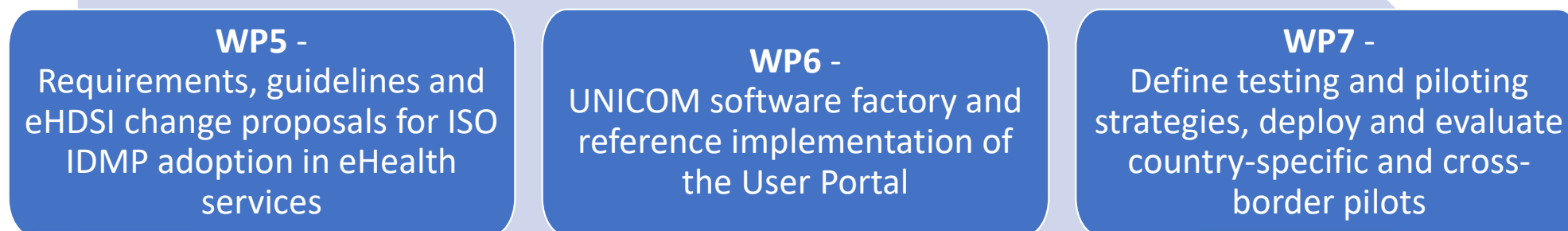


WPs 5-7: *X-Border* IDMP implementation requirements – response to eHDSI Wave-6 priorities

- ▶ **Co-operation with CEF eHDSI eP Cluster and eHMSEG Semantic Task Force is fundamental to reach the project objectives**
 - **Liaison to start the preparation of the Change Proposals for including IDMP attributes (based on NCAs implementations for SPOR) – those groups are counting with us!**
 - **Try to solve the issue of complex medications and complex packaging**
 - **Strict cooperation on the implementation phase (WPs 6-7)**



WPs 5-7: *X-Border* IDMP implementation requirements – response to eHDSI Wave-6 priorities



Strict cooperation between UNICOM and eHDSI communities

- ✓ Identify the requirements (business, semantic and technical)
- ✓ Elaboration of the Change Proposals
- ✓ Implementation of IDMP in the eHDSI systems
- ✓ Solving complex medication and packaging issues



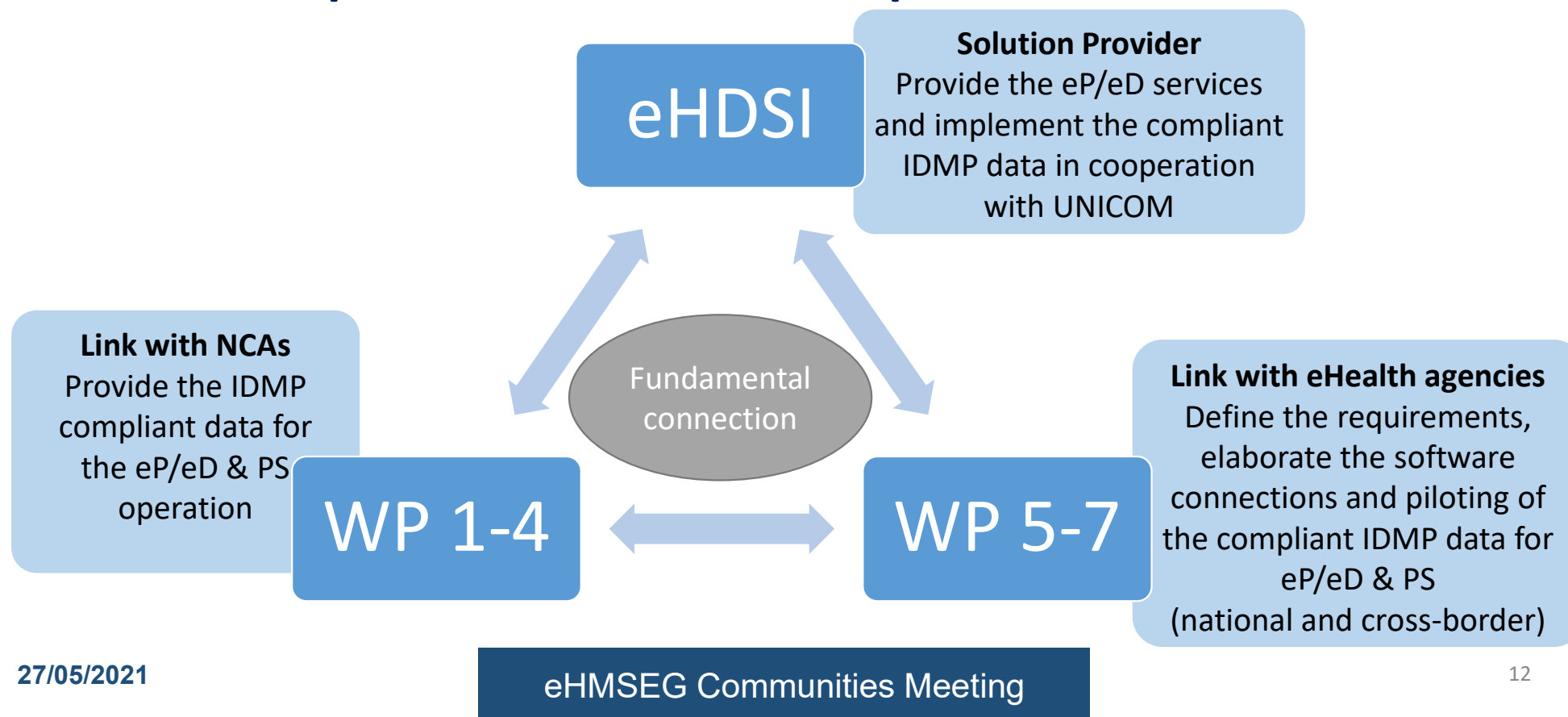
CEF eHDSI communities (eP/PS clusters, Semantic Task Force: Architecture & Semantic)

IDMP implementation in Wave 6

eHN SG on Semantic: PS / eP Guidelines



WPs 5-7: *X-Border* IDMP implementation requirements – response to eHDSI Wave-6 priorities





WPs 5-7: *X-Border* IDMP implementation requirements – response to eHDSI Wave-6 priorities

- ▶ **Collaboration with WPs 1,2,3,4 to define the medicinal products attributes list required for eHealth services**
- ▶ **Attributes relevant to NCAs**
 - **What information is possible to provide**
- ▶ **Attributes relevant to CEF eHDSI (eHealth)**
 - **Priority order**

**Common list of requirements for
IDMP adoption considering the
needs and availability of the
different agencies that integrate
UNICOM
eHealth agencies & NCAs**



WPs 5-7: *X-Border* IDMP implementation requirements – response to eHDSI Wave-6 priorities

► Status of activities:

- ✓ **Improved eP/eD and PS Business Requirements:** ready for consideration as a source for a Change Proposal
- ✗ **Define extended Data Set for eP/eD and PS** including IDMP attributes and identifiers (cfr. eHN eP Guidelines Rel 2. & eHN PS Guidelines Rel. 3)
- ✗ **Validate extended Data Set** with NCAs and eHMSEG eP Cluster & STF
 - **What** we can get from European Marketing Authorisation Application submission system
 - **When** we can get IDMP implementation by National Medicines Authorities
- **Define eP/eD and PS Implementation Guide** with eHMSEG eP / PS Cluster & STF
- **Define enhanced architectural requirements and CDA Display Tool Requirements**
- **Provide beta reference implementation** of enhanced OpenNCP components, CDA Display Tool, Gazelle eP/eD & PS documents scrutiny test tools






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Q & A

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