UNICOM Final Conference

NH Bloom, Brussels, Belgium (https://maps.app.goo.gl/6LTGup4RkJjKxQU79)

UNICOM meets for its Final Conference on 25-26 April 2024, in Brussels**.** The two-day conference will showcase results achieved in collaboration between 41 beneficiaries over 4.5 years. The second day focusses on European and global alignment and scaling up efforts, thereby featuring high-level panellists.

The final conference highlights in particular the need for further progress in:

1. Establishing IDMP compliant data sources at National Competent Authorities for Medicinal Products (NCAs) level for sustainable data management
2. Connecting trusted sources for shared medicinal product data in Europe
3. Ensuring medication safety along the patient journey.

Who participates:

Day 1 – Internal consortium meeting (round table discussions)

Day 2 – High-level Open Final Conference (plenary panels)

UNICOM Project facts: https://unicom-project.eu/

- H2020 Innovation Action
- Duration: 11.2020 – 05.2024 (54 months), 21M € Total Budget
- Outputs: 90 Deliverables (135 incl. updates)
- Consortium: 41 partners, 19 countries
  - ▷ 9 Standard Development Organisations
  - ▷ 11 National Competent Authorities (NCAs) for Medicinal Products
  - ▷ 10 National eHealth Competence Centres / National eHealth Contact Points
  - ▷ 4 Industry partners (Health IT)
  - ▷ 2 Research Organisations
  - ▷ 2 Medicinal Database Providers
  - ▷ 3 Non-profit organisations

UNICOM's ambition centres on the conversion of key regulatory and clinical processes using the International Organization for Standardization suite of Identification of Medicinal Products (ISO IDMP) standards. These information value chains must be converted over their full length from data input to data repositories to data usage. Project work spans all three areas, focusing on the most challenging, the implementation of EU and national SPOR (substances, products, organisations, referentials) databases, including establishing an EU Substance Reference System (EU-SRS). Such information is fundamental to cross-border ePrescription where safe dispensation may require reliable identification of substances in available products. NCAs play a central role in achieving a univocal drug identification system, essential for safe cross-border data exchange and the delivery of cross-border Patient Summary, ePrescription and / eDispensation, relevant also for further European Electronic Health Record Exchange Format (EEHRxF) services such as Hospital Discharge Reports. UNICOM's impact is substantial, as it facilitates health data exchange within the EU while also contributing to clinical research and pharmacovigilance.

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Agenda Day 1 – Thursday, 25 April 2023: Consortium members only

09:00 – 10:00	*Coffee, registration and exhibition setup*
10:00 – 10:30	Welcome by Project Coordinator and EC Project Officer Veli Stroetmann and Farah Diehl-Fahim, empirica; Christos Maramis, HaDEA
10:30 – 12:00	**Value chain vs. local approach** ***Discussion Points:*** • NCAs current dataflow • Resume: how did IDMP implementation impact me? (need to look at all business cases in the value chain and anticipate evolutions) • Use concrete existing and prospective examples from countries • Advantages, implications and enablers With • Jose Simarro, AEMPS • Rutt Lindstorm, TEHIK • Ursula Tschorn, IDMP1 • Frederic Doc, VIDAL • Anja van Haren, CBG Moderator: Christian Hay
12:00 - 13:30	Lunch and exhibition
13:30 – 14:30	**Ensuring sustainability** ***Round 1:* Scaling up implementation**: EU-SRS and ISO IDMP SPOR; eAF (PLM); IHE processes ○ Priority actions expected from main actors at EU and national level ○ Common public-private collaboration space (testing and validation) With: • Georg Neuwirther, AGES • Torarne Berg, NOMA • Maja Fatiga, HALMED • Veronica Lipucci Di Paola, EMA • Jose Costa Teixeira, IHE • Sofia Franconi, IHE Moderator: Luc Nicolas
14:30 – 15:30	**Ensuring sustainability** ***Round 2:* Stakeholder perspectives on scaling-up and meeting ethical standards** ***Discussion Points:*** • Funding IDMP – the costs of a national and European ecosystem creation • Explore the efficiency gains from a deeper integration of workflows (ensuring data quality and consistency in the value chain, reducing duplication) • Explore ethical standards from stakeholder perspective With: • Veronica Lipucci Di Paola, EMA • Annet Rozema, CBG - EU SRS • Robert Van der Stichele, i~HD • Nicole Veggiotti, DWIZ • Robert Stegwee, NICTIZ Moderator: Petra Wilson

15:30 – 16:30	Coffee Break and exhibition
16:30 – 18:00	**Way forward** • The UNICOM white paper and its call for actions • How to best use the results from UNICOM after project ends ***Discussion points:*** • UNICOM Policy recommendations • What have we achieved, what did we not succeed to agree upon (and why) • Explore a coordination between EMA and UNICOM next. With: • Karin Grondahl, SEMPA • Marc Lange, EHTEL • Dmitry Etin, EMA • Peter Bachmann, ex. BfARM • Marcello Melgara, ex. ARIA • Alexander Berler, GNOMON Moderators: Farah Diehl-Fahim and Christer Backman
18:00	End of day 1
19:00	Consortium Dinner

Agenda Day 2 – Friday, 26 April 2023: High Level Conference Open registration (up to 250 People)

	Plenary
8:30 – 9:00	Registration and Welcome coffee
09:00 – 09:30	**Welcome and introduction to UNICOM Project and Conference Panels** **Veli Stroetmann** - Director empirica, UNICOM Coordinator, **Christos Maramis** - EC Project Officer, **Luc Nicolas** – Communication & Dissemination Lead **Introduction to UNICOM key achievements**
09:30 – 11:00	**Policy Panel: Towards a wide IDMP implementation in Europe** ***Objectives:*** Highlight UNICOM achievements and discuss with high level policy makers and experts the need for further alignment and key actions required to speed up the process towards achieving interoperability in the **European Health Data Space** and delivering added value for citizens and society. UNICOM is highly strategic aiming to make significant progress towards the implementation of the IDMP suite of standards in Europe and extending its use beyond pharmacovigilance along the whole value chain. It holds the promise of a **fully integrated medicinal products ecosystem** which will be delivering important added **value for the citizen and society as a whole**. The panel will discuss how the use of IDMP can help to advance safe and secure supply of medicines, promote equitable access to medication whilst driving efficiency and sustainability in healthcare system; and support personal autonomy. The panel will explore UNICOM's potential to help EU healthcare systems in reaching these objectives, focussing on what actions are needed to speed up the process. The session will bring the key public actors and decision makers at European and national levels around the same table to agree on key actions needed to take UNICOM from promise to reality. ***Panellists****:* • **Saila Rinne,** Acting Head of Unit eHealth, Wellbeing and Ageing, DG CNECT.H.3, European Commission • **Jérôme De Barros**, Policy Officer, EHDS/ Digital Health, DG SANTE.C.1, European Commission • **Isabel Chicharo**, Head of Data and Information Lifecycle Management Service, European Medicines Agency • **Audun Hågå**, Director General, Norwegian Medicines Agency • **Klara Jirakova**, MyHealth@EU eHealth Member States Expert Group (eHMSEG) Co-chair, Vysočina Region Regional Authority, Czech Republic • **Eamonn Coyne**, Digital Health Specialist Assistant Principal eHealth Unit Department of Health, Ireland. Co-Chair eHMSEG, UNICOM National eHealth Agency • **Melanie Fysentzou**, National eHealth Authority (NeHA) Cyprus & Extended EHR@EU Data Space for Primary Use (Xt-EHR) Joint Action *Moderated by:* **Petra Wilson,** UNICOM lead on Legal / Ethical aspects and Information Governance Expert at The European Institute for Innovation through Health Data (i~HD)
Background information	Prior to the conference, all participants to the conference will be provided with the UNICOM white paper which summarises UNICOM key recommendations.
11:00 - 11:30	Coffee Break

11:30 – 13:00	**Beyond the EU: Towards Global Alignment** ***Objectives:*** UNICOM activities to support global alignment, challenges for global identifications and terminologies, status of IDMP pilots, next steps to align outcomes with national and regional implementation in Europe, North America and other countries. This session will analyse the activities pursued by UNICOM and its associated partners to support global alignment and disclose what future progress can be expected. UNICOM has provided crucial input to the Standards Development Organisations (SDO). It started with the gap-analysis, which is feeding the ISO revision processes for IDMP standards, as well as for other SDOs. UNICOM experience has also provided important input to addressing gaps, improving communication and education. Challenges for global identifications and terminologies have been triggered by UNICOM's feedback. That was for dose forms, substances, their combination with units of measurements to calculate the Pharmaceutical Product Identifier (PhPID) on a global level –a milestone which is still in pilot phase. How can this be aligned with national and regional implementation in Europe, North America and other countries? We will further hear what can be done to expand IDMP use in other processes such as those defined by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and WHO classifications and more. ***Panellists***: • **Isabel Chicharo**, Head of Data and Information Lifecycle Management Service, European Medicines Agency (EMA) • **Ron Fitzmartin**, Center for Biologics Evaluation and Research (CBER), Food and Drugs Administration (FDA), United States • **Sonya McHugh**, Business Services Coordinator, HPRA Ireland, UNICOM National Competent Authority • **Malin Fladvad,** Product Portfolio Manager**,** WHO Uppsala Monitoring Centre (WHO-UMC), Sweden • **Frits Stulp**, Life Sciences & Healthcare Industry Leader for Deloitte in the Netherlands • **Giorgos Georgiannakis,** Acting Head of Unit, Information systems, DG SANTE.R.4, European Commission *Moderated by*: **Christian Hay**, UNICOM standards alignment lead, ISO TC 215 convenor and GS1
Background information	• IDMP in a capsule • FDA IDMP guidance
13:00 – 14:00	Lunch

14:00 -16.00	**Scaling up across the healthcare landscape** The closing panel discussion of the conference will focus on **how to maximise and accelerate the benefits IDMP can bring to healthcare systems, healthcare professionals and patients**. It will be a two-hour session with two panel discussions. ***Objectives*** of these sessions are to explore: • The needs, opportunities, benefits (use cases) from embedding and exploiting IDMP across the healthcare landscape • The solutions and the learnings from UNICOM that can contribute to this uptake and value realisation • Stakeholders critical to this uptake, what calls to action should we promote ***Panel 1: Impact on end-users and exploring new use cases*** The first panel will focus on the use cases and patient care situations in which the standardised identification and representation of medicinal products (across and within borders) could reduce risk and improve clinically effective decision-making regarding the prescribing, dispensing, utilisation of and adherence to medicines. The panel will comprise different health and care stakeholders, including a patient representative. ***Panellists:*** • **Alexandra Pacurariu,** Scientific administrator, European Medicines Agency - Darwin project • **Olivia Dalleur**, Hospital pharmacist UC Louvain University Hospital, Belgium • **Benjamin Fauquert,** Medical Doctor and evidence-based medicine developer**,** Belgium • **Lisbeth Siderius**, Paediatrician, Patient perspective for rare diseases, The Netherlands (TBC) • **Bart Vannieuwenhuyse**, Senior Director Health Information Sciences at Janssen, Pharmaceutical Companies of Johnson and Johnson, Belgium ***Panel 2: Sustainable UNICOM resources for EU and National projects*** Having understood the use case opportunities, the second panel will involve representatives from projects and initiatives to critique the resources developed in the UNICOM project and consider how these might be used to deliver those use cases. It will also suggest if there are complementary resources relevant to IDMP adoption, developed by others, that should be brought into the frame. ***Panellists****:* • **Kyriacos Hatzaras**, Programme Officer – EU policies, DG-CNECT, European Commission • **Zoltan Lantos,** Potential Large Scale Pilot on ePrescription, Head of Department of Virtual Health Guide Methodology, Hungary • **Anne Moen,** Coordinator GravitateHealth IMI project**,** Professor at University of Oslo, Norway • **Nicole Veggiotti**, UNICOM Patient Facing App, Technical Project Manager, Datawizard, Italy • **Frederic Doc**, Medicinal Product Dictionary, Vidal, France *Moderated by:* **Dipak Kalra**, UNICOM clinical value chain lead, President at The European Institute for Innovation through Health Data (i~HD)
16:00	Coffee Break
16:00 – 17:00	**Poster session** UNICOM Work Packages and the 11 National Competent Authorities have produced posters highlighting main achievements. These are displayed throughout the day and project members will be available to engage in an interactive discussion with the participants. All posters will be published on the UNICOM website. **Countries represented:** Austria, Belgium, Croatia, Ireland, Estonia, Finland, Germany, Norway, Portugal, Spain and Sweden.