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Deliverable abstract

UNICOM first year dissemination strategy had as priority to increase awareness within the first inner circle of the ISO-IDMP impacted value chain. Although the COVID-19 context has not stimulated contacts and has strongly limited the possibility of direct interactions, UNICOM objectives and challenges are now known by an extended community of expertise and working relationships have been established with the main EU related bodies. The first results obtained have immediately been made available to a wider audience via different channels.
The communication team has been created and the engagement of all partners in the communication strategy has been secured. Both closed and open events have been organised in order to collect supplementary inputs while increasing knowledge. Preparatory work for future organisation of events targeted at end users has been done.

During the second year of the project, the focus has been put on enlarging the UNICOM audience beyond the first inner circles, reaching out the stakeholder's segments which are not directly represented in the project, deepening strategic partnership with key game-changer organisations and fora, and adding additional communication channels and tools such as the UNICOM newsletter or the IDMP in a capsule format. *With a name well established, a "structural" presence in strategic fora and clear propositions to identified gaps, the project was thus equipped to base its communication in 2022 on the first results and concrete proposals.*

During the third year of the project, UNICOM was directly confronted by concrete implementation issues and to the different needs and timing associated with the different use cases to be tested during the last phase of the project. It coincided also with the first major IDMP related EMA "go-live" in November 2022 related to the electronic submission of variation forms or the EU-SRS. This has led to many important alignment discussions between the different WPs and with external stakeholders. This has also contributed to a better understanding of what was needed, what was still missing and of the different possible solutions. The publication of a number of scientific articles directly related to critical open issues has also greatly contributed to the credibility of the project. Most importantly, all actors involved in the project have integrated the vision of a globally integrated eco-system where critical actors such as National Competent Authorities have use cases in mind and thus play a pivotal role in providing Medicinal products interoperable data to all their national health actors.

Keywords:

UCT, engagement, knowledge transfer, ISO IDMP awareness, website, social networks

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List of abbreviations

Abbreviation	Complete form
CAP	centrally authorised product
CEF eHDSI	connecting europe facility eHealth digital service infrastructure
EAEP	European Association of E-Pharmacies
eAF	electronic application form
EAHP	European Association of Hospital Pharmacists
eD	eDispensing
EDQM	European Directorate for the Quality of Medicines & HealthCare
EFPIA	European Federation of Pharmaceutical Industries and Associations
eHMSEG	eHealth Member States Experts Group
eHN	Art. 14 eHealth Network established under Directive 2011/24/EU
EMA	European Medicines Agency
eP	ePrescription
FDA	Food and Drug Administration of the United States
GIDWG	Global IDMP Working Group
HL7	Health Level Seven
HMA	Heads of Medicines Agencies
ICH	international council for harmonisation of technical requirements for pharmaceuticals for human use
ISO IDMP	International Organisation for Standardization for the identification of medicinal products
ISO TC 215	ISO Technical Committee for Health Informatics
MedDRA	medical dictionary for regulatory activities
MP	medicinal product
NCA	national competent authority
PGEU	Pharmaceutical Group of the European Union
PhPID	pharmaceutical product identifier
PLM	product lifecycle management portal (EMA)
SDO	standards developing organisation
WHO-UMC	Uppsala Monitoring Centre

1 Executive summary

*This deliverable provides an update of the dissemination activities performed during the third year of activity of the UNICOM project**. To make reading easier, the 2022 additions appear in italic**. It thus builds upon the deliverable created at the end of the first two years of activity with an update of all the sections where new information is available.*

The third year of UNICOM activity has been taking place in a post-COVID-19 context where physical interactions have progressively been possible again and saw the consortium members meet for the second time in September 2022. This was also the case for a number of meetings organised by the different WPs. The participation of UNICOM to external physical events has also restarted while the participation to virtual events has remained intense.

Disseminating about UNICOM is not an easy endeavour. Drugs identification is a very complex issue and the contribution of IDMP standards to the solving of this issue is only known by a limited community of expertise, even within the premises of the environments where the solution can be the most beneficial. Given the high level of abstraction, the availability of concrete solutions or at least of explicit demonstrators, matched to demonstrated use cases, is indeed needed to reach out a wider audience.

Consequently, the UNICOM dissemination strategy has established that it was first of all required to inform and extend the level of information and awareness of the first inner circle of concerned people and organisations. This is also needed to obtain the feed-back, the support and the buy-in of the many actors who need to be involved but are not direct UNICOM partners. To support this goal, the activities performed by WP1 (Open community of expertise monthly webinars) and by WP4 (Knowledge transfer workshops for National Competent Authorities) have been completed by the participation of UNICOM to a number of strategic meetings and events organised by project partners or contributors. In parallel, working contacts have been established with the relevant EU bodies, such as the European Medicinal Agency (EMA) or the eHealth Network.

UNICOM has also established a solid basis to be able to gradually extend further its dissemination activities: A dedicated communication team has been created and all partners have been informed about the role they are expected to play. The UNICOM website has been created and extended and the pertinent social networks have been activated. Internal communication tools have also been developed in order to make publicly available as soon as possible all resources created by the project so that they can be consulted by the widest possible audience. Important preparatory work has also been done in order to avail mailing lists which will allow UNICOM to reach, in most EU Member States, the audiences targeted by the project.

This objective has been further pursued and reinforced during year 2 with specific dissemination activities directed towards the e-Heath community and the end -users (clinicians, pharmacists, patients) while regular dissemination and engagement activities in WP1 and WP4 have been opened to a larger audience. UNICOM has also begun to address decision making at European, Trans-Atlantic and global levels with a number of remarkable successes such as the presence of UNICOM in eHealth network meetings and eHmseg fora, the first Trans-Atlantic meetings and the creation of an IDMP working group between EMA, WHO-Upsala and FDA. All segments of the UNICOM consortium have also finalized the elaboration of value propositions on which more fine-tuned communication messages rely upon. Additional communication channels such as the UNICOM Newsletter or “IDMP in a capsule” have been created to help reaching out to a wider and more diversified community and collaboration agreements with projects such as Gravitate-Health which can support the project objectives and help us to reach specific stakeholders have been concluded.

The third year of the project coincides with an increased focus on "sustainability" which got translated in our key recurrent message: "UNICOM creates interoperability at the source".

The project duration has been extended by a period of 6 months in order to align UNICOM timing with timelines external to the consortium and in particular the one related to eHDSI where implementation is now attempted in routine operation. The third year of the project has seen the delivery of major results greatly impulse and supported by UNICOM such as the first official release of the Substances referential in April 2022 and the go-live of the IDMP compliant web-based Human Variations electronic application form (eAF) for centrally authorised products (CAPs) in November. UNICOM has intensified its communication on those topics. From UNICOM, a lot of efforts have been accomplished by a number of NCAs to provide UNICOM IDMP FHIR Server with the data needed in order to conduct the pilots and provide both a training ground and a vitrine for all European NCAs.

The dissemination activities of WP3 have been oriented, in close collaboration with EMA, towards the appropriation of the FHIR standard related to Medicinal Products and variations by NCAs, both at managerial and technical levels while WP4 has relaunched a new series of knowledge transfer webinars opened to all EU NCAs which are now definitely oriented towards results and next steps rather than objectives. Those webinars are also instrumental in documenting gaps and requests related to communication between NCAs and EMA. Although a bit less numerous than during year2, the Community of Expertise organised by WP1 are also providing excellent results with a high level of attendance and a universal coverage. Discussions around the global governance process has intensified both within the consortium and with strategic actors such as EMA, FDA and WHO-Upsala with now clearly documented open issues, paving thus the way for concrete solutions. The release during this year of a number of critical scientific articles, let alone the publication of posters and proceedings of external events, provide also new insights and suggest concrete solutions. It is also an important milestone as it further consolidated UNICOM credibility and contribute to maximize impact. The UNICOM policy to disseminate quickly important deliverables as "working papers" has also been continued. All communication channels and supports have been maintained and extended and new concepts have been introduced such as e.g. the personal interviews of NCA representatives. Specific actions have also been conducted to reach out to certain categories of end-users with this year a focus on Industry (EFPIA) and Pharmacists while the eHealth community has also been specially targeted considering the direct link now established with the upcoming eHDSI release waves.

2 UNICOM Dissemination Strategy

With 39 partners representing all the value chain originating from 21 EU countries, Norway, UK and the USA UNICOM is in itself a wide eco-system. The UNICOM Dissemination Strategy is thus somewhat specific as internal dissemination within the consortium is essential to reach out an enlarged and diversified community.

The UNICOM dissemination strategy follows thus two parallel workstreams: Establishing direct communication channels to reach out new audiences and empowering project partners to engage in more targeted dissemination in their local eco-system.

2.1 UNICOM Actions and timeline

The UNICOM four main dissemination actions are aligned with the project cycle. While awareness raising will remain a central preoccupation during the whole life of the project, other actions are more dependent on the availability of results and resources which will be only available at a later stage.

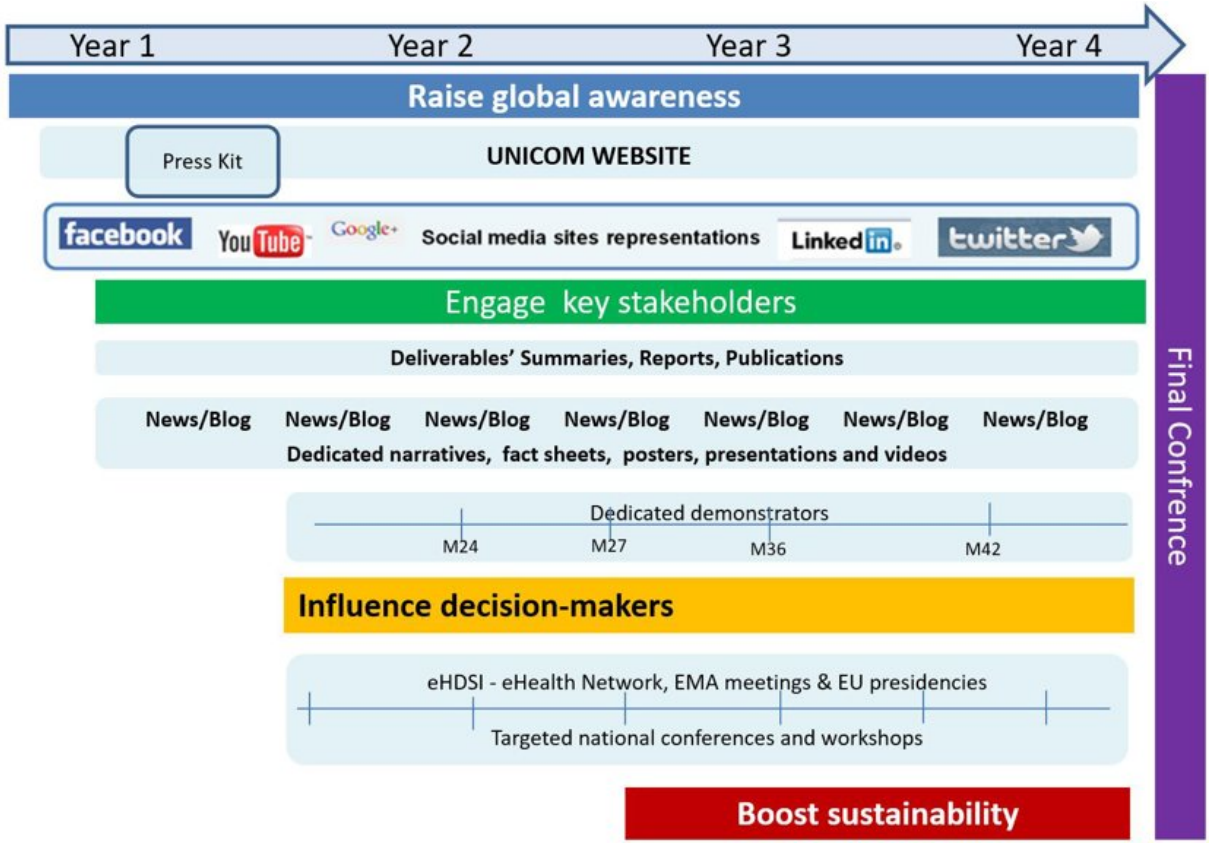


Figure 1. Unicom Dissemination timeline

2.1.1 Current timeline

The first year of the project has established the initial infrastructure and the communication channels to support UNICOM objectives. The "branding" of UNICOM was a priority objective and so was the engagement of the first inner circle of related community of expertise at National Competent Authorities, Industry and Standard Development organisations levels. This preliminary work has been mainly

addressed within the premises of each work package or through the participation of UNICOM to targeted external events.

During the second year of year of the project, the key focus of the dissemination strategy has been put on increasing the level of engagement (both quality and quantity wise) of the different categories of stakeholders impacted by IDMP implementation, including the end-users. The many activities performed by several Work packages such as WP1 (Community of expertise), WP4 (NCAs knowledge transfer) and WP5 (eHealth community) have succeeded to build an extended network of contacts which is now actively used to support all major dissemination activities and develop new communication channels (such as the UNICOM newsletter or "UNICOM in a capsule"). The name of UNICOM has thus now firmly established: analysis has been progressing and that solutions begin to be proposed, activities associated with influencing decision makers have been also gaining in importance and relationships with strategic bodies such as EMA, FDA, WHO competent centres and the eHealth Network have also been progressing significatively. With the availability of the first results such as the gap analysis report or the results of first surveys organised by WP5 and WP8, UNICOM key messages will increasingly be adapted and re-oriented towards the practical solutions proposed by the project.

The third year of the project coincides with a progressive focus on "sustainability": This would not be possible in the absence of concrete results and the sustained and reinforced engagement of the key stakeholders. This is precisely what took place: Among the participating NCAs, 2022 has seen a major change in the public attitude of public bodies: NCAs, even the more conservative ones, are now feeling increasingly confident to reflect on their progress and objectives and to apprehend their critical role in federating a global ecosystem. This was not possible at the beginning of the project as there was clearly a lot of questions, fears and hesitations. The dissemination activities pursed by UNICOM have thus used all its channels and formats to amplify the voice of the most engaged stakeholders and have also used new channels such as scientific publications to reinforce its credibility and audience. A lot remains to be done but the key questions remaining to be solved are now exposed and generic solutions for Europe and beyond (see transatlantic aspects in particular) have been proposed. The various dissemination activities performed with the support of the different WPs have been increasingly oriented towards disseminating results, supporting the acquisition of the necessary skills and knowledge, identifying good practice and discussing solutions for the most important remaining pending issues. The fora established during the previous year's such as the Global IDMP WG gathering EMA, FDA and WHO the have been maintained and further reinforced.

2.1.2 Covid-19 context

The work performed by the UNICOM project has only indirectly been impacted by the ongoing COVID-19 pandemic. During the second-year physical meetings remained impossible to organise. Major external events were again either cancelled, postponed or substituted by virtual events. Most of the National Competent Authorities which have been under constant stress since the start of the pandemics experienced again difficulties to allocate all the time and resources they wanted to the project. Nevertheless, significant progress has been achieved both in term of gaps analysis and preliminary developments.

Like many others, UNICOM has thus adapted to this new context and has made an extensive use of teleconferencing services.

It is however clear that the lack of direct interactions during physical meetings or events has somewhat minimized the impact of some UNICOM activities as this is usually prone to trigger supplementary exchanges and communication opportunities.

UNICOM has somewhat compensated this by a more pro-active approach in identifying virtual events and meetings which allows the consortium to reach new audience mainly but not only through "decentral dissemination "via all project partners while maintaining a permanent presence in a number of fora and workgroups. This has further been reinforced in 2022 but from March 2022 on, physical meetings became finally again possible although many organisations have been slow to adapt their policy and approve travels abroad. From summer 2022 this restriction has been lifted but one notices that attendance to physical events and conferences has not yet reached the pre-covid level. Hybrid events are thus some kind of a must now but come with important associated costs. The UNICOM consortium has finally succeeded to meet physically in September 2022 and physical attendance to external events by UNICOM members has also been substantial during the second part of 2022. Physical attendance has without any doubt highly contributed to reach consensus within the consortium on a number of sensitive issues.

Finally, the Covid-19 context can also be seen as an opportunity for UNICOM: The growing call for a coordinated response in term of vaccines registration and pharmacovigilance can allow UNICOM as a strategic partner capable to bring together in a short lapse of time all the key players.

2.2 UNICOM dissemination objectives

In this section, we review each of the UNICOM objectives described in the UNICOM dissemination strategy deliverable (DEV 12.2) and identify the activities undertaken by the consortium to support them during the second year of the project.

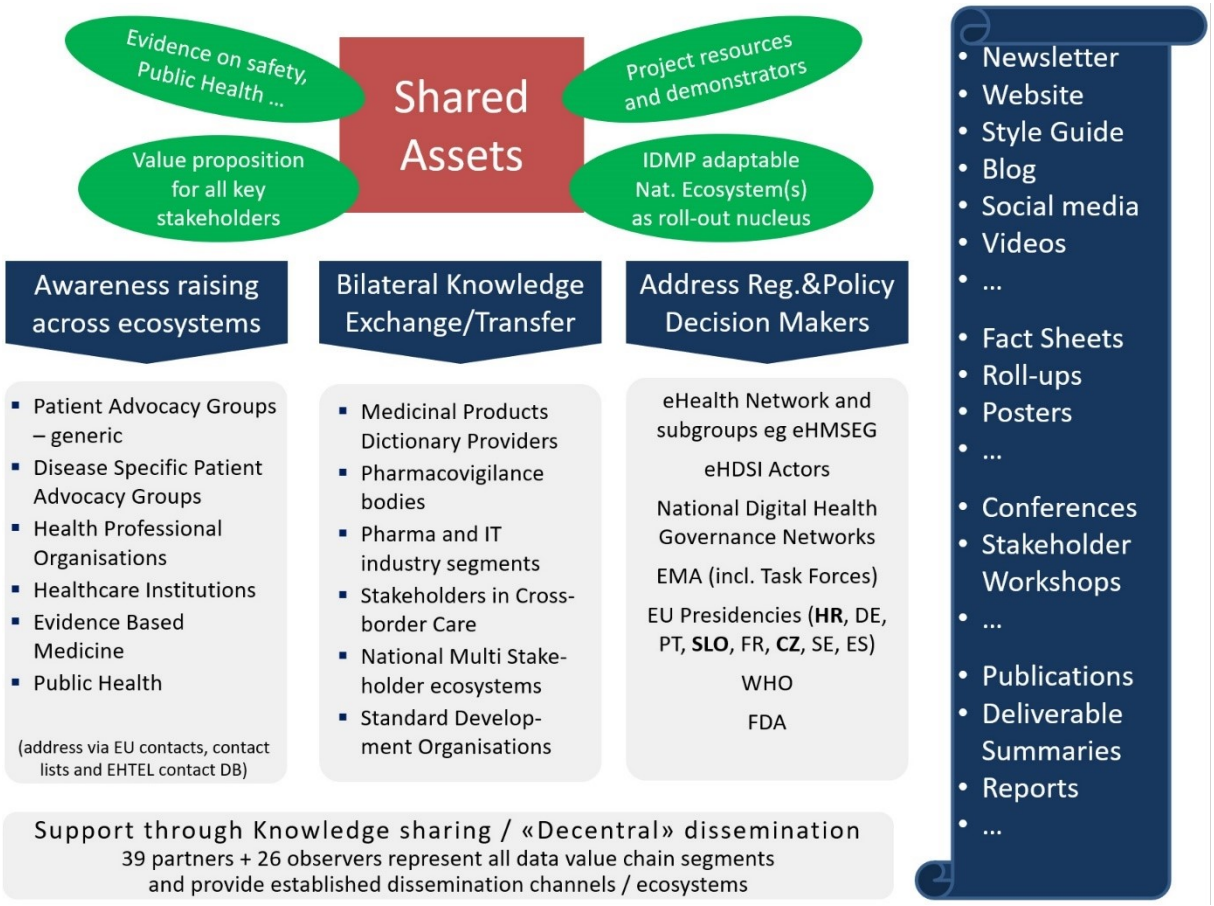


Figure 2. Unicom Dissemination objectives

2.2.1 Awareness raising across systems

Dissemination Objective 1 (DO1) concerns raising wide awareness and dissemination such that information on all key initiatives is **spread to** and **understood by** national and international stakeholders through tailored methods and channels to increase awareness and insights into the **concrete role** IDMP can play for them in future.

UNICOM understands the critical importance to address end-users sufficiently early in the project cycle and to be able to communicate UNICOM messages in such a way that they become meaningful for an audience which is not familiar with the standardization issues. Some important preparatory work (mailing lists, networking) has been done during the first nine months of the project so that targeted activities could actually be started from December 2020 onwards. UNICOM has tried to identify national organisations in each EU Member States, to build a dedicated mailing list on order to be in the capacity to address and target each category of end-users independently. This list has been partially created with the active support of UNICOM partners and include patients, pharmacists, evidence medicine and

hospitals national umbrella organisations. UNICOM has thus been in a position to organise successfully in 2021 its first end-users-oriented event, developing stories adapted to each category of end-users. UNICOM has also participated to a number of events which also targeted or included end-users (**See updated list in annex)**.

The decentral communication via the project partners or the information sharing through national eco-systems plays here also a key role. The end-user's representatives can indeed play an important role to convince competent authorities to take active steps towards IDMP implementation provided that a clear rationale demonstrating its added value for them can be elaborated. When no real solution can be found at national level, stakeholders' engagement is also instrumental in developing alternative scenarios. The involvement of a wider eco-system is thus a necessity in Europe but also in other regions of the world and in particular, in the United States. *UNICOM has made complementary preparations in 2021 and 2022, with tools such as the demo "IDMP in a capsule" which was translated in French while a German version is now well advanced. Given the complexity of the issue and the need to rely on a controlled vocabulary, we have also developed a strategy to have this tool translated in other EU Member States where English is not widely understood. This will thus materialize in 2023 and should support the different national meetings/events due to take place in a number of EU MS with the involvement of NCAs active within UNICOM in 2023 now that implementation and roles are becoming clearer. In strategic countries where there is no active UNICOM NCA, we plan to rely on other partners and use actively the SDOs network affiliates of WP1 to organise those meetings/events. In 2021, a first multi-stakeholders' event has been organised in a non-active and participating NCA country -Greece- with an excellent level of attendance. This will be repeated again in December 2022 in Greece but with this time a more active involvement of the Greek NCA and the organisation of a dedicated workshop supported by a global pre/post event communication strategy. Depending on the opportunities and reactions of NCAs active in UNICOM, we will be selecting the best available option.*

UNICOM has been put at the agenda of the meeting of the EU eHealth stakeholders group organised by the European Commission but the COVID-19 context has led the EU Commission to change the agenda at the last minute. UNICOM will however keep the pressure to use this forum to reach end-users EU umbrella organisations. The UNICOM end-users' organisations with a status of observers in the consortium will of course be also more actively involved.

UNICOM has already participated to a number of events which also targeted end-users (See list in annex). Let's mention for example the participation of UNICOM NCA BFARM to an event organised by the "Tallinn Health Care College (THCC) in October 2020 on the theme: "Public Health & Healthcare in the Move — Opportunities and Challenges in Research, Practice and Policy or the EHTEL webinar dedicated to UNICOM in September 2020 and another session during the November 2022 EHTEL symposium on the theme "creating interoperability at the source" (See list in annex). Another example is the participation of UNICOM in GPs fora, such as the CISP club in Belgium on November 6 2020 and again in November 2022 where the added value of IDMP was presented in the context of decision support tools. Finally specific efforts have been initiated to inform and involve more pharmacists' associations and consider different configurations and needs, namely Hospital pharmacists, online pharmacies and independent pharmacies with several meetings organised with representative associations with the objective to both increase awareness and collect feed-back and additional requirements.

2.2.2 Bilateral Knowledge exchange/transfer

Dissemination Objective 2 (DO2) addresses mainly **the stakeholders directly represented i**n the UNICOM consortium. *This has been a central focus of UNICOM dissemination activities since the first months of the project where each category of stakeholders has launched initiatives to reach out a wider community.*

13 National Drugs Competent Authorities (NCA) are direct beneficiaries of the consortium *although not all of them are involved in WP4*: 11 of them are EU members while Norway and UK are also represented. Slovenia is present in an observatory role. The 14 EU Competent Authorities not represented in the consortium need thus to be addressed through dedicated channels.

During the first months of UNICOM activity, the priority has been given to knowledge transfer between the NCAs active in the consortium via the activities of WP4 and in particular the knowledge transfer workshops organised from October 2020 on where each NCA shares with the NCA community the experience, open questions and challenges linked to IDMP concrete implementation. *Ireland, Sweden, Estonia, Austria and Croatia were the first 5 countries to have accepted to undertake this exercise during the last trimester of 2020 while Spain, Norway and Finland have presented their case during the first trimester of 2021 and Germany and Belgium have made it in November 2021. Portugal was provided with the same opportunity to exchange informally with the UNICOM NCAs community in January 2022. Preliminary analysis of the results of those workshops demonstrated the importance of putting considerable effort into informing within and outside the organisation on the* ***long-term impacts*** *of IDMP implementation. Convincing* ***administrative, scientific and regulatory experts in*** *the domain of the value of IDMP, be it only on the pharmacovigilance domain, is no trivial issue, especially at a time when* ***health systems in Member States*** *are under huge stress. The lessons learnt via those workshops are instrumental to identify specific gaps, define appropriate messages and scenarios targeted at the NCAs not active in the consortium. They are also essential in order to put NCAs in a position of constructive contradictory debate on how far should IDMP be implemented and their responsibility not only in the regulatory domain but also as a central player of the global eco-system.*

Since April 2021, WP4 has also initiated the organisation of webinars opened to ***non-participating Agencies****. 4 such webinars have been organised in 2021 with the last one was organised in December 2021, focusing on the use FIHR in support of IDMP implementation with WP3 input. The topics selected are directly related to key elements of the IDMP implementation; those webinars have thus first as primary objective to provide the non-participating NCAs with the most recent information and knowledge produced by UNICOM partners and to stimulate a concrete debate within each agency: The significant progresses achieved by a critical number of NCAs should indeed be interpreted as a clear signal that stand-by is not an option anymore.*

In 2022, all webinars were per default opened to all European NCAs and with the progress achieved in the past 3 years, the presentations were now oriented towards reporting on implementation as such. 3 countries volunteered from June 2022: Ireland, Sweden and Estonia. In the latter case, a full demonstration of the new IDMP system developed and deployed was performed. The tone of the messages was definitely positive as exemplified by this citation of Sean d'Art from the Irish Agency: ***"IDMP consistent implementation in the Irish Agency requires greater discipline but that the extra effort to improve and maintain data quality is NOT excessively time consuming and benefits are quick to become visible! we absolutely need to explain the longer-term vision within and outside its premises."***

In June and July 2022, UNICOM also organised two webinars directly related to the preparation of the "go'live" of the EMA variation forms. Few within European Agencies had deep knowledge with the FHIR standard and it was thus decided to organise a first webinar to explain how FHIR deals with Medicinal

products before getting into the details of the EMA variation forms. Those webinars were organised in very close collaboration with EMA in order to make sure to align timelines and organise supporting activities for the impacted stakeholders in a timely manner.

This activity will be pursued during 2023 and, once sufficient results and conclusions will be reached, invitations to NCAs beyond the European sphere will also be considered.

3 Major Standard Development Organisations (SDOs) are members of the consortium while 4 other SDOs (ISO, CEN, GS1, medDHRA, edQm) are currently closely associated to UNICOM activities as observers. WP1 has been extremely active since March 2020 in shaping and creating a community of expertise associating the widest possible audience. While the first activities related to the gap analysis were only targeted to a closed community (UNICOM members and invited experts), WP1 has started since June 2020 to organise **monthly open interactive webinars**. They target a wider public access to the UNICOM Community of Expertise and discuss current IDMP topics and further issues related to the identification of medicinal products in regulatory and clinical contexts. The webinars are complemented by an extensive questions and comments section. Issues discussed also support UNICOM to enrich its "Gap-Analysis" helping to identify open and new issues around the IDMP suite of standards and their implementation. *These webinars, although rather technical, have attracted an important audience (an average of over 100 participants live with roughly 50% of people external to the consortium). A detailed analysis of the audience is provided later in a dedicated section in the document but it is clear that the webinars have attracted experts from many non-EU countries such as the USA, Canada, Brazil, Japan, China, India, the Philippines, Bangladesh or Tunisia, only to name a few. About one third of the participants are essentially related to SDOs, while the rest of the participants are roughly equally shared between the research, clinical and regulatory domains. The timing of those webinars has been chosen in order to allow participation from experts from all continents. From March 2022 onwards, and due to resources constraints, it has been decided to organise those events on a bi-monthly or quarterly basis. The topics selected are always directly related to the most recent developments with the objective to provide the audience with new concrete inputs. We also created a summary of all Community of expertise webinars on the UNICOM website to provide a global overview of all the topics during the 21 events which have been organised so far.*

The survey initiated by WP8 on patient facing Apps targeted mainly at **European SMEs** has not only collected important inputs but has also provided a first awareness about IDMP potential benefits in this key segment of industry.

The other survey organised by WP5 about ePrescription/eDispensation (eP/eD) and Patient Summary (PS) systems and the legal basis of eHealth services (eP/eD and PS) has also provided a first level of information and visibility on UNICOM potential benefits to the wider **eHealth community**.

Supported by 7 NCAs, the activities of WP3 which aim at delivering web-based application forms compatible with IDMP standards also closely associate representatives from the **Pharma Industry**. In concertation with EMA, it has been decided to align UNICOM WP3 objectives with the EMA technology strategy in order to guarantee sustainability. Through this joint channel, one can be confident that knowledge transfer with the industry will actually take place. *UNICOM has also taken direct contact with Pharma Industry through EFPIA in November 2022 in order to provide it a global overview of the current developments and collect feed-back. A presentation to the EFPIA pharmacovigilance Working Group has been delivered and contacts have also been established with the Public Policy Working Group. The partnership established with the IMI project, Gravitate Health, also includes an important number of pharma industry actors and is also instrumental in this respect. UNICOM has been invited to make a comprehensive presentation at the Gravitate Health consortium meeting in February 2022.*

An initial workshop aimed at defining a value proposition has also been organised within each stakeholder's sub-cluster ((Pharma, EHR industry, SMEs, SDOs, NCA, eHealth competence centres) with the participation, in some cases such as the SMEs, Pharma and EHR clusters of both UNICOM and non-UNICOM partners). They are annexed to this document and provide a first view of the "needs/wants/ fears and expected benefits and expectations of each category of stakeholders. The material will be used to adapt the messages to each category of stakeholders and identify the topics which need to be further discussed between the several work packages.

In 2022, UNICOM maintained its participation to a number of selected events in order to inform each category of stakeholders of the progress achieved and upcoming milestones. (See list in annex)

14 EU countries and Norway are officially represented within UNICOM but 5 EU countries have no public or private partners participating in the UNICOM consortium (also in an observatory role): Denmark, Latvia, Slovakia, Hungary, Romania and Bulgaria. UNICOM will thus continue to pay particular attention to attract stakeholders from those countries in the future WP level or general events that UNICOM will organise and specific actions for those countries are considered under 2.2.3.

2.2.3 Influence Regulatory/Policy decision makers

Dissemination objective 3 (DO3) intends to influence decision-makers: "Ensure that the activities of policy-minded organisations are aligned to reinforce the scaling up of a univocal identification of medicinal products." This requires, in particular, a targeted addressing of regulatory and (health) policy decision makers.

The availability of concrete results and substantiated timeline is important when addressing decision makers. The COVID-19 context did not facilitate initially the possibility to address directly key decision makers or to stimulate national events around topics which are considered not to be top priority at this very moment. In Europe in 2021, National Competent Authorities had also to deal with the implementation of the Veterinary Medicinal Products Regulation and the new Medical Devices Regulation which has mobilized a number of critical resources. *In 2022, as already outlined before, National Competent Authorities began to feel increasingly confident in achieving results and have become more vocal in disseminating the UNICOM global vision and in assuming a role in distributing interoperability assets. Each participating NCA has been asked to propose to either organise and participate in a national dissemination meeting or event in 2023. Some resistance still however exists in some countries, especially in those where interoperability issues have already been partially solved.*

A structural collaboration with the eHealth network and the eHDSI Member State Expert Group

In 2022, UNICOM has further consolidated the contacts established in 2020 with the official ***European fora and committees involved in eHealth*** *both at strategic and operational levels (****See DEV.5.8 v.3*** *for more details and for a detailed list of all the meetings).* UNICOM was featured in the 18th meeting of the European eHealth Network (eHN) in November 2020: The eHN has mandated its Subgroup on Semantics to revise the guidelines and standards applied for the implementation of EU-wide ePrescription services. They need to reflect new developments, particularly also the pending implementation of ISO IDMP (Identification of Medicinal Products) standards and coding systems by National Medicines Authorities and the European Medicines Agency. The eHDSI provides two core cross-border services for European patients: electronic exchange of Patient Summaries (PS) and of ePrescriptions (eP). The UNICOM coordinator, Prof. Dr. Karl A. Stroetmann of Empirica GmbH, has been invited to participate in the monthly meetings of the subgroup as a permanent guest. At the operational level, UNICOM is closely associated to the work performed by the eHDSI Member State

Expert Group (eHMSEG) Communities, and in particular the semantic community and the ePrescription Cluster and indirectly also the patient summary cluster.

Furthermore, UNICOM organised in February 2021 the first UNICOM/eHDSI workshop dedicated to EU eHealth cross-border services More than 80 people attended the two-day workshop with attendees from national and regional eHealth Agencies, National Drug Agencies, the European Commission, and the wider stakeholder community.

In September 2022, a new workshop was organised with the extended European eHealth community in order this time to expose and agree on the next concrete steps foreseen in the wave 6 of eHDSI services deployment and the assets needed to support it. It was again attended by an audience of more than 80 participants originating from 21 EU countries and 3 non-EU countries (Norway, UK and Canada).

EMA is now aligned with UNICOM timeline

WP2 has been in direct contact with all EU National Competent Authorities concerning the EU-SRS (European Substance Registration System): The EU-SRS implementation plan had been endorsed in March 2020 by the Heads of Medicines Agencies (HMA) although it has since suffered some light delay. *EMA has been confronted to very substantial human resources limitations and until quite recently it proved difficult to implement and maintain critical actions on their side. This has finally evolved a bit more positively since the end of the pandemic and summer 2022, although numerous issues still remain pending. EMA is at least now releasing via its website the official non-confidential substances list* ***since March 2022*** *on a continuous basis and UNICOM has pre-released in November 2022 six important guidelines related to chemicals, Polymers, Proteins, Human vaccines, Veterinary vaccines and Homoeopathic in connection with EU-SRS which have been widely disseminated and welcomed, including by colleagues on the other side of the Atlantic. As the availability of the substances referential was a major obstacle to IDMP implementation, UNICOM has certainly been essential to keep the momentum. We have used all our dissemination channels to keep this action as high as possible on EMA's agenda.*

Work packages 3 and 4 have also been in direct operational contact with EMA and ***substantial progress has been achieved*** *in 2022 with the end of the DADI project and the official "go-live"* ***in November 2022*** *of the web-based Human Variations electronic application form (eAF) for centrally authorised products (CAPs) on the new Product Lifecycle Management (PLM) Portal hosted by EMA. UNICOM WP3 has been contributing e.g., by acting as the product owner (jointly with a second product owner from EMA). The new tool implemented in EMA's technical platform (Microsoft PowerApps) organised and executed by EMA. As already mentioned, EMA and UNICOM have been working hand in hand since June 2022 to communicate actively on this topic and provide the adequate training support to all impacted stakeholders. EMA has also been invited to take part in the WP4 knowledge transfer webinar which also prove instrumental to identify gaps and define new requirements for EMA and provide direct and detailed information to EMA on the success and challenges faced by National Competent Authorities.*

WHO-Uppsala positioned as the PhPID owner

In the context of the COVID-19 crisis, WP2 had initiated contact in 2020 with the FDA in the USA together with EMA, WHO in Geneva and UMC in Uppsala in a call to share resources and adopt a joint approach to vaccines identification and registration. WP8 has also been in contact with UMC Uppsala in order to discuss aspects linked to research and pharmacovigilance. This has been instrumental in engaging directly WHO-Uppsala in UNICOM activities (WP1 and WP8 in particular) and positioning WHO-Upsala as the owner of the production of future PhPIDs, and guaranteeing them a direct access to all public resources necessary for the production of this identifier.

Furthermore, UNICOM is now also in close contact with the WHO Collaborating Centre for Drug Statistics Methodology Centre located in Oslo at the Norwegian Institute of Public Health and funded by the Norwegian government. In collaboration with WHO, the Centre develops and maintains the ATC/DDD methodology. The Director of the ATC/DDD Centre has welcomed the outreach of the UNICOM Project towards the Centre and has confirmed the interest of maintaining the link between ATC and more granular global identification of medicinal products.

In 2022 the privileged contact with WHO-Uppsala has been reinforced and the organisation has been associated to all the major discussions held in the consortium related to the PhPID topic and to some important external dissemination activities such as the Community of expertise webinars. UNICOM has now officially fine-tuned its message by availing the expertise of WHO-Uppsala with a key responsibility in term of global governance and PhPID maintenance. The discussion is thus not anymore on IF this needs to be done but, on the process, and timeline. WHO-Uppsala is also associated to the work around the UNICOM FHIR® IDMP server as the data collected by UNICOM from NCAs are being used to document the validation process of PhPIDs. WHO-Uppsala is also closely associated to the transatlantic discussions and has been promoting via their channels the now official Global IDMP Working Group (GIDWG). This was strongly supported by UNICOM dissemination channels.

Creating the necessary links with FDA

The ongoing COVID-19 crisis which has put most regulatory agencies (and thus also FDA) under stress, an administrative issue with the partner (CITDHL) which is driving the Trans-Atlantic dissemination task and finally to the need to reach a number of preliminary conclusions before engaging the discussion with the US stakeholders had postponed the start of this essential activity to 2021.The first contacts have been established through the WP1 Community of Expertise in which an average of 12 experts from the USA (and FDA in particular) were present. The timing of those webinars (late afternoon in Europe) has been precisely set up in order to allow a US participation. The FDA has also been invited to make a presentation in the session dedicated to the Pharmaceutical Dose Form on the 22nd of January. Attendance to all WP1 Community of expertise from the US community has remained constant and significative while almost half of the visits on the UNICOM website originate from North America.

In April 2021, the conditions were met to launch a more operative cooperation. Preliminary discussions with the FDA led to a joint presentation of WHO-UMC and FDA at the ISO/CEN W6 on the 2nd of June meeting which also provided important inputs on how UNICOM plans to use EDQM (and derived SPOR) to determine the (administrable) dose form for the production of the Pharmaceutical Product Identification (PHPID).

On the 8th of June UNICOM organised its first Transatlantic event, which brought together 25 experts to debate on the situation in the US (with US FDA representatives), in Europe (with an EMA representative) and globally (with a WHO UMC representative).Those discussions have brought immediate benefits as proven by the webinar organised by FDA on the 11th of June where some important work released to date by UNICOM (such as the Gap Analysis Report and the 34 substances identified in close collaboration with the WHO-Uppsala Collaborating Centre to be the base for the UNICOM products pilot list) were considered as solid assets by the FDA.

A second successful meeting – again only by invitation-has been organised on 16 November 2021 and gathered some 30 participants including 13 representatives from FDA and representatives from research (Harvard University), SDOs (Cdisc, HL7, OHDSI,.) and Industry (Cerner,..) together with UNICOM WP1, 2, 3 and 4 representatives. The meeting was thus built around the first UNICOM achievements and included a number of proposals of alignments and direct collaborative actions.

The third trans-Atlantic meeting took place on the 4th of April 2022 with the aim to introduce the activities regarding adoption of IDMP standards and the data model in the US. Additionally other global IDMP activities were addressed. It was again a closed meeting with representatives from the following organisations: FDA, EMA, UMC-Uppsala, WHO, EFPIA, HL7, CBG (The Netherlands) and AGES (Austria). This meeting reinforced the role of the GIDWG as a global forum to focus entirely on global use cases, implementation and use of IDMP standards. The GIDWG is chartered since 2019 and includes members of EMA, FDA, WHO and UMC. The main goal is to conduct and report on pilot projects leading to the establishment of a framework for the global implementation of the ISO IDMP standards and maintenance of global identifiers. The main points which need to find an answer are the need to organise empirical tests for the calculation of the PhPID, based on 4 characteristics of dose form versus EDQM (more granular), the need to support the position for a global substance identifier and the need to discuss global coding systems for grouper of substance (Precise Active Ingredients and Moiety). The need for ISO IDMP ontology which would work together with the ISO IDMP Logical Model in progress and developed in collaboration with the industry has gained momentum. The fourth meeting has taken place on the 7th of December 2022 with an important participation of Pharma Industry and a face-to-face meeting is now planned for February 2023 in the USA.
As mentioned elsewhere, those discussions have been strongly supported by the publication of a number of scientific articles by UNICOM partners. Beyond the work done within the GIDWG, UNICOM is now considering using complementary US channels in 2023 such as Harvard University or the National Language of Medicine to help achieve quicker progress and decisions on those critical issues.

2.2.4 Facilitate decentral dissemination (Knowledge sharing)

This decentral dissemination through partners is foreseen as an additional channel to extend the reach-out of the project, and, at the same time, to initiate and trigger activities which should be continued beyond the life cycle of UNICOM by all partners. It coexists with direct (“central”) communication and dissemination tools like project website, social media accounts, printed matter etc. that serve for building awareness for globally promoting ISO IDMP and UNICOM.

Given the project-internal multi-stakeholder community, UNICOM offers now a multitude of channels, knowledge sharing opportunities and gateways to external networks while benefitting from partners’ ecosystems (e.g. through partners which are in a national or international coordinating role within the IDMP global community).

When creating the UNICOM Communication team, a number of priority actions have been proposed to all partners. They are detailed later in this deliverable.

UNICOM makes also sure that all resources produced by the project by a specific WP or for a specific event are available for reuse by project partners or are made publicly available through the website as soon as possible.

Decentral communication happens thus at the initiative of each project partner. In some countries, public partners such as NCAs have requested to use first this form of dissemination before UNICOM addresses directly their own eco-system via more direct channels or events.

As already mentioned under 2.2.1, this will be a central point of attention for the UNICOM dissemination activities in 2023.

UNICOM is a huge consortium and although a lot of energy is spent on organising open events to update all partners and guarantee cross-fertilisation between the different stakeholders, keeping them constantly updated remains challenging and we still notice communication

issues sometimes between the partners from different Work packages. We thus decided to innovate with the creation of a UNICOM Newsletter which summarizes the most recent achievements and progress. It aims both at providing a global although short update to the consortium and at providing them with a communication tool which can facilitate decentral communication. As already mentioned, the "UNICOM in a capsule" format is a second tool created to support wide decentral communication. The translation of this tool in major European languages will further increase its attractiveness.

3 UNICOM Communication team

3.1 Team set up

The UNICOM Communication team (UCT) is organised at three levels:

A virtual **WP12 coordination** meeting takes place on a monthly basis between Empirica and EHTEL. During this meeting, concrete operational issues such as website and resources management, events planning and priority actions to be discussed with WP leaders are handled.

The **UCT WP level communication team** gathers representatives from all Work Packages. It meets on a monthly basis and addresses the main operational questions associated to dissemination of interest for the whole consortium. It is thus the main channel fort the continuous update and concrete implementation of the dissemination plan. Since September 2020 it has been decided to integrate the meetings of the UCT WP level team with a dedicated slot in the monthly PEC meetings. This allows EHTEL to have a direct access to the last important information and progress and to make sure that proposed actions are taken on board by all WP leaders.

This team is more particular in charge to:

- Prepare and validate the Dissemination Strategy
- Prepare and validate strategic meetings/events
- Define common key messages and narratives

The **UCT partner level Communication Team** gathers representatives from all partners. The meeting takes place usually twice per year and -if feasible- once in the context of the annual Project General Assembly.

Figure 3. Unicom Team gathered in Bonn for the kick-off meeting

The objective is here to:

- Build the UNICOM enlarged Communication Team (UCT) with the involvement of each partner
- Update all partners about UNICOM dissemination strategy and concrete activities
- Inform all partners of the different communication channels and resources developed by the project to support dissemination activities
- Inform all members on methods to be individually engaged with social networks
- Mobilize each organisation own communication channels
- Define shared and individual responsibilities and support work at Stakeholders “cluster” level Collect proposals and suggestions (Actions, support tools, events, templates etc.)

While the overall principles of the dissemination strategy were presented during the kick-off in Bonn, the first formal meeting took place on the 13th of May 2020.

Unicom Communication Mini-Questionnaire

Dear Unicom Colleagues,

This first meeting of the UNICOM communication team (partner level) has the following objectives:
a) Help to build the UNICOM enlarged Communication Team (UCT)
b) Share with you the main content of the proposed dissemination strategy (as detailed in DEV 12.2)
c) Share information on first steps already taken at your end.
d) Define shared and individual responsibilities
d) Discuss a number of short term actions

Please take two minutes to fill this short questionnaire prior to the meeting.

We are asking each partner to mandate one (and only one) person to be part of the enlarged UNICOM communication team.

* Required

Prior to this meeting, a short questionnaire had been sent to all project members in order to **nominate one person by organisation** to be part of the UNICOM UCT team and to have a global overview on the volume and type of internal resources which could be mobilized to support UNICOM dissemination objectives.

Figure 4. Questionnaire sent prior to the first UCT meeting

After the initial meeting, it has been decided to work as much as possible within the already planned coordination fora and events. The Partner level UCT meetings have thus been taking place during the UNICOM consortium meetings in November 2020 and November 2021.

It has finally been possible to organise a face-to-face consortium meeting in Brussels on September 1-2, 2022 and a specific slot has been allocated to the evaluation of past dissemination activities and discussion of the next priority actions to undertake, with the key messages to push forward. The consortium meeting was well attended and has been instrumental after a long COVID-19 period to bring all Work packages together and proceed to the necessary alignments.

Figure 5: Discussing Dissemination strategy update in Brussels (Sept 2022)

3.2 Mobilizing partner resources

The fourth axis of the UNICOM dissemination objectives (Decentral dissemination) relies partially on the use of each partner internal resources and test the readiness of partners to engage in more time demanding communication activities. During the first year, we had thus surveyed the availability of those resources. It quickly appeared that Public Authorities were less ready to make use of their official channels to promote UNICOM outputs.

During the virtual consortium meeting which took place in December 2021, we again surveyed the UNICOM partners in order to have a better idea of the degree of involvement of the partners, in particular public partners, in the dissemination activities within their own organisation. As shown in figure 6, important progress has been achieved since the first year of the project but there was still an important margin of progression. During the year 2022, efforts have thus been produced to further engage all UNICOM partners in dissemination activities. For NCAs, the main objective was to achieve a higher engagement of the business units, according to the profiles of people attending the WP4 knowledge transfer webinars, this objective has now been achieved. NCAs seem much more ready today to announce publicly important ambitions.

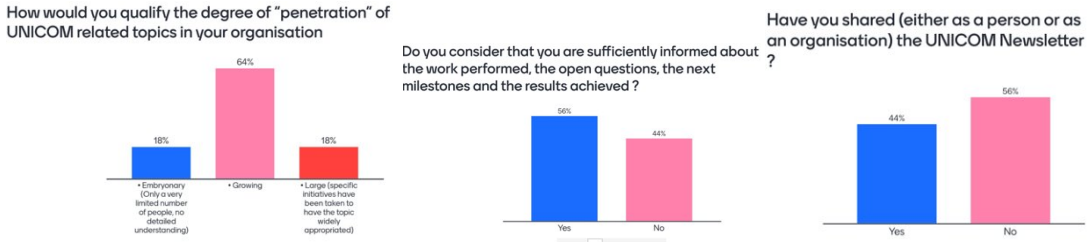


Figure 6: Survey on mobilisation of partners resources to support dissemination

Partners were requested to provide more visibility to UNICOM on their organisation website, either via a news or via a dedicated page. We will pay specific attention to this objective in the upcoming period (2023) asking all partners to update this information and show related results.

Figure 7: Examples of UNICOM presence on partners 'websites

3.3 Internal Communication Management tools

In order to support WP leaders and individual partners to provide usable and meaningful inputs for dissemination purpose, two sets of guidelines have been produced and presented to all UNICOM partners. Those guidelines cover the effective use of Twitter and the editorial policy for writing News which is (also) meant to be pushed via the social media.

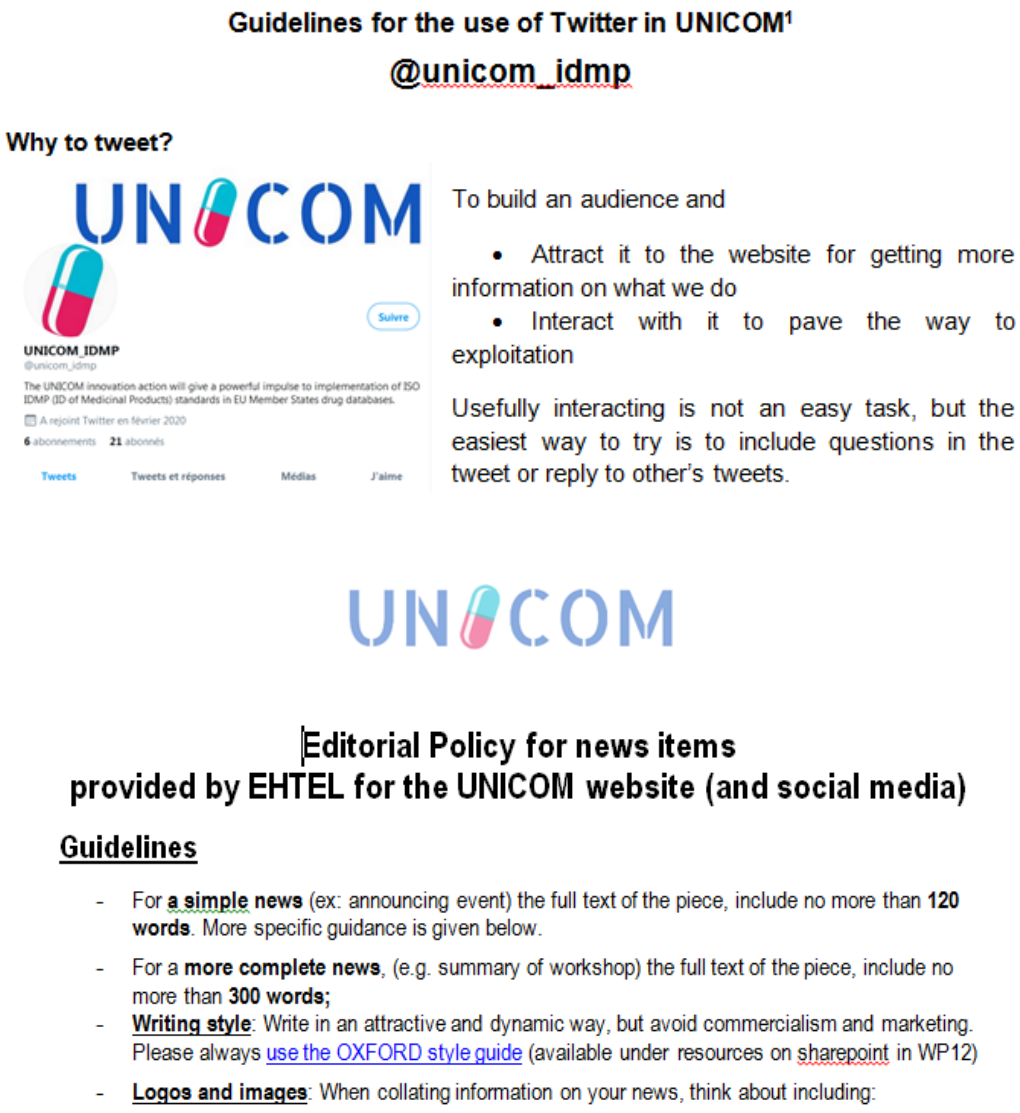


Figure 8. UNICOM guidelines for social networks use

Two supplementary simple tools have been created in order to have a permanent and always updated overview and registration of all UNICOM dissemination activities.

In order to provide all members with a global information on all UNICOM related happenings, **an internal calendar** has been created on SharePoint. All Work Package leaders and project partners have been invited to register here proactively all meeting and events, both internal and external. External events related to UNICOM work can also be mentioned. The information filled is succinct but sufficient to be able to track the information and ensure that needed follow-up actions are undertaken, such as the promotion of the event via a tweet or a news, the later confirmation of the event details and the possible production of resources (video, ppt, report...) which can be made available later via the UNICOM website.

It also acts as prompts to advertise events on the UNICOM "events" calendar on the website.

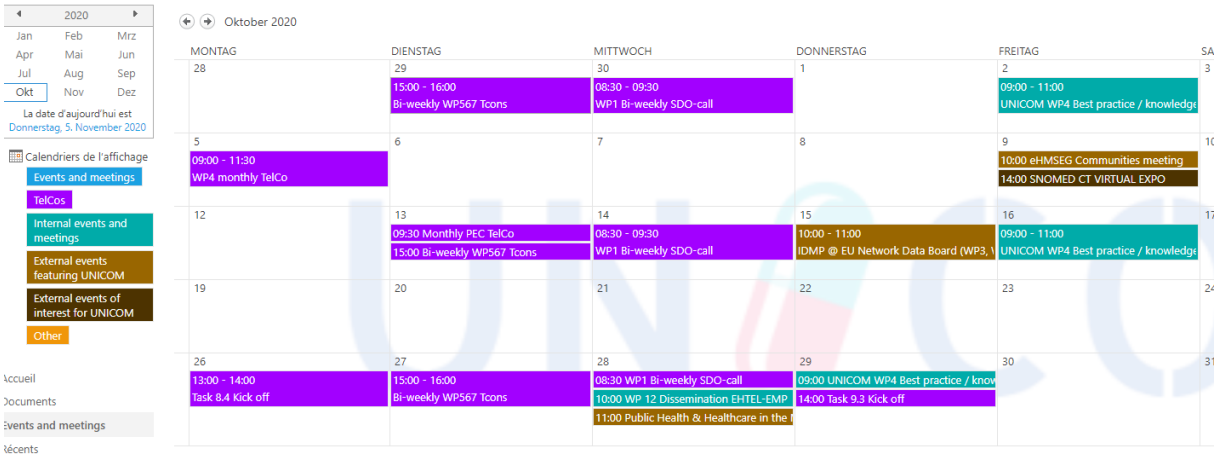


Figure 9. UNICOM internal calendar

Furthermore, **a logfile has also been created on SharePoint** to register all necessary of details linked to the participation of UNICOM partners to external events. The closed internal events organised by individual Work packages are reported upon within the premises of those WPs.

Considering the complexity and high amount of information channelled through the project, with the need to maintain updated information and guarantee alignment in dissemination, reference slide decks have been created by several WPs and shared on the project cloud. Furthermore, in important events, the related slides are shared among WP leaders. Finally, the UNICOM Newsletter has also an important internal dissemination purpose as the UNICOM mailing list contains about 280 names with very different level of involvement.

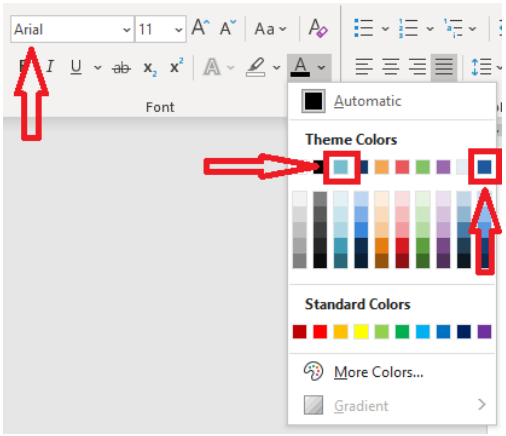
Certain categories of stakeholders such as the NCAs need to be addressed specifically to make sure that the most important messages are clearly understood and that there are no major information gaps between the different partners. To make sure this does not happen, all WPs are also invited to take part in the monthly meeting of WP4. In the future, specific messages will be sent to the NCAs community summarizing inputs from the Community of expertise meetings (WP1) to make sure that important messages are correctly captured.

*Finally, the serial of meetings organised in 2021 around the "Pilot Product List" have also been instrumental in both identifying gaps, diverging points of view and obtaining in due time the necessary larger possible consensus. This has been continued in 2022 with the "**strategy board meetings**" which are called every 4 months and is composed of UNICOM Action line leads and their deputies.*

4 UNICOM priority external dissemination channels

4.1 Branding

The UNICOM visual identity was defined in cooperation with Empirica. The branding of the project includes the logo, banners and icons based on the values of the project and therefore provides it with dissemination and communication coherence. Presentation templates, a graphical charter for the portal, and other dissemination materials were designed following this guide.



The text font is Arial.

The two main blue colours used are:

Dark Blue: RGB 29 89 156;

Light Blue: RGB 228 237 244;

Third complementary colour: RGB 118 189 208.

4.2 Website development

The first basic version of the UNICOM website was initially launched on 30.01.2020 by Empirica. The daily management of the website is the responsibility of Empirica but key decisions are jointly taken with ETHEL which is mainly responsible to provide the website inputs. The website is accessible at this home page: https://unicom-project.eu/. It was designed according to the UNICOM corporate design principles and is also easy to use with tablets and smartphones.

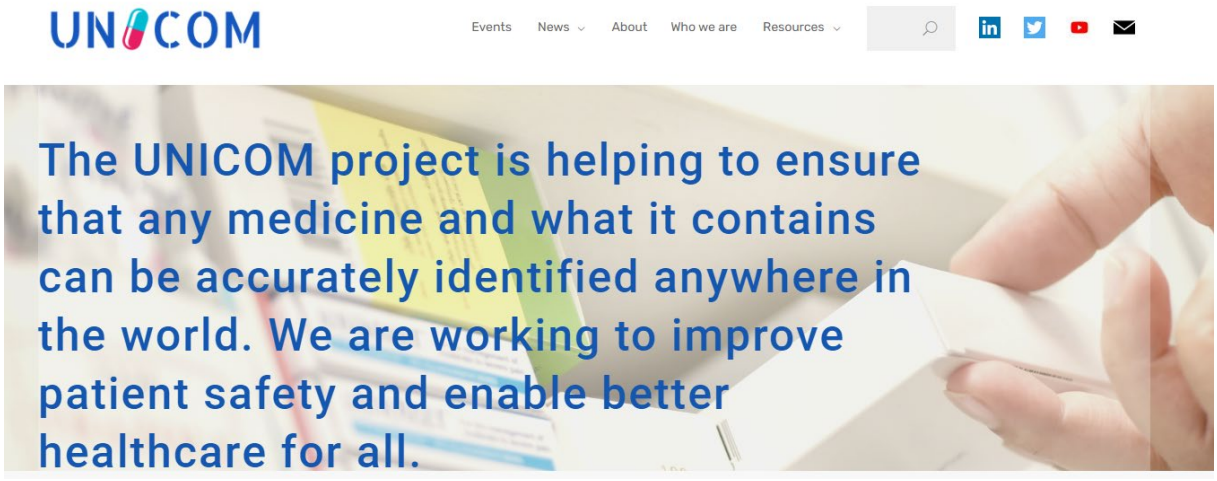


Figure 10. UNICOM website homepage

The UNICOM website overall structure was discussed during the first WP level UCT team meeting.

The website serves as **the central hub** for semi-permanent information about UNICOM, by providing general details about the project objectives, status, and updates on work package developments. It also provides access to all the public resources created by the project (such as deliverables, videos,

publications, white papers, and presentation slides). It informs visitors about the participation of UNICOM project members at important events.

The key project statement has been adapted so that it is both accurate and understandable by all targeted audiences.

It was decided to keep a very simple menu structure with a limited number of 5 entries but to have all critical information on a kaleidoscope on the left side of the main page, allowing each visitor to immediately grasp the key challenges tackled by the project. Contrary to many other projects, it was decided not to give specific visibility to Work Packages as this is of limited interest for an external audience and to concentrate our efforts on making our key messages and resources accessible and understood. The content of the kaleidoscope items has been validated by all WP leaders.

Given the size and diversity of the consortium, it appeared extremely important to show that the consortium included all the value chain and to give sufficient visibility to all partners. The menu item “who we are” has thus received a specific attention. The partners have been clustered in several segments, showing immediately who represents the segment within UNICOM.

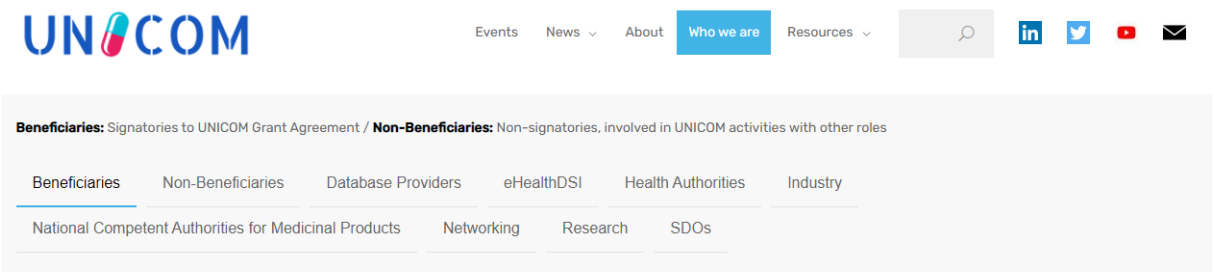


Figure 11. UNICOM website members clustering

Quite a number of organisations are not direct beneficiaries of UNICOM but are however closely associated to the work performed in different work packages. It has thus been decided to also give them visibility on UNICOM website as it also benefits to the global image and power of influence of the project.

The identification of the organisation is made easy thanks to its logo and the mention of the country.

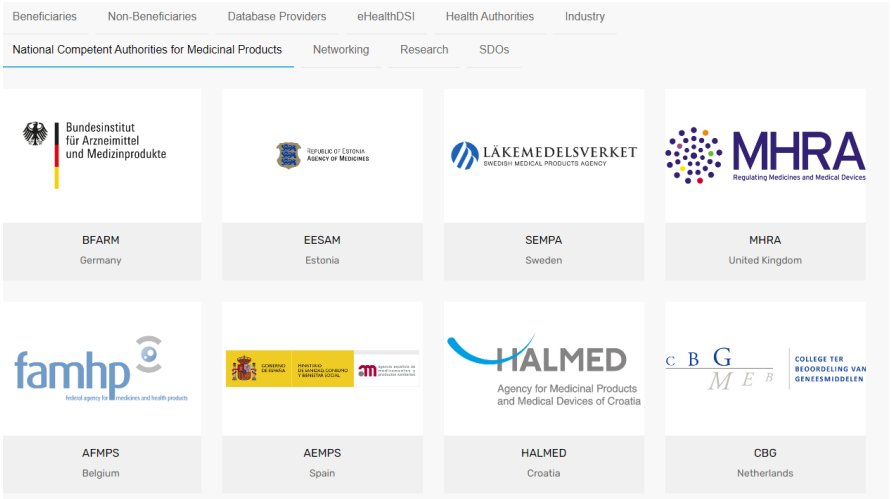
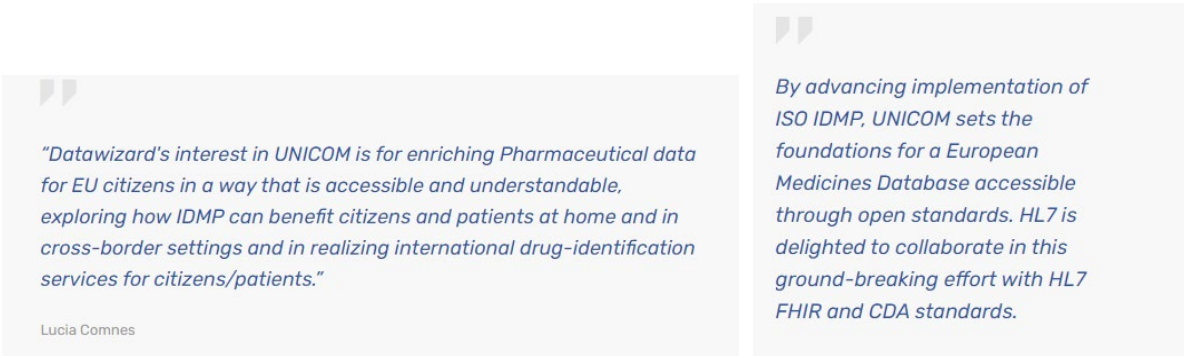


Figure 12. UNICOM website partners description

When clicking on the organisation, one has access to a more detailed description of the organisation mission statement. Each partner has also been asked to provide a simple sentence which describes best why their decided to get firmly engaged within UNICOM. This proved however a bit more

challenging for public bodies, mainly due to complex internal decision process and need of multiple official back-ups.



The other menu item which received a lot of attention is the "resources" section (see also section 7)

Although the consortium has not yet produced many exploitable results, it has been decided that all resources which have an added value should be made available via the website as quick as possible, including thus also the content of official deliverables which have not yet been approved, with an appropriate discloser.

We have differentiated resources produced by the UNICOM project from "related" resources which have been produced by other projects or for specific external events but of particular relevance for UNICOM. A third entry gives specific visibility to multimedia material such as videos and presentations. An internal procedure has been put in place to ensure that the resources do not include content which is protected.

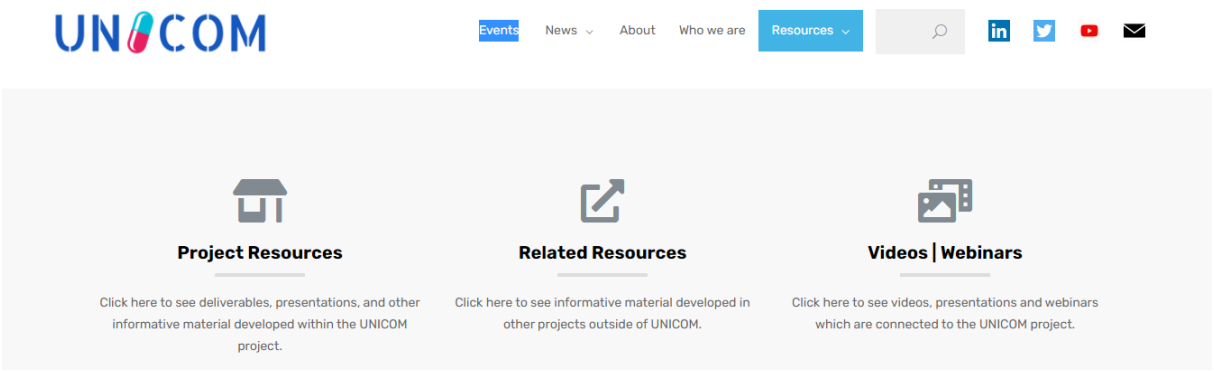


Figure 13. UNICOM website resources exposure

All public webinars are recorded and after editing are also published on the website and on the UNICOM _YouTube channel.

The number of resources has been growing steadily and it proved necessary to provide the visitor with a method to identify resources through the UNICOM search engine.

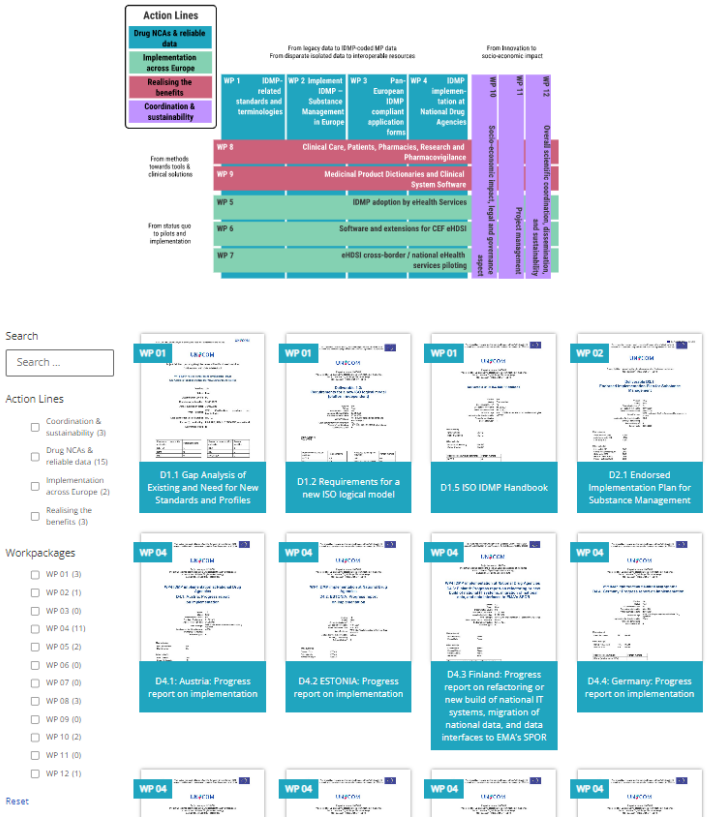
In order to improve the search results, each published resource is briefly described and a number of metadata are attached to the resource: Those metadata include simple categories linked to UNICOM use cases, tags and three levels of accessibility (High, medium and low which will be featured by different colours) depending on the level of complexity of the resource.

The other menu items include a list of all the news which have been published with a possibility to subscribe to the future UNICOM newsletter and an entry to the UNICOM calendar which provides an overview of main UNICOM related events of interest.

The lower part of the UNICOM main page is used to promote latest developments and news and gives a specific visibility to last Tweets.

In 2021, we decided to rework partially the lay-out of the UNICOM front page in order to increase the overall readability and user experience and make sure that the key messages and resources can be grasped without effort. The generic information about the project was repatriated under the "about" bullet while the resources produced by WP1 (Community of Expertise public webinars – IDMP in a capsule) were specifically promoted in the upper part of the page. *We provide now a global overview of all Community of expertise in a specific table, allowing thus easy access to both videos and slides. Finally, the public version of the UNICOM glossary has been set in a good place on the UNICOM front page. We also decided to keep permanently the link to the event recording of the end-users' event organised in April 2021 as this remains an excellent entry point for end users.*

Public Deliverables



After the approval of the first batch of deliverables by the European Commission we have created in January 2022 a new section to make all public deliverables available. A number of those deliverables were first released as "working papers" in the section "resources" of the website. This in order to be able to use those important materials to support discussion in the different events organised by UNICOM and to obtain early feed-back from informed stakeholders. We opted in this section for a very original presentation which allows to list the deliverables according to multiple criteria: Action lines, work package or semantic search.

Figure 14: Publication of public deliverables on UNICOM website

The website is since then stabilised and can accommodate in a smooth and flexible way all supplementary new requirements.

As shown by the figure 11, visits on the UNICOM website have increased from September 2020 onwards and has kept on increasing over time. We observed a first high peak end of August 2021 which coincides with the UNICOM Community of expertise on "Substance identification using INN and ATC – governance, use, and relation to IDMP" which has attracted a lot of new visitors. Another important peak was observed during the 2021 Christmas break on the 26th of December with visitors from the USA where the UNICOM "events" pages were consulted. The highest peak so far was observed on May 31st 2022 with a total of 801 visits again with a huge majority of visitors from the USA. More generally we

notice that we reached a new level in August 2022, coinciding with the community of expertise related to the topic "navigating global and national identifiers using IDMP and FHIR" which connects more closely IDMP and FHIR and has provided more insights about the UNICOM demonstrators and the UNICOM IDMP FHIR© sever.

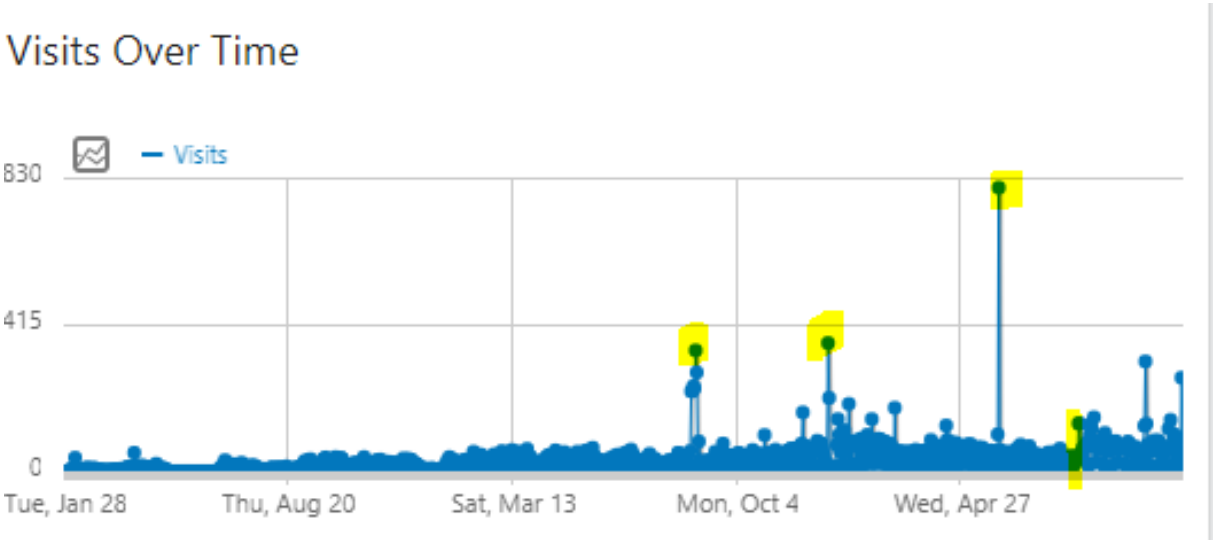


Figure 15: Unicom website visits over time

As shown under table 1, when comparing the main indicators of the UNICOM website for 2020, 2021 and 2022, one can see a dramatic increase of all major KPIs.

Unicom Website KPIs	2020 (As of Nov)	2021 (As of Nov)	2022 (As of Nov 16)	Delta 2020/2022	Delta 2021/2022
nber of Visits	2459	10733	32682	1329,08%	304,50%
Nber of unique visitors	1343	8586	22566	1680,27%	262,82%
Nber of pages	9718	19812	55970	575,94%	282,51%
Nber of Unique pages	5487	16270	45512	829,45%	279,73%
Nber of unique searches	182	403	990	543,96%	245,66%
Nber of unique keywords	57	65	215	377,19%	330,77%
Nber of downloads	321	1088	2620	670,40%	240,81%
Nber of unique downloads	290	988	2152	903,45%	217,81%
nber of unique outlinks	320	1003	3011	940,94%	300,20%

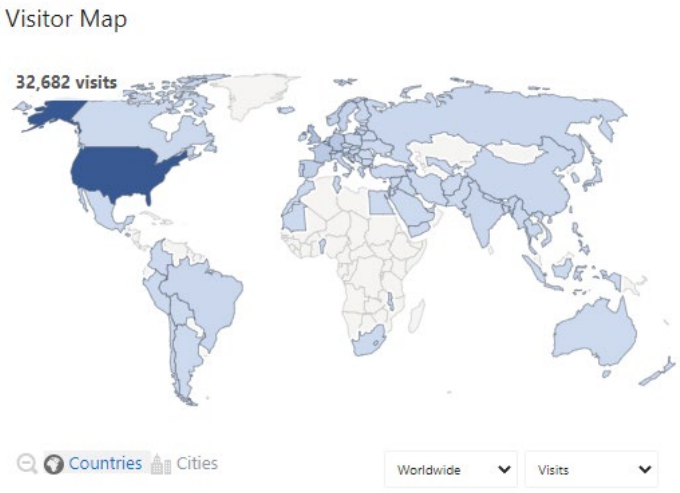
Table 1: UNICOM website KPIs

*Notably the UNICOM website has been visited by 22566 unique people in 2022, more than 13 times the score achieved in 2020 and **3 times more than in 2021.** The ratio between nber of unique pages/ nber of unique visitors has remained stable in 2022 with roughly 2 pages viewed by each unique visitor. With 45.512 unique pages visited in 2022, the results are positive.*

*We recorded a total of 2152 **unique download** in 2022, **doubling again the figure obtained in 2021**. This figure related to downloads is however underestimated due to technical issues related to the website statistics methodology used by the application Matomo for which no alternative solution could be found to date. The English version of "IDMP in a capsule" has been downloaded 1327 times while the French version 400 times. According to the website statistics, the other most downloaded resources are the cleansed-substances-report" (147 DL), the DADI questions and answers (136 DL the UNICOM factsheet (118 DL),) the Gap-Analysis report (79 DL).*

In 2022 the most frequent consulted pages have been the ones related successively to events, resources, project objectives, partners, news and finally contact. When looking at single pages, in 2021 the news related to the Community of Expertise events came on top of the list, in 2022, the most attractive pieces of information have been the news related to the achievements of the DADI project, the PhPID governance and EU-SRS.

The number of unique out links has also been multiplied by three over the period showing an increased interest in referencing the UNICOM website.



When looking at the country of origin of the visitors, we had since the creation of the website, visits from 83 different countries and the first group of visitors is by far the USA which alone represents 45% of all unique visits on the UNICOM website. This is a constant statistic since the start of the project but some caution is however needed as statistics tend to always overestimate the USA due to the use of proxies.

Figure 16: Map of visiting countries

The following table provides a detailed view of the repartition of the visits over the different continents. As seen, Europe and North America are almost equally represented but the share of visitors from the USA has again increased in 2022.

Continent	Visits 2021	Visits 2022	% 2021	% 2022
North America	4808	14586	45,33%	47,80%
Europe	5137	13639	48,43%	44,69%
Asia	220	1133	2,07%	3,71%
South America	77	312	0,73%	1,02%
Africa	11	41	0,10%	0,13%
Oceania	11	28	0,10%	0,09%
Unknown	343	778	3,23%	2,55%
Total	10607	30517		

Table 2: Unicom Website visits by continent

When looking carefully on the detailed list of the 83 visiting countries, one notice that a number of countries have a higher engagement rate (above 100): This is the case in Europe for France, Germany, Estonia, Italy, Spain, the Netherlands, Hungary, Slovenia, Iceland and Latvia. In Europe, Slovakia and Lithuania show the lowest level of interest. This is important as some of those countries are not part of the consortium. We also perceive a high interest in Asia (Japan, China, South Korea, Thailand, Taiwan, Singapore and Indonesia) and also a strong interest in Brazil. This will further be reinforced by the statistics of the Community of expertise events;

Table 3: List of website visiting countries and engagement rate

Country	Visits	Actions	Maximum actions in one visit	Total time spent by visitors (in seconds)	Unique visitors (daily sum)	Engagement Rate= Time spent/unique visitors
United States	14480	24202	56	1013898	13669	74
United Kingdom	2796	5341	35	250944	2558	98
Germany	1883	5184	138	336190	1667	202
France	1686	5258	48	478827	1326	361
Netherlands	1322	2822	31	142028	1136	125
Norway	888	1757	27	90350	813	111
Spain	888	1900	59	106106	798	133
Unknown	777	931	16	14798	767	19
Italy	755	1790	32	120008	668	180
Sweden	698	1034	21	29711	663	45
Portugal	456	919	23	42163	414	102
Greece	377	664	14	34019	359	95
Finland	333	700	22	34450	317	109
India	310	467	44	11865	289	41
Brazil	299	644	23	37184	264	141
Japan	231	477	16	41804	212	197
Estonia	198	564	18	35547	170	209
Russia	196	289	17	7046	187	38
China	190	345	18	16408	178	92
Poland	141	258	11	12332	131	94
Hungary	140	240	15	17423	120	145
South Korea	135	319	49	15921	130	122

Denmark	102	206	15	8066	95	85
Czechia	98	209	21	7931	91	87
Slovenia	94	221	18	11911	88	135
Austria	90	158	12	7491	77	97
Canada	86	136	9	8133	83	98
Belgium	73	139	14	6039	70	86
Taiwan	73	94	6	1379	70	20
Turkey	73	112	9	6040	71	85
Croatia	72	109	9	2364	70	34
Ireland	54	84	6	2973	51	58
Latvia	49	138	18	6359	47	135
Thailand	48	177	30	14084	42	335
Slovakia	38	76	14	1614	30	54
Australia	37	54	7	1876	35	54
Vietnam	35	40	3	737	33	22
Romania	33	53	12	990	31	32
Bulgaria	26	30	5	143	26	6
Azerbaijan	24	27	3	254	24	11
Switzerland	22	40	7	1761	22	80
Israel	20	24	4	303	20	15
Mexico	20	28	4	1489	18	83
Ukraine	19	26	3	427	18	24
Lithuania	16	24	5	496	15	33
Egypt	14	14	1	0	14	0
United Arab Emirates	13	14	2	48	13	4
Indonesia	11	15	3	1193	11	108
Serbia	11	12	2	161	11	15
Singapore	11	21	5	1760	11	160
Iran	7	9	3	32	7	5
Argentina	6	7	2	31	6	5
Cyprus	6	7	2	211	6	35
South Africa	5	7	3	35	5	7
Hong Kong SAR China	4	6	3	91	4	23
Uzbekistan	4	4	1	0	4	0
Chile	3	3	1	0	3	0
Iceland	3	6	2	484	3	161
Morocco	3	3	1	0	3	0
New Zealand	3	3	1	0	3	0
Pakistan	3	7	3	407	3	136
Saudi Arabia	3	5	3	25	3	8
Tunisia	3	4	2	91	3	30
Colombia	2	3	2	33	2	17
Myanmar (Burma)	2	5	4	604	2	302
Syria	2	2	1	0	2	0
Afghanistan	1	1	1	0	1	0

American Samoa	1	1	1	0	1	0
Bangladesh	1	1	1	0	1	0
Belarus	1	1	1	0	1	0
Benin	1	1	1	0	1	0
Bolivia	1	1	1	0	1	0
Bosnia & Herzegovina	1	1	1	0	1	0
El Salvador	1	1	1	0	1	0
Iraq	1	1	1	0	1	0
Jordan	1	1	1	0	1	0
Luxembourg	1	1	1	0	1	0
Malawi	1	1	1	0	1	0
Mauritania	1	1	1	0	1	0
Nepal	1	1	1	0	1	0
Peru	1	1	1	0	1	0
Philippines	1	1	1	0	1	0
Yemen	1	1	1	0	1	0

4.3 UNICOM Glossary

The correct identification of medicines is a complex issue with multiple connexions to different domains and disciplines which all approach it from their own perspective, often in very technical terms. It appeared thus quickly that it was necessary to develop a common approach to manage concepts, definitions, words and synonyms throughout all work packages, to avoid confusion.

It seems also necessary to provide a public interface on the UNICOM website in order to allow visitors to check the definition of any word commonly used within UNICOM key resources (deliverables, presentations, factsheet etc.).

WP1 and WP9 have thus taken the initiative to propose to update and reuse a simple tool which had been developed by the OPENMEDICINE project which has, since the closure of the project, been maintained by Eurorec/I-HD.

After initial contact with Eurorec/I-HD, it appeared that the tool could be upgraded with available resources to accommodate the specific needs of UNICOM. It was also made clear that although sophisticated alternative tools existed on the market, they were designed for dedicated specialised terminology work while here the direct operational aspects were first seen as the priority.

The key objectives of UNICOM were thus to use appropriate tooling and governance to

- ▷ Maintain a common Glossary of Terms and Abbreviations across UNICOM
- ▷ To be used by all WP's
- ▷ To be shared with other EU projects (e.g. such as the X-eHealth project)
- ▷ To be maintained after the course of the UNICOM projects and other EU projects involved

Initial functional requirements discussed with EUROREC: I-HD were:

- ▷ Ability to author, edit and review terms, synonyms and abbreviations

- Ability to author, edit and review alternative definitions for the same term, depending on context
- Ability to provide links to (authoritative) sources and/or documents for the definition of terms
- Ability to produce dedicated subsets per project, work package, deliverable
- Ability to publish directly online within the UNICOM website and other project websites

The tool will also support the production of UNICOM Deliverables

- One common tool to use across UNICOM
- Pre-populated with identified content from OpenMedicine, Antilope, and eHDSI Glossary
- Documentation on the use and governance of the tool, including validation of definitions

This tool will thus be an important instrument to manage words and concepts in a collaborative manner but is also very instrumental to support a coherent and fluid communication strategy.

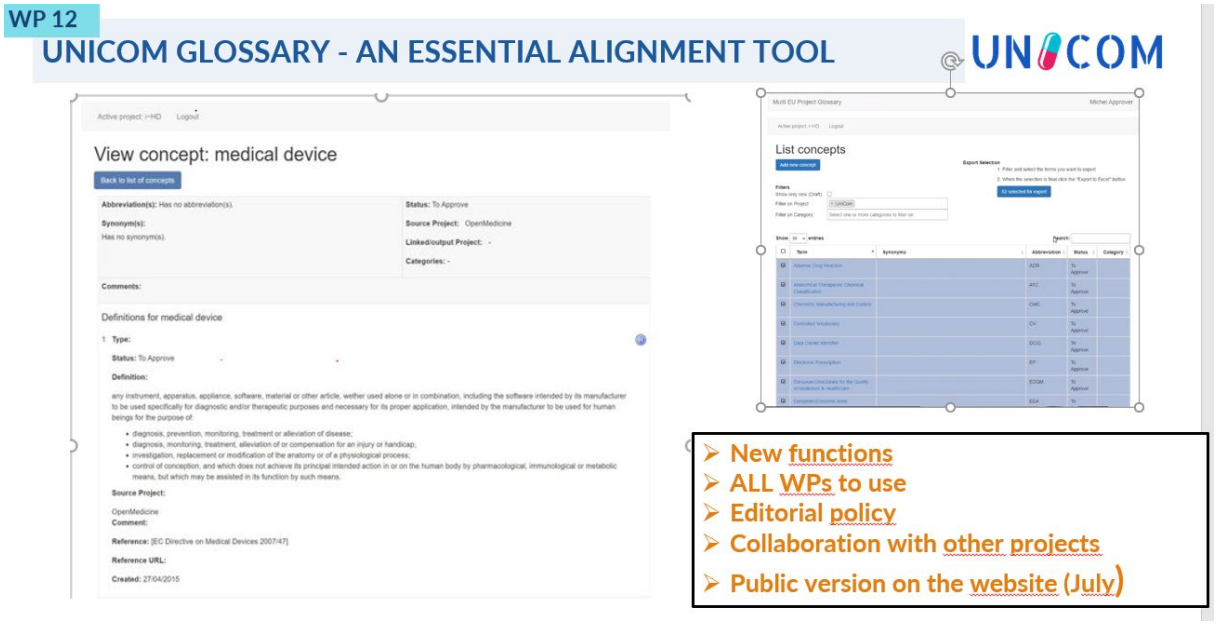
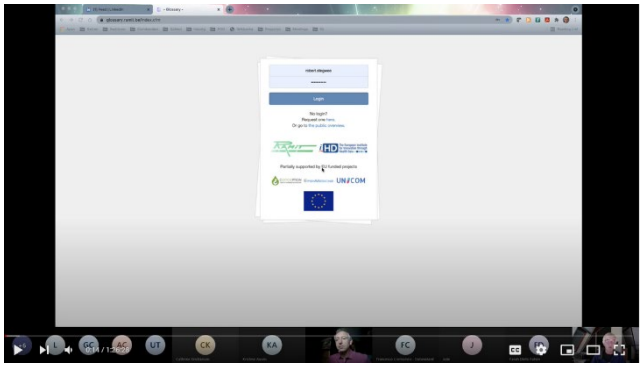


Figure 17. UNICOM glossary tool mock-up

A set of terms and definitions collected in different work packages have been gathered and imported in the tool in order to allow a first publication

All the terms are revalidated by the chief editorial team established within UNICOM (WP1/WP12). The tool has been tested in December 2020 and went live in February 2021 onwards.



Each Work Package had been required to identify its editors who have been provided with the appropriate rights. A practical editorial guide has then been drafted and a recorded training session has been organised.

All Work Packages are now required to enter all the terms and abbreviations they use in their deliverables in the UNICOM glossary and export their list from the glossary.

This glossary is also shared with the IMI project concePTION in order to maximize its use and increase its sustainability. Each project is however sovereign in its decisions but concertation is established when conflicts are becoming apparent.

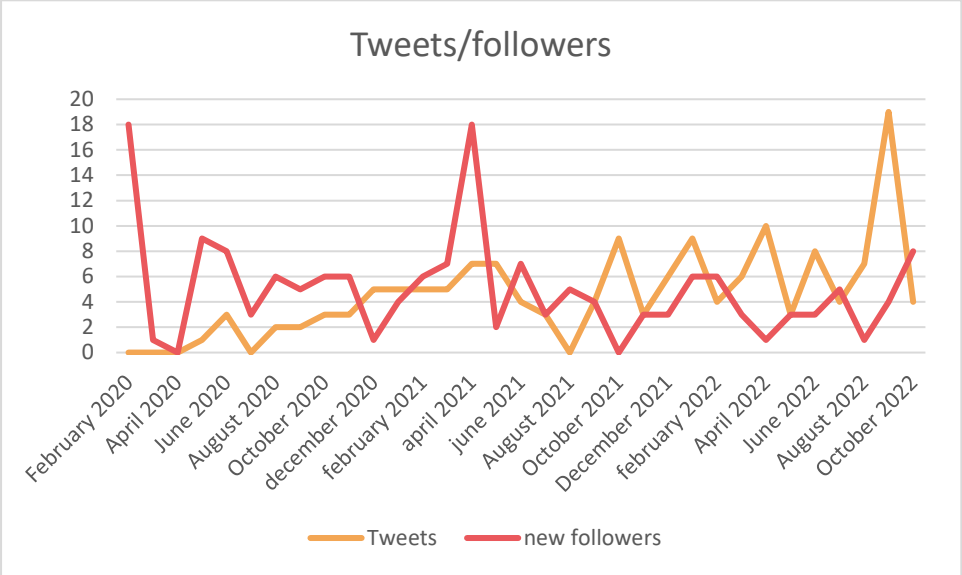
The editorial team has met again regularly in 2022 and has approved all pending concepts and has provided guidance to all the editors. This work is essential to maintain semantic consistency across work packages but requires some discipline from all consortium members who have at times been reluctant to spend the time necessary to use the tool. The management team has agreed that the export of abbreviations from the glossary must be part of the Deliverables quality assurance process.

4.4 Social media

UNICOM has decided to concentrate mainly on three social media platforms: Twitter, LinkedIn and YouTube. These media have been identified by the UCT as the most adequate to develop interest in IDMP implementation and reach out to a wider community in all segments of the value chain.

4.4.1 Twitter

The UNICOM twitter account has been created in February 2020 but the account only became active on 15th of May 2020. The name UNICOM had already been chosen by quite a number of other organisations and it was thus decided to open the account under the UNICOM_IDMP label. During the first 10 months of UNICOM activity, 21 tweets had been produced. In the period Nov 2020-Oct 2021 we released 46 tweets and from Nov 2021-October 2022, 84 tweets have been produced. The total activity since the start of the project amounts to 154 tweets and a total of 250 tweets and retweets.



The number of followers has kept on increasing month after month to reach 181 followers in mid-November 2022. As seen, UNICOM production of original tweets has been constant over the period with a peak high in October 2022.

Figure 18: Number of Tweets/Followers

As shown by the examples below, the impression volume is quite satisfactory. The objective remains however to increase both the number of followers and the engagement rate of the published tweets during the last period of the project. Many Public Institutions are however reluctant to actively use Twitter and individuals associated with a public body have usually a cautious attitude. This communication channel will thus be used in priority to disseminate general news and messages without being always in a position to engage formally organisations with stricter communication protocols.

In order to reach this objective, UNICOM will also have a pro-active policy in term of re-tweeting relevant tweets. In figure 19, we provide a few statistics on UNICOM tweets. We use 3 indicators to evaluate the impact of a tweet:

Impressions: number of times the users saw a tweet on Twitter. This number shows how wide our tweet went, something like a media coverage: in other words how a tweet has been successful in reaching as many people as possible.

Engagement: number of actions that users did on a single tweet. Includes clicks (anywhere on the tweet), retweets, replies, follows and likes. The sum of all those actions represents the engagement rate of a tweet.

Engagement rate: this is a ratio, showed as a percentage, that illustrates the number of engagements divided by the number of impressions. It shows how the tweet was able to call people to action, regardless of how many people it actually reached.

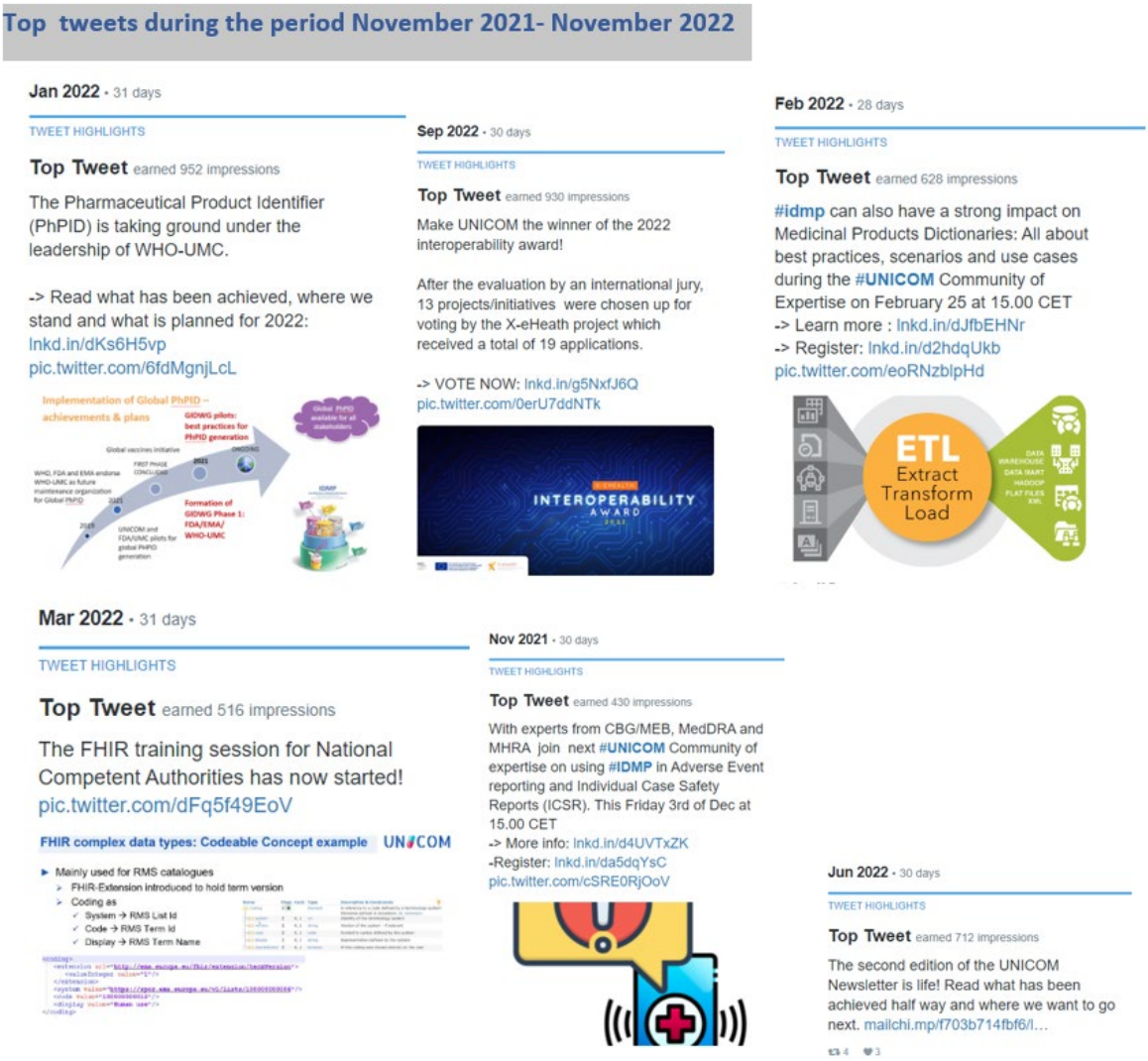


Figure 19. UNICOM most popular tweets

The top 6 tweets of the period Nov 2021 -Nov 2022 had all an impression inferior to the most popular tweets during the previous periods. This is partially related to the fact that the "Community of expertise webinars" have been organised less regularly and were less connected to a new specific audience and the effect of "novelty" has partially disappeared. The tweets which had the highest impression rate were related to the PhIPD governance, the community of expertise webinars on Medicinal Products Dictionaries and adverse event reporting, the participation of UNICOM to the X-eHealth awards, the FHIR training for NCAs and the UNICOM second Newsletter.

The average engagement rate of each tweet which used to be around 4.2% for the previous period has very significatively increased during the period February – November 2022 reaching an average of 11% with peaks up to 20% (UNICOM newsletter) or above 15% for each tweet which was directly connected to a new result or a declaration by one of the main UNICOM influencers or related to the publication of scientific articles.

Summer is always a calmer period with the absence of major events but the global engagement has remained at an average of 2.200 per month. The indicator of the Profiles visits is also interesting as it

*provides an indication on the number of **new visitors**. We observed a steady increase of the number of profile visits in 2022 with a very high peak in October 2022 (3269 profile visits). This is a clear indication that the curiosity towards UNICOM has drastically increased. Lastly the number of mentions which was quasi null during the first two years has begun to rise in 2022 with 19 mentions for example in September 2022.*

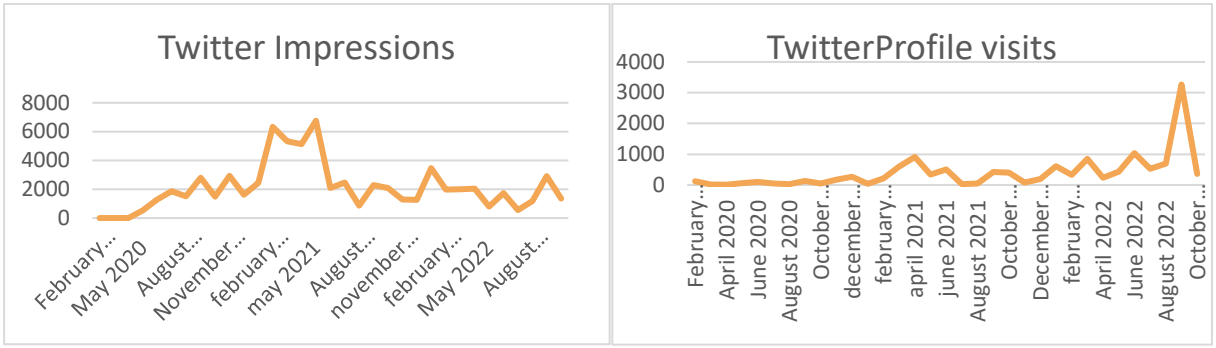


Figure 20: Twitter impressions/profile visits

4.4.2 YouTube

The UNICOM YouTube channel has been created in October 2020. It is a strategic important channel to increase the impact of the dissemination activities organised by UNICOM. Quite a number of people register to events and webinars but do not finally show up. The YouTube channel allows thus to review the webinars at any time and also reach out to new interested audience. This is also an excellent format to diffuse content and messages which are not directly dealt with during the webinars or use the channel to provide deeper dive into specific implementations, such as the interviews of NCAs representatives. We publish three types of videos on this channel:

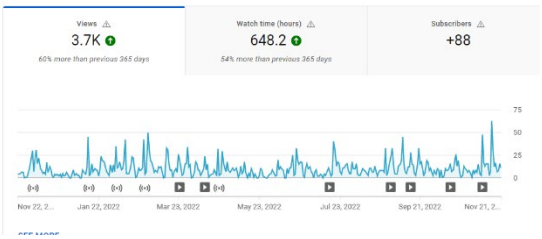
- *Public videos*
- *Videos accessible to a wide audience but only through invitation (WP4 and WP5 webinars)*
- *Private videos (Internal to the consortium)*

UNICOM will also cross reference on its YouTube channel videos and recorded webinars where UNICOM have been featured during external events, provided of course that access to the material is public.

Figure 21: UNICOM YouTube first published videos

The UNICOM YouTube channel proves today to be an extremely powerful and useful tool as it has been now connected to telecommunication platform such as Zoom, making it possible to attend UNICOM public events even if they have not registered (they however lose the possibility to interact with the organisers). All WP1 UNICOM Community of Expertise webinars are available on the Youtube channel. We have also tried to have some of the WP4 knowledge transfer webinars published on the channel.

Finally, the channel also has released a number of interviews to provide early inputs on topics related to specific use cases.



In the period Nov 2021- Nov 2022, we recorded a total number of 3.738 views- a 60% increase over previous period- representing more than 425 hours of watching . We observe a number of peaks which are, related to the WP1 Community of expertise webinars and the WP3 & WP4 knowldege transfer webinars.

If we compare the views from new viewers and returning viewers, we notice that both categories are well represented but that the number of new viewers has been growing significatively during the last period.

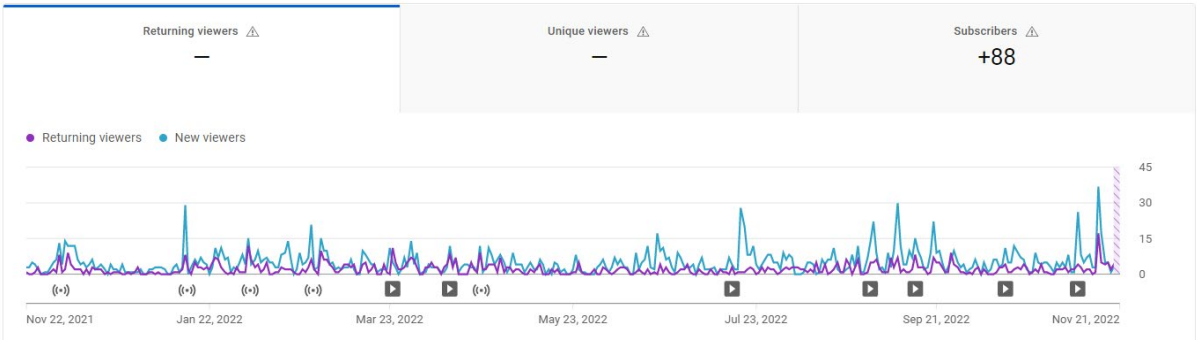
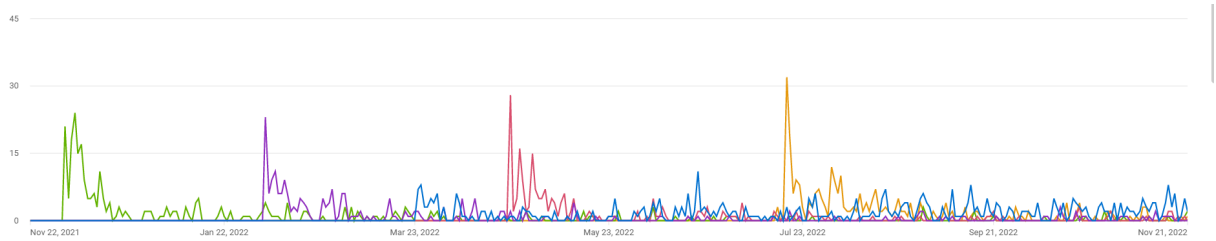


Figure 22: YouTube channel main statistics

When looking at statistics of individual videos which reached 100 views over the last 12 months, we observe that the main lifecycle duration of the Webinars of WP1, WP3 and WP4 is about three months while other videos have a much more constant flow. The number 1 video for this period is the "IDMP in a capsule tutorial" with a total to date of 446 views. Among the Community of expertise webinars, the one on adverse event reporting has mobilized the largest community while the WP3 FHIR© EMA Dadi on variation forms has also been very popular. Let's also mention the very good score reached for the interviews with Estonia and Croatia.

Since the beginning of the project, the channel has accumulated a total of 73.528 impressions demonstrating its strategic importance of this tool in the project dissemination strategy. It is also important to notice that reference videos keep on been viewed by a new audience even after a long period. The UNICOM eHealth Stakeholders outreach Webinar, for example, has still recorded 80 New views during the last period. If one considers the impression rate, the video on the Community of expertise related to pharmaceutical dose forms comes on top of the list with a total of 5.674 impressions while the average for other videos is around 2.000 (1.000 -3.000 range).



Content	Views	Average view duration	Average percentage viewed
Total	**3,738**	**10:24**	**13.9%**
IDMP in a capsule Tutorial	446 11.9%	8:58	27.2%
UNICOM - Using IDMP in Adverse Event reporting and Individual Ca...	296 7.9%	10:35	11.9%
FHIR TRAINING (EMA DADI FHIR variation forms)	276 7.4%	8:58	10.1%
UNICOM - Clinical applications for IDMP	234 6.3%	14:59	17.2%
UNICOM - IDMP Semantic Specifications for eHealth Services	217 5.8%	13:28	14.4%
UNICOM – Draft Guideline for Medicinal Product Dictionary	215 5.8%	14:43	16.6%
UNICOM - Community of Expertise: Perspectives on substance and...	170 4.6%	11:43	12.7%
UNICOM - UNICOM - Vaccine challenges - cleansing, confidentiality ...	148 4.0%	18:20	19.7%
Making EU-SRS sustainable: CoE 04/11/2022	144 3.9%	6:26	7.8%
Making HALMED (Croatia) IDMP compliant The refactoring choice	139 3.7%	6:26	25.5%
UNICOM Community of Expertise: Navigating global and national id...	138 3.7%	14:17	15.7%
UNICOM Knowledge Transfer Training workshop on FHIR 20220330	113 3.0%	10:49	9.4%
The role of Dose Forms for the generation of a global Pharmaceuti...	103 2.8%	10:01	11.2%
Interview Toomas Silla - Development Manager at EESAM- the Esto...	101 2.7%	4:43	21.4%

Figure 23: UNICOM YouTube channel: Most viewed videos

4.4.3 LinkedIn

The UNICOM LinkedIn account has been opened in June 2020 and has succeeded as of Nov 22 2022 to attract 661 followers (260 people in November 2021), a very good 254% increase over 2021 demonstrating that the level of interest and engagement has seriously increased over the last year and that the interest for UNICOM has now been extended well beyond the usual "IDMP inner circles". This places the LinkedIn tool in a top position to support all stakeholder's engagement activities.

Here again, aside from the pertinence and frequency of information, the degree of engagement of individual people is key. *Unlike twitter, LinkedIn is widely used by people working in public administrations and UNICOM has consistently used references both to individual and organisation accounts to stimulate engagement*.

UNICOM has also short listed a number of projects and initiatives which could be interested in synergetic collaboration. This is thus the case for example of the Implementation of Regulatory Information Submission Standards forum (IRISS forum), the European Medicines Verification Organisation (EMVO), the International Coalition of Medicines Regulatory Authorities (ICMRA) or The International Council for

Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) or *the Gravitate Health project* just to name a few.

Each UNICOM Consortium meeting has provided the opportunity to remind all members of the role they can play to boost UNICOM both at corporate and individual levels.

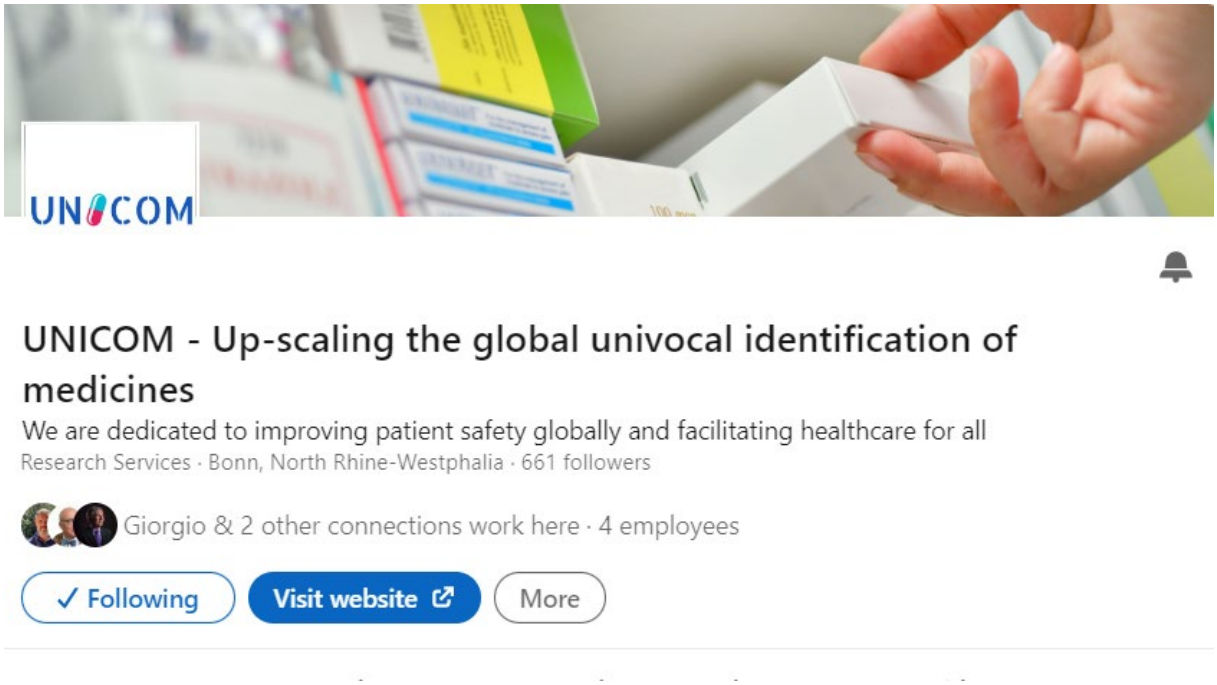


Figure 24. UNICOM LinkedIn account

When looking at the job profile of the LinkedIn visitors, we notice that the first group of people remains the one related to business development (11.20%) followed by consulting (7.41%). In comparison with the previous period, we notice an important increase in the share of consulting, program and project management, Information Technology, operations and education, a diminution of engineering while the relative share of research, education and media segments has remained stable, with a relative stagnation of research. Very encouraging is also the arrival of other categories of stakeholders related to business such as Healthcare Services, Product Management, Community and Social Services, Sales, Purchasing and Marketing which altogether represent now 15% of our followers indicating clearly that the topic is now reaching business.

When considering the size of the organisations and companies, the large companies with 1000 employees plus represent more than 32% while medium size organisations (200 - 1000 employees) represent 29% and small organisations 39%, with here again a very good diversity.

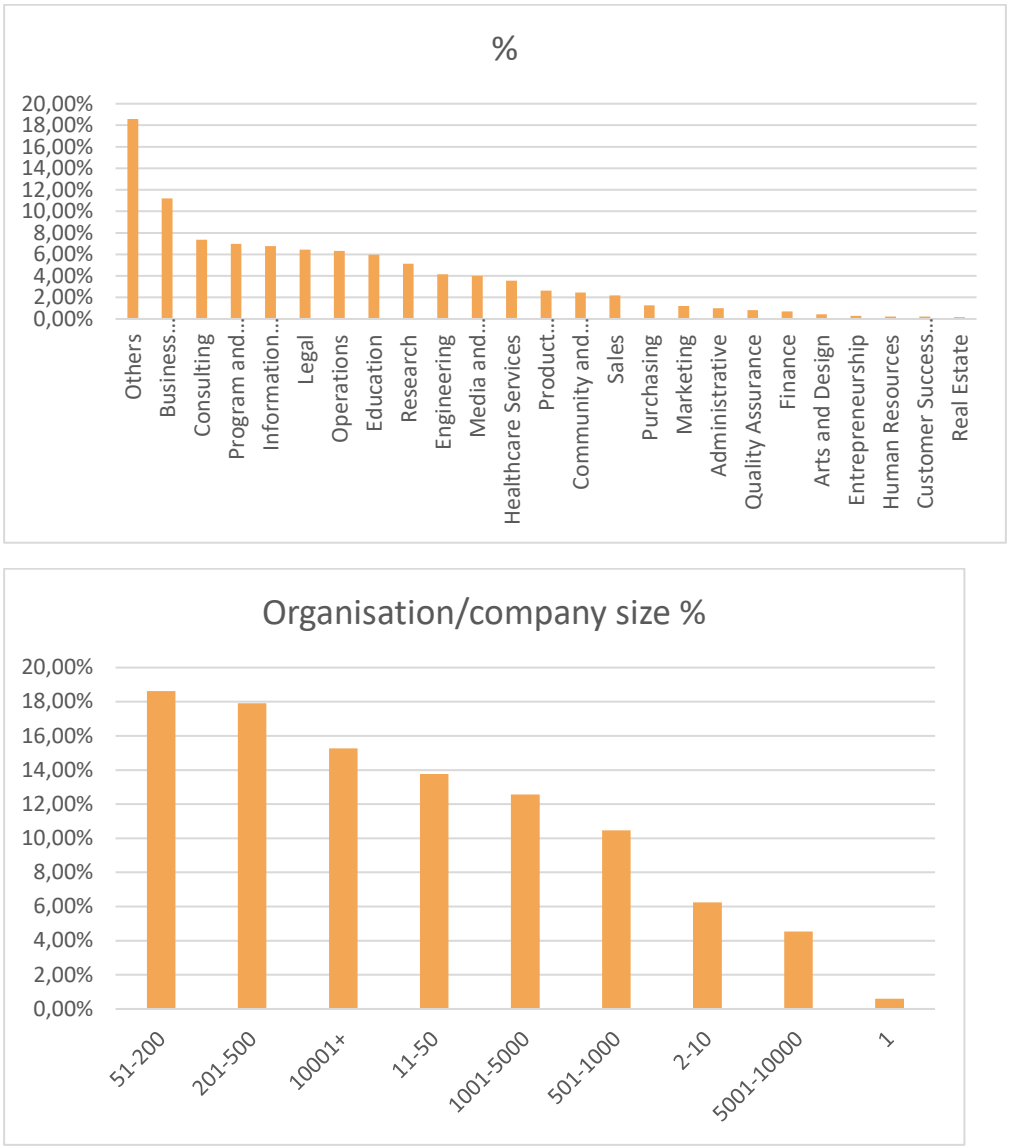


Figure 25: Profile of UNICOM LinkedIn visitors

As for the number of page views, this is rather stable with around 100 views per month over the period Nov 2021- Nov 2022 with however a significant increase in September 2022 which coincides with the UNICOM consortium meeting which has been the opportunity to make a number of important statements and thus to involve a more important number of stakeholders.

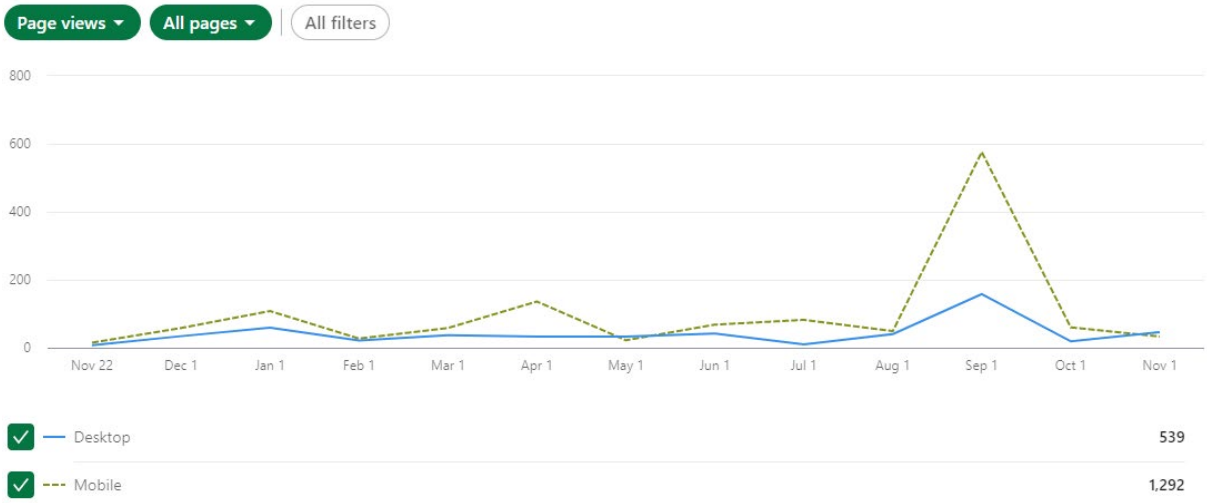


Figure 26: Page viewed on LinkedIn

4.5 UNICOM Newsletter

In September 2021, UNICOM has sent its first newsletter to all the contacts which have been (and will be) collected during the first 18 months of activity, either via the website or though the registration to events organised by UNICOM, such as the community of expertise interactive webinars. The mailing list constituted to reach out end-users will also be used.


UNICOM

Make medicines safely and accurately identified anywhere in the world

September 2021 ISSUE 01

Why do we need a standard for the identification of Medicinal Products (IDMP) ?

You are reading the first issue of the UNICOM newsletter. .After 20 months of activity in a Covid-19 context, we think it is important to provide the wide UNICOM communirty with a first status on what has been achieved to date and what we want to do next.

The UNICOM Innovation Action is about improved patient safety and better healthcare for all. This four-year trans-Atlantic project focuses on further development of the International Organization for Standardization (ISO) suite of IDMP (Identification of Medicinal Products) standards, their testing, implementation, and diffusion for regulatory purposes by National Drug Agencies, for global pharmacovigilance and research, and for advancing European cross-border ePrescription services. It will benefit all the actors of the value chain.

Understand what IDMP can concretely bring to patients and healthcare professionals

The newsletter provided a summary of UNICOM major achievements up to September 2021 and promoted the main key assets which have been made available through the website resources section.

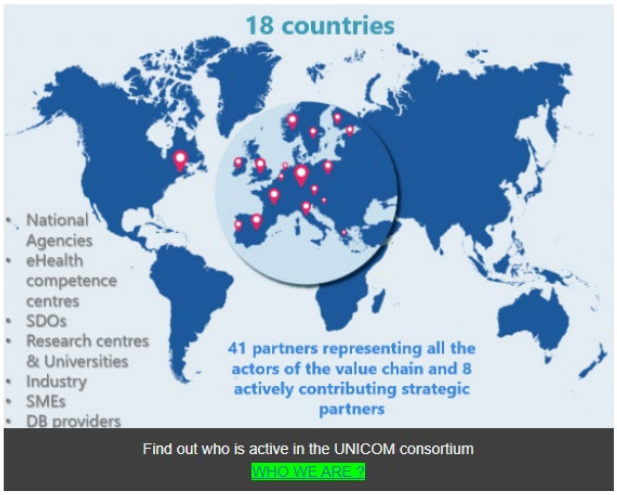


Figure 27: UNICOM first Newsletter

A second edition of the UNICOM Newsletter has been released in June 2022.

It provides a comprehensive although summative overview of the results of the project after 18 months of activities and provides access to the most important resources in UNICOM, both from a content and

didactic point of view. The Newsletter has been sent to an address list which includes now no less than 1.800 individual contacts all over the world.

Figure 28: Extract of the second UNICOM newsletter

In the meantime, UNICOM has requested from its partners to make use of their internal newsletter to communicate on UNICOM expected benefits and events and further disseminate the UNICOM Newsletter (See the IHE example in figure 29).

UNICOM has also been presented in the June edition of the DG CONNECT -Health and Well Being- newsletter.

Figure 29. UNICOM featured in external newsletters

4.6 COLLABORATION WITH OTHER PROJECTS

In order to be able to reach out categories of stakeholders less present in the UNICOM consortium, to discuss possible additional use cases and to possibly consider the organisation of common events which would provide additional value, UNICOM has pro-actively approached other relevant projects and in particular IMI projects. Several preparation meetings had been taking place with the project "Gravitate Health" in 2021 and different collaboration possibilities have been discussed and agreed upon. They included the following concrete actions:

1. Communication and dissemination activities including mutual support in social media and news promotion, cross participation in workshops and webinars, common participation to external events…
2. Drive the development of funding opportunities focusing on ePi aimed at furthering the future work on ePI at EU level by building new opportunities for collaboration involving relevant stakeholders.
3. Jointly explore the potential for added value and capacity building by exploring sustainability strategies.
4. Planning a common webinar on IDMP and pharmacovigilance and how to involve patients.

In 2022, the collaboration with Gravitate Health has mainly been focusing on the preparation of the HL7 FHIR© Vulcan accelerators related to patients' information leaflets for medicines. During a Gravitate Health consortium meeting, UNICOM had also the opportunity to provide a comprehensive overview of the work performed and the expected results. A joint public session UNICOM – Gravitate Health will also take place in Greece on December 14, 2022 while the two projects have agreed to consider a common end-users-oriented event during the course of 2023.

The project EHDEN is also very relevant and UNICOM will approach it in 2023 to explore together the relationship between IDMP and OMOP and where possible draft some common recommendations.

5 Events and meetings

As mentioned earlier, the actual start of the project has been simultaneous to the first COVID-19 wave in Europe. Consequently, to the exception of the kick-off meeting in Bonn, *until April 2022* there has been no possibility of physical meetings and only virtual encounters have been possible. This lack of direct "physical" interaction with an audience has of course not prevented UNICOM to get engaged and present on many different fronts. This has however had some impact on the level of engagement of the reached audience, partially due to the overall fatigue of webinars. *From April 2022 it has again become possible to travel but organisations have been slow to adapt their travel policy and one had to wait till fall 2022 to see all limitations lifted. The level of participation of UNICOM partners in external meetings, either virtual or physical has increased in 2022.*

This section will thus provide a short description of the type of events organised by UNICOM or to which UNICOM has been requested to provide a contribution.

5.1 Interactive webinars organised by WP1

After the six closed sessions organised in April/May 2021 to identify the main remaining gaps, it has been decided to organise open monthly interactive webinars on different topics of interest for the wider UNICOM community of expertise. The webinar is open to everybody, but the registration is compulsory.

From March 2022, due to resource limitations, it has been decided that the community of expertise webinars would take place on a bi-monthly or quarterly basis.

The objective here is triple:

- Increase awareness and reach out to a wider community
- Collect supplementary feed-back from external experts on UNICOM priority topics
- Enrich UNICOM mailing list of contacts

*To date **21 interactive webinars** have been organised. While the first webinar had a duration of 60 minutes, it has been extended to 90 minutes from September 2020 onwards. The table 4 gives an overview of the registration and the attendance to all the webinars organised since the start of the project. As mentioned already, one needs to add all the views on the UNICOM YouTube channel to have a global overview of the outreach.*

*With only one exception, all webinars organised during this reporting period have reached a number of registrations beyond 200 people, thus the **double of the previous period**. Only one webinar in 2021 (INN ATC) had reached that level in 2021. The webinar related to the draft Guideline for Medicinal Product Dictionary which took place on the 24th of February 2022 is to date the most popular webinar while the one related to" Using IDMP in Adverse Event reporting and Individual Case Safety Reports (ICSR)" in December 2021 had the best live participation.*

Table 4. WP 1 interactive webinars

Nber	EVENT	Total Registration	ATTENDED	NON ATTENDED	%no show
1	1/07/2020: IDMP, False Medicines, Detection, and Parallel Trade	60	50	10	16,67%
2	04/09/2020 PhPID	96	76	20	20,83%
3	2/10/2020 Standards Gaps Analysis	98	66	32	32,65%

4	12/11/2020 Pilot Product List	114	75	39	34,21%
5	4/12/2020 COVID Vaccines	108	83	25	23,15%
6	22/01/2021 Pharmaceutical Dose forms	84	60	24	28,57%
7	LM 19/02/2021 Common Logical Model	131	102	29	22,14%
8	24/03/2020 EMA IG V2	135	102	33	24,44%
9	29/04/2021 Medicinal Product Dictionaries	112	81	31	27,68%
10	28/05/2021Representation of clinical information	135	96	39	28,89%
11	29/06/2021 Cross-border ePrescription	112	85	27	24,11%
12	27/08/2021 INN ATC	204	126	78	38,24%
13	01/10/2021 Role of Dose forms for PhPID	112	76	36	32,14%
14	29/10/2021 Substance & strength	132	74	58	43,94%
15	06/12/2022 UNICOM – Using IDMP in Adverse Event reporting and Individual Case Safety Reports (ICSR)	203	145	58	28,57%
16	17/01/2022 UNICOM – Vaccine challenges – cleansing, confidentiality and vaccine naming	199	137	62	31,16%
17	04/02/2022UNICOM – IDMP and Clinical applications	185	103	82	44,32%
18	24/02/2022 UNICOM – Draft Guideline for Medicinal Product Dictionary	277	157	120	43,32%
19	21/04/2022 UNICOM – Semantic specifications for eHealth services	96	59	37	38,54%
20	26/08/2022 UNICOM – Navigating global and national identifiers using IDMP and FHIR	237	130	107	45,15%
21	04/11/2022 EU-SRS	182	115	67	36,81%

The availability of the webinar on the YouTube channel has somewhat influenced the participation rate since August 2021 as people who had registered had however the opportunity to watch it later. The live attendance rate remains however beyond the usual acceptable norm.

Table 5: Categories of stakeholders CoE

Sector	2020/2021	2021/2022	All time
NGO	2%	**3%**	3%
Clinical	6%	**7%**	6%
Other	9%	**12%**	10%
Business	10%	**14%**	12%
Research	15%	12%	14%
Public authority	22%	20%	21%
Standardization	36%	32%	34%

The statistics cover all webinars held to date with the exception of the first for which an elaborate registration system had not yet been put in place.

When looking at the profile of the attendants, about one third of the attendants are originating from the SDOs sector, followed by Public authority, Research and Business. We have noticed a slight increase of the participation of Business, Clinical and Others in 2022. Given the technical content of the debates, the participation of end-users is very much related to the topic debated, with an active presence, for example, during the guideline on Medicinal Products or the adverse events debates.

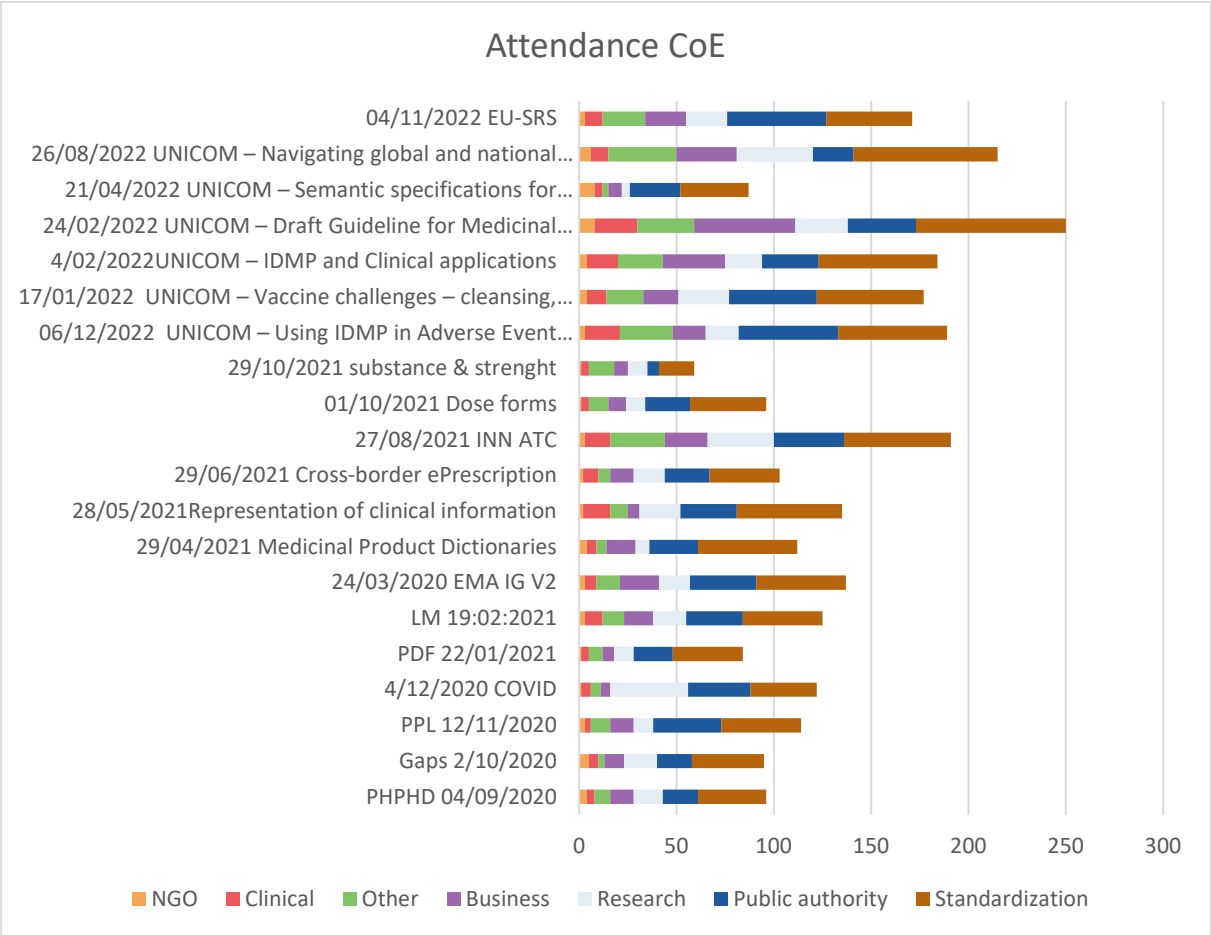


Figure 30: Attendance CoE

If we analyse the countries of origin of the participants, we can conclude that the geographical coverage of these webinars has once again been extending in a very significant way and is now truly universal.

- *All continents represented*
- *59 countries represented in 2021, **77 countries represented in 2022***
- *34 European countries (**5 more than in 2021**)*
- *In 2021, 23 countries had attended at least 5 sessions; in 2022, **24 countries attended at least 10 sessions.***
- *More than 300 different organisations*

A deeper analysis of the participating countries provides some interesting and complementary information.

The following tables provide information about both the number of webinars attended per country together with the total number of individual participations (all webinars together) for that specific country.

Table 6: Attendance of European Countries CoE

Continent	Country	# Webinars attended	# individual attendance
EUR	DK	11	30
EUR	GR	14	30
EUR	DE	15	167
EUR	AT	17	38
EUR	HR	17	72
EUR	ES	19	89
EUR	IT	19	77
EUR	PT	19	108
EUR	SE	19	95
EUR	UK	20	231
EUR	BE	20	156
EUR	CH	20	87
EUR	EE	20	47
EUR	FI	20	69
EUR	FR	20	149
EUR	IE	20	94
EUR	NL	20	207
EUR	NO	20	128

Country	# Webinars attended	# individual attendance
AL	1	2
ME	1	2
MT	1	1
RS	1	1
LU	2	5
MK	2	7
RO	2	3
UA	2	6
LV	3	3
SI	5	5
GE	6	62
CY	7	9
CZ	7	7
HU	8	16
PL	9	18
SK	9	11

People from a number of European countries with NCAs not active in UNICOM have attended all CoE sessions. This is especially noticeable for France, Switzerland while Italy has attended all sessions held during this second year. This is relevant given the importance of those countries in Europe. Although not part of the EU anymore, the UK has been part of all the discussions with the highest number of individual participations. The level of participation of Greece and Denmark which was already significant in 2021 has also been on the increase.

In general countries active in UNICOM have also been very active in the Community of Expertise webinars with 6 NCAs having attended all the webinars. The level of engagement in a number of countries, and particularity Eastern European countries, is also increasing with an active participation of Slovakia, Poland, Hungary and the Czech Republic in 2022. 2 EU countries did not participate in any webinar (Bulgaria and Lithuania) with Latvia and Malta finally being represented in at least one webinar in 2022. Let's also mention the sustained participation of Georgia (with a high number of individual participations). The "new" European countries are Albania, Ukraine and Macedonia.

Table 7: Attendance CoE non-European countries

Country	# Webinars attended	# individual attendance
BT	1	1
LK	1	1
MV	1	1
NP	1	1
PK	1	2
TH	1	1
CN	2	2
MY	2	2
PH	2	2
TW	2	2
SG	3	6
BD	5	6
AU	6	10
KR	10	14
IN	16	119
JP	19	42

If one now looks at the participation of non-EU countries, we can notice an increase in the participation of Asian countries with a participation (although limited to one session) of 6 new countries. Japan has been represented in all webinars but one, while India has also been very active with a high number of individual participations. South Korea has also been active with however a lower level of individual participation. The level of participation of Australia remains below expectation while China has also been represented (with a single individual) in two webinars.

The participation from the USA, Canada (with less people however) has remained constant with an active participation in all webinars and in the case of the USA the highest number of individual

participations. The interest of Brazil has also been constant but with a limited number of individual participations. We also note a contact with a number of new countries from South America during this period. In Africa and Middle East, Tunisia and Egypt have been the most active countries but here again we have succeeded to establish contact with 7 new countries in the Middle East and 5 new countries in Africa.

	Country	# Webinars attended	# individual attendance
S-AM	AR	1	1
S-AM	CL	1	1
S-AM	VE	1	1
S-AM	CO	2	2
S-AM	CR	2	11
S-AM	MX	2	5
S-AM	PE	2	3
S-AM	SV	2	12
S-AM	UY	3	6
S-AM	BZ	5	5
S-AM	BR	12	29
N-AM	CA	19	54
N-AM	US	19	339

Continent	Country	# Webinars attended	# individual attendance
AFR	AO	1	1
AFR	GH	1	1
AFR	SZ	1	1
EAST	AE	1	1
EAST	AF	1	1
EAST	AZ	1	1
EAST	BH	1	1
EAST	IL	1	1
AFR	MA	2	2
AFR	ZA	2	2
AFR	TN	4	4
AFR	EG	7	12

5.2 Strategic Meetings attendance

UNICOM has initiated a working relationship with working groups established by a number of strategic initiatives.

UNICOM has been provided with the opportunity to present the IDMP opportunities and challenges to the **EU eHealth DSI semantic community**. The semantic Working Group of this semantic task force has organised in May 2020 a specific teleconference to provide the members of the group with an extended briefing over the possible contribution of UNICOM to the concrete work of this group. In October 2020 a second encounter took place, but this time at the level at the coordination of the task force. The first objective is here to target eHDSI Wave 6 assets extension, by including the appropriate requirements, specifications and implementation to exploit the potentialities of IDMP Identifiers and attributes both for ePrescription and Patient Summary. Some of these Requirements have been already considered in the Draft of eHN Patient Summary (PS) Guideline Release 3 under consideration to the November 2020 eHN Meeting.

As of June 2021, the UNICOM coordinator, Prof. Dr. Karl A. Stroetmann of Empirica GmbH, has been invited to participate in the monthly meetings of the subgroup as a guest.

UNICOM has been instrumental in consolidating the business requirements for proposed extension and the identification of key data elements to be added as IDMP attributes to the medicine data set in ePrescription/eDispensation and in PS for Medication Summary, Allergies and Vaccinations.

A major milestone has been reached in September 2022: a new UNICOM workshop was organised with the extended European eHealth community, this time to expose and agree on the next concrete steps foreseen in the wave 6 of eHDSI services deployment and the assets needed to support it. It was attended by an audience of more than 80 participants originating from 21 EU countries and 3 non-EU countries (Norway, UK and Canada). The major development here is that the "pilot" implementation originally planned will actually become routine operation with Software tools from UNICOM to be used as an option in Member States implementation.

The annex 1 provides a full list of all the meetings of the ePrescription Pharmaceutical and Technical Work Group and eHealth Network semantic community meetings to which UNICOM is continuously providing inputs.

UNICOM has also been invited to present its work during the 12th of November eHealth Network meeting. Beyond the contribution to the eHDSI services, it has provided the project with the possibility to address the broader picture of IDMP and the role of the individual Member States to use IDMP to address the needs of their national eco-system.

HL7 is a member of the UNICOM consortium and specific efforts have been undertaken to inform the widest **HL7 communities**: Two meetings have thus been organised with two separate HL7 Working groups: The first one took place in May 2020 with the HL7 FIHR and the second one with the Biomedical Research & Regulation (BR&R) Working Group. *In 2021, HL7 has also organised a roundtable discussion of groups including representatives from UNICOM T8.4 involved in Adverse Events which was hosted by the FHIR Clinical Research Accelerator "Vulcan". Those activities have been further continued and reinforced in 2022 with the active participation of UNICOM in the Vulcan accelerator, in close collaboration with the Gravitate Health Project, related to the requirements for the patient information leaflet.*

In September 2022, a specific activity featuring UNICOM has also been taking place in Montreux, Switzerland, in the context of the IHE (Integrating the healthcare Enterprise - UNICOM partner) Connectathon experience days organised by IHE Suisse (in collaboration with eHealth Suisse) and IHE-Europe.

At the Industry level, UNICOM provides a monthly regular update, in particular related to EU-SRS, to the IRISS forum RISS which is a pharmaceutical industry trade organisation, which provides a mechanism to collaborate with other trade organisations within the pharmaceutical industry (ie PhRMA, DIA, RAPS, HL7) as well as global Health Authorities. The participation to meetings and events organised by different organisations sur as Drug Information Association (DIA) or CBG in the Netherlands has also contributed to a wide dissemination of UNICOM objectives and results in this cluster. *In 2021, UNICOM had started active discussion with EPFIA which has an observer role in UNICOM. New contacts have been established with two new working groups in EFPIA in November 2022: pharmacovigilance and public policy. We will extend this also to EMVO in order to have Industry more actively and directly involved in some Work package tasks. In 2023, we also plan an end-users-oriented event together with the Gravitate Health project.*

*Several interactions also take place between UNICOM WPs and the **EMA instances**. Let's mention here again in particular the decision of the WP3 Steering Group on the 13th of August 2021 to align with the EMA technology strategy and to contribute UNICOM WP 3 resources aiming at developing a web-based application form tool to a new joint telematics initiative to be setup by the end of Q4/2020. Although the operational responsibility had been transferred to the EMA Dadi project, WP3 remained deeply involved in the requirements, implementation and testing of the tool. WP2 and WP4 are also closely connected to EMA through the SPOR and EU Network Databoard meetings. With the increased contacts and cooperation, the tension on resources on the EMA front observed in 2021 has been released in the last trimester of 2021 and substantial progress- notably on substances and on the go live of the electronic variation web form - have been achieved in 2022. The different discussions which took place during the WP4 webinars have however been instrumental in identifying new important requirements to support NCAs in their transition to IDMP. Those requirements will need to be discussed in 2023. It had proved difficult in 2021 to convince EMA to provide more public visibility to the work and inputs provided by UNICOM, but the situation has evolved positively since June 2022 where EMA and*

UNICOM (WP3) have accepted to work together to provide the appropriate support to all stakeholders impacted by the go live in November 2022 of the EMA web-based Human Variations electronic Application Form (See 5.3). EMA has also accepted to provide UNICOM with a visibility in its own Newsletter.

At the international level, UNICOM has been present in 2021 and 2022 in a number of important events: One may mention in particular:

- The International Pharmaceutical Regulators Programme (IPRP) event. IPRP was created to establish a forum for its regulatory members and observers to exchange information on issues of mutual interest and enable regulatory cooperation.

- The International Conference on Informatics, Management, and Technology in Healthcare (ICIMTH 2021)

- The Global Pharmaceutical Regulatory Affairs Summit in Berlin

- The 38th International Conference for PharmacoEpidemiology (ICPE 2022)

- The pHealth Conference in November 2022 in Oslo.

Transatlantic cooperation is also a major work axis of UNICOM and as demonstrated by the statistics provided in previous sections, there is a high interest in UNICOM work on the other side of the Atlantic. After a few preparation meetings, this activity was officially started in June 2021 with a first closed event aimed at presenting the project globally to a closely selected panel of influential people. For sustainability purpose, UNICOM has decided to closely associate EMA and WHO-Uppsala to those discussions. It was followed by a second meeting in November 2021 with a slightly extended panel which focused more in details on results achieved by WP2,3 and 4. The third trans-Atlantic meeting took place on the 4th of April 2022 with the aim to introduce the activities regarding concrete adoption of IDMP standards and the data model in the US. This meeting strongly reinforced the role of the GIDWG as a global forum to focus entirely on global use cases, implementation and use of IDMP standards; a number of critical issues to be solved for ensuring global governance have now been identified. This axis will be further reinforced in 2023 with the use of a number of additional communication channels in collaboration with Harvard University and the National Library of Medicine.

5.3 Closed events (decentral communication) (WP4)

WP4 has launched in October 2020 a serial of knowledge transfer workshops. Those workshops are for the moment closed events only opened to the participating NCAs: Each NCA is provided with the opportunity to present its strategy, how it deals with IDMP implementation and learn from other NCAs experience. An average of roughly 30 very motivated participants took part at those workshops.

After a first round of workshops in 2021 and early 2022 (Portugal) where each participating NCA has been provided with the possibility to explain its strategy and challenge, it has been decided to organise a second round of webinars focusing this time on the progress achieved in real implementation.

WP4 had however organised in the first 2021 semester 3 specific webinars focused on the following topics: Ingredients - Manufactured Items & Packages and Pharmaceutical Products to which all European NCAs members have been invited to attend while external people who would introduce a specific request could also be accepted. Table 9 provides an overview of the degree of participation of countries to those webinars (Green: three sessions attended, blue: two sessions and yellow one session).

22 EU countries out of 27 participated at least to one session and 11 EU countries (plus Norway) attended the three sessions. Let's mention in particular here the strong attendance of Denmark and Poland and the good attendance of France, Italy, the Czech Republic and Romania, all countries not active in UNICOM.

Lithuania, Bulgaria, Malta, Luxemburg, the UK and the Netherlands did not attend any of those initial meetings. For the last two ones, this was however partially compensated by an active participation in other UNICOM workstreams.

The number of attendees for a significant number of countries had remained however below expectations demonstrating the need to reinforce dissemination within each NCA.

Table 8: Country participation to "open" WP4 webinars in 2021

WP4: Special topics- Ingredients - Manufactured Items and Packages - Pharmaceutical Products

	Countries/Sessions	Attendees		Countries/Sessions	Attendees
Austria	AT	10	Iceland	IS	1
Belgium	BE	2	Italy	IT	6
Cyprus	CY	1	Latvia	LV	1
Tchek R	CZ	7	Norway	NO	6
Denmark	DK	14	Poland	PL	3
Estonia	EE	10		PRI	1
	EMA	6	Portugal	PT	8
Spain	ES	6	Romania	RO	3
Finland	FI	9	Sweden	SE	8
France	FR	5	Slovenia	SI	2
Germany	GE	8	Slokakia	SK	2
Greece	GR	2		UNICOM	11
Croatia	HR	10		(vide)	6
Hungary	HU	7		ES(I)	1
Ireland	IE	12		ES (I)	1
				Total attendees	169

Sweden and Estonia have been the first two countries which have volunteered for this second round. The WP4 webinars have furthermore been opened since summer 2022 to all European NCAs.

The lessons learnt from those workshops are detailed in WP4 deliverables. But they also define the content of the ***UNICOM key messages and requirements****.*

Table 9: WP 4 knowledge transfer workshops

Date	Agency	Country in focus
02.10.2020	Implementation at HPRA	Ireland
16.10.2020	Implementation at SEMPA	Sweden
29.10.2020	Implementation at EESAM	Estonia
13.11.2020	Implementation at AGES	Austria
27.11.2020	Implementation at HALMED	Croatia

05.02.2021	FHIR experience at NOMA	Norway
26.02.2021	Implementation at AEMPS	Spain
12.03.2021	Implementation at FIMEA	Finland
04.11.2021	Implementation at BFARM and AFMPS	Germany and Belgium
16.02.2022	Implementation at INFARMED	Portugal
21.06.2022	Implementation at HPRA	Ireland
13.10.2022	Sweden implementation results	Sweden
25.11.2022	Estonia implementation results and demonstration	Estonia

The level of participation during the four WP4 webinars in 2022 is very satisfactory with an audience which has more than doubled in comparison with the open webinars organised in 2021:

- *The "Portugal" webinar in February 2022 gathered 92 participants. More detailed statistics were collected for the second round of webinars.*
- *The HPRA (Ireland) webinar in June 2022 recorded 59 participants from 19 different countries.*
- *69 people from 20 EU countries (plus UK and Norway) attended the webinar focusing on Sweden in October 2022 with an excellent level of attendance from **Croatia, Germany, The Netherlands and Italy**.*
- *107 people had registered and 86 people from 22 EU countries (plus UK, Norway, Iceland and EMA) have attended the demo of the new system developed by Estonia in November 2022 with a high attendance rate from **Croatia, Germany, Latvia, The Netherlands and Sweden**. When looking at the profile of the people who attended the meeting, we have now a higher participation from business (35%) and other (19%) with thus IT still predominant (46%). This video has also been made public with the agreement of the Estonian Agency.*

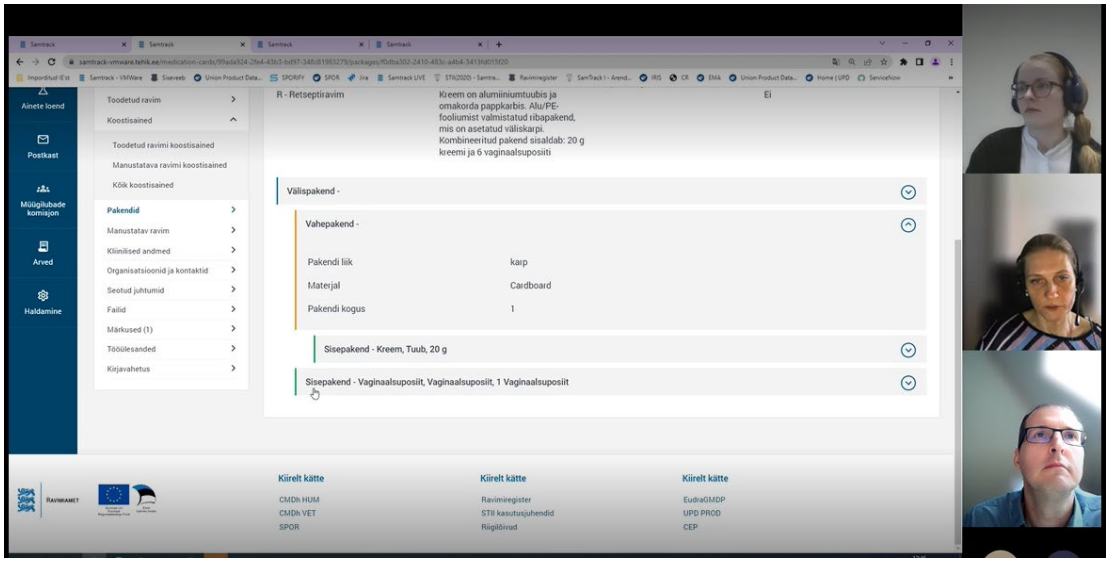


Figure 31: Demonstration of the system developed EESAM in Estonia

As already mentioned, UNICOM partner AGES has also organised two webinars in 2022 in order to help NCAs to get acquainted with both the FHIR standard and the DADI electronic variation form. While the first webinar was meant to provide a global overview of the FHIR© standards and the resources used for medicinal products, the second one was more directly targeted at the ICT directors and main architects. Contrary to other WP4 webinars, the recording of those webinars has been made public on the UNICOM YouTube channel and, beyond the people who attended the events live, has thus reached an important extended audience.

During the first webinar in March 2022, 100 representatives from 24 European countries and EMA had registered for the event with an attendance rate of 64%. Slovenia, Slovakia, Ireland and Greece had registered but did not participate live. Cyprus, Denmark, Bulgaria and Lithuania did not register for the event. Let's also mention the presence of Iceland and Norway. The countries with the highest level of effective individual attendance were Croatia, The Netherlands, Norway and Spain.

The high level second webinar held during the holiday season in July 2022 attracted 45 people (13 no show) from 22 EU countries. This was however an excellent rate given the period. This invitation was also strongly supported by EMA. The following EU countries were not represented during the live session: Latvia, Lithuania, Croatia, Slovakia and Malta. The recorded video on the UNICOM channel is on the top three in term of views. We may thus bet that our objective to reach all CIO, architect and business leads from all EU NCAs has been reached.

5.4 Events organised by UNICOM

In 2021 UNICOM had directly organised two major events targeted at a wide eco-system, one in February 2021 directed towards the cross-border community and another one in April 2021 targeted at the end users, who are only indirectly represented in the consortium.

More than 80 people attended a two-day workshop dedicated to the beneficial contributions of this project to the European-wide eHealth Digital Service Infrastructure (eHDSI)/eHealth Network (eHN) communities. Attendees included representatives from national and regional eHealth Agencies, national drug agencies, the European Commission, and the wide stakeholder community. It provided a very educational insight into the history and present status of the organisational structure, institutions involved, decision taking processes, data flows and technical architecture of the cross-border ePrescription/eDispensation and Patient Summary healthcare services in all their details.

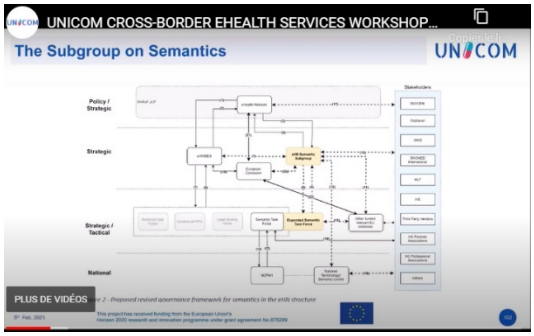


Figure 32: Cross-border eHealth Services workshop

As already mentioned, a second meeting addressing the European eHealth community was called in September 2022 and gathered again more than 80 participants more originating from 21 EU countries and 3 non-EU countries (Norway, UK and Canada).

It also provided a preliminary glimpse of the new requirements resulting from IDMP implementation and the process required to implement them. Later on, UNICOM will test and then pilot in a real life cross-border setting the exchange of IDMP compliant e-Prescriptions as well as of active medicines lists in Patient Summaries.

On Wednesday 21st of April, UNICOM organised its **first workshop dedicated to end users**. It explained the issues at stake via the use of true-to-life stories. It has highlighted the concrete benefits

of IDMP implementation for at least four stakeholder groups and has collected feedback from stakeholders' representatives (citizens, patients, physicians, hospitals, pharmacists…).

Countries	Participants	Countries	Participants
Austria	3	Lithuania	3
Belgium	21	Malta	1
Croatia	10	Netherlands	10
Czech Republic	7	Norway	16
Estonia	2	Portugal	4
Finland	6	Slovakia	4
France	9	Slovenia	5
Germany	12	South Korea	2
Greece	7	Spain	2
Hungary	1	Sweden	5
Ireland	12	Switzerland	2
Israel	1	UK	17
Italy	14	United States	5
TOTAL	**181**		

Table 10: Country origin attendees end-user event

Without taking into consideration the number of people who watched the event on YouTube after the event, 181 people from 27 countries registered for the event with 13 countries without NCAs present in the consortium. Presence of people from Lithuania, Malta Slovakia, Greece and the Czech Republic is also truly encouraging as the consortium needs to have good relays in those countries.

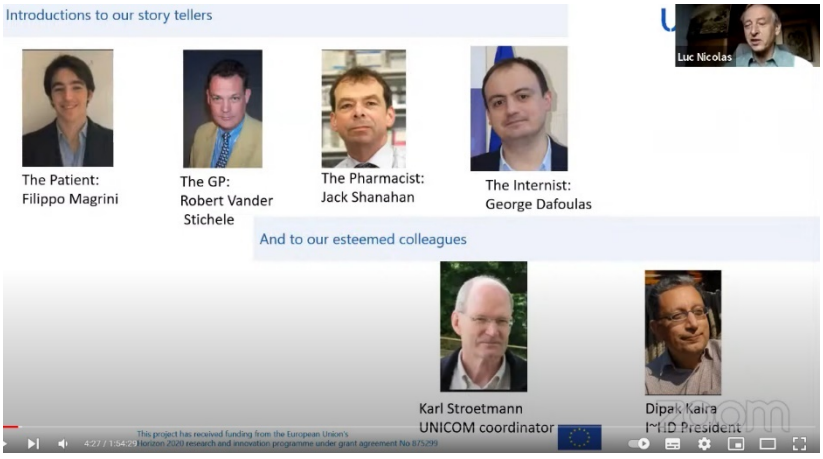


Figure 33: The 4 personas of the end user's event

In 2022, UNICOM focused its attention in priority on the pharmacy segment and direct contacts have been taken with three European Associations of Pharmacists, each of them representing a different segment of that end-user category, namely: the European Association of Hospital Pharmacists (EAHP), the European Association of E-Pharmacies (EAEP) and the Pharmaceutical Group of the European Union (PGEU). In the course of November 2022, dedicated online meetings have been organised with an extended board of EAHP and EAEP with the active participation of UNICOM WP8 given their strong involvement in use cases of importance for pharmacists such as pharmacovigilance and decision support systems. Once again, we could only observe that IDMP as such and the global change it will support was hardly known from the members of those associations who are supposed however to be most informed among their peers.

Let's also mention the renewed direct contact established with the European Federation of Pharmaceutical Industries and Associations (EFPIA): aside from the contacts established in 2020 and

2021 in the context of the regulatory use case and the involvement of a number of Industry representatives in the UNICOM Community of Expertise webinars and in the Global IDMP Working Group (GIDWG) supporting transatlantic efforts, direct contact has also been established with the pharmacovigilance and Public Policy working groups where a dedicated meeting has been organised. Here again, we noticed the importance to multiply the channels of dissemination. The Pharmacovigilance working group has in particular insisted on the need to also involve Japan as much as possible in the high-level discussions.

5.5 Participation to external events

UNICOM has been invited to present the project objectives, challenges and results in a number of International, European or national events. The events related to the period under review (Nov 2021 – Nov 2022) are listed under ***table 15 in ANNEX 1.***

Since the beginning of the project, UNICOM has been invited to interact with an external audience in a very significant number of external meetings and events. Two third of the events attended during the period were European events while roughly 30% had an international dimension and only 3 events had a national dimension. As announced in previous sections, this will be a major focus for the year 2023. Three quarter of the events had a limited number of attendants (less than 50) as they were held with a very specific target and closed community. All the other events had a much more diversified and open audience.

Scope	Nber of events	%
European	**51**	**66,23%**
>1000	1	
>100≤300	2	
>50≤100	4	
≤50	44	
International	**23**	**29,87%**
>500≤1000	3	
>100≤300	3	
>50≤100	3	
≤50	14	
National	**3**	
>100≤300	1	**1,30%**
≤50	2	
Total	**77**	

Nber of attendant	Nber of events	%
≤50	60	77,92%
>50≤100	7	9,09%
>100≤300	6	7,79%
>500≤1000	3	3,90%
>1000	1	1,30%
Total général	77	

Since the beginning of the project, a total of 169 attendance to external events has been recorded with 46% of all events having taken place during the period under review, demonstrating thus a much more pro-active approach to connecting UNICOM with the wide community.

Event/Meeting scope	Number (Jan 2020 - Nov 2021)	Nov 2021- Nov 2022	Total	%
European	**59**	**51**	**110**	65,09%
>1000		1	1	
>300≤500	1		1	
>100≤300	1	2	3	
>50≤100	10	4	14	
≤50	47	44	91	
International	**27**	**23**	**50**	29,59%
>500≤1000	1	3	4	
>100≤300	2	3	5	
>50≤100	15	3	18	
≤50	9	14	23	
National	**6**	**0**	**6**	3,55%
>100≤300	2	1	3	
>300≤500	3		3	
≤50	1	2	3	
Total	**92**	**77**	**169**	

Table 11: External events statistics

Considering the categories of audience reached, at least 5 events during this period had a multi-stakeholder's audience which included all the actors of the value chain. The policy makers and national administrations remain the categories of stakeholders addressed in the largest number of events and meetings. This is largely related to UNICOM presence in the EU cross-border fora. Representatives from Healthcare providers have also been part of a significant number of events while the events involving industry have increased by 30% in comparison with the previous period. One need also to notice the participation of UNICOM to major events which gathered a very large audience of Research oriented organisations and standardisation bodies compensating thus for the lower number of events targeted at those groups.

During 2022, with the availability of adapted dissemination tools such as IDMP in a capsule and to the availability of several slide decks adapted to the different use cases and stakeholders targeted, it was possible to be precise in our messages and content with an increased focus on the progress made and the solutions now well visible on the horizon. In 2023 we will put extra efforts in supporting national actors involved in UNICOM and -when needed- adapting the material to the language and context of individual countries. This will already be the case for the Major Greek event to be held in December 2022. If no national external event relevant to feature UNICOM can be identified, UNICOM partners will consider organising it directly. The communication team will also work on a new 2023 plan of participation to a few major European and International events, including, if possible, event to be held in the USA.

Figure 34. Session dedicated to UNICOM during 2022 EHTEL symposium

Figure 35: Poster presented during the FIP conference in Sevilla

Poster Number: 78
Publication Number: 1123

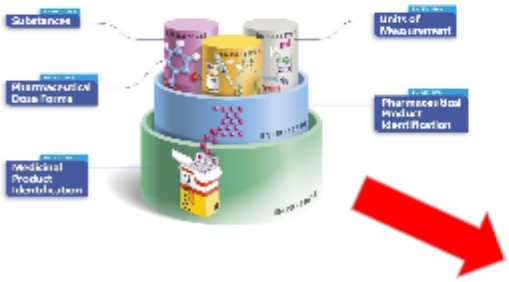
Will the implementation of ISO/CEN Standards for global Identification of Medicinal Products (IDMP) make any difference for pharmaco-epidemiology?

Authors : Robert Vander Stichele, MD, PhD[1,2]; Miriam Sturkenboom, Pharm, PhD[1,2]; Carlos Duran, MD, PhD[1,2]; Luc Nicolas[3], Dipak Kalra; MD,PhD[1,2]
Affiliations : [1] European Institute for Innovation through Health Data; [2] University Medical Center Utrecht; [3] Unicom.

What if ?

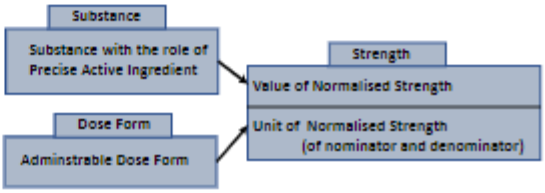
We would be able to identify any medicinal product
from anywhere in the world anywhere in the world ?

That is the ambition of 5 ISO/CEN Standards !



Creating established rules to represent
3 core identifying concepts of medicinal products :
- Substance
- Dose form
- Strength,

and governing also
the relationships between these concepts



For a broad range of use cases across the life cycle of a medicinal product !

Supported by

- Supported by 3 consecutive European Projects of 4 years each: epSOS / Open Medicine / UNICOM (2021 to 2024)
- Supported by ICH (International Council of Harmonisation) and a global Working Group (bringing together FDA, EMA, WHO_Uppsala Monitoring Centre for Pharmacovigilance)
- Supported by UNICOM, a large action program, from the EU Horizon programme, with a 20 MEURO Budget, and 44 participating organizations, among which 11 National Competent Agency for marketing authorization of Medicinal Products. https://unicom-project.eu

What is in for Pharmaco-epi ?

- Possibility of global identification of medicinal products in clinical trials, pharmaco-vigilance, and observational studies in databases
- Evolution to a more precise Common Data *Model for medicines in Big Data*
- *Agile relationship between local individual medicinal products and various International Drug Classifications*
- Alignment of drug terminologies for substance, dose form, unit of presentations, route of administration in a multilingual context.
- Intense comparison of national pharmacotherapeutic arsenals
- Facilitating global deployment of Evidence-based Guidelines, Drug Information and Decision Support Systems

This project has received funding from the European Union's Horizon 2020
Presented at the 38th International Conference of Pharmacoepidemiology.

Figure 36: Poster presented during ICPE 2022

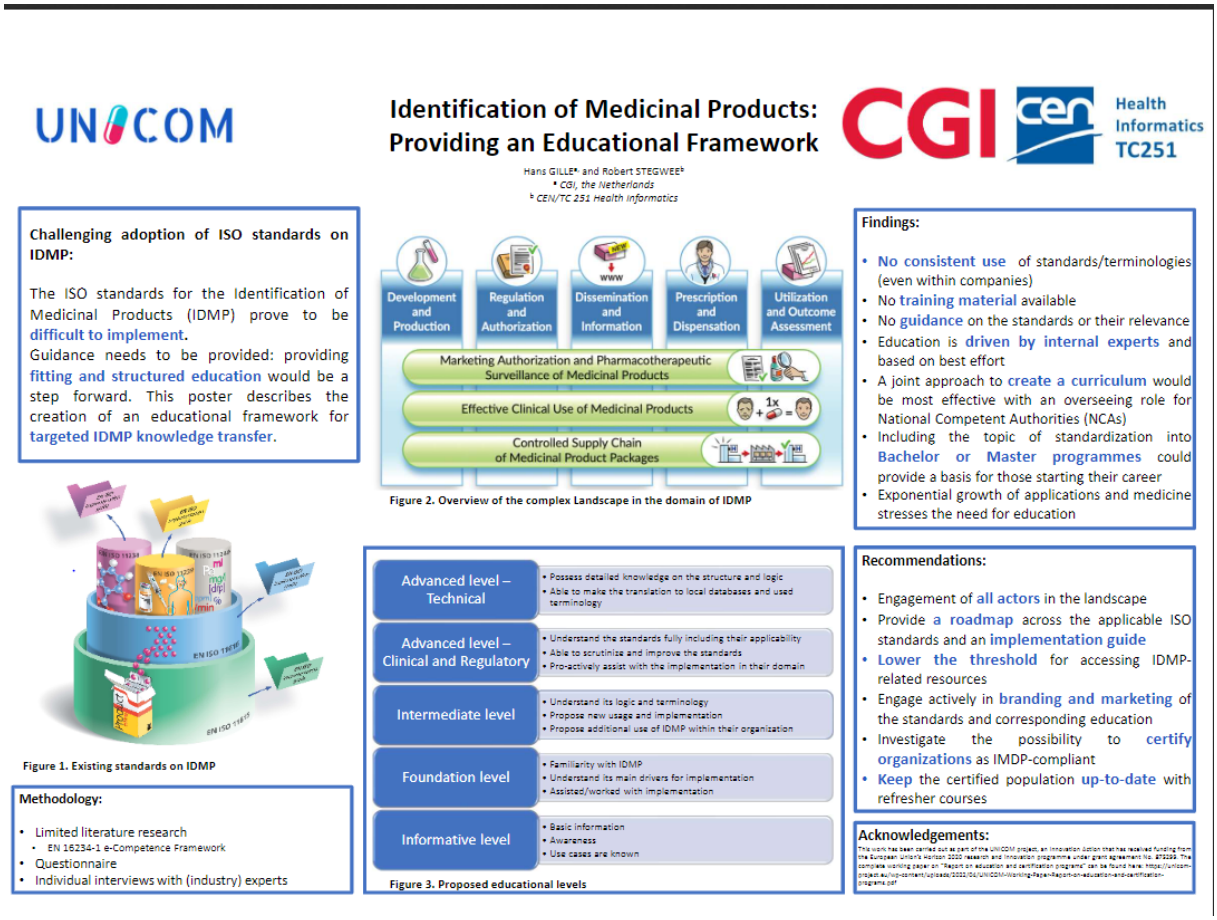


Figure 37: Poster presented during the Personalised Health (pHealth) conference in Oslo

6 Project resources and assets

6.1 Deliverables

All public deliverables are made available through the “project resources” section of the website. Public deliverables which are still pending approval by the EU Commission are published as “working document” in order not to delay the timely dissemination of the project results. When appropriate an executive summary of internal deliverables will be made

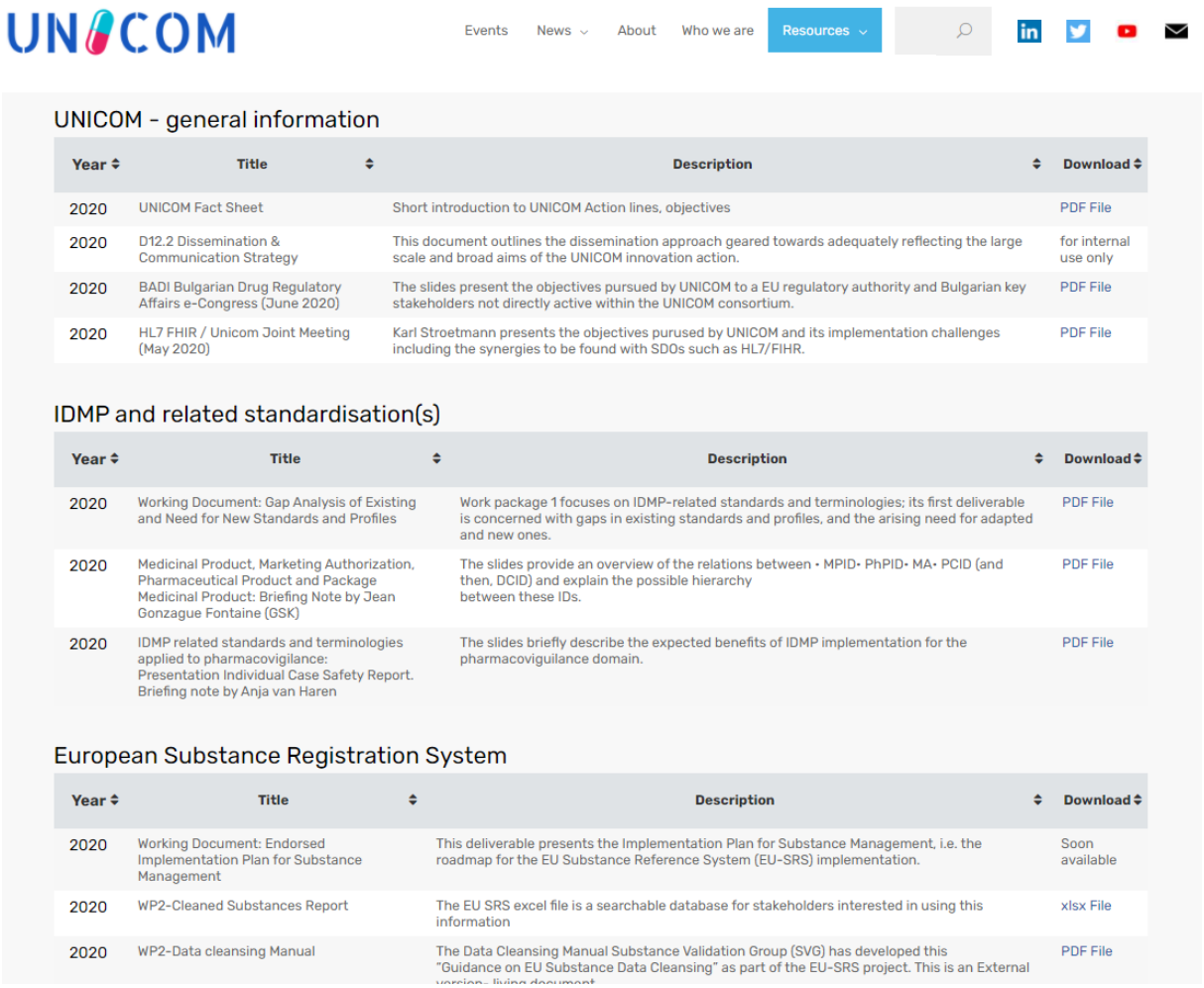


Figure 38: UNICOM published project resources

6.2 Recorded video

It sometimes takes a while to obtain a publishable written resource. Unicom has thus decided to fill this gap by interviewing UNICOM key actors in order to provide the external audience with the first insights and bring attention to follow-up events and activities. A first interview has thus been conducted in June with WP leader, Christian Hay, on the first results of the gap analysis series of workshops. A second interview has been conducted in 2021 with Robert Van Der Stichele (WP8) focusing on the benefits of IDMP to support evidence base medicine and decision support tools in particular. *Two supplementary interviews have been conducted in 2022: the first one with the Estonian Drugs Agency EESAM and the second one with the Croatia Drugs Agency HALMED in order to provide a lively and interactive presentation of the challenges of IDMP implementation by NCAs and focus on the choices made in order to make their system IDMP compliant.*

Interviews

Figure 39: Sample of UNICOM interviews published on the Youtube channel

6.3 Scientific publications

As already mentioned under section 4, a significant number of partners have notified their intention to publish a scientific article related to UNICOM outputs. *One should however not forget that UNICOM is a very specific project with a mix of innovation and real-life implementation and as such, the type of publications to be expected are very different from those released by other type of projects.*

This has materialized in 2021 and much more in 2022 with the publication of a number of important articles which are focusing on the key issues which need to find solutions, if possible, at a global (and not only European) level. Those publications are essential to support the discussions in order to be able to rely on concrete facts in order to agree on 1) key problems to be solved 2) the requirements 3) the possible solutions and 4) the possible processes. UNICOM partners have produced ***no less than seven publications*** *in the period Nov 2021-Nov 2022. The full list of all publications can be found in* ***annex 2****.*

Following EHTEL symposium on the thematic of UNICOM possible contribution to the emergence of medicinal products related European Health Data Spaces, a factsheet has been produced summarizing the webinar key outputs. The factsheet outlines in particular the expected benefits of IDMP for the pharmacovigilance domain.

We took already advantage of the COVID-19 momentum to produce a first article (commentary) dedicated to the urgent need **to track and trace the global use of COVID-19 vaccines**. Initially vaccines were considered out of scope for UNICOM but given the overall context, it was reintegrated.

The article has been published on November 24th by the review Vaccine (Elsevier). This is an important milestone as it acts as a UNICOM recognition of the important messages that had to be conveyed urgently: In this commentary, the arguments are presented in a tactical and scientific way, so they come over as well-founded good practice recommendations for the benefit of our collective learning. The

involvement of WHO-Uppsala in writing this article is another demonstration of the level of engagement of this organisation in the UNICOM consortium. As shown by the statistics, the article has succeeded to make a breakthrough with no less than 6 citations in articles published in 2022 such as this one: "International Non-proprietary Names (INN) for novel vaccine substances: A matter of safety"

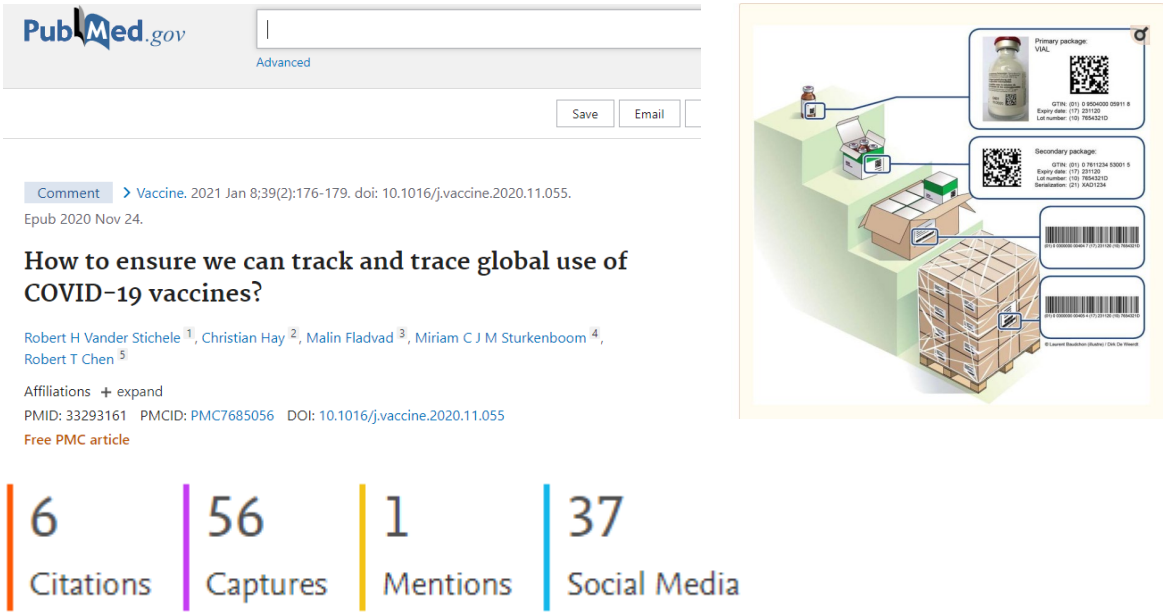


Figure 40: Article published in vaccine

The work performed in certain work packages (with WP8 and WP9 in particular) is without doubt the most prone to publications but work performed by WP1 and more unexpectedly WP4 has also led to publications, due to the participation in conferences which have published the articles as proceedings.

Let's mention, in particular, two papers which are meant to provide substantial contribution to the discussion on the use of EDQM versus RX Norm and have also been instrumental in introducing change requests to EDQM. The first article published in April 2022 has been viewed 772 times to date while the second has been essential to support the transatlantic discussions.

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Alignment of two standard terminologies for dosage form: RxNorm from the National Library of Medicine for the United States and EDQM from the European Directorate for the Quality in Medicines and Healthcare for Europe

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[b] Harvard Medical School, Boston, MA, USA
[c] European Institute for Innovation through Health Data (I-HD), UNICOM Innovation Action; Department of Medical Informatics, Ghent University, Ghent, Belgium

Figure 41: Articles published supporting the discussion on dose forms

This article published as a proceeding of the eTelemed 2022 conference is an important milestone as this is the first direct and extended public written contribution of a National Competent Authority. It does not only provide a detailed overview of its transformation process but it also insists on the deep change of roles in key actors to produce, maintain and distribute interoperability.

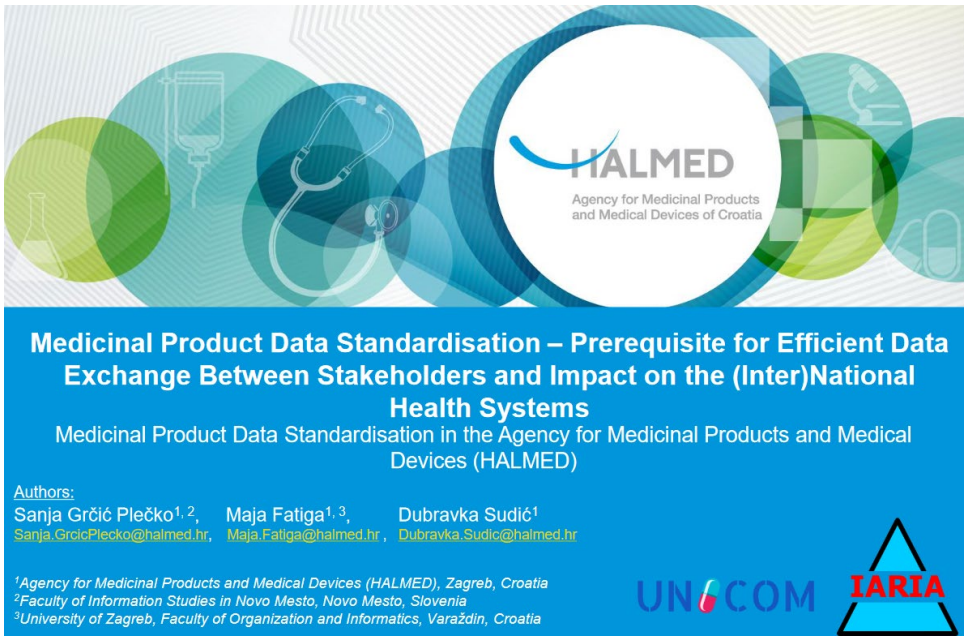


Figure 42: Article published by HALMED

7 UNICOM story lines

The UNICOM dissemination strategy (DEV 12.2) outlines in its section 4 the need to develop adapted narratives whose general purpose is: **"to feed the launch messages and thus to provide a first contribution towards European-wide awareness raising for the expected benefits and impact of a wider IDMP roll-out in national health systems and for cross-border services".**

Narratives are indeed instrumental for awareness building, and also for stakeholder engagement and alignment. The arguments which support the need for IDMP implementation need to be translated in words adapted to the targeted stakeholders. The concrete context of implementation and use of each segment of the value chain needs also to be taken into consideration.

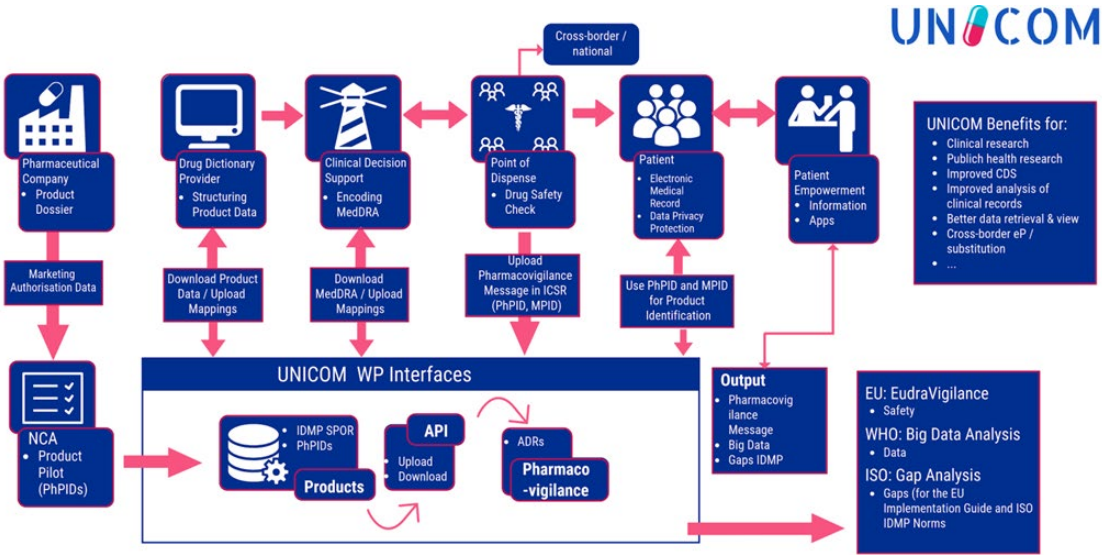


Figure 43: UNICOM value chain

UNICOM will initially work with three reference core use cases and narratives will mainly refer to them, but more use cases (or benefits) can of course be taken on board during the project lifecycle.

The narratives will be progressively built around a number of keywords (related to data and processes): Accessibility, quality, consistency, integration, security, user acceptance and friendliness, simplification, redundancy avoidance, synergies are examples of those keywords.

During those first months of activity all UNICOM partners have been clustered in a Stakeholders category segment. Within each segment, a leader has been identfied to drive the process. Work package leaders play of course a leading role but in certain segments, such as the SME, other partners can come forward.

The process has been the following:

Each Stakeholders segment present in the consortium (Medicinal products National Competent Authorities, National/Regional Competence Centers, SDOs, Industry EHR, Industry Pharma and SMEs) have first developed their own value proposition from their own perspective. This exercice took place from November 2020 till April 2021 (See Annexes 2-7) .The initial drafts were discussed in an extended group either through a decidated WP meeting or a cluster meeting. The contribution of organisations belonging to a specific cluster in an observatory role or external to the consortium is here welcome. The expectations from other actors of the value chain should here be made explicit.

The initial value propositions have been used as a preliminary reference content for all messages targeted at this category of stakeholders.

In a second step, the value proposition of each category of stakeholders will be reviewed and commented by the other stakeholders. The comments collected during this phase will be gathered and used for an alignment workshop to be organised in 2022 and will be connected to UNICOM outputs and demontrators.

The end-users perspective (clinicians, pharmacists, patients …) will be built during dedicated events with the support of a number of clinical partners present in UNICOM in an observatory role and on the basis of the inputs provided by Work packages, in particular WP 8 and 9. Those inputs were used, among other things, for the production of “UNICOM in a capsule” which was released in september 2021.

Those narratives will also provide strong arguments for the sustainibility of UNICOM outputs. The preliminary analysis of stakeholders engagement activities perfomed those first two years, such as the knowledge transfer worskhops organised in WP4, has also taught us that in order to convince and commit stakeholders, realistic implementation scenarios of a gradual IDMP implementation need to be defined and communicated.

The Value Proposition aims at capturing two different views related to a specific proposition.

On the right side, we want to express the pains (Fears), the gains (Needs) and the more general requirements (Wants).

On the left side, we consider what the proposition (ISO IDMP) can bring in term of Experience (Products and services made available) Benefits (Gain creator) and Features (Pain relievers).

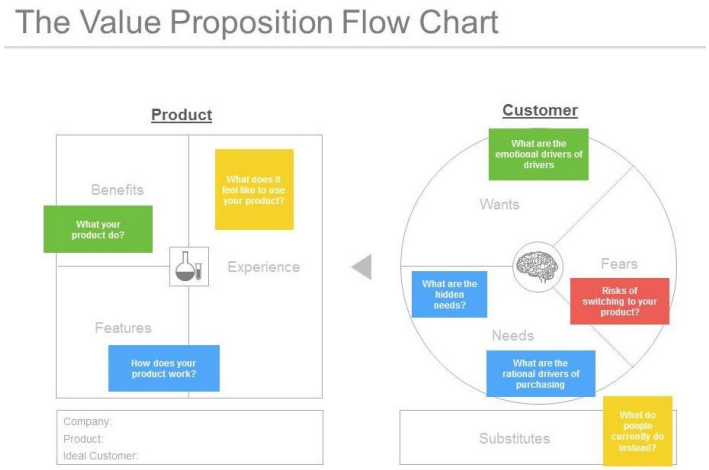


Figure 44: Value proposition diagram

Although the same method and tools have been proposed to all the clusters, it proved difficult to maintain a strict discipline over the different clusters leading to different output formats. All of them are however respecting the philosophy of the value proposition concepts although the left part of the model (product and features in particular) have not developed with the same enthusiasm by all clusters.

8 Recommendations from the technical reviews

Recommendations 7 and 8 of the first technical review related to this deliverable specifically and have been addressed in the previous version of this deliverable. The second report of the UNICOM technical review only mentions the need to better understand why the level of participation of certain countries to key dissemination events is either low or inexistent.

As described at length in other sections of this deliverable, we have been working in an active way to identify and engage relays in all cluster segments and improve significantly the geographical coverage of UNICOM. We have also tried to identify the countries which were not responding to our invitations: we believe that subsequent progress has been achieved during the period under review with a wider representation of EU countries, although in a number of cases, in a still limited form (either in term of number of individuals involved or number of events attended). Lithuania and Bulgaria are today the two countries with whom no real contact has been established yet. We plan to make use of the ***Swedish Presidency*** *and its related official events to have a better idea of why those countries have not shown interest to date and to gain insight in the state of awareness and implementation plan of all National Competent Authorities not active within UNICOM.*

As mentioned, we want to make 2023 the year of national events – engaging thus also end-users' representatives through either a dedicated session in a public event or a dedicated meeting. The national standardisation bodies will also be associated to this process.

Pharma Industry has been engaged in different ways in 2022: via the Community of expertise webinars, directly via the contacts established with Working Groups under EFPIA and also via the partners of the Gravitate Health project where Industry is strongly represented.

Table 12: Key updated action points for Year 4

Actions	Stakeholder's impacted
Cross-participation in standardization fora	SDOs
Extended Community of interest/expertise webinars: Focus on demonstrations and collection of new requirements related to electronic communication with SPOR (EMA)	*SDOs, research, Pharma, NCAs, end-users, EMA*
Connect further UNICOM results and resources with testing environments (such as HL7 FHIR© accelerators/IHE connecthaton's).	*SDOs, Industry, NCAs*
New round of knowledge transfer webinars focusing on implementation results, challenges and identified gaps.	*All European NCAs*
Extend influence through social networks	All key segments

Adapted Communication kits (IDMP in a capsule and slide decks)	All key segments
Pro-active participation to selected events:	SDOs, EHR industry, Pharma Industry, SMEs, Research
Initiate synergies with other projects (events, joint consultation): *Gravitate Health and EHDEN in particular*	SDOs, Pharma Industry, Research
Plan local events and roadshow with NCAs. Use partners in the consortium to reach out to official representatives in selected countries and extend communities (e.g. HL7/IHE).	*All NCAs involved in UNICOM and SDOs (in particular in countries not active within UNICOM).*
Assess the status of preparation/implementation of NCAs non active in UNICOM. Organise a dedicated session during the Swedish Presidency of the EU and ensure presence in major global (physical) events with a political component	*NCAs*
*Focus pro-actively on **targeted NCAs in countries** not present in UNICOM and with low level of participation (awareness): e.g. Bulgaria, Lithuania, Romania, Luxemburg, Poland; Identify pro-actively relevant contacts in those countries and stimulate their participation to events through a dedicated communication*	*NCAs*
Further support transatlantic cooperation with complementary activities related to identified action points reaching an increased number of US influencers with the support of Harvard University and the National Library of Medicine.	*NCAs, Industry, Research, SDOs, end-users*
Create dedicated mailing-lists and exploit them	Patients, evidence base Medicine, Pharmacists, Physicians, University hospitals
Create UNICOM own events – Possibly in collaboration with Gravitate Health	End-users
Produce adapted material (video, *"Unicom in a capsule" translated in different languages), interviews*, report)	All key segments
Continue in strategic partnership with other relevant projects	Industry, Research, end-users

9 Conclusions and next steps

The COVID-19 situation experienced from March 2020 till March 2022 did not make it easy to target or organise events and a real fatigue with virtual webinars is now observed making it very challenging to have people actively concentrated and engaged. Fortunately, the situation has begun to change from April 2022 onwards, although in a progressive manner.

The first year of the UNICOM dissemination strategy was mainly dedicated to create an identity, make UNICOM name and ambitions known to key actors of the value chain and to make concrete steps towards the establishment of a first very engaged enlarged community. The results obtained in this regard can be seen as very satisfactory.

Through the different surveys conducted in several WPs and through the knowledge sharing meetings and webinars organised by WP1 and WP4 a number of lessons had already been learnt and the main attention points have been identified.

The second year of UNICOM has focused on deepening the dissemination in the first inner circle with an increased focus on concrete and realistic implementation plan scenario allowing thus also to address directly an extended circle of directly impacted stakeholders and to initiate a pro-active communication with the stakeholders which are not directly represented in the consortium, such as the end-users.

In this second year, we indeed began to touch the reality ground and got into concrete implementation scenarios as NCAs had to consider how to adapt their database to comply with the new requirements and begin to learn about new standards such as FIHR. *As demonstrated by the discussion around the UNICOM Products Pilot List, finding common agreements across use cases is not a simple task and assigning responsibilities for the production and distribution of key data* ***is still a very active debate****.*

The value proposition exercise has been very instrumental in defining the initial viewpoint and requirements of the different key stakeholders. UNICOM messages need to incorporate the need to combine global vision and realistic targeted IDMP implementation plans based on clear use cases and needs.

During the third year, in 2022, important official milestones have been reached, mainly related to the first official release of the Substances referential by EMA (WP2) and the go live of the EU Electronic Application Forms – Human Variations (WP3) but also to important implementation progress achieved by a number of NCAs (WP4) which have already deployed their IDMP compliant new or refactored system. Much remains to be done both at EMA and with NCAs but the first implementation results had a major symbolic impact: that the closed circle of IT architects becomes also a priority topic for business staff. For many different reasons, EMA was (and is still partially) under heavy pressure, timelines have been adapted several times during the last two years but the movement is launched and will not be stopped. The positive evolution experienced in 2022 has provided a global signal to all NCAs: time to move up! The new Regulation for Medicinal Products (Human) currently in discussion contains a number of new (digital) requirements and is thus due to provide additional impetus.

Although organised now every other month, WP 1 has continued to extend its network and is now truly a worldwide community, having succeeded to attract an impressive number of skilled people: the Community of Expertise webinars allow an extremely rapid dissemination of the key findings and proposals emanating from other work packages and are increasingly capable, thanks to the availability of UNICOM scientific and project resources, to provide attendants with concrete and rich material.

UNICOM is also dealing with moving targets as UNICOM is proposing new solutions to identified gaps while certain developments are already being put in place which could be requestioned. Change management is also usually very complex in public organisations which usually tend to adapt only marginally. UNICOM is thus often walking on the edge and needs to constantly negotiate the necessary openings with all the consortium partners. *This remained largely true in 2022.*

All countries active in WP4 had been provided the opportunity to share their experience and questions in 2021 and a new series of webinars has been launched in 2022, much more focused on implementation. The objective to inform and train all EU NCAs in relationship to the use of the FHIR© standard and variation forms has also been reached and a strong dissemination partnership with EMA has been established. All WP4 webinars are now open to all EU NCAs while the recorded videos are increasingly published with an "public" status. The number of participating countries has seriously increased in 2022 and more pro-active actions will only be needed in 2023 for a few countries.

After the major event organised by UNICOM in 2021, end-users engagement is best undertaken at national level: NCAs active in the consortium have thus been requested to take new initiatives to enlarge the number of people involved in the agencies and to take the lead in discussing the issue (including the data distribution question) with the whole National eHealth ecosystem and identify the relevant national events in which IDMP impact can be featured or organise a dedicated semi-public meeting on the topic. Although evolving positively, it is however clear that the situation remains very different from country to country and that in some cases, some important political decisions will need to be taken in order to move towards a globally integrated eco-system where the regulatory and eHealth domains have established structural connections. The scientific articles and the working papers produced mainly by WP8 and WP9 have also played a key role in disseminating IDMP purpose and impact to a number of important users, such as those involved specifically in pharmacovigilance, decision support systems and medical products dictionaries. The choice of the topics dealt with in the scientific papers have been chosen so that they can support critical decisions at European and International levels.

UNICOM is constantly updating and adapting its communication tools and channels in order to reach extended circles. This will again be the case in 2023 with e.g. the proposal to translate IDMP in a capsule in national languages. Many actors now feel more confident to support UNICOM messages and we have seen in 2022 much more individual engagement in social media.

Direct and very concrete relationship has also been established with key bodies such as the eHDSI community (eHMSEG taskforce), the eHealth Network, EMA and (WHO) UMC Uppsala. *As a project affiliate active in all important internal and external meetings, WHO-Uppsala is also now a key UNICOM player which has officially accepted to take over the responsibility of the PhPID creation and maintenance in the context of UNICOM but also more globally at international level though its active participation in the Global IDMP Working Group. A second important meeting took place in September 2022 with the eHDSI community in order to act the important milestone of wave 6. The alignment of the requirements and timelines between regulatory and eHealth authorities and technical experts in order to support the deployment of priority cross border services has been a key subject of discussion in 2022 with the difficulty here to face a direct real implementation challenge where UNICOM will provide software tools that can be sued by Member States in eHDSI in their routine operation. UNICOM has however largely communicated over its essential contribution to the success of wave6 and has presented UNICOM results as a major contribution to the creation of the European Health Data Space. In 2023 UNICOM will also reinforce its efforts to partner with SDOs in order to make use of the results and data of the projects in the context of HL7/IHE lab initiatives.*

The urgent need to work on correct vaccines identification has also triggered an accelerated cooperation with FDA in the USA*. Four transatlantic meetings including EMA, UNICOM, WHO Uppsala and FDA representatives, gathering key influential US stakeholders have been organised in 2021 and 2022 (fourth one in December 2022): there is now a formal name for this cooperation:* With the support of UNICOM partner CTADHL, the Gl*obal IDMP Working Group (GIDWG) was formed in October 2021. GIDWG was set up to pursue projects leading to the establishment of a framework for the global implementation of the ISO IDMP standards and maintenance of global identifiers. It works with the ISO Technical Committee on Health Informatics Working Group 6 (ISO TC 215 WG6) and the Health Level Seven (HL7) Working Group on global health data interoperability. Now that the GWGIG has been formally established, more sensitive issues (such as the possible use of EDQM full classification (with some minor adaptations) for dose forms and the management of global identifiers for substances) are now on the table of discussion.*

During the last period of the project, UNICOM communication will target in priority national ecosystems and major international events, in particular those, with a political dimension. Sweden leads WP4 and will ensure in 2023 during the next EU Presidency a unique opportunity to bring the results of the project at the highest level. As mentioned, several times in this document, 2022 has seen a major change of tone and pace with the front-runners not being afraid to pass ambitious messages. We gave them the best possible echo chamber and will further intensify our efforts during the last 18 months of the project.

Annex 1: UNICOM participation to external events and meetings

Table 13: Participation to external events and meetings (Nov 2021 – Nov 2022)

Date of event	Name of the Event/meeting	Geographical scope of Event/meeting	Brief description of the event/meeting	Location	Organiser	Targeted audience	Number of beneficiaries	UNICOM Contribution: Who? What?
Dissemination Events								
17/10/2021	19th International Conference on Informatics, Management, and Technology in Healthcare (ICIMTH 2021)	International	On Sunday 17th of October, UNICOM has presented a tutorial based on IDMP in a capsule	Virtual	ICIMTH	Research and Academia,	≤50	WP1 (Robert Stegwee)
09/11/2021	27th meeting of the eHealth Network sub-group on Semantics	European	ePrescription guidelines (revision of existing guidelines) o Alignment of work with UNICOM, ePI work of EMA and the Patient Summary guideline 3? (inclusion of planned care and possible other use cases that might arise in the future).	Virtual	eHN SG on Semantics	Policy-makers, Public healthcare providers	≤50	Update of the project status
15/11/2021	CTADHL: UNICOM Trans-Atlantic Workshop	International	Introducing WP2, WP3 and WP4 current results to a panel of influencial and decision making American Panel	Virtual	CTADHL	Research and Academia, National public administration, Industry representatives , Policy-makers	≤50	Update of the project status
19/11/2021	Project update at CEN/TC 251 Health Informatics Plenary Meeting	European	Regular plenary meeting of the Technical Committee with representation from national member bodies, liaisons and observers.	Virtual	CEN/TC 251	Policy-makers, Public healthcare providers	≤50	WP1 - Christian Hay and Robert Stegwee

21/11/2022	Meeting with EAHP: European Association of Hospital Pharmacists	European	Robert Van Der Stichele and Luc Nicolas introduce the IDMP topic for European Hospital Pharmacists and analyse potential impact and benefits for this specific group	Virtual	EAHP	Private healthcare providers	≤50	WP8 & WP12
13/12/2021	Substance Work Group 1 meeting	European	Industry + regulators meeting, with topic Cleansing results chemicals, as well as impact on industry of changes in SMS data.	Virtual	EMA/CBG	Industry representatives, Policy-makers	≤50	Liaise with industry on impact cleansing SMS substances data for industry
14/12/2021	eHN SG on Semantics	European	28th meeting of the eHealth Network sub-group on Semantics	Virtual	eHealth Network	Policy-makers, Public healthcare providers	≤50	WP5
16/12/2021	Substance Work Group 2 meeting	European	Industry + regulators meeting, with topic exchanging vaccines data.	Virtual	EMA/CBG	Industry representatives, Policy-makers	>50≤100	Provide insight in results of a test of importing/exporting vaccines records between industry and regulators
10/01/2022	presentation during Vulcan / Gravitate Health / UNICOM track of HL7 FHIR Connectathon	European	An HL7 Fast Healthcare Interoperability Resources (FHIR®) Connectathon features hands-on FHIR development and testing. This is a chance to get your hands dirty and learn by helping evolve the FHIR specification.	Virtual	HL7	Policy-makers, Industry representatives	>50≤100	WP1
11/01/2022	Contribution to FHIR Standard for Information Leaflets of Medicines (Gravitate Health)	European	Open discussion in parallel to the HL7 FHIR Connectathon track to discuss the FHIR standard for Patient Information Leaflets	Virtual	Gravitate Health	Research and Academia, National public administration, Industry representatives , Policy-makers	>50≤100	WP1
11/01/2022	eHN SG on Semantics	European	29th meeting of the eHealth Network sub-group on Semantics	Virtual	eHealth Network	Policy-makers, Public healthcare providers	≤50	WP5
17/01/2022	PS Cluster meeting	European	eHMSEG PS cluster regular meeting	Virtual	PS Cluster (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5

18/01/2022	Project update during HL7 International Working Group Meeting (BR&R, Pharmacy, Patient Care)	International	Regular joint meeting of the HL7 work groups that have an interest in medication information.	Virtual	HL7	Industry representatives	≤50	WP1
01/02/2022	X-border meeting	European	X-Border regular meeting	Virtual	X-border (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
03/02/2022	STF meeting	European	STF regular meeting	Virtual	Semantic Task Force (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
08/02/2022	eHN SG on Semantics	European	30th meeting of the eHealth Network sub-group on Semantics	Virtual	eHealth Network	Policy-makers, Public healthcare providers	≤50	WP5
17/02/2022	STF meeting	European	STF regular meeting	Virtual	Semantic Task Force (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
17/02/2022	Gravitate Health Consortium meeting	European	UNICOM key partners provide a complete overview of the project objectives, results and expected impact	Virtual	GravitateHealth project	Research and Academia, Industry representatives	>50≤100	WP1, WP5 and WP8
03/03/2022	STF meeting	European	STF regular meeting	Virtual	Semantic Task Force (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
03/03/2022	eHMSEG meeting	European	23rd eHMSEG meeting		Trimestral eHMSEG meeting (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
07/03/2022	eP Cluster meeting	European	eHMSEG eP cluster regular meeting	Virtual	eP Cluster (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
10/03/2022	STF meeting	European	STF regular meeting	Virtual	Semantic Task Force (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
14/03/2022	PS Cluster meeting	European	eHMSEG PS cluster regular meeting	Virtual	PS Cluster (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5

17/03/2022	STF meeting	European	STF regular meeting	Virtual	Semantic Task Force (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
29/03/2022	X-border meeting	European	X-Border regular meeting	Virtual	X-border (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
30/03/2022	DIA Europe	European	Overview of the UNICOM project	Virtual	DIA Europe	RA experts	≤50	WP1: Christian Hay
31/03/2022	UNICOM overview at DIA	International	Brief update on UNICOM and WP3		DIA Europe	Public healthcare providers, National public administration	>100≤300	WP3: Georg Neuwirther
31/03/2022	STF meeting	European	STF regular meeting	Virtual	Semantic Task Force (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
06/04/2022	Global Pharmaceutical Regulatory Affairs Summit -Berlin	International	IDMP implementation will be the central topic on April 6 but many other sessions will also have IDMP in the background. UNICOM was represented in two sessions at 10.45 and 15.45 on April 6.	Virtual	IQVA: a leading global provider of advanced analytics, technology solutions and clinical research services	Research and Academia, National public administration, Industry representatives, Policy-makers, private and public healthcare organisations	>100≤300	WP1 (Vada Perkins) and WP4 (Georg Neuwirther and Peter Bachman)
11/04/2022	PS Cluster meeting	European	eHMSEG PS cluster regular meeting	Virtual	PS Cluster (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
12/04/2022	X-border meeting	European	X-Border regular meeting	Virtual	X-border (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
14/04/2022	STF meeting	European	STF regular meeting	Virtual	Semantic Task Force (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
03/05/2022	LinkedIn event: Let's discuss FHIR standard for Patient Information Leaflets of Medicines	International	LinkedIn Event accompanying the HL7 FHIR May 2022 Connectathon track organised in a collaboration between the Vulcan FHIR Accelerator, the Gravitate Health project and the UNICOM project.	Virtual	Gravitate Health	Research and Academia, National public administration, Industry representatives, Policy-makers, private and public healthcare organisations	>50≤100	WP1

04/05/2022	Scenario development and testing during Vulcan / Gravitate Health / UNICOM track of HL7 FHIR Connectathon	International	An HL7 Fast Healthcare Interoperability Resources (FHIR®) Connectathon features hands-on FHIR development and testing. This is a chance to get your hands dirty and learn by helping evolve the FHIR specification.	Virtual	HL7	Industry representatives	≤50	Esther Peelen Robert Stegwee Catherine Chronaki Giorgio Cangioli
09/05/2022	Project update during HL7 International Working Group Meeting (BR&R, Pharmacy, Patient Care)	International	Regular joint meeting of the HL7 work groups that have an interest in medication information.	Virtual	HL7	Industry representatives	≤50	WP1
10/05/2022	X-border meeting	European	X-Border regular meeting	Virtual	X-border (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
10/05/2022	eHN SG on Semantics	European	33rd meeting of the eHealth Network sub-group on Semantics	Virtual	eHealth Network	Policy-makers, Public healthcare providers	≤50	WP5
27/05/2022	MIE 2022 in Nice: "Challenges of trustable AI and added-value on health"	European	A UNICOM abstract has been accepted. UNICOM is part of the official programme with a full oral presentation with topic: Virtual drug models	Nice (France)	European Federation for Medical Informatics (EFMI)	Research and Academia, Industry representatives Other	>1000	WP8 (Robert VDS)
07/06/2022	eHN SG on Semantics	European	34th meeting of the eHealth Network sub-group on Semantics	Virtual	eHealth Network	Policy-makers, Public healthcare providers	≤50	WP5
08/06/2022	Project update during ISO/TC 215 WG6 meeting in Arlington / The Hague	International	Regular working group meeting of WG6 Pharmacy and Medicines Business	Arlington/ The Hague	ISO TC 215, WG 6	Other (SDOs)	>50≤100	WP1: Christian Hay, Robert Stegwee, Robert Vander Stichele
08/06/2022	US NLM meeting	International	Outreach to US NLM team responsible for RxNorm, to align dose form specifications	Washington (USA)	US NLM	National public administration	≤50	WP1 & WP8: Robert Stegwee, Robert Vander Stichele
09/06/2022	ISO/TC 215, WG 6	International	Varied discussion on ISO work, providing input from the UNICOM project.	Arlington/ The Hague	ISO TC 215, WG 6	Other (SDOs)	≤50	Christian Hay, Robert Vander Stichele, Robert Stegwee, Julie James, José Costa Teixeira, Leonora Grandia

13/06/2022	eP Cluster meeting	European	eHMSEG eP cluster regular meeting	Virtual	eP Cluster (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
16/06/2022	Project update at CEN/TC 251 Health Informatics Plenary Meeting	European	Regular plenary meeting of the Technical Committee with representation from national member bodies, liaisons and observers.	Hybrid	CEN/TC 251	Other (SDOs)	≤50	WP1: Christian Hay, Robert Stegwee
26/06/2022	Fourteenth International Conference on eHealth, Telemedicine, and Social Medicine: eTELEMED 2022	International	The Croatian Medicinal products and medical devices Agency (HALMED) will be presenting its roadmap to IDMP implementation at this event.	Porto (Portugal)-Hybrid	E-TELEMED	Research and Academia, National public administration, Industry representatives , Policy-makers, private and public healthcare organisations	>100≤300	WP4 (HALMED)
08/07/2022	eHN SG on IOP	European	Sub-group on Technical Interoperability (bi-weekly meeting)	Virtual	eHealth Network	Policy-makers, Public healthcare providers	≤50	WP5
12/07/2022	eHN SG on Semantics	European	35th meeting of the eHealth Network sub-group on Semantics	Virtual	eHealth Network	Policy-makers, Public healthcare providers	≤50	WP5
28/07/2022	STF meeting	European	STF regular meeting	Virtual	Semantic Task Force (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
22/08/2022	eP Cluster meeting	European	eHMSEG eP cluster regular meeting	Virtual	eP Cluster (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
24/08/2022	ICPE 2022: 38th International Conference for PharmacoEpidemiology	International	UNICOM WP8 leader Robert Vander Stichele has presented a poster on the theme: Will the implementation of ISO/CEN Standards for global Identification of Medicinal Products (IDMP) make any difference for pharmaco-epidemiology?	Copenhagen (Denmark)	ICPE	Public healthcare providers, Healthcare professionals, Research and academia	>500≤1000	WP8
25/08/2022	STF meeting	European	STF regular meeting	Virtual	Semantic Task Force (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
30/08/2022	X-border meeting	European	X-Border regular meeting	Virtual	X-border (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
05/09/2022	eP Cluster meeting	European	eHMSEG eP cluster regular meeting	Virtual	eP Cluster (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5

13/09/2022	UNICOM Presentation at IHE Experience Day in Montreux	European	Leading interoperability experts reflecting various perspectives presented on existing and new interoperability projects from across the globe. European experts associated with the European Union's digital interoperability programmes provided up-to-date material showing the benefits that the IHE way of working provides for vendors, users, procurement organisations and government institutions	Montreux	IHE Europe	Other	>100≤300	Christian Hay (WP1, ISO)
14/09/2022	UNICOM day at the IHE Connectathon in Montreux	European	Task 1.5 of UNICOM deals with Testing and assessment and is being led by IHE Europe. We would like to familiarize the UNICOM partners and their stakeholders with the well-established and robust IHE testing and certification process, including the tooling available to support these processes.	Montreux	IHE Europe	National public administration, Industry representatives, Other	≤50	Sofia Franconi, Christian Hay (WP1, IHE)
15/09/2022	UNICOM WP3 presentation at the Interagency Discussion eSubmission Group IADUG	International	The IADUG sees itself as an independent open forum for authorities worldwide, covering current topics from the regulatory area; ones that are relevant for the eReview of submissions and the day-today work of all participants.	Virtual	WP3	Public healthcare providers, National public administration	≤50	WP3: Georg Neuwirther
18/09/2022	Presentation during Vulcan / Gravitate Health / UNICOM track of HL7 FHIR Connectathon	International	This track is Phase 4 of an ongoing series, spanning multiple Connectathons, to test the creation, exchange and display of electronic Product information (ePI) and the International Patient Summary (IPS) as FHIR Documents.	Baltimore	HL7 International	Research and Academia, Industry representatives, Other	≤50	Catherine Chronaki (WP1, HL7)
19/09/2022	FIP Congress	International	The theme of the conference: Pharmacy united in the recovery of health care	Sevilla	FIP	Public healthcare providers, Healthcare professionals, Research and Academia	>500≤1000	Leonora Grandia, Annet Rozema, Malin Fladvad, Ursula Tschorn, Julie James, Robert vd Stichele, Jane Millar
19/09/2022	eP Cluster meeting	European	eHMSEG eP cluster regular meeting	Virtual	eP Cluster (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5

20/09/2022	Project update during HL7 International Working Group Meeting (BR&R, Pharmacy, Patient Care)	International	HL7 International Working Group Meetings are held three times each year to carry out and coordinate the standards development work in HL7 International.	Baltimore	HL7 International	Other,	≤50	WP1: Christian Hay, Giorgio Cangioli, José Costa Teixeira
22/09/2022	STF meeting	European	STF regular meeting	Virtual	Semantic Task Force (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
27/09/2022	EDQM September 27, Standard Terms Working Party	European	Robert VDS provided a complete analysis of EDQM as a global terminology for dose forms , propose a few improvements and introduce a proposal for an ontology of dose form	Strasbourg (France)	EDQM	Others (SDOs)	≤50	WP1 and WP8
28/09/2022	HMPWG meeting	International	Explanation on work done by Substances Work Group 3, on homoeopathic substances. This meeting was a kick-off to start joining forces on taking care of the 13.000 homoeopathic substances in SMS/EU-SRS	Webex + Rome	HMPWG	Policy-makers,	≤50	WP2: Edyta Burda, Gerlinde Kugler, Giuliana Rampino, Annet Rozema
03/10/2022	eP Cluster meeting	European	eHMSEG eP cluster regular meeting	Virtual	eP Cluster (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
05/10/2022	ISO TC 215 WG 6	International	UNICOM update	Virtual	ISO TC 215 WG6	SDO experts	≤50	WP1 Christian Hay
06/10/2022	STF meeting	European	STF regular meeting	Virtual	Semantic Task Force (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5
13/10/2022	IRISS	International	UNICOM update	Virtual	IRISS	RA experts	≤50	Christian Hay
14/10/2022	Webinar series: E-medicine management	National	"How to avoid the whispering game" - ISO IDMP is a univocal language that should be used by all the actors in the communication chain, - from industry to patient.	Virtual	The Norwegian Centre for E-health Research	Public healthcare providers, Research and Academia, National public administration, Healthcare professionals	>100≤300	Kristine Aasen: How ISO IDMP should be used by all actors in the value chain
20/10/2022	STF meeting	European	STF regular meeting	Virtual	Semantic Task Force (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5

21/10/2022	Meeting with EAEP/ European Association of E-Pharmacies	European	Robert Vander Stichele and Luc Nicolas introduce the topic for European e-Pharmacies and analyse potential impact for e pharmacies with this specific group	Virtual	EAEP	Private healthcare providers	≤50	WP8 & WP12
08/11/2022	poster presentation on D1.3 IDMP Educational Framework at pHealth Conference 2022	International	The 2022 edition of the pHealth Conference will emphasize the interrelated aspects of pHealth, i.e. advanced digital health ecosystems.	Oslo	Norwegian University of Science and Technology	Research and Academia,	≤50	WP1: Robert Stegwee
10/11/2022	IRISS	International	Brief update on EU-SRS: publication of guides announced + link to CoE meeting shared	Virtual	Iperion	Policy-makers, Public healthcare providers	>50≤100	WP2: Annet Rozema
10/11/2022	EFPIA pharmacovigilance WG	International	Anja Van Haran (CBG) presents to the working group the objectives, results and expected impact of the project to the Pharma Industry members.	Virtual	EFPIA	Industry representatives	≤50	WP8 & WP12
11/11/2022	Annual meeting of the CISP-CLUB, the association of french affectionado's of ICP – International Classification of Primary Care	National	Robert Vander Stichele made a presentation mainly focused on Decision support systems and pharmacovigilance	Lille (France)	CISP Club France	Private healthcare providers	≤50	WP8
16/11/2022	GS1 global HC	International	Global conference organised by GS	Hybrid	GS1	Supply chain and RA experts	>500≤1000	Christian Hay
29/11/2022	EHTEL Annual Symposium on European Data Spaces 'Session 8)	European	In a dedicated session named "Creating interoperability at the source" Robert Vander Stichele exposes the global governance in the making to break all silos. Malin Fladvad from WHO-Uppsala is also part of the panel discussion.	Virtual	EHTEL	Research and Academia, National public administration, Industry representatives, Policy-makers, Public and private healthcare providers	>100≤300	WP8 and WP12
30/11/2022	Webinars: FHIR professional forum	National	"Clinicians on FHIR" - How an API can create joy and safety in health care - SAFEST	Virtual	HL7 Norway	Public healthcare providers, Private healthcare providers, National public administration, Other	≤50	Kristine Aasen (NoMA) & Bernd Moske (South-Eastern Norway Regional Health Authority) explain how medicinal product master data can be

								transformed into FHIR resources and distributed through an FHIR API for clinical use
07/12/2022	X-border meeting	European	X-Border regular meeting	Virtual	X-border (MyHealth@EU)	Policy-makers, Public healthcare providers	≤50	WP5

Annex 2: UNICOM publications

Date of publication	Name of the Publication	Title of the publication	Geographical scope of Publication/Event	Brief description of the publication content	Language of publication	Targeted audience	UNICOM Contribution: Who? What?	Partner responsible for the publication	URL link to the publication
Publications									
AEMPS Publication	Implementar la interoperabilidad semántica en los medicamentos en la Unión Europea	Implementar la interoperabilidad semántica en los medicamentos en la Unión Europea	Spain	A Summary of the UNICOM project and the AEMPS participation	Spanish	Healthcare professionals Industry representatives Research and Academia	National Competent Authority_ISO IDMP implementation	AEMPS	Link to article
15/06/2020	UNIT H3 NEWSLETTER	UNIT H3 NEWSLETTER	European	Summary of project objectives	English	Policy-makers Research and Academia Regional/local administrations	EHTEL L Nicolas	EHTEL	NA
21/09/2020	EHTEL FACTSHEET	EHTEL	European	UNICOM possible contribution to European Data Spaces	English	Policy-makers Research and Academia Regional/local administrations	Miriam Sturkenboom, Karl Stroetmann, L Nicolas	EHTEL	Link to article
05/12/2020	Commentary published in the open source journal Vaccine on December 5 2020.	How to ensure we can track and trace the global use of COVID-19 vaccines?	International	The authors detail the actions needed to ensure we can track and trace the global use of COVID-19 vaccines.	English	Industry representatives Research and Academia	Robert H Vander Stichele, MD, PhD; Christian Hay, LLM; Malin Fladvad, Pharm.D; Miriam C Sturkenboom, Pharm;D, PhD; Robert T; Chen, MD, PhD	IHD	Link to article
01/12/2021	Article published in the volume 21 of the review healthmanagement.org	Ensuring COVID-19 Vaccine Traceability	European	After the article published in Vaccine highlighted the need for global monitoring of vaccine use, HealthManagement.org has asked the authors about the challenges of implementing such system in practice	English	Research and Academia Public healthcare providers Private healthcare providers	Robert H Vander Stichele, MD, PhD; Christian Hay, LLM; Malin Fladvad, Pharm.D; Robert T; Chen, MD, PhD	IHD	Link to article

				and possible measures to minimise the accompanying risks.		Healthcare professionals			
25/04/2022	Scientific article published in APPLIED SCIENCE	How Granular Can a Dose Form Be Described? Considering EDQM Standard Terms for a Global Terminology	International	The aim of the article is (1) to analyse the features of the EDQM terminology, (2) to formulate proposals for minor changes and (3) to create a small ontology of dose forms, based on characteristics of EDQM, and suitable for alignment with other dose form terminologies	English	Policy-makers Research and Academia Industry representatives Other	Robert H. Vander Stichele, ,Joseph Roumier and Dirk van Nimwegen	IHD	Link to article
26/06/2022	Proceedings of eTELEMED 2022: The Fourteenth International Conference on eHealth, Telemedicine, and Social Medicine	Medicinal Product Data Standardisation – Prerequisite for Efficient Data Exchange Between Stakeholders and Impact on the (Inter)National Health Systems: Experience from Croatia	International	The National Medicinal ¨Products Agency of Croatia explains in details its migration journey to IDMP	English	Policy-makers Research and Academia	Sanja Grčić Plečko, Maja Fatiga & Dubravka Sudić	HALMED	Link to article
28/08/2022	Proceeding of the 2022 ICTH conference in Oslo	Will The Implementation of ISO/CEN Standards for Global Identification of Medicinal Products (IDMP) Make Any Difference for Pharmaco-Epidemiology?	International	Will The Implementation of ISO/CEN Standards for Global Identification of Medicinal Products (IDMP) Make Any Difference for Pharmaco-Epidemiology?	English	Policy-makers Research and Academia Public healthcare providers	Vander Stichele RH, Sturkenboom MCJM, Duran C, Nicolas L, Kalra D, Fladvad M.	IHD	Link to article
01/09/2022	Scientific article published in International Journal of Medical Informatics Volume 165, September 2022, 104826	Alignment of two standard terminologies for dosage form: RxNorm from the National Library of Medicine for the United States and EDQM from the European	International	FDA has expressed a need to establish interoperability between US- based dose form descriptions and European-based EDQM. This has been piloted with the FDA SPL nomenclature. •Interoperability has been established between the drug-classification systems of other countries, such as Canada, and RxNorm What did this study add to our knowledge? •RxNorm	English	Policy-makers Research and Academia Industry representatives Other	This paper was written by Natalie Karapetian under the guidance and revision of Robert Vander Stichele and Yuri Quintana.	IHD & Harvard University	Link to article

		Directorate for the Quality in Medicines and Healthcare for Europe		dose forms can be aligned to EDQM dose form descriptors using RxNorm DF codes and EDQM RCA, ISI, TRA, and AME codes31/10/2022 This alignment process requires further validation but is a promising bridge in harmonizing drug descriptions internationally.					
08/11/2022	Proceeding of the pHealth conference Identification of Medicinal Products: Providing an Educational Framework	Identification of Medicinal Products: Providing an Educational Framework	International	This framework indicates the required level of knowledge for the various identified roles within the organisations working with IDMP. Based on a combination of desk research, a questionnaire, and individual interviews, relevant roles were identified covering the various organisations (Users, Educators, Medicine Authorities, Standard Developing Organisations, and IT-suppliers) and five levels of required knowledge were determined, including applicable roles and educational components. Furthermore, this article lists several recommendations that should be taken into consideration whilst developing content and implementing educational modules for IDMP.	English	Academia	Summary of D1.3 Report on Education and Certification	Nictiz (on behalf of CEN/TC 251)	Link to article

Annex 3: Value Propositions for Pharma industry from the wider adoption of IDMP

About these Value Propositions

The project is developing value propositions for each of the main stakeholders that need to be proactive in adopting IDMP internally, and/or encouraging or actively supporting its adoption by other adjacent stakeholders.

The list of potential benefits (value) from the wider adoption of IDMP for the Pharma industry is presented on the next two pages, structured under three headings.

1. What does value mean for Pharma with regard to IDMP implementation?
2. What are the Pharma-relevant use cases for implementation of IDMP?
3. Where can investments be exerted by Pharma to foster IDMP implementation?

What does value mean for Pharma with regard to IDMP implementation?

- Improve operational excellence within industry
  - Cheaper and better business intelligence, due to an internationally adopted consistent and accurate identification of medicinal products within real world data sources (e.g. EHRs), and the documentation of medicines within RWD more reliably
    - Real World Evidence data collection on needs, outcomes and patient preference
    - Faster evaluation of (correct or incorrect) signal detection in PV
    - Better view on drug utilisation (indication related) of the products
    - Better scouting of evolving scientific evidence and guideline development
    - More efficient pharmaco-epidemiology (both risk minimisation studies, comparative effectiveness, and safety studies)
    - Efficient use of social media analysis for detection of adverse events, abuse, and unexpected indications, because natural language processing and data analysts will accurately map free text drug names and descriptions to an IDMP identifier
  - Improving global consolidation of supply chain
    - Facilitation of cross-border prescription and movement of drug sales
    - Linkage with programmes/processes around good manufacturing practice/falsification of products
  - Facilitating a comprehensive IT-infrastructure and strategy
    - Facilitation of R & D: conduct and management of clinical trials, through the improving documentation of concurrent medication in clinical trials, especially for multicentre, multi-national studies
    - Enhance reporting of concomitant medication in clinical trials
- Improve business relations, due to an internationally adopted consistent and accurate identification of medicinal products by and with Regulators and eHealth solution providers
  - Improvement of relationship with regulatory networks
    - Global synchronising of regulatory drug description of NDAs in pre-submission period
    - Speedier marketing authorisation
    - Improving price setting documentation
    - Closer integration of Marketing Authorisation Information and Health Technology Information and Reimbursement information
    - Better relations with EU funded scientific projects outside IMI
    - Correct and honest substitution and INN prescribing rules
  - Improvement of cross-stakeholder involvement
    - Cooperation in development of national drug dictionaries (and authentic sources of medication information) and their implementation

        - Closer integration with IT-Technicians of EHR-vendor systems and national ePrescription systems
        - Improvement of data quality in PHR, EHR, Real World Databases
        - Closer integration with Personal Health Records and medication-related apps for patients
    - Excellence in product information
        - Management of multilingual, multinational drug labelling
        - Structuring of information in drug labelling
        - Excellence in health literacy improvement
    - Improvement of public appreciation of the company and the industry as a whole

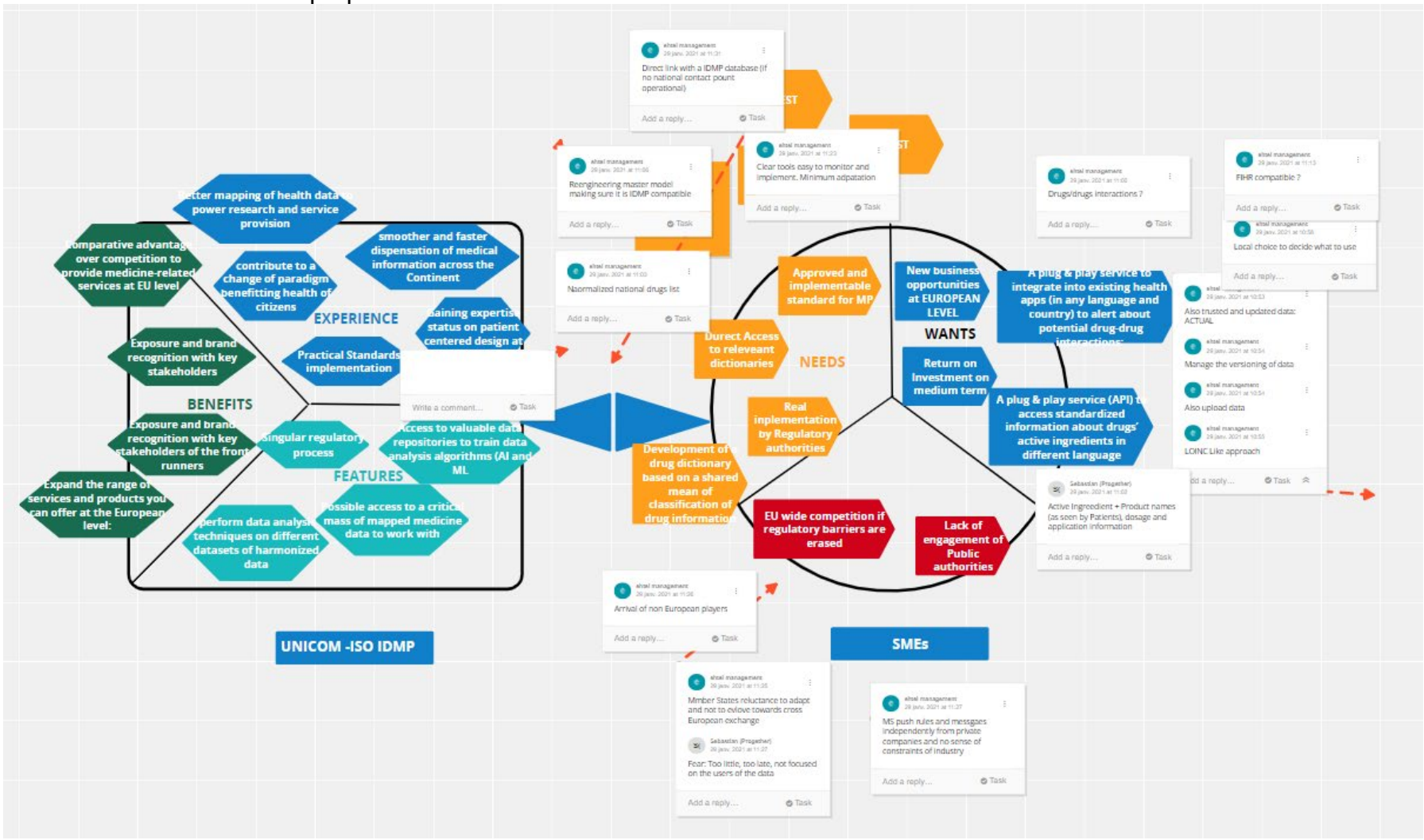
What are the Pharma-relevant use cases for implementation of IDMP?

- Pharmacovigilance
- PHPID, MPID, PCID production process
- Patient information (information to patients, data collected by patients e.g. via bar codes)
- Computerized decision support
- Common data models in RW data
- Quality of pharmacotherapeutics
- Quality of Real World Data
- Intensified analysis of variation in national therapeutic arsenals

Where can investments be exerted by Pharma to foster IDMP implementation?

- Adopting IDMP internally
    - Adoption of IDMP directly by Pharma within document management systems, preparing labelling for submission
    - Adopt within their own real world databases
- Sponsoring adoption initiatives
    - Encouraging vendors to adopt IDMP, setting up and co-financing projects with vendors
    - Sponsoring projects presenting information to patients, promoting apps for patients
    - Co-investing in adoption within post-marketing surveillance and pharmacovigilance systems, to enable the accurate analysis of safety reporting data

ANNEX 4: UNICOM Value proposition SME



1. What do SMEs seek?

SMEs NEEDS
• **Have access to relevant drug dictionaries**: Digital SMEs operating in the European healthcare industry need to access large datasets in order to build their data models. Such necessity is constant, as access to greater pools of data significantly improves the accuracy of the developed models. Moreover, obstacles and difficulties in accessing the repositories have negative consequences for their operations, as they are fundamental to power the digital services marketed by the companies. Furthermore, the data repositories need to be updated and maintained over time, in order to result depictive of the whole drug market. In this sense, a constantly updated dictionary at EU level seems the most efficient solution, rather than having different dataset for each MS, where the maintenance responsibilities are left at MS discretion.
• **Development of a drug dictionary based on a shared mean of classification of drug information**: SMEs need to access different data repositories in order to deliver their digital services successfully. Nonetheless, the lack of coordination among the existing ones make their integration challenging, as it raises the costs to conduct business. SMEs thus need a standardized common model for the classification of drug information valid across the EU, to better connect the multiple repositories and foster the exchange of information across the continent. Such an exchange network would highly benefit the operations of digital health SMEs', as it would allow them to easily access large pools of standardized data thus developing more accurate models. Moreover, by standardizing the means in which drug informations are collected and stored, more complex and comprehensive services can be developed in an efficient way, thus without the costs related to the integration of datasets. Beside the specific pharmacovigilance information, SMEs have identified as necessary to standardize other drug informations, such as dosage, packaging, value of reimbursement etc.
• **Adoption of a common standard (ISO-IDMP) by the different regulatory authorities:** in order to make business in the EU digital healthcare industry, SMEs need to face the least amount of market barriers when providing services at EU level, as they severely hinder their ability to scale beyond their home country's market. In the status quo, SMEs that aim to deliver services in a cross-border manner are required to comply with the different National regulatory authorities. By introducing a common standard of drug classification valid for the different regulatory authorities, SMEs would be faced with less costs to operate in the market, allowing them to focus their resources on the innovation's delivery. Moreover, a common classification model would also benefit the users' perception of the proposed services, as it would have an increased scope (and utility) and provide a secure and transparent mean to access drug information. Therefore, the proposition of such a sustainable framework is considered to be fundamental for the growth of private entities in the industry, as well as to gain the users' trust in the information provided.
SMEs FEARS
• **Lack of engagement by public authorities**: SMEs are aware of the need to have a standardized mean of drug classification valid at EU level, to eliminate certain market barriers

and more efficiently provide their services across the continent. Furthermore, the industry is aware that the power to conciliate the various national regulations lays in the EU, either in a direct manner (through legislation) or an indirect one (funds provision). Nonetheless, the inability of the EU governance to yet deliver effective results in the interests of the private sector raises questions regarding their ability and interest going forward. Such scenario highly concerns SMEs, as the prospect of encountering market barriers at European level discourage them to attempt business strategies involving the scaling of their services across the various MSs. Such is due to the possible medium-long term maintenance of the status quo, that consists of a different regulatory reality for each MS.

- **Fear of EU wide competition if regulatory barriers are erased**: due to the status quo, many SMEs have prospered from the lack of external competition in the provision of health-related services, benefitting from the market barriers faced by "foreign" providers hence their privileged position in the "home" market. The introduction of an ISO-IDMP standard (or any standardized means of drug classification) would level such disparity, allowing SMEs to provide their services freely across the various MSs, thus eliminating the comparative advantage "home" solutions possess. Such eventuality highly worries those SMEs that are more sensible to competition, whose risk is to be replaced by "external competitors" in the provision of healthcare services.

SMEs WANTS

- **New business opportunities at European level for the medium-long term investments**: the main goal for digital health SMEs is to secure business opportunities in the medium-long term, as they are well aware of the fundamental changes that will transform the industry in the future. Therefore, through planned investments in the present, their main objective is to secure a return in the medium-long term future, both in financial and market positioning terms.

- **A plug & play service (API) to access standardized information about drugs' active ingredients in different languages**: in order to develop innovative and scalable healthcare services, SMEs expect to have access to a plug & play service to power the development of more complex services aimed at patients, citizens, pharmacists, doctors etc. Such P&P service allows those users' categories to be able to type in the name of an active ingredient in their language (or any number of synonyms) and receive a standardized result (in english)

- **A plug & play service to integrate into existing health apps (in any language and country) to alert about potential drug-drug interactions:** to scale at European level healthcare services involving the management of prescriptions, medication lists and personalized care paths etc, patients and caregivers need to have access to services that alarm about negative drug-drug interactions. The aim is to help caregivers to better understand the risks faced by patients and mitigate them accordingly.

2. Why is UNICOM valuable for an SME? Why should they participate in the program?

ECONOMIC INCENTIVES

1. **UNICOM** represents an **opportunity to expand** the SMEs existing market, functioning as **gateway for growth opportunities**
● Expand the range of services and products you can offer at the European level: The implementation of the EU-wide IDMP standard opens the door to many opportunities for new and innovative services for cross-border medicine access, research, safe medicine use, trusted health information sources and mapping between countries. Once the standard is fully implemented, SMEs will be able to develop healthcare services valuable across the EU, that until now are impossible to scale due to the incompatibility of the different data repositories of each member state. Such tools will have the possibility to make an impact at an EU level, so not only regionally in some countries, but in multiple regions and states, for example Spain and Italy, as much as in Germany and Croatia, providing a cross-borders use case yet to be exploited.
● Expand the geographical reach in the wider context of "Europe of integrated health processes": by implementing a singular ISO IDMP standard, SMEs operating in the EU health industry would face less barriers in providing their services across the Union, as the standard will be connected to a singular regulatory process. UNICOM will therefore make smoother and faster the dispensation of medical information across the Continent, in line with the Commission's ambition to foster the exchange of medical information. In this enlarged context, SMEs are able to provide their services efficiently to wider user bases, thus representing great opportunities for business development.
● Exposure and brand recognition with key stakeholders: the SMEs' participation in EU funded Innovation Actions represents a great opportunity to showcase their skills and products, building a name for themselves and to establish important connections with key stakeholders. UNICOM is no different, providing a relevant platform to expose the company to the wider industry and outline their value.
2. The scope of UNICOM allows to **exploit new markets** for data sciences, as a common IDMP standard will allow to perform data analysis techniques on different datasets of **harmonized data**
● Scale existing services at EU level:
● Better mapping of health data to power research and service provision: the standardized storing of medical information will offer SMEs participating in the UNICOM project access to a critical mass of mapped medicine data to work with. The mapped data will serve as a base upon which services can be developed and research can be conducted, providing short-term opportunities for business development.
● Access to valuable data repositories to train data analysis algorithms (AI and ML): the participants in the UNICOM consortium have unique access to the data repositories of the different partners, that can be used for the training of specific UNICOM-related services provided by the SME.
3. Benefits from the **early adoption** of the standard:
● Comparative advantage over competition to provide medicine-related services at EU level: in the prospect of an European-centred classification of medicinals information, the early adoption of those means of classification represents a comparative advantage over the competition. Moreover, by participating in the consortium designing the innovative

standards, SMEs will have an early grasp on the way the new framework operates, thus will be decisively advantaged in implementing the ISO IDMP in their services.
SOCIAL INCENTIVES
• IDMP-implementation will facilitate patient-facing services and thereby their empowerment, and more personalised healthcare
• Possibility to contribute to a change of paradigm benefitting health of citizens: the implementation of a ISO IDMP standard for medical products has the potential to decisively shape the way in which medicine information is provided, in a way to better benefit the user specifically through patient safety and access to medicine. Through a solid dissemination plan, both internal (company) and external (consortium), the SME's participation in the project may outline the company's user-friendliness, positively impacting the consumer's approach towards its products
• Groundstage for the implementation of a patient-centered approach in Health: the UNICOM project is part of a broader strategy of the EU that aims to ensure the provision of service across the borders through the harmonization of the various regulations and standards. By ensuring a patient-focused nature of the framework, SMEs will pioneer an innovative approach that seeks to be disruptive for the industry, thus gaining expertise status on the matter that might lead to commercial opportunities.
• It will help solving the dispensation problem which emerged when piloting cross-border ePrescription services: It finally will allow the univocal identification of medicines specified in a foreign prescription and, if necessary and substitution is allowed locally, the identification of an equivalent medicine readily available in the pharmacy.

Workshop participants statements:

"We need an API which calls to search on drugs, so full list of EU or world online to search, in various languages (patients will search with their own language) local text, and return all the codes and information and other languages, including dosage, recommendations, interactions and contraindications, even if links to other DB, and then possibility when has text in one language, to switch to another language.

Drug data is dynamic and changing all the time.

- What would be the ideal flow of information in this case?
- The most important thing is that the data is **trusted and updated**.
- APIs based on data exchange, must be able to check for changes, so if referencing data, make sure to know what has changed in history. Seems simple but in reality, very difficult to manage.
- Trusted data from NCAs, at the end after all transformation, it is still trusted actual and updated data.

"As a user of the ideal UNICOM system, then I expect we get the latest version of the information, but we must manage the versioning. Make the system lighter. When lab sends data to patient, we download the lowing codes that go with it. Just a few hundred or thousands on the smartphone. Cant go online all the time to look up. Very practical aspect. Already what we try to do is take relevant fields from NCAs to make data lighter, the other step is then on SME to filter relevant products"

The PhPID should support the generic grouping of drugs, choose those products that are relevant to you."

“What would be useful is to deal with **drug-drug interactions** via API””

“Concentrating only on 35 substances PPL, to use to offer a playground / sandbox to play with real data in a restricted amount, try to integrate into other applications. After 3 years, **UNICOM needs to give implementation guides and publish the experience of integrating**, but there will not be a UNICOM API at the end of the project.

“We need to have a non-ambiguous ID of drug so we can relay this to our partners - eP partners that need to handle drug lists non ambiguously in pharmacovigilance and cross border prescriptions ” (Vidal)

“Today, we reinvent the wheel every time we cross a border, every drug list needs to be re standardised from zero according to VIDAL rules / standards”

“The dream is that all member states can plug in their own data, regulatory or economic data, and get a standardised output?”

“How do you intend to integrate metadata from IDMP to existing MPDs? Are you referencing or replacing master data? “

“We are actually working in re-engineering our drug logical model, major concerns for us **is to ensure both models work together**; I would be happy to replace what we have in house, if we **have a robust IDMP info to include**; but maybe because of different factors, this is not easy to say to customers that you will have information in a different way, and replaced by IDMP info.”

“How does IDMP and FIHR work together? What is the current level of maturity?

“Local market will determine whether SMEs can be leaders or laggers, providing services outside your own country, is to enable to provide similar services with minor interventions in a cross-EU platform

“We need to have clear trusted interlocutors: UNICOM first? EMA? National NCAs?”

“I fear that EMA discussions will last long and will end-up in a new ad hoc FHIR solution. Cross border information environment is currently not FHIR based, and we need to make this end meet with the regulatory domain.”

“Each member state is aiming to keep its own staff and own regulation, so quite a while before we can have a true EU market for drug information. The best would be to have 1 single EU network, to connect solutions and provide services on top of it, but we are very far from that…”

“A wide IDMP implementation might be opening up the EU market to non EU players, but up to private players to be at the right level and stay competitive”.

“The ambitions and means of Member States are not clear: In France, health authority raised some alerts in ePre and eDis flows, pushing some rules to be implemented by vendors, but not enough industrial strength to make it implementable”

“In Italy, there is a lack of engagement of public authorities which are mainly concerned at the reimbursement level: There is a lot of resistance to change the data model in Italy and MPDs often rely on solutions paid by region or state.”

“We know there will be different scenarios, now we have some ideas on what needs to be solved, but at national levels the response will be different. Degree of engagement is not the same, even for UNICOM funded partners.”

“We see some member states reluctant to adapt to a more global initiative since they solved the problem locally. So we can’t rely only on national agencies to provide the cross border ecosystem “

Annex 5: UNICOM Value Proposition for EHR vendors

VALUE PROPOSITION FROM A EHR VENDOR PERSPECTIVE

Ben McAlister from Cerner, a US-based EHR vendor with strong EU presence, presented the challenges for the digitalisation of workflows from the admission to the discharge of patients. Through his perspective he's trying to reflect both the EHR vendor as a client/consumer as much as a supplier.

There is value in a unified approach that improves consistency and coherence among MPD, leading to potential gains in terms of research, (cross-border) data exchange, patient empowerment and real-world data. This of course needs to be balanced against the costs involved.

At the same time there are a number of open questions, in particular with regard to the coherence with for example SNOMED CT and UDI, as well as ongoing initiatives in the space of cross-border data sharing.

CHALLENGES AND OPPORTUNITIES AND OTHER INPUTS FROM HER VENDORS

It may be unrealistic to expect existing MPDs to change (completely). It was indicated a development rather than a change would be expected? This could for instance happen in the case of a cross-border exchange where the information being received is either coded in IDMP or gone through a local conversion from a national classification to an IDMP version.
It was also highlighted that within the current value chain EHR vendors' direct interaction with IDMP standards may be limited as the process will mostly managed for them by the MDP vendor community.

There was belief that the UNICOM project could be a catalyst for a more organic harmonisation process through which there could be a wider uptake of structured formats.
In terms of timeline it was informed that the pilot product list was under development, the timeline on a FHIR reference implementation if at all possible was however unclear for now.
The UNICOM project will also include other pilot projects more towards the end of the project, for instance an eHDSI pilot for cross-border exchange, one on pharmacovigilance based on adverse event information registered within EHRs and a pilot on personalised medicine. Overall the UNICOM project will run for 4,5 years (until May 2024).

Based on a gap analysis performed it was concluded that without an IDMP logical model the risk of divergence between systems would be too large.
Initiatives to drive the uptake of IDMP standards were mostly run through local eHealth strategies, which certainly from a transnational level were considered suboptimal. However, the European Commission lacks the competence and instruments to give strong recommendations to the Member States.

It was mentioned that endorsement by authorities through tendering and procurement processes (for instance similar to the listing of IHE profiles) could be beneficial, although it wasn't considered a silver bullet.

CONCLUSIONS on best value proposition for EHR vendors

- A more harmonized approach through the wider uptake of IDMP standards was in general considered beneficial, however probably more in the long term, with some question marks on the direct impact on the EHR vendor community.

- A more consistent approach on identifying medicinal products could lead to better and new insights from research, including an enabling role for big data analytics and AI based on EHR information.

- There would be a need for a clear and transparent change management process to limit any costs of conversion and implementation for the EHR vendor community.

- In particular in case of a reference implementation model it would be necessary to address practical questions around the coherence with existing standards and FHIR resources that could give rise to any unclarity, confusion or ambiguity on the terminology and value sets used.

- It should be further evaluated what would be the key incentives to drive the uptake of ISO IDMP standards, and which stakeholders would be best targeted to make it most effective.

Annex 6: UNICOM Value Proposition for Standard Development Organisations (SDOs)

1. Who are the SDOs?

Standard Development Organisations relevant to the work of UNICOM include the following organisations:

- ISO/TC 215 Health Informatics (International Organisation for Standardization)
- CEN/TC 251 Health Informatics (European Committee for Standardization)
- HL7 Europe (Health Level Seven, part of HL7 International)
- IHE Europe (Integrating the Healthcare Enterprise, part of IHE International)
- SNOMED International (Healthcare Terminology)
- MedDRA (Medical Dictionary for Regulatory Activities)
- GS1 (Global Standards for Identification and data exchange)
- EDQM (European Directorate for the Quality of Medicines & HealthCare, a directorate of the Council of Europe)
- WHO Collaborating Centre for Drug Statistics Methodology – hosted by NIPH (Norwegian Institute for Public Health) in Oslo
- WHO Collaborating Centre for International Drug Monitoring – operated by UMC (Uppsala Monitoring Centre) in Sweden

2. What do SDOs seek?

SDOs are organisations which develop, maintain standards and support implementation. Their process is led by a specific governance, which ensures that the user community is influencing their activities and deliverables. This governance is specific to each SDO, but usually includes characteristics such as consensus, balance of interest, transparency of process, ability to comment and to propose change proposals, etc. The SDOs take backward compatibility very seriously, in order to protect user's investments in the implementation of their standards and to uphold the correct interpretation of (historic) health data.

Many SDOs are organised as non-profit associations of members, where the members are directly involved in the development and maintenance process. The members eventually are the implementers of the standards.

Stakeholders	UNICOM
Needs / Fears / Wants / Motivation	**Benefits / feature / experience**
High-level Need: It is of the highest importance for SDOs to benefit from implementers' experience to capture needs, comments, and gaps. These should flow into the regular standard development / maintenance process. Fears: There is a risk that implementers diverge from standards, which then in turn become a	UNICOM is an outstanding opportunity to engage standard developers and implementers in a mutual exchange of insights and a joint learning process. Both SDOs and implementers shall find and keep communication channels, so their respective goals are taken into consideration and interoperability is enabled.

loose reference and do neither support interoperability nor sustainability. Wants: Especially when more than one standard is used, in the sense that one standard addresses the conceptual and logical model, another addresses the physical model, and a combination of terminologies and value sets is used, the need emerges to adopt a collaborative effort, which is not a standardized procedure for SDOs.	***Ultimate benefits***: Meet regulatory purposes of national medicinal products authorities, Global health, reliable master data, safe medication, cross border prescription/dispensation, effective global pharmacovigilance, public health services, clinical research, big data analysis and AI applications.

Why is UNICOM valuable for SDOs? Why should they participate in the program?

ECONOMIC INCENTIVES
UNICOM provides an opportunity to learn from implementers
● Implementers engaged in UNICOM include ○ Regulators such as NCA with their IDMP implementation projects ○ Medicinal product dictionary providers and their need to comply with IDMP ○ Prescription and dispensation system suppliers used in patient care/healthcare facilities ○ Patient summary suppliers with information generated from electronic health record systems ○ And other innovative application suppliers using structured health data
● Scale existing services at EU level: Use of international standards supports interoperable solutions which benefit the EU citizens in managing their health and the EU member states in achieving health system objectives, including a healthier and active ageing population
● Decreasing the number of Adverse Drug Events (ADE) With the wide implementation of the ISO IDMP standards the medicinal product will be correctly identified within borders and at cross-border level. The number of prescription and dispense errors thus will decline. This will directly reflect on the number of ADE reported, reducing the need for medical treatment in response to erroneous medicine identification. Reported adverse drug events will be more easily analysed at a global level. The conclusions can be swiftly disseminated and actions be taken more effectively across the global clinical community, including patients using the specific medication leading to safer global health.

Annex 7: UNICOM value Proposition for eHealth Competent Centres

1. Who are the eHealth Competent Centres and National Authorities?

National competent centres and authorities include the following groups:

- Ministries of Health
- Regional Health Authorities
- eHealth Agency (responsible for the provision of eHealth services at regional, national and cross-border levels)
- National Contact Point for eHealth (NCPeH) (cfr. Dir 2011/24 art. 6)
- Other National institutions, like e.g. the Agencies for Standardisation in eHealth, universities, hospitals, etc., ….

2. What do eHealth Competent Centres and National Authorities seek?

eHealth Competence Centres and National Authorities are hereinafter referred as stakeholders.

The large majority of the aforementioned Stakeholders have the mandate of working in synergy to ensure the correct identification of medicinal products. Even though they have different functions, it is extremally important their constant commitment to ensure an updated database and correct services operationalisation.

The eHealth Competent Centres are responsible for **operationalisation of the eHealth services** such as the ePrescription/eDispensation and Electronic Health Record, and also for the National Contact point for eHealth, that allows the provision of these services at cross-border level. **The governance model of these centres is different between each country, but always connected to the Ministry of Health**, for national level and cross-border services.

Stakeholders	UNICOM
Needs / Fears / Wants / Motivation	**Benefits / feature / experience**
High-level Need: There is a need at national level to improve/establish a truly operative medicinal products database that can be accessed by the eHealth Competent Centres, to provide eHealth services. There is a need to establish a univocal identification of the national authorised medicines to match similar products among other Member States at cross-border services, reducing the possibility of error. There is a need to define which medicinal product-related information/data should be exchanged and how this data needs to be	ISO IDMP standards provide a common language of identifiers for medicinal products, that will be adopted on an international scale, using international interoperability standards. UNICOM will enable a semantically interoperable meaningful exchange of medicinal product information, which ultimately provides knowledge for the stakeholders to ensure a safe and univocal identification of medicines, which impacts the full cycle of the medicinal product and contributes to citizens' safety.

exchanged for optimised and safe semantic interoperability across languages. There is a need to identify new requirements and processes for the ISO IDMP implementation at the national and cross-border level. **Fears**: Lack of interoperability between the different medicinal products identification systems, leading to impossibility / erroneous identification of medicines that can lead to adverse reactions. Loss of information associated with the identification of medicinal products in different MS on a cross-border scenario. External dependency of identifiers and standards that cannot reflect the national needs. Use of legacy systems that do not allow updates and alignment with new structures and messaging standards. **Wants**: Interoperable systems that allows the medicine identification by different attributes and ensuring, in the majority of cases, the identification of the correct medicine. Harmonisation of data sources (and services) in order to be able to provide, in a seamless and constantly updated way, all the data needed to operate the high value eHealth services. Identify on the distribution channels to clients (healthcare professionals and patients) their needs and identify by the validation process the possible gaps that can be solved through this analysis. **Motivation:** Increase the number of eDispensations of medicines correctly identified.	In addition, UNICOM will strengthen the exchange of information between stakeholders including cross-border collaboration. UNICOM will identify new requirements to the existing processes and provide solutions to facilitate the ISO IDMP implementation. ***Beneficiaries***: Cross-border eHealth Competent Centres and National Competent Authorities.
ePrescription / eDispensation (eP/eD) and Patient Summary (PS) services: The exchange of medicinal product information across countries faces many challenges which can ultimately endanger citizen well-being. eP/eD and PS include	The implementation of ISO IDMP is essential for the identification of medicinal products throughout the countries for a continued successful and safe deployment of CEF eHDSI services.

medicinal product information which may need to be translated to another language in order to facilitate the interpretation of the eP/eD & PS information and assure a safe dispensation / care / treatment. Thus, these services benefit from a fully and unequivocal identification of the medicinal products among the different countries.	UNICOM will facilitate the identification of a medicinal product in a standardised manner (identifiers, attributes and common language), and contribute to finding matches between medicinal products in eP/eD and PS from different countries, or facilitate the discovery of a possible alternative for that medicinal product. UNICOM will also provide new business models that positively affect the CEF eHDSI dataset and models, providing solutions to systems that need constant update to face the challenges in the cross-border context. The adoption of the ISO IDMP on the eHealth systems and National Competent Authorities can support the correct identification of the medicinal products through their attributes and ensure correct dispensation of the medicines. ***Beneficiaries***: eHealth Competent Centres
Pharmacovigilance: Adverse Drug Event (ADE) reporting in the country of origin and across borders is an important process to monitor the safety of medicinal products throughout their use in healthcare practice. Pharmacovigilance is operated by the marketing authorisation holder, national competent authorities and EMA. The EU pharmacovigilance system operates through cooperation between EU MS, EMA and European Commission. There is a need for the ADE reports to be based on a harmonised set of product definitions, to improve the quality of data used for the management of ADE. The eHealth Competent Centres have been supporting the NCAs in this task of harmonising data sets. In some Member States IT mechanisms are in place to report ADE and allergies to medicines in eP/eD and PS.	The implementation of the ISO IDMP standards is important to support and enrich the exchange of medicinal products information between stakeholders and enhance the interoperability of systems in EU and international ecosystems. UNICOM will provide the knowledge to facilitate the identification of the medicinal product in a standardised manner, which will improve the tracing, analysis and management of ADE by creating an unequivocal identification of the medicinal product. In addition, the implementation of ISO IDMP attributes could further facilitate electronic reporting of ADE. ***Beneficiaries:*** National Competent Authorities, EMA; eHealth Competent Centres
Regulatory processes: There is a need to create a consistent standard to capture and manage data, which in turn allows information on medicinal products to be shared across different procedures and among regulators.	By providing a model of ISO IDMP implementation and respective requirements, UNICOM will facilitate the adoption of ISO IDMP, and the identification of medicinal products, while considering the required flexibility to support the variances at the national regulatory processes level. This

There is a need to orchestrate/organise the implementation of the legal and regulatory basis and process (including reimbursement conditions) to operative IT protocols, in order to ensure that the IT systems reflect the legal conditions on the Member States.	will be achieved by close collaboration with the national competent authorities. ***Beneficiaries:*** National Competent Authorities and EMA
Exchange of expertise: UNICOM project has plans that align with the agendas of the main regulatory agencies and Standard Developing Organisations (SDO), such as EMA, USA FDA, WHO, ISO, CEN, GS1, HL7, IHE, among others. So, knowledge exchange can improve the path for standardisation of the identification of medicinal products.	Within the UNICOM consortium there are several members from regulatory agencies and SDOs, working directly or collaborating as observers. This collaboration promotes exchange of expertise between organisations and UNICOM. The results of these activities have improved the sharing of knowledge and ensures the continuity and applicability of the several on-going initiatives. ***Beneficiaries:*** the eHealth Competent Centres and National Authorities

3. **Why is UNICOM valuable for an eHealth Competence Centres and National Authorities? Why should they participate in the program?**

ECONOMIC INCENTIVES
4. UNICOM represents an opportunity to expand existing systems, functioning as gateway for growth opportunities
• Expand the geographical reach in the wider context of "Europe of integrated health processes": by implementing a singular ISO IDMP data model, eHealth Competent Centres and National Competent Authorities would face less barriers in the exchange medicinal products information across the Union, as the standard will be connected to a singular regulatory process. UNICOM will therefore make the dispensation of medical information across the countries smoother and faster, in line with the European Commission's ambition to foster the exchange of medical information.
• Scale existing services at EU level: UNICOM can contribute to reinforcing activities for the promotion of awareness and information about the benefits of ePrescription services and PS data exchange at cross-border level. Furthermore, it can help foster the interoperability of technical systems among producers and supplier of ICT, institutions, insurers and other relevant stakeholders. The IDMP has already been considered on the eP Guidelines update and is expected to be included on PS guidelines also.

- Advance existing infrastructures:

  By creating the knowledge and optimisation of ISO IDMP implementation, UNICOM will indirectly contribute to advance infrastructures linking systems and services, such as interconnection services, data integration services, and data presentation. It is also expected that UNICOM will identify a need to develop another guideline that fits in this overall European framework, supporting the eHN and CEF eHDSI communities.

- Increase economic efficiency of existing workflows

  By creating a consistent standard to capture and manage medicinal product-related data, it can improve the workflow by which the data is managed at the national-level and improve the exchange of information among MS, which in consequence increases the efficiency of the existing systems, and indirectly positively affects economic efficiency of this sector. At national level, the adoption of the ISO IDMP could also support the improvement or adaptation of the national medicine databases through the alignment with IDMP data model, building a generic and scalable way to identify the authorised national medicines. It can facilitate the identification of similar medicines and accelerate the identification of new medicines on the national databases.

- Decreasing the number of Adverse Drug Effects

  With the wide implementation of the ISO IDMP the medicinal product will be identified more safely at a cross-border level and the numbers of dispense errors should decrease. It will directly reflect on the number of ADE reported, decreasing the number of medical treatments for erroneous medicine identification.

5. Benefits from the early adoption of the standard:

- Comparative advantage to provide medicine-related services at EU level:

  In the likelihood of a European-centred classification of medicinal information, the early adoption of these methods of medicinal products identification positively strengthens the collaboration between MS, as well as aligns with the EU agenda. Moreover, the collaborative environment within the UNICOM consortium provides eHealth Competent Centres and National Competent Authorities an opportunity to share their needs, which in turn facilitates the way the new framework will operate. Thus, an early adoption of standard will be a clear advantage to promote the seamless implementation of the standard, and improve the flow of the medicine lifecycle at the national level and across borders.

SOCIAL INCENTIVES

- IDMP implementation will facilitate patient-facing services and thereby their empowerment, and more personalised healthcare. It will also strengthen the possibility to use the cross-order eHealth services (eP/eD & PS).

- Possibility to contribute to a change of paradigm benefitting health of citizens: the implementation of an ISO IDMP standard for medical products has the potential to decisively improve the way in which medicinal product information is provided, in a way to better benefit the user, specifically through patient safety and access to medicine. Through a solid dissemination plan, both internal and external, eHealth Competent Centres and National Authorities' participation in the project may outline the user-friendliness, thus

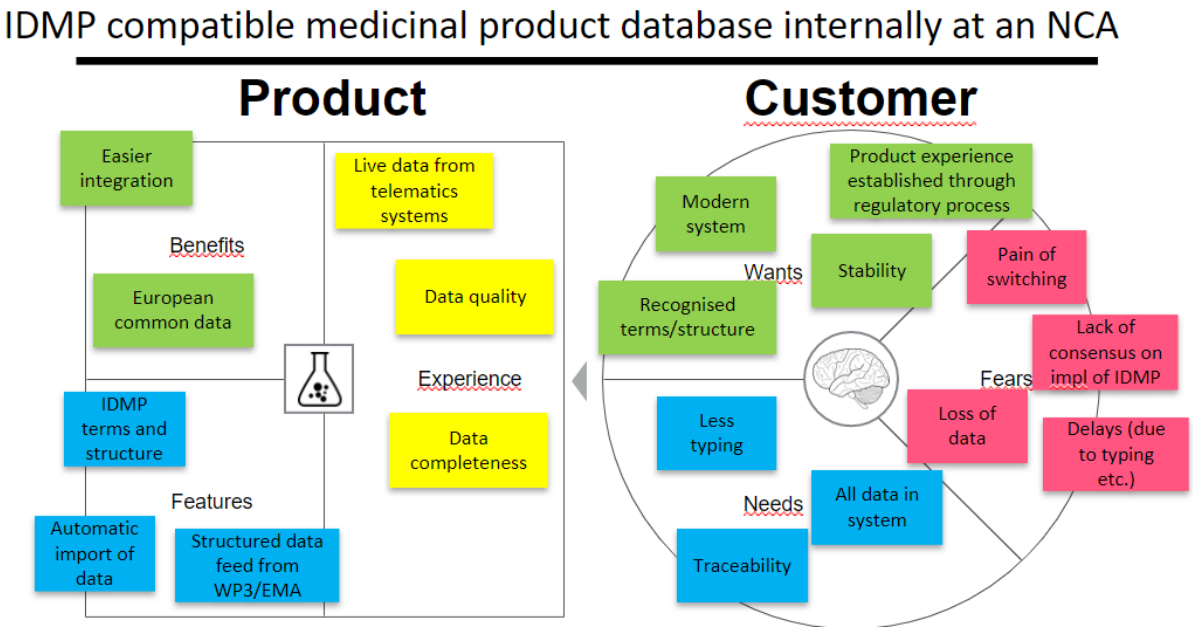
positively impacting the approach towards the exchange of medicinal products information across border.
• Ground stage for the implementation of a patient-centred approach in Health: the UNICOM project is part of a broader strategy of the EU that aims to ensure the provision of service across the borders through the harmonisation of the various regulations and standards.
• It will help solving the dispensation problem which emerged when piloting cross-border ePrescription services: It will allow the univocal identification of medicines specified in a foreign prescription, by the use of this data model, and, if necessary, the substitution when allowed locally, the identification of an equivalent medicine readily available in the pharmacy.

Annex 7: UNICOM internal value Proposition for National Medicinal products Competent Authorities

An NCA need a product database to assess and approve medicinal products

- IT department delivers the product
- ”Business” is the customer (uses the database)
- Administrators inputs data in the system
- Assessors verifies data and evaluates it from a scientific perspective
- Database is used as a baseline for future variations, assessment on generic substitions, etc.

The first VPC explore internal needs, wants and fears concerning the implementing of IDMP in the internal database

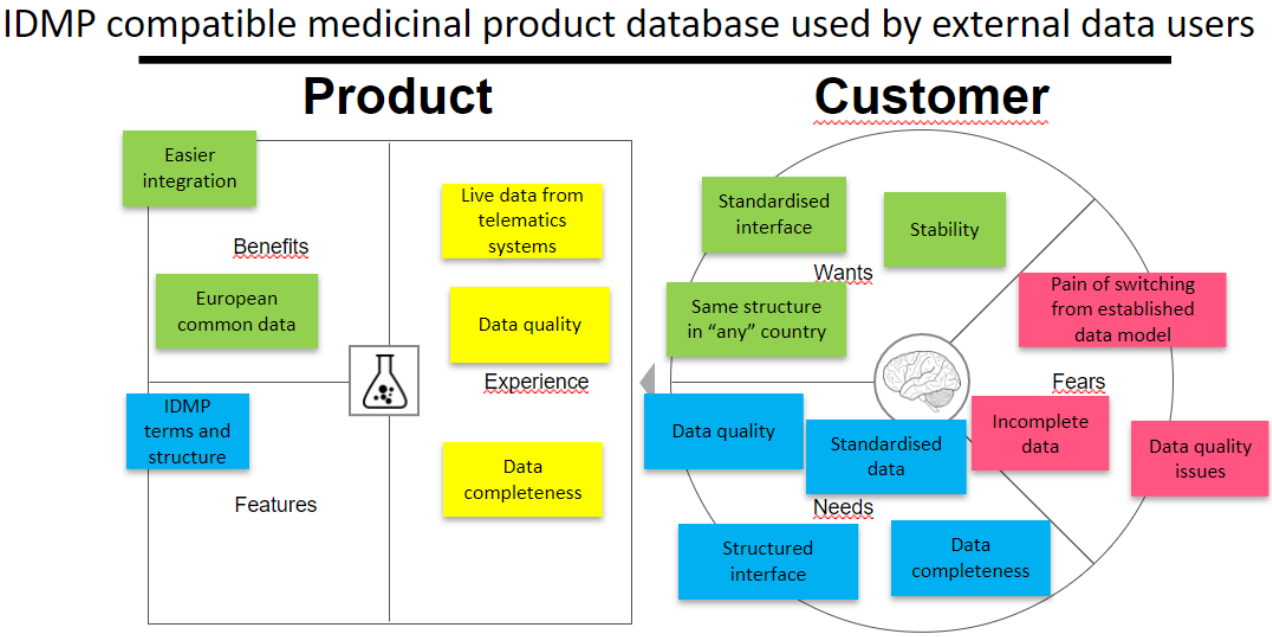


An NCA may have a product database as an enabler to publish data to external users

The NCA delivers the product as interfaces to external users

External users may use data in systems for prescriptions, patient healthcare records, logistics, etc.

The second VPC explore internal needs, wants and fears concerning the use of IDMP compatible database by external users:


IDMP compatible medicinal product database used by external data users
Product
Customer
Easier integration
Benefits
European common data
IDMP terms and structure
Features
Live data from telematics systems
Data quality
Experience
Data completeness
Standardised interface
Stability
Wants
Same structure in "any" country
Pain of switching from established data model
Fears
Data quality
Standardised data
Incomplete data
Data quality issues
Needs
Structured interface
Data completeness