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Deliverable abstract

This document outlines the dissemination approach geared towards adequately reflecting the large scale and broad aims of the UNICOM innovation action. It welcomes the UNICOM consortium multi-stakeholder constituency and designs active roles for all partners as impact multipliers – leveraging their existing ecosystems. D12.2 develops a communication strategy and outlines the first steps of the action plan which will be further developed over the coming months.

The dissemination approach and strategy focus on initial building blocks of communication goals and objectives, target audiences and mapping of stakeholders, priorities for dissemination, and – as a structural element – the UNICOM communication team.

The preliminary communication and dissemination action plan reviews these topics:

- ✓ Dissemination channels and their relevance for reaching different audiences
- ✓ Initial dissemination actions
- ✓ Narratives - UNICOM story line and value propositions
- ✓ Branding, website and social media
- ✓ Printed matter (screen-readable documents / printing on demand)
- ✓ Document pool, multilingualism, tool kits for dissemination and press
- ✓ Results reporting and publications
- ✓ Dissemination events and stakeholder outreach

A final issue concerns quality assurance and monitoring including Key Performance Indicators (KPIs).

Keywords: dissemination approach, strategy, target audiences, stakeholder involvement, dissemination channels, communication modalities, quality assurance

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UNICOM initial glossary

In the regulatory, pharmacovigilance, clinical, and cross-border domains a host of abbreviations and acronyms are used. To improve understanding and gaining easier access to such terms and their definitions, UNICOM is developing a comprehensive glossary which will also be useful for dissemination and communication activities. After further expansion, it will become available internally as well as via the website.

Abbreviation	Complete form
AI	Active Ingredient: biologically active ingredient in a pharmaceutical drug
ANSI	American National Standards Institute
API	Application Programming Interface
ATC	Anatomical Therapeutic Chemical classification system (WHO)
CEN/TC 251	Health Informatics: Technical Committee of the European Committee for Standardization (CEN) (see also ISO TC 215).
CDSS	Clinical Decision Support System
CEF	Connecting Europe Facility (EU funding scheme)
CESP	Common European Submission Portal
DIA	Drug Information Association
DDD	Defined Daily Dose (WHO)
EFPIA	European Federation of Pharmaceutical Industries and Associations
eHDSI	eHealth Digital Services Infrastructure
eHMSEG	eHealth Member States Expert Group installed by the eHealth Network (eHN)
EMA	European Medicines Agency
eHN	Art. 14 eHealth Network established under Directive 2011/24/EU on the application of patients' rights in cross-border healthcare
FDA	Food and Drug Administration , the United States' regulator for the safety, efficacy and security of human and veterinary drugs, and medical devices
HL7	Health Level Seven (International) provides a set of standards for electronic transfer of clinical and administrative data. It is an SDO accredited both by ANSI and ISO
HMA	Heads of Medicines Agencies - a network of the heads of the 'National Competent Authorities' (for Medicinal Products). These are responsible for the regulation of human and veterinary medicines in the individual countries of the European Economic Area (EEA)
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDMP	IDentification of Medicinal Products refers to five standards: ISO 11615, ISO 11616, ISO 11238, ISO 11239, ISO 11240
INN	International Nonproprietary Names (WHO)
ISO	International Organization for Standardization
ISO/TC 215	ISO Technical Committee for Health Informatics

ISO/TC 215/ WG 06	Working Group on "Pharmacy and medicines business"
LOINC	Logical Observation Identifiers, Names and Codes - a universal code system for clinical and laboratory tests, measurements, and observations maintained by the Regenstrief Institute
MAA	Marketing Authorisation Application - a procedure to gain the authority to market a specific medicinal product in a country or EU-wide
MAH	Marketing Authorisation Holder
MDP	Medicinal Products Dictionary
MedDRA	Medical Dictionary for Regulatory Activities - a coding system designed for use in the registration, documentation and safety monitoring of medicinal products owned by ICH
MP	Medicinal Product
MPID	Medicinal Product ID
NCA	National Competent Authorities for Medicinal Products. The term "National Drug Authorities" is used as synonym
PhP	Pharmaceutical Product
PhPID	Pharmaceutical Product ID
SDO	Standards Developing Organization
SPOR	Substances, Products, Organisations and Referentials (EU-wide master data – maintained by EMA)
UMC	Uppsala Monitoring Centre - an independent, non-profit foundation and centre for international pharmacovigilance services and scientific research dedicated to promoting safer use of medicines for patients
WCAG	Web Content Accessibility Guidelines
WHO	World Health Organization - manages e.g. INN; ATC/DDD Controlled Term Lists.

1 Executive summary

UNICOM is a global interoperability endeavour that aims to be a **game changer for coding issues around medication**. As an innovation action, UNICOM builds on previous, successful projects such as OpenMedicine. It also relies on results delivered by world-wide and European standardisation initiatives and has integrated Standards Developing Organisations (SDOs). The emerging cross-border ePrescription services between EU member states will become a large showcase changing cross-border prescriptions for all European people.

In the **first two years** of the project, most efforts will be directed towards **increasing awareness about IDMP expected benefits** across all stakeholders, regions and countries:

- ▶ **Awareness raising across ecosystems**; wide dissemination through digital and social media will be used to increase the number of supportive stakeholders at all levels.
- ▶ **Bilateral knowledge exchange and transfer**: Good practice use cases and advanced national initiatives based on an ISO IDMP approach will serve as starting points for dialogue. Moreover, engaging a more vertical approach through European stakeholder's organisations will spread and reinforce key messages.
- ▶ Addressing **regulatory and policy decision makers**: UNICOM will liaise with European and global decision makers. For Europe, continuous liaison will be established with EMA, the eHealth Network and eHDSI actors. Globally, WHO, FDA and the Standards Developing Organisations are partners. Upcoming EU Presidencies may become important allies, given European initiatives like the European Health Data Space.
- ▶ **Knowledge sharing and "decentral" dissemination**: Given the spread of ecosystems in the consortium, well-structured "decentral" communication, orchestrating consortium partners and their stakeholder networks will play a key role.

The **last two years** of the project will be focused on **dissemination of concrete results** obtained by the project making an active use of the demonstrators produced and adapting the content in order to make those results easily accessible and actionable by stakeholders.

This dissemination strategy provides a plan of the steps to be taken in order to achieve these goals. Resulting actions are defined with respect to dissemination targets and channels. The dissemination strategy will be evaluated and updated on an annual basis.

- ▶ Chapter 1 Introduction informs on the scope of the document and its intended audience.
- ▶ Chapter 2 "Dissemination and Communication Strategy" starts from goals and objectives. It analyses the target audiences in the format of an elaborated stakeholder mapping. As detailed, many relevant networks and projects are within or close to UNICOM. The UNICOM communication team will pursue the defined priorities for dissemination.
- ▶ Chapter 3 presents a preliminary Communication and Dissemination Action Plan.
- ▶ Chapter 4 presents the Quality Assurance, Evaluation and Key Performance Indicators.

2 Introduction

2.1 Scope of UNICOM

To better understand the overall context within which the UNICOM dissemination approach has to be set, the challenges UNICOM responds to are briefly summarised.

Medication errors impact significantly on patient safety, quality of life as well as public finances. On the regulatory side, during the life cycle of a medicinal product its data must often be re-entered in different media by organisations using different coding systems. This hinders not only data consistency, accuracy, and the seamless flow of such data across actors and across borders, but also blocks data availability. Pharmacovigilance processes e.g. sometimes suffer from long delays from reporting to aggregation, analysis, action.

These challenges will be reflected in a set of key messages to be further developed towards feeding into the diverse dissemination tools, modalities and channels, adapted to the context and environment of the respective actor and stakeholder groups addressed.

In UNICOM, many key actors like national drug agencies jointly drive the large-scale roll-out of the ISO IDMP family of world-wide agreed standards for univocal, semantically coded drug identification. Thus, they will enable a seamless digitisation that overcomes media disruption of any kind. Without this important step, medication data will be unable to safely travel between systems, regions, countries or use-cases.

UNICOM will contribute to significantly changing the way medicinal products, their characteristics and attributes, are globally specified, i.e. it will become a kind of **game changer for their univocal identification**. It does so by supporting the implementation of ISO IDMP in key domains like medicinal product registration and market authorisation, medicinal product dictionaries, clinical decision support systems, ePrescription including cross-border services, pharmacovigilance. UNICOM will demonstrate the benefits of clear and unambiguous identification along the whole life cycle of drugs in all these domains. As an innovation action focusing on implementation, UNICOM builds on previous, successful projects such as OpenMedicine. It relies on results delivered by world-wide and European standardisation initiatives and it has integrated into its consortium all key Standards Developing Organisations.

Remaining gaps in the IDMP suite of standards and coding systems will be identified and tackled while demonstrators and pilots exemplify the added value of IDMP for different use cases. The emerging cross-border eMedication services (ePrescription transmission, eDispensation reports) between EU member states built on the eHealth Digital Service Infrastructure (eHDSI) and will become a particular large showcase for the application of IDMP, thereby substantially improving cross-border prescription services for all European people.

The last two years of the project will be focused on dissemination of concrete results obtained by the project, making an active use of the demonstrators and pilots produced, and adapting the content in order to make those results easily accessible and actionable by stakeholders.

This dissemination strategy provides a plan of the steps to be taken in order to achieve these goals. Resulting actions are defined with respect to dissemination targets and channels. The dissemination strategy will be updated on an annual basis.

2.2 Intended audience

This planning document is intended for usage and implementation by UNICOM, as well as for individual UNICOM project partners, project observers and the affiliated stakeholder organisations.

It is intended as a blueprint to guide the organisation of dissemination activities which lie in the hands of the Project Communication Officer (PCO) who is supported by Communication Managers to be appointed by each of the work packages delivering results (WP1 to WP10). The role of the PCO will be filled by EHTEL.

2.3 Structure of the document

- ▶ Chapter 1 Introduction informs on the scope of the document and its intended audience.
- ▶ Chapter 2 “Dissemination and Communication Strategy” starts from goals and objectives with a focus on benefits expected from UNICOM and corresponding action lines. It then analyses the target audiences in the format of an elaborated stakeholder mapping. It details relevant networks and projects while a high level of synergy has already been established by inviting successfully key actors as partners or observers to the UNICOM consortium. Based on this, priorities for dissemination are defined.
The UNICOM communication team (UCT) is a key organisational element to implement the communication strategy. Managed and led by the Project Communication Officer, the UCT regularly convenes the work package leaders respectively their dissemination and communication officers. Moreover, contact persons of all partners will act in the role of a liaison.
- ▶ Chapter 3 presents a preliminary Communication and Dissemination Action Plan. The emphasis is on elements that respond to specific UNICOM communication and dissemination needs like the development of narratives for the mission critical improvements of the medicinal products data value chain implied by IDMP implementation. Chapter 3 is completed by an outline of operational elements like branding and media as well as an assessment of how to best orchestrate UNICOM’s role in relevant events.
- ▶ Chapter 4 provides Quality Assurance, Evaluation and Key Performance Indicators.

3 Dissemination and communication strategy

3.1 Dissemination approach and strategy building blocks

The dissemination and communication strategy supports the complex challenges inherent in delivering initially the project mission and later its results to a highly diverse community of actors, stakeholders and policy makers. This huge task can only be successfully tackled through joining forces with all partners of the consortium and actors from a wide range of organisations and stakeholders. The overall approach, high level objectives and diverse media and channels to be employed are sketched in *Figure 1*:

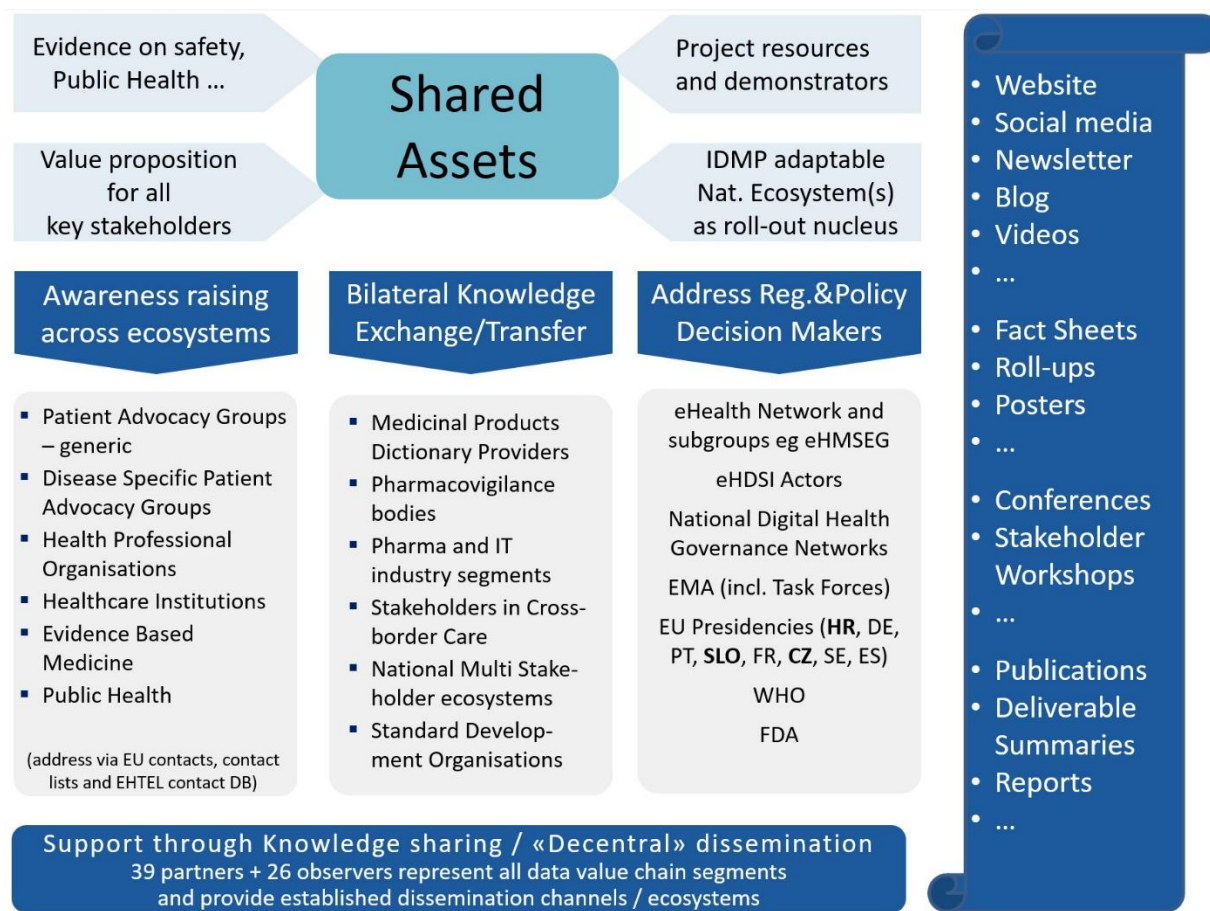


Figure 1: UNICOM dissemination approach and core strategy elements: knowledge sharing, awareness, stakeholders, decision makers

Given the **wide interest** for the UNICOM initiative, **diversity and quantity of its stakeholders** and the maturity of ISO IDMP, the dissemination strategy aims to support the kick-start of IDMP adoption and implementation in established stakeholder ecosystems, as well as the communication of knowledge on benefits to the wider health system community:

- The identification of major stakeholders along the data value chain coupled to the elaboration of a value proposition for each of them will allow selecting the appropriate channels and adapting the dissemination content.
- Concrete narratives related to the use cases in various languages will be developed in order to better exemplify the situation “as is” versus “to be”.

Key objectives are to

- ▶ Empower end users and external stakeholders with information and knowledge **identifying expected benefits from IDMP** and to make other stakeholders and **decision makers aware of tangible benefits in turn**
- ▶ To empower and coordinate project partners for active involvement in stakeholder networking, e.g. to orchestrate and operate liaison activities to
 - ▶ Involve end users like health professionals (pharmacists, physicians etc.), patients/citizens (stakeholder liaison)
 - ▶ Leverage synergies with existing stakeholder networks and other initiatives.

In the **first two years** of the project, most efforts will be directed towards **increasing awareness about IDMP expected benefits** among stakeholders, regions and countries:

- ▶ **Awareness raising across ecosystems**; wide dissemination through digital and social media will be used to increase the number of supportive stakeholders at all levels.
- ▶ **Bilateral knowledge exchange and transfer**: Good practice use cases and advanced national initiatives based on an ISO IDMP approach will serve as starting points for dialogue. Moreover, engaging a more vertical approach through European stakeholder's organisations will spread and reinforce key messages.
- ▶ Addressing **regulatory and policy decision makers**: UNICOM will liaise with European and global decision makers. For Europe, regular liaison will be established with EMA, the eHealth Network of Member State representatives, and eHealth Digital Service Infrastructure (eHDSI) actors delivering cross-border health services. Globally, WHO and its Uppsala Monitoring Centre (UMC) for Pharmacovigilance, FDA and all relevant Standards Developing Organisations are partners. Upcoming EU Presidencies may become important allies, given European initiatives like the European Health Data Space.
- ▶ **Knowledge sharing and "decentral" dissemination**: Given the spread of ecosystems participating in the consortium, well-structured "decentral" communication, orchestrating consortium partners and their stakeholder networks will play a key role.

The UNICOM Consortium is a **multi-stakeholder community** in itself and as such offers already "internally" a multitude of channels and external networking opportunities. The communication strategy foresees to make best use of knowledge sharing within the consortium and on leveraging synergies with ecosystems of project partners. Individual partners and their dissemination and communication officers will be empowered by the UNICOM communication team (UCT) under the leadership of the Project Communication Officer. This is a key organisational element to implement the communication strategy, particularly with respect to "decentral" wide communication and dissemination.

Wide dissemination, i.e. in particular awareness raising, will happen via a variety of channels such as events, print, website to multimedia and social media. Operational objectives are to

- ▶ Reach project audience(s) at European, national and regional levels
- ▶ Based on this **communication** strategy, enable and orchestrate **dissemination** activities through project partners
- ▶ Promote the project outcomes like implementation by NCAs, software companies, Smart APPs and demonstrators to **accelerate** the use of the IDMP-related coding systems and tools

- ▶ Stimulate publications on project interim results and outcomes by the respective WPs (with support of partners some elements will be produced as multi-lingual communication)

Targeted dissemination, i.e. stakeholder engagement, will be implemented through addressing broadly stakeholder networks. This will be realised through the concertation of stakeholder liaison activities through project partners in the consortium, e.g. those active in national medicinal products regulation and market authorisation (National Drug Authorities), as well as through their European and, where feasible, global associations. The same holds for healthcare service providers, including pharmacists and cross-border services, and those servicing them with software products, medicinal product dictionaries etc.

The national/regional stakeholder engagement will be targeted through a preliminary evaluation of the existence/absence and dynamism of local ecosystems in order to be able to focus on the countries which require special attention and support.

3.2 Communication goals and objectives

IDMP is a **global interoperability endeavour** aiming to be a **game changer for standardisation and coding issues around medicinal products**. Thus, from the viewpoint of benefits, UNICOM aims likewise to act as a game changer for medicinal products regulatory issues, pharmacovigilance and patient safety as well as seamless data exchange in healthcare, public health, and clinical research:

- ▶ After more than 10 years of development, time is now ripe for **large-scale implementation** of the ISO IDMP family of internationally agreed standards for the identification of medicinal products.
- ▶ As a concerted effort **convening around 40 partners from 19 countries**, UNICOM is committed to give a **powerful impulse** for establishing ISO IDMP usage along the whole life cycle of medicinal product data across Europe and even worldwide.
- ▶ UNICOM will become a key enabler for borderless digitisation of health and care services.

UNICOM efforts dedicated to communication and dissemination have four dissemination **objectives** (DOs). While all are equally important, their priority will evolve over the lifecycle of the project with main emphasis on awareness (DO1) in year 1:

- ▶ **DO1. Raise awareness:** Ensure that all UNICOM key initiatives are disseminated (spread and understood) to national and international stakeholders through tailored methods, modalities and channels to increase awareness and feedback.
- ▶ **DO2. Engagement of key stakeholders:** Sustain the engagement of stakeholders who are already involved in implementing or supporting the integration of cross-border ePrescription services, at the same time as reaching out to all those who will have a role to play (e.g. clinical actors, medicinal products database producers and others who need to support the implementation of the IDMP standard, semantic interoperability stakeholders, among others), but might not yet be doing so due to a lack of awareness, resources or incentives.
- ▶ **DO3. Influence decision-makers:** Ensure that the activities of policy-minded organisations are professionally informed and aligned to reinforce the scaling up of the univocal identification of medicinal products through IDMO implementation.
- ▶ **DO4. Boost sustainability:** Ensure sustainability of the results achieved and the outcomes implemented during and after the end of the project. Building on the

consortium's strengths, the partners will work at the beginning of the project to cooperatively design an effective dissemination strategy that uses a combination of online and off-line tools. The partners will use all these tools and communicate both at the national level and, where feasible, at the international level with a wide range of political and implementation actors to maximise visibility in multiple stakeholder groups. All of this will improve political awareness of the relevance of and benefits from IDMP, which in turn will facilitate initial implementation as well as securing support (and budgets) for long-term sustainability.

This dissemination strategy provides a plan of the steps to be taken in order to achieve these goals. Resulting actions are defined with respect to dissemination targets and channels.

3.2.1 Challenges and benefits to be communicated

The *lack of univocal identification* of drugs is a challenge to patient safety and a major roadblock to the digitisation of the health domain and the seamless flow of data on medicines prescribed and dispensed. To inform and buttress the dissemination activities, challenges and benefits must be understood by all partners involved and communicated in their respective context to core audiences.

Challenges

The missing semantic interoperability of medicinal product data prevents people moving across Europe from hassle free access to the necessary medication in another Member State. Moreover, it hinders the whole process chain of development, market authorisation, usage, adverse effects reporting etc. This is due to various obstacles like

- ▶ The same name may identify a medicinal product with a different active ingredient in another country, or a product with identical composition may carry a different name elsewhere. Unless such challenges can be resolved on the spot, it **renders dispensation impossible**, even where substitution by a pharmacist is legally allowed (or may result in a grave health hazard).
- ▶ Similarly, *pharmacovigilance* reporting will be considerably improved once medicinal products, including their active substance, can be uniquely identified by drug agencies around the globe, and thereby reports on the same issue be easily and without delay related to each other, thus **safeguarding universal patient safety**.
- ▶ The same will hold for *clinical information* on drugs patients have taken recorded in medication histories (stored within Electronic Health Records) or being used within eOrdering/ePrescribing as well as in Clinical Decision Support Systems.

Benefits

On the benefits side, IDMP will enable seamless processes around medicinal products authorisation and every form of drug referencing. This will enable worldwide pharmacovigilance, safe cross-border ePrescription and eDispensation, meaningful use of medication data for improved clinical decision support. On the end user side, patients will be empowered by getting access to more precise and meaningful drug information. Healthcare and Health Professionals will encounter moreover benefits in public health and clinical research.

New opportunities will also arise for pharma industry, software developers, SMEs providing smart apps and others, thereby fostering their innovation capacity and competitiveness.

Based on such considerations, UNICOM dissemination and communication activities will target these overall *operationalised benefits*³:

- ▶ Improved cross-border patient services: substantially enhanced probability of successful identification of a medicinal product specified in a foreign ePrescription, and of its dispensation
- ▶ Enhanced patient empowerment: better, safer personalised information on medicines, also when abroad. The coding of data and information will allow for easier, safer translation.
- ▶ Better healthcare: reliable semantic harmonisation of records of medicinal products dispensed to a patient (e.g. integration of patient data across several electronic patient records, and over the treatment and medication history of, e.g. a chronically ill patient)
- ▶ Faster and more effective pharmacovigilance: more efficient processes, more reliable and faster identification and results integration of medicines mentioned in adverse event reports globally
- ▶ Availability of interoperable, high-quality data on medicines: for Big Data analyses; Public Health policy making and data exchange across Europe, trans-Atlantic and globally; clinical & pharmaco-economic research
- ▶ More efficient regulatory processes: reliable input & consistent exchange of electronic data over the life cycle of a medicine between industry, NCAs, EMA, medicinal product dictionary providers, national ePrescription services and eHealth Agencies, including pharmacovigilance agencies.

3.2.2 Packaging project objectives through Action Lines

The main communication messages will follow the core project objectives. Given their complexity, some “packaging” is needed to reach out to audiences beyond IDMP experts.

Awareness raising among wider audiences will also benefit from grouping objectives along the three content-oriented Action Lines (ALs) of UNICOM. Dissemination activities will be carried out at AL-level by the partners involved, using messages specifically tailored to their respective extended networks and subcommunities.

UNICOM Action Lines

- ▶ AL 1: Reliable IDMP-coded Medicinal Product (MP) data for regulatory purposes and health system actors
- ▶ AL 2: Safe implementation in ePrescription and eDispensation services and seamless flow of MP data across borders of Member States/Europe
- ▶ AL 3: Realising the benefits from IDMP implementation in pharmacovigilance, clinical and Public health Contexts

3.3 Target audiences and mapping of stakeholders

The work and results of UNICOM would go unnoticed by some actors with stakes in the implementation of ISO IDMP. Although expected benefits are considerable, increasing the

³ An analysis of the expected main benefits per stakeholder is provided under 2.3.2

awareness among audiences on whose agenda the matter does not yet figure is particularly challenging.

A good understanding of the issues at stake by **all stakeholders in the IDMP data value chain** is necessary. This overall task can only be successfully tackled through actively seeking support from all actors, organisations and stakeholders involved in the data value chain, from data input to data repositories to data usage.

Stakeholders range from pharmaceutical companies submitting Marketing Authorisation Applications (MAA) to national regulatory authorities, to national eHealth agencies, Medicinal Products Dictionary (MPD) providers, clinical software producers (EHR systems, decision support systems, ePrescribing systems), providers of pharmacy systems, implementers of cross-border messaging services, or also start-ups developing intelligent apps for patient empowerment. UNICOM will engage these actors and support them in identifying a window of opportunity to create a general, flexible eco-system which will provide coherence, consistency and reliability while avoiding duplication of data, resources and investment. This will support national competent authorities (and indirectly through their involvement as 'observers' European and international actors like EMA) to focus on the data and metadata under their responsibility while making full use of commonly developed resources.

3.3.1 Preliminary mapping of stakeholders

As exemplified by the number and diversity of partners involved in UNICOM, the number of stakeholders potentially impacted by UNICOM is huge. One needs however to differentiate between the **stakeholders directly impacted** by IDMP standards implementation and those who have a **decision-making or influential role**. Among the directly impacted stakeholders, one can naturally expect that IDMP awareness and interest are already present BUT it will be essential to provide the project partners with information, content and channels which will allow them to influence their own ecosystem. Internal dissemination needs thus here to be considered as a dissemination objective per se.

As for external communication, it is proposed to focus in priority on the national stakeholders which are essential for the **creation/development of an ISO IDMP compatible ecosystem capable to support all use cases** in their respective national health systems: National authorities and administrations, EHR Software industry and Drug Dictionaries producers. Countries with a low participation in UNICOM will be partially prioritized.

The degree of awareness within the pharmaceutical world is already high with implementation due to take place as soon as the necessary info- and infrastructure will have been put in place, although the weight of legacy systems is to be high.

End users such as patients and health care professionals might play a role as individual national influencers but are not seen as key initial drivers, especially when stand-alone, efficient national solutions are already in use. Scientific medical national organisations and patient umbrella organisations must however remain targets of the dissemination strategy, especially when they are already associated to the eHealth global ecosystem.

Table 1 provides an exemplary assessment of awareness and interest for UNICOM results by primarily concerned stakeholders.

Table 1: Exemplary assessment of UNICOM related awareness, interest and impact for concerned stakeholders

Stakeholder	Awareness	Interest	Impact
National Competent Authorities for MPs	High	High	High
Health Authorities / Statutory Insurances	Variable	Potential	Medium
National eHealth Competence Centres	Variable	Potential	High
EMA and EMA European Task Forces	High	High	High
eHDSI	High	High	High
Standards Developing Organisations	High	High	High
Medicinal Product Dictionary providers and information brokers	Medium	High	High
Pharmaceutical companies: Market authorization holders	High	High	High
IT/eHealth solutions vendors and representative organizations	Low	Medium/High	High
Clinical Decision Support System vendors	High	High	High
Scientific medical organisations and other interest groups and organizations	Low/medium	Medium/High	Low/medium
Healthcare professionals, prescribers and dispensers and representative organisations	Very low	Potential	High
National patient umbrella organisations	Low	Medium	Medium
Global and transatlantic stakeholders	High	High	High

National Competent Authorities and (e)Health Authorities

Although national regulatory authorities are most directly impacted by IDMP implementation, involvement of other public institutions such as Public Health Institutes, Health Ministries, healthcare insurance agencies, National Health Services, pharmacovigilance bodies and eHealth competence centres is also necessary in order to increase awareness and communicate benefits to be expected from IDMP implementation.

26 National Competent Authorities for Medicinal Products marketing authorization participate either directly as beneficiaries (11) or in an observer role (15). The number of countries where a concrete starting point of an ISO IDMP national ecosystem associating all key national players (involved authorities, eHealth agencies, EHR producers, pharma industry and medicinal products dictionaries producers) exists is however limited.

Some countries have already developed **a national conceptual model for drug information** in order to support most priority use-cases. The costs related to the creation of these ecosystems have been substantial. Medicinal products data bases and dictionaries have been created in national silos for market authorisation and pharmacovigilance, prescription, reimbursement; scientific evidence on side effects and interactions have been partially or fully integrated into dictionaries, and also national governance models have been established. As

a result of this process, the national reference database or dictionary can then be used directly by end users or become embedded in IT products used by final users. Of course, various challenges arise when such legacy systems are subjected to IDMP adaptation. **Considerable to huge investments for the next steps will be needed.** Decision-makers will need to understand the benefits and European-wide needs in order to accept IDMP as a priority investment.

UNICOM will attempt to rely for these players on existing ecosystems, governance and networks to raise awareness concerning IDMP rapid implementation benefits and equip health authorities with knowledge and information to proceed with necessary investment. Most of the agencies which are official beneficiaries of UNICOM are in this situation. UNICOM will here essentially have a supportive role.

While we face very diversified situations across EU countries, **no nucleus of such an ecosystem probably exists in various of the countries not directly represented in UNICOM.** Those countries, having limited legacies to phase out, could be direct beneficiaries of UNICOM key outputs. National drug agencies might also in the future integrate themselves directly in the EMA infrastructure. **A local community of interest needs however to be created** in order to create the necessary awareness, visibility and interest. Specific efforts need thus to be devoted to the establishment of an appropriate network, in close cooperation with UNICOM participating NCAs and EMA. UNICOM will have a pro-active role and more efforts will need to be deployed in a number of selected countries to be identified and analysed when further developing this dissemination strategy.

EMA and EMA related taskforces

The project is in close relationship with the European Medicines Agency, and **bilateral channels of communication** between UNICOM and EMA have been established, including communication with the **EU Data Board** which is part of the EU Telematics action plan setting standards from EMA and the multi stakeholder **EMA/ISO IDMP Task Force** created in 2015 to contribute to IDMP implementation in Europe: This Task Force includes terminology organisations, software vendors and developers of medicinal product dictionaries or databases, and is advising on the planning, development, implementation and maintenance of the ISO IDMP standards in the EU, in line with requirements defined at international level and based on agreed EU implementation principles. Some UNICOM partners are members of this Task Force.

eHealth Network, eHMSEG and eHAction; eHealth Digital Service Infrastructure

The EU Member States collaborate in the Art. 14 eHealth Network (eHN) on implementing Cross-border eHealth services according to Directive 2011/24/EU on patients' right in cross-border healthcare. eHN (Member States) Co-Chair Professor Henrique Martins is a member of the UNICOM Steering Board, SPMS a member of the consortium.

The eHN has been supported by Joint Actions funded by DG Santé. Currently the eHAction Joint Action is coordinated by UNICOM project partner Shared Services of the Ministry of Health (SPMS) in Portugal.

Providing the framework and starting point of UNICOM work packages 5, 6 and 7, **ePrescription and eDispensation Services are implemented as functionalities of the**

eHealth Digital Service Infrastructure (eHDSI). While the European Commission is involved as the eHDSI infrastructure service provider, the eHDSI healthcare services of the Member States receive funding from the Connecting Europe Facility (CEF). The eHMSEG (eHealth Member States Expert Group) and its Semantic Task Force define semantic assets necessary for the selected use cases. **IDMP implementation is essential for the successful deployment of those services** and consequently UNICOM foresees an active engagement of all actors involved. Through the Finnish partner KELA, the current chair of eHMSEG is involved within UNICOM. Moreover, it is foreseen that in turn the UNICOM Coordinator will be invited to eHMSEG to present the project. Thus, UNICOM is closely linked to relevant eHDSI key actors. The most suitable format of this collaboration will be further defined and established.

Standards Developing Organisations

Key standardisation organisations and initiatives such as ISO, CEN, HL7, GS1, SNOMED International and IHE are already directly involved in the consortium; many standardisation experts with an active role in the consortium are also actively involved in relevant standardisation processes such as ISO TC 215 (Health) WG 6 (Pharma). Others like MedDRA are “affiliated” with UNICOM and participate in some activities. Thus, UNICOM will strongly support coordinate and communication between SDOs and users of standards, provide an exchange forum and advice on further development and implementation guides for standards on medicinal products.

On the semantic level, there are several dictionaries relevant to UNICOM that are maintained by various organizations including regulators. Such dictionaries are SNOMED CT, MedDRA, DD, ATC, LOINC, EDQM, etc. The terms in these dictionaries represent different concepts and there are not always unequivocal mappings between them although some progress has been made recently (e.g. mapping between SNOMED CT and MedDRA within the IMI RADR projects). Sometimes there are even multiple synonyms for the same terms. *Reaching agreement on which dictionaries to use for what purpose and the mapping between reference dictionaries is a critical issue*, especially in a cross-border environment and for all uses associated with clinical research and decision support.

UNICOM results and proposed choices – in close cooperation with EMA and FDA - **will thus have a direct impact on the work of SDOs which will have to include them in their processes and/or decide to undertake necessary mapping.** Dissemination activities will thus here also be focused on the project's results and its consequences for major standards used in the healthcare sector while facilitating expert knowledge and usage experience exchange across diverse actor groups towards further improving the quality and usability of IDMP. Furthermore, the concrete availability (and conditions attached to) of those resources will need to be disseminated to all key stakeholders (data organizers and consumers).

Medicinal Product Dictionary providers

This category of stakeholders covers actors which have developed (IT) systems that gather, collate and provide complete lists and information about authorised medicinal products in national markets. Because healthcare is also in the EU a national responsibility and not part of the EU-wide “Single Market”, Medicinal Products Dictionaries (MPDs) need to be developed to meet the needs of the respective national (or even regional) healthcare system. Besides

data on medicinal products as available from pharmaceutical companies applying for marketing authorisation, from national drug authorities or EMA, they usually also contain information on the national market authorisation code (or univocal national ID), pricing and reimbursement (in health insurance-based/Bismarck systems), known side effects or contra-indications etc. Rather than transferring MP data from paper documents, ***the availability of IDMP based national and European public MP data sources will be a major breakthrough***, even in the absence of well-developed national ecosystems.

With the support of the members of the consortium, UNICOM will thus need to ***identify in each country*** the private, not-for profit or, in some, ***the ‘official’ producers of drug dictionaries***. They should be approached together with other priority stakeholders in their respective data value chain, but a targeted vertical direct dissemination to this group is also necessary.

Pharmaceutical companies: marketing authorisation holders

When applying for the authorisation to market a new MP in EU countries, pharmaceutical companies have the possibility (or, in certain instances, must) apply for a so-called central marketing authorisation at European level with EMA through the

- ▶ "Centralised procedure" which allows the marketing-authorisation holder to market the medicine and make it available to patients and healthcare professionals throughout the EU based on a single marketing authorisation.

Alternatives are

- ▶ The “mutual recognition procedure”, where an application may be addressed to one or more EU countries. The applications submitted must be identical, and all EU countries notified.
- ▶ The “decentralised procedure”, which allows for the common assessment of an application submitted simultaneously to several Member States. One of the Member States will take the lead in evaluating the application as reference Member State.

UNICOM will ***support the complete replacement of legacy Portable Document Format (PDF) technology based application forms with a web based CESP*** (Common European Submission Platform) Dataset Module, providing for IDMP compliant electronic tools. It will support initial applications, variations and renewals activities towards IDMP to collect well-structured IDMP data for all and integrate it with EMA’s SPOR services. This will render it possible ***to start, automate and feed regulatory processes with IDMP compliant/structured data and easily re-use the data*** in EU-wide eHealth services along the entire life cycle of a medicinal product.

UNICOM dissemination will target all stakeholder groups involved, particularly pharmaceutical companies (through EFPIA) and those providing services to them, as well as regulators. Part of this will involve training for applicants and regulators, perhaps also involving video tutorials.

Health IT/eHealth software vendors

With a few exceptions, the market for ***EHR systems remains segmented*** between nations both in the primary and secondary care sectors. Although some vendors have developed individual medicinal products dictionaries, ***most vendors implement dictionaries developed by specialised private vendors or public actors***.

Most EHR systems include ePrescribing functionality, access to scientific information, pre-prescription authorisation, reimbursement status and notification of drug interactions and contra-indications. Additional services are communication tools for medication histories and current medication schemes. EHR vendors are hence important mediators for ISO IDMP roll-out, particularly also in support of ePrescribing by health professionals, and it is essential to raise awareness for ISO IDMP in this community. ***EHR software systems may stimulate faster adaptation of ISO IDMP for drug dictionary services*** to be used ***through*** the adapted interfaces with ***IDMP compatible APIs*** of the MPD providers. The recognition and demonstration of how to overcome existing gaps could serve to accelerate the adoption processes of IDMP, hence EHR vendors are important contributors to ISO IDMP local and global ecosystems. Increasing awareness about IDMP benefits and objectives and providing timely access to relevant resources will be key in order to stimulate early buy-in from this critical category of stakeholders.

Clinical Decision Support System vendors

Closely related to the preceding actors is the market of Clinical Decision Support Systems (CDSS), a highly international market; the degree of awareness about the added value of ISO IDMP is already high among vendors in this field. ***Communication can thus be planned more vertical and targeted*** towards directed concrete achievements, availability of resources and implementation schedule.

Scientific medical organisations and other interest groups and organisations

Although not directly impacted by IDMP implementation as such, other organisations such as *scientific and (para)medical organisations* which advocate good healthcare practice, specific networks such as those created to support *patient safety initiatives* and *hospital networks* are also efficient channels to increase general awareness and create the conditions for wide IDMP acceptance and implementation. *University hospitals* are mandated to conduct clinical research and as such can also benefit from a wide IDMP implementation. All those actors can have a critical influential role on the decision-making process at regional/national levels.

Appropriate national and global contact lists will thus need to be assembled to support targeted communication activities.

Healthcare professionals: prescribers and dispensers

Individual healthcare professionals will benefit from IDMP implementation but ***are not seen as main drivers for implementation***. Influential individuals and ***professional representative organizations*** both at EU and national levels are expected to be more receptive and ***can play an important influential role*** in the decision-making process. Participation in UNICOM activities by several European, national and regional pharmacists' associations as observers will in particular contribute to efficient communication of project results.

Patients and patient organisations

The individual patient is ultimately the main beneficiary of IDMP implementation but ***will not be targeted by the project***. ***Patient umbrella organisations and disease focused patient organisations*** with strong engagement in the clinical side of research and treatment are however identified as important actors who ***may influence the decision-making process***. A

specific effort will need to be made to bring the adequate narratives to this group in order to bring them on board.

Trans-Atlantic and global stakeholders

The most prominent among the global stakeholders is the *World Health Organization (WHO)*, which manages several terminologies and coordinates global pharmacovigilance through its *Uppsala Monitoring Centre (UMC)*. It is strongly interested to participate in UNICOM activities and has been accepted as a direct observer of the project. As such it will be continuously informed and **closely associated to all major project communication**. On the global level UNICOM has already established contacts to the “*International Council for Harmonisation (ICH)* of Technical Requirements for Pharmaceuticals for Human Use (ICH); it is an initiative that brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product development and registration. UNICOM has also identified the Drug Information Association (DIA) and will approach other associations with whom cooperation and exchange of information on UNICOM activities and transfer of know-how developed will be sought.

FDA (Food and Drug Administration) is the United States’ Regulator. The “openMedicine” project had already initialised a fruitful collaboration with FDA. **These existing trans-Atlantic communication lines will be reinforced** in order to stimulate early buy-in of the project’s results. Coordination is also ensured via the USA participants in the consortium, which will strongly support all trans-Atlantic dissemination and knowledge exchange. Specific events, preferably in close cooperation with the EC and the UNICOM PO, are envisaged.

3.3.2 Stakeholder specific benefits

UNICOM aims at a **semantically interoperable, meaningful exchange and use** of medicinal product information and data to enable more efficient marketing authorisation processes, improve patient safety, support patient information exchange nationally and across borders, and drive innovation and growth of digital health industry. A core aspect of UNICOM dissemination will be to **transport meaningful messages on the beneficial impact to be expected for all involved actors and stakeholders**. Table 2 provides an initial overview of such benefits triggered by the implementation of IDMP – messages to be further explored and expanded based on concrete experience of UNICOM partners and observers.

Table 2: IDMP-triggered Benefits per Actor and Stakeholder

Stakeholders	Awareness
Pharmaceutical companies	The availability of fully standardised, coded univocal data and information on medicinal products over their full life-cycle will provide for various benefits: It will <i>foster the innovation capacity and efficiency</i> of regulatory processes of pharmaceutical companies by <i>simplifying and speeding up the registration</i> of new products, and afterwards of follow-up information on already marketed products and pharmacovigilance information, <i>Multi-site clinical trials</i> will benefit from the use of the same drugs conceptual model paving the way for more effective and ambitious approaches.

Stakeholders	Awareness
EMA (and related European task forces)	EMA will be supported in its coordination and implementation undertakings focusing on regulatory and pharmacovigilance processes; it will be able to <i>further build on the experience, solutions and demonstrators</i> provided by UNICOM and the accelerated implementations by UNICOM partners.
National Competent Authorities for Medicinal Products (NCA-MP)	They benefit from standardised, consistent and high-quality data input by marketing authorisation holders and applicants, finally leading to identical information across diverse NCAs and EMA, and to more efficient regulatory processes. IDMP implementation also opens the way to a <i>global integrated ecosystem</i> which will save scarce resources and avoid or limit duplication of data.
Patient Safety /Pharmacovigilance	The <i>pharmacovigilance cycle is closed</i> , by ensuring that from marketing authorisation to adverse event reporting and product discontinuation the pharmaceutical products are univocally identified, even if they are specified in different ways by clinical actors during this cycle. IDMP implementation also opens the way to a globally integrated pharmacovigilance ecosystem which will save harm to patients, scarce resources, and avoid or limit duplication of data.
National Health Services (Beveridge system) / Statutory Health Insurances (Bismarck system)	Consistent and fully understandable medication information of patients will lead to <i>improved healthcare processes and greater patient safety</i> , thereby to better outcomes for their clients and cost savings. The quality of data and evidence for pharmacovigilance and pharmacoeconomics will be greatly enhanced, their integration as well as their analysis for public health policy decision facilitated.
National eHealth competence centres	All actors of national digital health infrastructure services and ecosystems are enabled to exchange univocal MP data not only nationally, but meaningfully and safely also globally in cross-border contexts. establishing a <i>seamless digital process and data flow</i>
eHDSI	With prescriptions and active medication records in patient summaries medicinal product information is at the core of cross-border health data exchange – i.e. the <i>reliability and safety of such data</i> in digital healthcare (such as ePrescription and Patient Summary services) <i>across Europe</i> will be greatly. enhanced. The planned core pharmaceutical (and related medicinal) product set of 250 PhPIDs at Level 4 should be equivalent to 2,000 plus MPIDs and as such already account for probably 80 – 90 % of actual drugs specified in prescriptions.
Standards Developing Organisations	New business models for SDOs will be developed, leading to <i>focused collaborative standards development</i> and low-cost standards implementation
Medicinal Products Dictionary providers	Rather than re-typing MP information from paper sources, the availability of electronic, IDMP-adapted or augmented data will fundamentally <i>improve the economic efficiency of data capture and processing</i> . The same may apply to

Stakeholders	Awareness
	pharmacovigilance and other types of information being part of a national dictionary. In parallel, the quality and reliability of Medicinal Products dictionaries will be greatly enhanced with the option to cover a wider array of use-cases, e.g. with respect to cross-border processing.
EHR vendors	For EHR and related software providers the introduction of IDMP might mean initially more work – the adaptation to new data fields and formats. But otherwise, their software will lose competitiveness in the market; and it may also allow developing and implementing new functionalities. Eventually, the use of stable and interoperable MP referential will support the digital economy by <i>providing a standard approach to identifying products across clinical and regulatory systems</i> , as well as production and logistic processes and will <i>improve efficiency</i> .
Clinical Decision Support System vendors	An individual patient's medication records from diverse sources can easily be integrated, validated, and used as input to computerised physician order entry (CPOE), clinical decision support and other (software) systems. In other words, IDMP may provide a <i>compelling business case for gaining new clients</i> .
Patient-facing software Industry, smart Apps etc.	IDMP coded data will provide content that enables innovative companies to create Digital Health or smart APPs that involve “endorsed” data and information for citizens, e.g. for those suffering from one or several chronic diseases, in a poly-pharmacy context, when abroad etc. They will be enabled to reliably detect side effects, contra-indications or other information to better manage their medications. It will also open up for the implementation of AI support in such contexts. Thereby SMEs, start-ups and other companies will <i>contribute to patient empowerment and more personalised medicine</i> .
University Hospitals (and actors Involved in Clinical Trials)	Improvement in the efficacy and <i>efficiency of clinical research and trials</i> particularly in multi-country contexts.
HCP Prescribers: physicians; nurses.	Clinicians reviewing a patient's summary, electronic health record or other documents containing information on medicines prescribed and dispensed <i>understand fully</i> the medicinal therapy information contained. <i>Access to evidence based</i> prescribing information and decision support is greatly facilitated.
HCP Dispensers: pharmacists	Community pharmacists can <i>univocally identify the medicinal (or pharmaceutical) product specified</i> in any prescription. Unless the same medicinal product is available in their national market, they can select – when substitution is allowed - what is the most equivalent medicinal product readily available that meets the specified attributes; thereby the probability of being able to indeed dispense on the spot a medication to the patient is considerably improved.
Patients	Patients' safe and informed medicine usage is supported by simplifying product identification in a great variety of contexts, particularly via smart patient-empowering applications and systems.

Stakeholders	Awareness
	<p>Citizens/Patients will benefit from <i>easier access to enhanced information services</i>. They may indirectly note that ISO IDMP helped in the background to defragment information spaces and to unify drug related information. In cross-border settings, patients can <i>obtain seamlessly at least a medicine equivalent</i> to the one prescribed in another country (in line with respective local regulations), Patient safety will be also improved e.g. as Identifiers or descriptive attributes can be used by any actor, also patients, in any country for obtaining the product's "properties", e.g. in an emergency for the reverse identification of a medicinal product.</p> <p>Patients, and in particular patients suffering from chronic conditions, can also <i>become more easily involved in drug surveillance and pharmacovigilance reporting</i> since information on medicinal products taken can be more easily and safely shared with the respective authorities, their doctors or pharmaceutical companies.</p>

3.4 Priorities for dissemination

Dissemination and communication activities are overall categorised as wide dissemination (awareness raising - DO1) and targeted dissemination (stakeholder liaison and engagement - DO2). In the following sections, strategic targets and approaches concerning both of these aspects will be explored. In addition, addressing regulatory and policy decision makers will be briefly sketched (DO3), to be followed by a discussion of issues related to DO4 - Boosting and maintaining sustainability of the results achieved and the outcomes implemented during and after the end of the project through reinforcing communication and dissemination activities by and with involvement of UNICOM partners. Finally, the establishment of a UNICOM communication team (UCT) is introduced as a key enabler and instrument to realise this dissemination strategy and to be concerned with further planning, implementing and sustaining the strategy by means of developing a much more detailed action plan – initially for the first two years of UNICOM, but eventually for the whole duration of this innovation action.

3.4.1 Awareness raising across end-user ecosystems

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 role IDMP can play for them in future. In line with the earlier identified benefit messages and to support awareness building for the general audience, UNICOM will develop and communicate messages on the added value of IDMP enabled services for health and healthcare around patient safety, improving medicine ordering and medicinal product supply, betterment of medical practice through enhanced Clinical Decision Support, better therapeutic options through research. ISO IDMP adapted tools are also an essential component for meaningful digitisation in the domain of medication management.

Addressing end users: To speed up the overall adoption process it will be essential to go beyond the network of people directly involved in medicinal product market authorisation, database producers, and software providers.

Given the widely lacking public awareness for the highly relevant contribution of ISO IDMP implementation on patient-safety and to complement the broad spread of UNICOM actions lines, a broad spectrum of 'end users' of UNICOM achievements must be addressed. Typical health care key stakeholders like citizens/patients, nurses, physicians and pharmacists need to understand the full benefits emanating from implementing the ISO IDMP family of standards. In other words, wide dissemination, e.g. through broad awareness raising, will need to address in particular these stakeholder groups:

- ▶ Citizens/Patients will be informed about **easier access** to enhanced information services. They may hence **indirectly note** that ISO IDMP helped in the background to defragment information spaces and to unify drug related information.
- ▶ Health Professional end users (nurses, physicians and pharmacists etc.) will be made aware of their better and seamless access to better medicinal product information services particularly in cross-border scenarios.
- ▶ Medical and pharmaceutical professional organisations will be empowered to better inform their members on the benefits for their service provision resulting from the implementation of ISO IDMP along the whole data value chain.

ISO IDMP implementation will only deliver its expected benefits once integrated along the whole data value chain, i.e. when such data become also available in the Health-IT systems established at the point of care, in pharmacies (incl. mail-order) and whole-seller processes.

3.4.2 Targeted information: bilateral information exchange and knowledge transfer

Related to the above is Dissemination Objective 2 (DO2): The targeted dissemination to key stakeholders who are already involved in implementing or supporting the integration of cross-border ePrescription services, plus at the same time also reaching out to all those who will have a role to play, but might not yet be doing so due to lack of awareness, resources or incentives. Here chief levels of attention for media-related messages are: local/regional, national, European and international. Similarly, both public and private sectors will be addressed. Given the geographic location of several of the upcoming EU presidencies, focus will be paid to Member States in Eastern Europe not yet among the EU avant-garde of NCAs which have already started implementing IDMP and which are represented in the present consortium. These not-yet participating countries will be encouraged to take advantage of the experience and lessons-learned of UNICOM, to engage in dissemination activities and expert workshops undertaken by UNICOM, and to prepare and aim for a timely adoption of the ISO IDMP system in their data value chains.

Other target audiences of UNICOM include the medicinal product community (pharma industry, pharmacists, health professionals, particularly prescribers, health authorities and national pharmacovigilance agencies), specialist physicians, nurses, national SDOs, as well as CEF eHDSI actors.

Stakeholder orchestration requires thus extra emphasis and differentiation in UNICOM: the 40+ partners present in the consortium constitute – within the project – in themselves a rich **multi-stakeholder community to be taken advantage of**, including:

- ▶ Network of 26 National Drug Authorities involved in the whole life cycle of medication (11 as partners, 15 as corresponding organisations).

- ▶ National eHealth Competence Centres in the role of Cross-border ePrescription service providers (EU eHSDI),
- ▶ Standard Development Organisations (SDOs),
- ▶ Health service providers,
- ▶ Health-IT industry,
- ▶ Medicinal Products Dictionary providers
- ▶ Clinicians' associations
- ▶ Patients' associations (generic and disease specific).

3.4.3 Addressing regulatory and policy decision makers

As stated earlier, 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.

Implementation of the ISO IDMP family of standards happens by default in a highly regulated domain and is as such closely related to global, European and national health policies and policy makers. In a targeted approach, UNICOM will actively update and involve policy makers as an integral activity of its Communication and Dissemination Action Plan.

Work packages 5-7 on cross-border services add an additional policy dimension since the eHealth Digital Service Infrastructure is implemented under close supervision of the Art. 14 eHealth Network of EU member state health ministries' representatives, co-chaired by the European Commission. Given the role of SPMS both within UNICOM (represented in the project steering board) and in the eHealth Network (Member States' Co-Chair), a rich flow of information to and from decision makers should help the project's awareness raising and dissemination processes.

These health ministries' representatives and decision makers will also be important addressees and mediators for raising awareness of ISO IDMP Standards and univocal identification of medicines in their respective Member States. Several of them have so far not yet started to implement the necessary infrastructure in their national health systems, but they should particularly benefit from learning about IDMP and gaining access to the experience and knowledge of those countries/national medicines authorities actively involved in UNICOM: Countries with ecosystems in an early status of development will be considered a priority when organising stakeholder awareness events and expert workshops for information exchange.

The upcoming Presidencies of the Council of the EU in former accession member states, i.e. Croatia (ongoing), Slovenia (2021-2) and Czech Republic (2022-2), may provide the project with extra opportunities to advance the awareness for ISO IDMP in these and neighbouring national health systems.

Complementary to focusing on core regulatory and health policy decision makers, further groups active in this 'environment' also should be addressed because they constitute stakeholders which have power through their members and their 'customers' to actively influence policy processes. The plan is to engage with these groups through:

- ▶ Creating momentum at interest group and stakeholder level: European-wide/global stakeholder organisations to establish vertical dissemination lines within their constituencies, e.g. COCIR for the Health-IT industry
- ▶ Creating momentum at national level, jointly with NCAs and eHealth Agencies: National stakeholder organisations are encouraged to enrich their communication and dialogues with dissemination around UNICOM, make IDMP their mission
- ▶ Leverage Synergies with EHTEL Networks: EHTEL, has established or is part of networks in a wide range of constituencies active in digitization in health and care.
- ▶ EHTEL has also a long track record in involving policy makers e.g. through thought leadership events: Ensure that the activities of policy-minded organisations are aligned to reinforce the scaling up of a univocal identification of medicinal products by supporting IDMP implementation.

3.4.4 Targeted knowledge sharing and ‘decentral’ dissemination

Given the project-internal multi-stakeholder community, UNICOM can offer 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).

Consequently, the communication strategy emphasises *internal* knowledge sharing within the consortium also as an instrument for *external* dissemination: Leveraging the ecosystems of project partners provides the project with a decentral communication and dissemination platform (see Figure 1). The final communication action plan will foresee extra tools in support of knowledge sharing and dissemination within and through UNICOM’s multi-stakeholder communities.

- ⇒ Knowledge sharing between partners needs centrally provided tools and media contents supporting cross-fertilisation within UNICOM
- ⇒ Partner’s organisations, being gateways to stakeholder communities, will get access to shared tools and resources for enabling them as intermediaries of dissemination and outreach activities.

This internal dissemination resources platform will be leveraged e.g. through easy to use, pre-packaged communication toolkits enabling partners to perform on their own awareness raising and dissemination tasks. At the same time, this form of knowledge sharing will save effort for partners when communicating with their national constituencies.

Exemplary actions empowering the partners to do dissemination activities themselves will concern:

- ▶ Shared content to be reused: Press releases, news/blogs, etc.
- ▶ Mutually pointing (linking) URLs:
Each partner to establish a UNICOM page in their website, also linking to UNICOM site. In turn, partner logos and descriptions at Unicom site are already linked to partner websites.
- ▶ Social media activities, tweets mentioning @Unicom_IDMP and WP Partners (cross-linking, i.e. mutual “follow”).
- ▶ Joining forces along the UNICOM action lines or other thematic clustering.

Moreover, these ecosystems will be instrumental for building stakeholder communities to advance the univocal identification of medicines along three dimensions:

- 1 National Community channels are governance structures around National Competent Authorities for Medicinal Products. These may engage a variety of national actors in medicinal product production and market authorisation, medicine use, reimbursement etc. They have a key role in addressing the implementors within their national working / collaborating environments. They are characterised by engaging national multi-stakeholder communities and thus joining forces with national organisations.
- 2 International Stakeholder channels: Reaching out to specific stakeholder audiences on the European and global level. Here, WP 12 and EHTEL will join forces with fellow stakeholder networking organisations (like COCIR) in the Consortium and other European level and USA-based stakeholder networks to play a role in Europe-wide, trans-Atlantic and global dissemination
- 3 Service channels are less defined by existing ecosystems, yet could be established at a later stage of UNICOM along the three domain specific actions lines of the project
 - ▶ ISO IDMP in medicinal product market authorisation and databases,
 - ▶ ISO IDMP-enabled cross-border ePrescribing, eDispensation and Patient Summary services,
 - ▶ ISO IDMP for clinical use and research.

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 will coexist 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.

3.5 UNICOM communication team

Coordinated by the Project Communication Officer (PCO), the UNICOM Communication Team (UCT) will facilitate Work Package Leaders, their communication experts and all partners involvement in communication and dissemination actions.

As such, it will also be instrumental for the tasks supporting Knowledge sharing and “decentral” dissemination. Hence, identifying established communication channels (per partner and/or constituency) is information requested internally with high priority and to be followed up in the immediate future. Overall,

- ▶ UTC is a working group to support and direct the further development of this dissemination strategy and in particular to translate it into an actionable roadmap with regular assessment of achievements and opportunities for further improvement,
- ▶ UCT is an internal channel for content identification and provision,
- ▶ UCT acts in a supervisory role to safeguard recency, continuity and quality of progress reporting through timely news publication and consistent website updates.

Given the large consortium, UCT will work along a flexible two-layer model, i.e. involving just Work Package Leaders for supervisory tasks, and enlarging the group for some tasks by

communication experts and partner representatives for content generation. Each partner will nominate one person responsible for dissemination objectives.

Over time, the management and coordination of the UCT will further be developed to integrate sustainable public relations and dissemination under the umbrella of the Innovation and Sustainability Group (ISG).

4 Preliminary communication and dissemination action plan

The communication and dissemination strategy is implemented via an action plan. The actions will follow a stepwise approach. Initially, European-wide and global awareness for UNICOM's work will be raised, based on the above explored messages and approaches. As the action progresses, focus will shift towards reporting on ongoing activities, intermediate results obtained, and initial lessons learned of interest for both targeted and wider dissemination. In the final year, dissemination will strongly support presentation of the project's end results, thereby also supporting sustainability efforts and ensuring the longer-term success of UNICOM achievements.

The action plan is accordingly organised in three phases with different foci:

- 1 Development of the project's branding/visual identity, its website, core messages, initial dissemination means, planning of dissemination events, etc.
- 2 Raising awareness of on ongoing activities, intermediate results obtained, and initial lessons learned; plus starting the involvement of various stakeholder groups
- 3 Dissemination the project results and the mechanisms put in place for achieving long-term sustainability as well as impact on regulatory processes, patient safety, clinical and cross-border healthcare services.

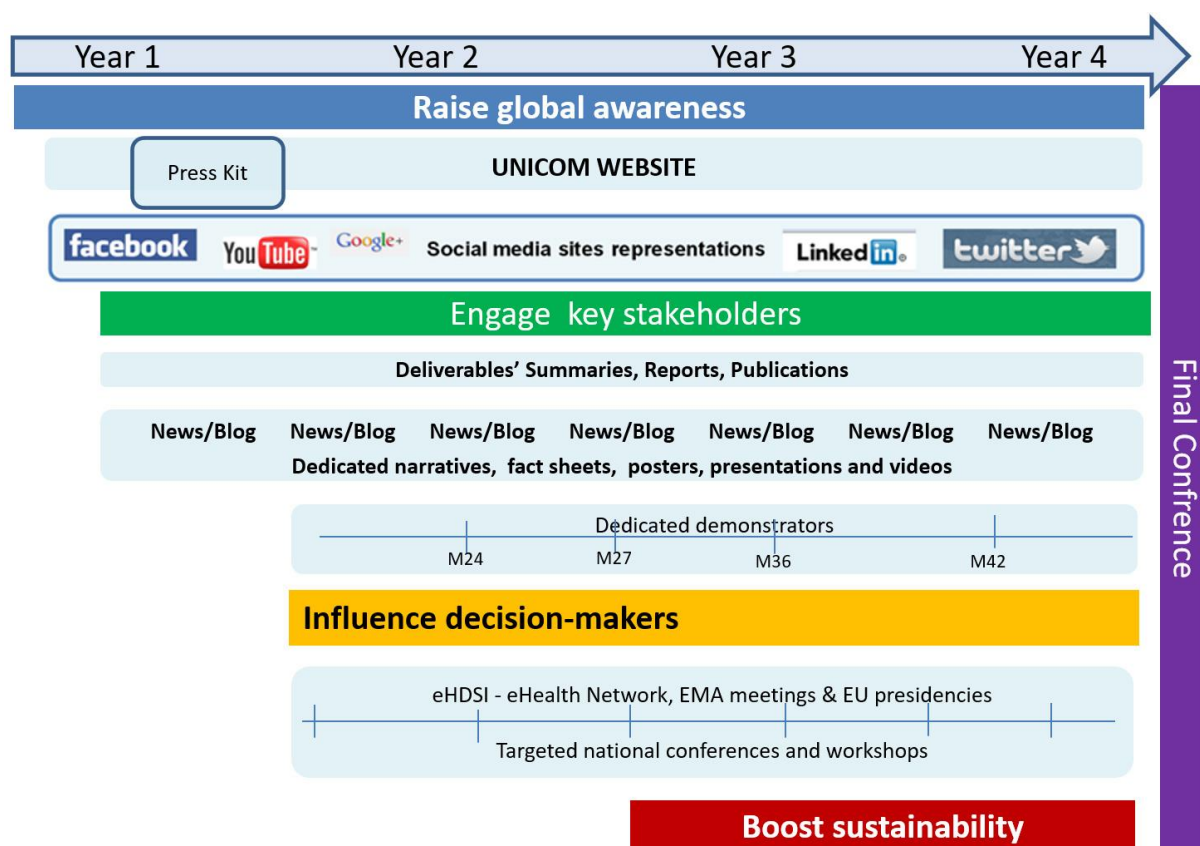


Figure 2: Overall timeline of the dissemination activities

The overall timeline of UNICOM dissemination activities is presented in Figure 3: The project will raise awareness for the benefits of ISO IDMP implementation from its start. First addresses will be those groups and associations which are directly or indirectly already involved in UNICOM or represented by selected members in the consortium; this is in order to optimise

fast initial awareness raising and dissemination of UNICOM's existence and ambitions. Furthermore, UNICOM will engage as early as possible additional key stakeholder groups at national, European and eventually also trans-Atlantic/global level. These elements will then support communication with key decision makers. All efforts are leading towards promoting the beneficial results of UNICOM, thereby strongly supporting efforts to ensure the sustainability of the project's outcomes. These objectives will be tackled from year 3 onwards.

4.1 Dissemination channels and their relevance for reaching different audiences

Communication and dissemination channels “modes” were introduced in Figure 1: “UNICOM Dissemination Approach and Core Strategy Elements: Knowledge Sharing, Awareness, Stakeholders, Decision Makers” (see Chapter 2). As a basic reference for developing the dissemination action plan and roadmap, the following Table 2 on “Relevance of dissemination modes to internal and external project communities” provides an initial assessment of dissemination modes vs. project target groups.

Table 3. Relevance of dissemination modes to internal and external project communities

Dissemination Channels vs. Target Groups	Project Partner & Obsv.	Patients incl. Rare D.	HCP	Health.IT EHR CDSS s	NCA (MP)	EMA, FDA, WHO	eHN eHDSI
Website	+++	++	++	++	+++	++	++
News/blog entries	+++	++	+++	++	+++	++	++
Social media	+++	+++	+++	++	++	+	++
Videos	+++	+++	++	+++	+++	++	+++
Fact sheets (*)	+++	(++)	++	+++	+++	++	++
*UNICOM in a Nutshell	++	+++	+++	++	+++	+++	+++
Roll-ups, posters	+++	(+)	(+)	++	+	(++)	(+)
Conferences	+++	+	++	++	+++	++	++
Stakeholder workshops	+++	++	++	++	+++	++	+++
Final conference	+++	(++)	+++	+++	+++	+++	+++
Publications	++	+	++	++	+++	++	+++
Deliverable summaries	+++	+	++	+++	+++	++	++
Reports	++	++	++	+++	+++	+++	+++

4.2 Initial dissemination actions

Some operational dissemination tasks, like designing a logo and launching the first version of the project website have already been realised in support of the project launch under the direct management of the project management office.

Another immediate challenge is to develop a set of UNICOM narratives 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.

Further steps will be supported by a project-wide editorial committee (constituted as a working group of the UNICOM communication team (UCT)) that will support and oversee the preparation and publication of content in digital format, referring to it in social media and the production of print material (incl. flyers and perhaps selected white papers as well as roll-ups and posters).

4.3 UNICOM impact and value propositions

End-user messages will be developed along the UNICOM story line (sequence and mutual interdependency of work package results and outcomes, reflecting the data value chain processes) and the main benefits anticipated for core application domains like regulatory affairs, healthcare services, patient safety and pharmacovigilance, but also for European digital health software industry and allied service providers (see also table 2). As mentioned earlier, finding the adequate narratives wording for end-users such as health professionals might prove challenging.

4.3.1 UNICOM story line

One UNICOM “story line” leads from implementation of ISO IDMP standards in EU Member States drug databases, to improved regulatory processes, better pharmacovigilance, much more usable cross-border ePrescription and Patient Summary services to better clinical decision support, quality gains in research, Big Data and AI.

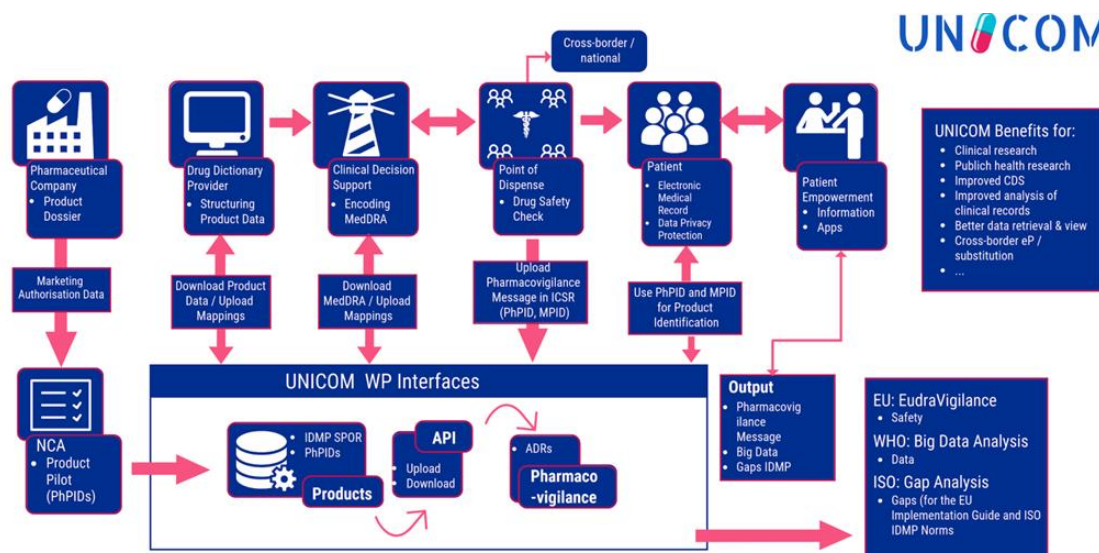


Figure 3: UNICOM data flow as one source for developing project narratives

The full data (and UNICOM work) flow can be conceptualised as **a complex sequence of 12 steps** as detailed in the DoA, where each step has already some complexity in itself. Narratives will be developed that “package” these steps into graspable information units, aiming at info graphics and texts presenting “UNICOM in a Nutshell”. There will be **multiple, complementary information elements that a) highlight shorter sequences within the**

workflow and b) highlight domains specific subsets like the UNICOM data flow (Figure 4).

4.3.2 Value propositions and narratives

Narratives will be instrumental for awareness building, and also for stakeholder engagement. Suitable messages need to be identified for establishing awareness for IDMP implementation and diffusion as an enabler for patient safety, improvement of quality and efficiency of healthcare services, public health support through Big Data analytics, AI-based decision support, etc.

Jointly with partners (via the UNICOM Communication Team) narratives will be developed and refined that matter for people (citizens and patients):

- ▶ IDMP facilitates the semantically interoperable, seamless flow of medicinal product data and thereby enables the European-wide defragmentation of information spaces, thus lowering the efforts for all health professionals to access more reliable and up to date drug related information recorded in software applications used in hospitals and physicians offices,
- ▶ IDMP provides for all stakeholders easier access to unambiguous, safe medicinal product information,
- ▶ IDMP-implementation will facilitate patient-facing services and thereby their empowerment, and more personalised healthcare,
- ▶ 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.

UNICOM will initially work with three or four core use cases and narratives related to them, but more use cases are expected to be developed during the initial months of the project in close exchange with partners.

Later on, the value proposition of each use case will be discussed and validated through a dedicated process (like an online focus group, dedicated sessions at an event, exchanges with stakeholder associations). These propositions will be translated into detailed narratives which will be used as input for the creation of dissemination materials.

The following keywords (related to data and processes) will be actively used when drafting the narratives: accessibility, quality, consistency, integration, security, user acceptance and friendliness, simplification, redundancy avoidance, synergies.

4.4 Branding, website and social media

4.4.1 Branding



Figure 4: UNICOM Logo

The branding of the project has already started by defining a project logo that is visually clear and sends a strong signal towards the medicinal product domain.

The UNICOM colour scheme is defined by two main blue colours, i.e. Dark Blue (RGB 29, 89, 156); Light Blue (RGB 228, 237, 244) and a third complementary colour (RGB 118, 189, 208).

Further branding relies on more detailed identification of project value-adds for stakeholder groups. On that basis, the visual identity is further developed to provide branding in the format of a project claim, key visuals, presentation templates, graphical charter for the web site and other dissemination material. The branding covers initially digital media (website, templates, social media accounts) and will be applied to printed dissemination material (roll-ups, postcards/flyers, fact sheets, leaflets and folders) as well.

4.4.2 Website

The **project website** acts as primary reference platform for dissemination. It will host e.g. information texts and progress notes, news, event announcements and it will be operated as the entry point to the public resources of the project. It is set up by EMP ensuring global exposure of project objectives, workshop outcomes, results and expected impacts. It will also address and outreach towards standardisation, scientific, medical, industrial, other stakeholder and political communities.

A WordPress version 5.3.2 with expected expanding by means of utilising additional plugins is exploited as a content management system (CMS). The CMS is running on a dedicated eight core, 16GB RAM Ubuntu 18.04 long-term support (LTS) server in command line interface (CLI) only mode. Once all pages are being created on the UNICOM webpage, it will create sitemap and robots files which are used by Google and other search engines to find a webpage on the Internet. Search engines' optimisation will be performed once all subpages of the UNICOM webpage will be created to ensure proper search engines' interaction with robots and sitemap files. Interface to be enriched by means of stock photos.

Through **responsive web design**, the website will display well on mobile and desktop devices. Usability for all user groups is safeguarded by observing EU web accessibility rules (Web Content Accessibility Guidelines – WCAG 2.1). The website is set up with the following milestones:

- ▶ Initial Website: M2 (online already: www.unicom-project.eu)
- ▶ Full version of Website, release I: M6

4.4.3 Social media

Social media activities will make use of presentations, news etc. in Twitter and LinkedIn. They will be linked to the website and the project's email account and contact form. The Twitter account @UNICOM_IDMP has been initialised early February 2020 (see figure 8 in Annex 3). The active use of social media incl. engagement with the social media channels of the European Commission will start as soon as content-related messages are agreed upon. Over the project's lifetime, social media will be particularly dedicated to lessons learned and any hands-on message that can be derived from there. Social media interactions will be both driven from a project account and all partners – with support by their communication departments where available. Twitter impact will be boosted by engaging partners and their networks as

multipliers, through sharing of content posted on the project Twitter account. Partners and other projects are also encouraged to cross-link social media accounts, leading to better visibility and meaningful stakeholder involvement.

4.5 Printed material

Paper-based materials as such will be few and focused on essential elements, to be handed over during workshops and conferences. All documentation being developed and used during the project will primarily be prepared as online documents for screen-reading and may be printed on demand by the actual user, thus reducing environmental load and optimising dissemination logistics. Paper-based materials may include postcards and small flyers. Documentation like fact sheets, leaflets, brochures, and a lay version of the final project report will be online only.

4.6 Document pool, multilingualism, tool kits for dissemination and press

The priority for online documents will result in a document pool, that will support knowledge sharing and dissemination by partners through their established communication channels. Project partners will receive – where feasible – all documentation material in open and editable formats. This enables consortium partners to brand or co-brand most material easily. Translations of text elements into local languages can be easily processed e.g. for bilingual editions.

Partner information tool kits will hold e.g.

- News/blog contributions/stories,
- Videos (published via YouTube to reach the widest possible audience),
- Demonstrators.

All this material will help and support both (1) consortium partners and (2) stakeholder organisations associated to UNICOM to communicate its results and function as potent multipliers into their respective communities. Their communication channels will be used to inform relevant national stakeholders about the project Europe-wide.

Tweets, blog article and news will also be sent to dedicated distribution lists of expert journalists and press contacts. Furthermore, it is foreseen and will be attempted to also make use of newspapers⁴ as well as radio and TV broadcasts at local/regional and national level as dissemination channels.

4.7 Results reporting and publications

The majority of deliverables will be put in the public domain. The website will play a major role in making them available to a large audience of interested parties.

Particular visibility will be given to

- Deliverables concerning new developments in IDMP standards,

⁴ One example of a candidate media for large scale dissemination is the German language “Apotheken Umschau”, produced by Wort und Bild-Verlag in Munich, Germany. The magazine is handed over to clients for free in Pharmacies, office based practices and outpatient clinics (covering its costs) and thus reaches a large proportion of German patients.

- ▶ Solutions envisaged and realised by various project partners (like realisation of an IDMP-based submission system for marketing authorisation for new medicines, or the establishment of a European Substance Reference System),
- ▶ New developments and piloting of cross-border health services or smart apps for patients,
- ▶ EU-wide and trans-Atlantic activities and achievements,

Short summaries published on core deliverables will drive attention (“traffic”) from expert audiences to the website. Moreover, they will be used also as teaser messages for organising and announcing **Webinars** on key project results.

Table 4: Examples for domain specific international journals

Domain specific international journals (examples)
Drug Safety: the Official Journal of the International Society of Pharmacovigilance
BioDrugs
MedCrave Online Journal of Proteomics & Bioinformatics
JAMA Internal Medicine
JECH - Journal of Epidemiology and Community Health
Journal of Clinical Pharmacy and Therapeutics
Pharmacy
LogForum – Scientific Journal of Logistics
International Journal of Medical Informatics
Health Informatics Journal
Healthcare Informatics Research
Journal of Medical Internet Research

4.8 Dissemination events and stakeholder outreach

Dissemination events will be organised in the format of face2 face workshops – enabling also intensive stakeholder dialogue – and, where feasible and meaningful, Webinars on key project results.

Where feasible and accepted by these partners, UNICOM will **join forces with other actors driving the global implementation of IDMP** standards, notably with the European Medicines Agency (EMA), the World Health Organisation (WHO), ISO/CEN, and the US Food and Drug Administration (FDA). Their meeting calendar(s) will be analysed and monitored for organising presentations at such events, attending and contributing to panels as well for hosting joint conferences. It goes without saying that an analogue approach will be pursued for joint events and conferences hosted or co-hosted by partners or observers in the project constituency.



Figure 5: Exemplary partnerships, events, liaison partnerships and digital media to use

The project will host under its own responsibility two public events/sessions, dedicated to presenting the milestones and the final results of the project (with a focus on lessons learned and tangible interim and final benefits for the addressed stakeholders):

- ▶ Mid-term workshop aiming to attract an audience of 50 to 80 persons
- ▶ Final conference aiming to attract participation by 100 to 150 persons.

We will explore options to organise both meetings in close temporal vicinity to another major European event, or perhaps even as a half-day/full-day sessions there.

Liaison activities with other EU projects will also be pursued to organise joint focus groups or other workshops as deemed mutually useful.

4.8.1 Side and satellite events

Along this line, the PCO and WP12 will explore – supported by consortium members through the UNICOM Communication Team (UCT) - opportunities for smaller side and satellite events and expert/validation workshops to well-attended meetings in the digital health, regulatory and healthcare domains, including cross-border and trans-Atlantic related opportunities, to maximise communication outreach and minimise economic effort.

Organisations within the consortium (partners or observers) – some represent large stakeholder communities and networks – will also be approached to act as intermediaries of hosted dissemination events to optimise outreach and impact of UNICOM communication and dissemination.

Events will be selected which offer the best perspective and potential to

- ▶ create momentum at national level
- ▶ create (or integrate/collaborate with) relevant ecosystems regionally, nationally and EU-wide
- ▶ bring core UNICOM/IDMP stakeholders together
 - ▶ National Drug Authorities and their affiliated stakeholder organisations are encouraged to enrich their communication and dialogues with dissemination around UNICOM, i.e. make IDMP an element of their mission.

- ▶ European-wide stakeholder organisation will establish vertical dissemination lines within their constituencies, e.g. COCIR for the Health-IT industry.

Some events for closer consideration are selected annual Digital Health conferences with European and global outreach such as (sorted by calendar date of the respective 2020 event)

- ▶ HIMSS Global, 8-13 March 2020 in Orlando, USA (cancelled on 5th March; 55.000 registered participants were reported).
- ▶ Portugal eHealth Summit, Lisbon (hosted by SPMS): 18-21 March 2020 [postponed] The event has a tradition of co-locating EU project workshops.
- ▶ eTELEMED – International Conference on eHealth, Telemedicine, and Social Medicine, next event 22 – 26 March 2020 in Valencia, Spain (cancelled)
- ▶ eHealth Week co-organised by the EU Presidency and the European Commission 2020 hosted by Croatia in Rovinj, 15 – 17 April 2020 (cancelled or postponed)
- ▶ MIE - Medical Informatics Europe (European Federation of Medical Informatics) MIE 2020 28 April – 1 May in Geneva, Switzerland, co-hosted by WHO, ITU etc.
- ▶ HIMSS Europe and Health 2.0 Annual Event, next event 26-28 May 2020 in Helsinki, Finland.
- ▶ Connected Health Conference (organised by Partners Health in October, not announced yet for 2020), Boston, USA.
- ▶ ICH Assembly and ICH Public Meetings by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (Next Meetings planned: 26 - 27 May 2020, Vancouver, Canada; 17 - 18 November 2020, Athens, Greece).

4.8.2 “Roadshows”, series of stakeholder workshops

For awareness raising, roadshow-like events, i.e. events organised based on a partially fixed agenda, will be organised jointly with stakeholders in the consortium to reach in particular national stakeholder audiences, and audiences with communalities organised by region or health system. Likewise, certain countries / groups of countries may be addressed in view of common deficits and needs in the ISO IDMS implementation sphere.

To efficiently organise those workshops their agendas will be combining re-usable and country-specific elements:

- ▶ A set of presentations to provide the framework (need for, policies, state of the art, what is new, what has to be achieved, what are the next steps in their respective ecosystem)
- ▶ Scenarios and Use Cases as “hands on” hooks in the first phase

Typical key mediators to join forces with as multipliers foreseen are:

- ▶ National Competent Authorities for Medicinal Products
- ▶ Health Ministries
- ▶ Provider organisations
- ▶ Insurances / reimbursement organisations
- ▶ Health professionals / pharmacists
- ▶ Patient organisations
- ▶ Pharmacies

- ▶ Pharma Industry
- ▶ Scientific organisations
- ▶ Health IT vendors and their organisations

These project milestones and demonstrators may qualify as focal points for organising a “roadshow-like” dissemination event and/or may become the lead trigger for a UNICOM webinar.

- ▶ M24 (Webinar) An educational video on the ISO IDMP standards family
- ▶ M42 (Event) A prototype for the revised medicinal products and marketing authorisation system (new forms, seamless data sharing, uniform coding). This event should be hosted by (or in the country of) one of the four more advanced and involved National Competent Authorities for Medicinal Products.
- ▶ M27 (Webinar) A video demonstrator for IDMP use in a cross-border scenario.
- ▶ M36 (Webinar or f2f event) Launch of the Patient App for ISO IDMP based Medicinal Products Information.

4.8.3 Event list identification and reporting

The PCO will, with support of the UCT, maintain a shared list of upcoming and passed events. Work package leaders and partners will notify via this list of upcoming events.

Notification records hold a summary of the event mission, venue and expected attendance. Moreover, WP leads/partners will file submitted abstracts and plans for presentations. Short reports and presentations will be made centrally available for all partners and will be as well published on the website for public events (subject to presenters' permission).

4.8.4 Synergies with other projects and networks

Below follows a brief review of potentially relevant running or recently finished projects financed by the European Commission, as well as of key stakeholder networks to be approached by UNICOM to explore opportunities for knowledge and expert opinion exchange, information dissemination, and learning from their experience.

▶ DigitalHealthEurope project – It will support large-scale deployment of digital solutions for person-centred integrated care by identifying, analysing, and facilitating the replication of highly impactful best practices, utilising its consortium's exceptional expertise on knowledge management and impact assessment (EIP on AHA repository of innovative practices, MAFEIP), twinning schemes, and mobilisation of stakeholders. UNICOM regards the project's vast network of more than 1,100 members representing national, regional, and EU-wide stakeholders as an asset to be explored regarding dissemination and knowledge exchange regarding UNICOM's patient-facing activities and patient empowerment pilots.

▶ GRAVITATE-HEALTH project – A team to which several UNICOM partners belong has been invited (as sole contender) by IMI2 ((Innovative Medicine Initiative) to submit a second stage proposal; we expect this project to start by the end of 2020. Its mission is to equip and empower citizens as users with digital tools that make them confident, active, and responsive in their patient journey, specifically encouraging safe use of medicines for better health outcomes and quality of life. To its core objectives belong the deployment of reference implementations and interventions, and the validation of user scenarios through proof-of-

concept pilots with multifaceted evaluation in 8 European countries. Here we see a strong commonality and partial overlap of mission and objectives, calling for cooperation, collaborative dissemination efforts and coordinated involvement of stakeholder groups.

► **WEB-RADR 2 project** – This IMI-supported activity built on the mobile application functionality delivered through the first WEB-RADR project to expand access to its platform and the reach of the information contained within it, like access to terminologies also relevant for UNICOM partners and stakeholders. It achieved this by making its information and functionalities available through application programming interfaces (APIs), meaning that third party organisations are enabled to embed WEB-RADR platform functionality into their own systems, applications and websites. An important component is its terminology mapping activity involving three core healthcare terminology owners: MedDRA MSSO, SNOMED and WHO, all of whom are also involved with UNICOM. This is relevant to a number of work packages in UNICOM to build further on work done in WEB RADR 2. The mapping will facilitate communication between regulatory and healthcare databases by establishing mapping protocols and delivering an initial mapping between a subset of key pharmacovigilance terms.

► **Share4Rare project** – a collective awareness platform of patients, caregivers, researchers and other stakeholders involved in the healthcare for patients with Rare Diseases. Based on a socially innovative approach, it engages and connects all relevant stakeholders. The platform is built around three important pillars: care, education and research. UNICOM will approach them to disseminate IDMP-related knowledge and collaboratively make use of their collective awareness platform reaching high-motivated groups of citizens linked to rare diseases and their expertise. The platform also provides a space for debate and co-creation, and to instigate further research. We anticipate that cooperation will be beneficial to the missions of both projects.

► **The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action** – It was created to support pharmacovigilance operations by EU drug NCAs. Drug NCAs participating in UNICOM are also members of this Action as well in several other groups of European and international/global regulatory networks. It is anticipated that these UNICOM partners continue to utilise these European and international structures to foster dissemination to, communication with and exchange of knowledge and experience of UNICOM.

► **ISO TC 215** – ISO is a global network of the world's leading standardisers. Through their members they bring together experts from all over the world to develop International Standards. The ISO IDMP standards were developed and are maintained by ISO technical committee ISO/TC 215, Health informatics, working group 6 "Pharmacy and medicines business". Various Drug NCAs are active members in ISO committees and WGs, contributing to and drawing on the knowledge generated there. Standard development organisations (SDOs) participating in UNICOM also work together in this WG (ISO/CEN, HL7, IHE, SNOMED, GS1), each having their own global outreach. UNICOM will attempt to take advantage of these relationships and connections to support its own dissemination and communication efforts. We expect this to also support trans-Atlantic cooperation, because the SDOs (and some NCAs) have relations with counterparts such as the US Food and Drug Administration and others, and also global connections.

► **The International Pharmaceutical Regulators Forum (IPRF)** – has an IDMP Working Group which is made up of pharmaceutical regulators and organisations responsible for regulating

medicinal products or Regional Harmonisation Initiatives (RHIs). It provides a venue for regulatory authorities and organizations to share information, discuss issues of common concern, discuss emerging scientific areas of relevance to drug development and regulation, and work towards regulatory convergence. IDMP is one of the main topics of the IPRP, and UNICOM will try to establish a closer relationship towards participating in or for bilateral dissemination efforts.

► Further networks and working groups which may become relevant for dissemination and communication of UNICOM results are:

- EU Telematics Management Board (EU TMB) – the strategic governance body that operates on behalf of the European Medicines Regulatory Network. The Network comprises the European Medicines Agency (EMA), the network of EU National Competent Authorities as represented by the Heads of Medicines Agencies (HMA), and the European Commission, as represented by DG SANTE.
- EU Network Data Board (EU NDB) – an advisory body co-chaired by the Head of Business Data and Support Department (EMA) and a National Competent Authority (NCA), and composed of representatives of Member States, EMA, and other key parties (e.g. EDQM, EC and other non-EU regulatory authorities).
- SPOR ISO IDMP Task Force – established by EMA, the task force also involves terminology organisations, software vendors and developers of medicinal product dictionaries or databases.

5 Quality assurance and monitoring

5.1 Editorial quality control by UNICOM Communication Team

The UNICOM Communication Team (UCT) serves also as **editorial committee** and will as such organise UNICOM partners' involvement in content provision with respect to their own and related national and, where relevant, international activities and involvement. The editorial committee likewise acts in a supervisory role to safeguard timely news publication to a high editorial standard by means of a fast-track quality review process of material to be submitted. At the same time, the team will also serve as a quality controller with respect to coherent website updates reflecting continuous progress within the project.

5.2 Involvement of partners in public relations

The UCT will leverage the experience and knowledge contributed by consortium partners towards lightweight and user-oriented presentation of complex subject matters. Moreover, it will establish methods to jointly address the communication and stakeholder networks of all partners by avoiding contact duplications and redundancies. The plan will be reviewed and adjusted periodically.

5.3 KPIs for monitoring

To continuously evaluate implementation, dissemination and communication activities, and their associated impact, some pre-defined key performance indicators (KPI) will be monitored. These dissemination and communication achievements and their impact will be regularly reviewed and reported (as part of the management report). The report will also help to adapt dissemination and communication measures to reach these goals. The following table displays KPIs grouped by communication channels and suggests minimum targets on annual base from 2020 to 2023.

As mentioned in section 2.5, each member of the consortium will be requested to take an active part in the dissemination activities and to promote UNICOM via their own communication channels. The planned actions will be constantly monitored by the Project Communication Officer (PCO). Both WP leaders and individual partners responsible to provide the agreed content or action will be regularly notified and actively supported to meet the objectives set by the UNICOM communication team.

Table 5: Key Performance Indicators (KPI) for UNICOM dissemination

ID	Indicator	Method of measurement	Expected Progress			
			Y1	Y2	Y3	Y4
1	N. of unique visits to UNICOM-project.eu website	Web statistics	500	700	850	1000
2	N. of social media campaigns	Key reports	2	3	6	8
3	N. of events published on portal	Web statistics	3	4	6	8
4	N. of news published on portal	Web statistics	10	10	15	15
5	N. of users reading tweets using UNICOM related hashtags	Twitter statistics	200	250	300	400
6	N. tweets using UNICOM hashtags	Twitter statistics	20	25	30	40
7	N. tweet impressions using UNICOM hashtag / Twitter-ID	Twitter statistics	3K	4K	5K	6K
8	N. of participants on average per webinar	Webinar statistics		20	30	40
9	N. attendees to the final conference	Conference minutes	n.a.	n.a.	n.a.	100 - 150
10	N. of dissemination leaflets, infographics	N. published on website	3	4	4	6

6 Annex 1. Initial UNICOM Fact Sheet

Overarching Goal	<p>Improving patient safety and facilitating better healthcare through</p> <ul style="list-style-type: none"> ➤ ISO IDMP (IDentification of Medicinal & pharmaceutical Products) standards-based free flow of semantically interoperable Medicinal Product (MP) information ➤ across Europe and trans-Atlantic
Concrete objectives	<ul style="list-style-type: none"> ▶ Support implementation of IDMP at EU level & in Member States (For submission of Marketing Authorisation Applications [MAA] by industry; at National Competent Authorities [NCAs]; by Medicinal Products Dictionary providers; in electronic prescribing systems, etc.) ▶ Facilitate mobility of European patients by cross-border ePrescription services adapted to IDMP for reliable dispensation
Core action lines	<ol style="list-style-type: none"> I. Adaptation and implementation of IDMP at EU/NCA level (Substance Data Bases; Common European Submission Portal [CESP] for marketing authorization applications; implementation by NCAs; training of implementers; links to European Medicines Agency [EMA] and its Substances, Products, Organisations & Referentials Management Systems [SPOR]) II. Adaptation of Member States cross-border digital health services (ePrescription; Patient Summary) to IDMP, testing, piloting and implementation III. Exploration and implementation of IDMP for pharmacovigilance, Medicinal Product Dictionaries (MPDs), digital healthcare support services, patient empowerment, Big Data <p>Horizontal support: Further development of IDMP, analysis of socio-economic impact; investigation of exploration & sustainability, legal and governance/data protection, and ethics issues; promoting dissemination of project results and cross-Atlantic cooperation (including with USA Federal Drug Agency [FDA])</p>
Benefits	<ul style="list-style-type: none"> ▶ Improved cross-border patient services: substantially enhanced probability of successful identification of an MP in a foreign ePrescription and dispensation ▶ Enhanced patient empowerment: better personalised information on medicines, also when abroad ▶ Better healthcare: reliable semantic harmonisation of records of medicinal products dispensed to a patient (e.g. across electronic patient records) ▶ More effective pharmacovigilance: more efficient processes, faster identification and results integration of medicines mentioned in adverse event reports ▶ Availability of interoperable, high-quality data on medicines: for Big Data analyses; Public Health policy making and data exchange across Europe, trans-Atlantic and globally; clinical & pharmaco-economic research ▶ More efficient regulatory processes: reliable input & consistent exchange of electronic data over the life cycle of a medicine between industry, NCAs, EMA ▶ Digital health industry & SME competitiveness: via open APIs access to univocally identified, reliable EU-wide medicinal products data for smart apps, medicine dictionaries, software systems and clinical applications
Stakeholder participation	<ul style="list-style-type: none"> ➤ Core actors participate as consortium members ➤ Other stakeholders are involved via their associations or as experts (Advisory Board, workshops, etc.) ➤ IDMP data value chain stakeholders are: pharmaceutical industry; national medicinal products & national eHealth agencies; EC & national cross-border digital health services; providers of medicinal product dictionaries; healthcare software producers; healthcare professionals (incl. pharmacists); patients; start-ups developing intelligent apps for patients; medical research; Public Health
Duration	Dec. 2019 – Nov. 2023 (4 years)
Budget	€ 21 m; European Commission funding € 19 m
Coordination & contact	empirica Communication & Technology Research, Bonn, Germany unicom@empirica.com; www.unicom-project.eu ; www.empirica.com

7 Annex 2. UNICOM Website (work in progress)

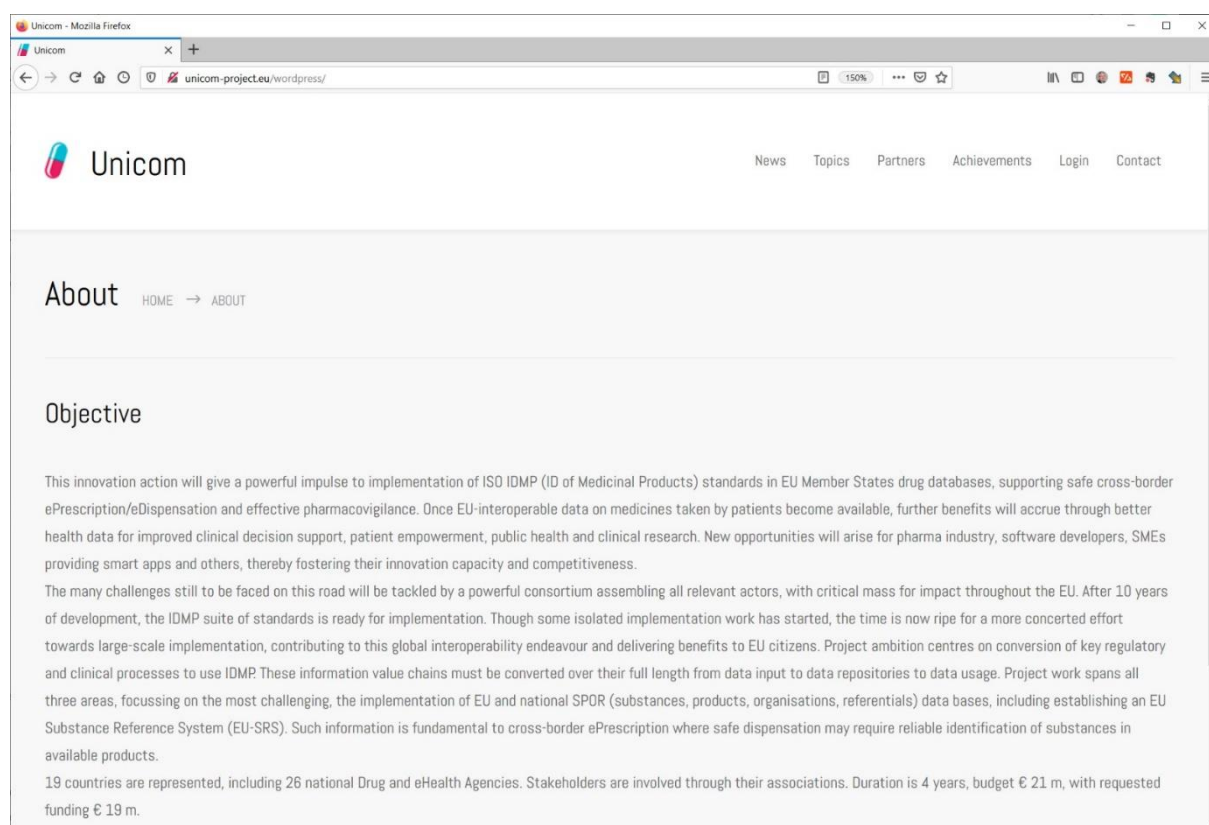


Figure 6: Initial UNICOM landing page

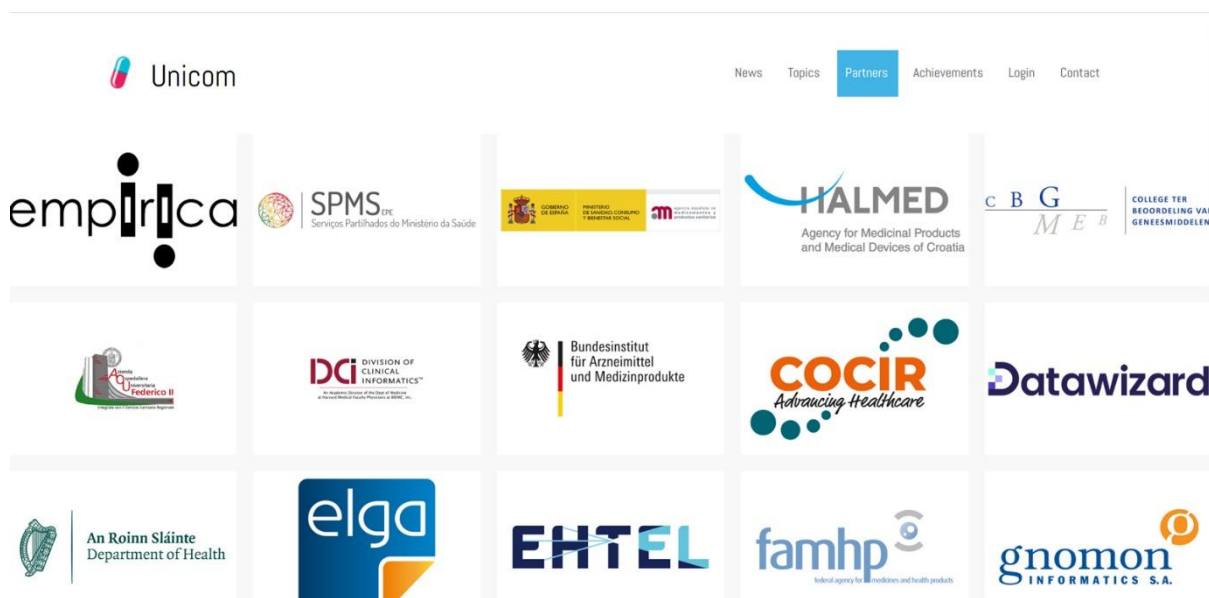


Figure 7: UNICOM partner page

8 Annex 3. UNICOM_IDMP Twitter Page



Figure 8: UNICOM_IDMP twitter (launch state)