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## Revision History

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### Abstract

This document presents the 2nd Communication and Liaison report of the openMedicine project. It covers the activities carried out in the period February 1, 2016 to December 31, 2016 of the openMedicine project.

### Keywords

Liaison, communication, dissemination activities

### Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.
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1 Executive Summary

This 2nd Communication and Liaison report provides a report on the communication and liaison activities of openMedicine carried out in months 14-24 of the project. The objectives of the openMedicine Communication plan as initially outlined in D7.1 and refined in D7.2 were to:

(a) raise awareness of openMedicine objectives and results especially among actors in the medicinal product (MP) lifecycle community;
(b) facilitate cooperation with/between the relevant stakeholders;
(c) engage SDOs: IHE, CEN/ISO, HL7, GS1;
(d) organize workshops engaging local actors in member states;
(e) promote adoption of the project recommendations and roadmap;
(f) facilitate cooperation between Europe and the United States.

The communication plan of the project centred on the following key message:

openMedicine addresses the medicine (medical, pharmaceutical products) univocal identification and substitution problems with a set of identifiers that bridges local, European, and global perspectives.

The openMedicine approach highlighted that meaningful exchange and use (i.e. interoperability) of medicinal products (MPs) information across borders is a social good, an aspect of patient safety, as well as a driver of innovation and growth. The key elements of the communication plan have been adapted from those in the first year to illustrate our growing understanding of the challenges involved in developing and sustaining a pan-European medicines database:

- engage early-on the different stakeholders in the medicinal product lifecycle by developing material and language that appeals to their values and viewpoints in a strategy that bridges local, EU, trans-Atlantic, and global perspectives;
- consult with the experts advisory council and partner with EC, WHO, eHN, and EMA;
- develop and maintain a stakeholder registry;
- execute targeted communication activities with quality assured content;
- use beneficiary networks, targeted communication, and publicity kits to increase impact and outreach;
- work with SDOs to maintain, engage in, and promote sustainability and follow-up project results;
- identify and approach influencers, enablers, policy makers, thought leaders and decision makers.

In accordance with the recommendations of the reviewers in the midterm review of openMedicine, the communication plan was updated to include targeted national workshops. In preparation for each workshop, agenda and key messages were fine tuned to local conditions and participating stakeholders. Following each workshop, next steps were planned based on lessons learned and in accordance to our overarching principles to pursue:

- actionable agile communication strategy that focuses on stakeholder engagement;
- inclusive and focused message delivery, adapting the language to the particular needs and values of the targeted stakeholders;
consultation and coordination with SDOs, EC, EMA, WHO and the eHN as well as leading stakeholders across the Atlantic (experts council);

attractive and informative www.open-medicine.eu portal and social media presence, communication kit (multiple languages/target audience), events attendance, and coordination with other PHC-34 initiatives.

Thus, the effectiveness of the communication plan was continually assessed and adjusted in consultation with the experts involved in project work and agreed upon indicators.

The following specific indicators provide an indication of the overall work undertaken and the impact achieved:

- **Website:** 1833 unique visits, 5251 page views, and 817 document downloads in 2016 (01.01.2016-31.12.2016) compared to visits 844; downloads 309 in 2015.

- **Events organised:**

  
  - Workshops (national workshops organised by openMedicine and invited sessions or workshops to well-known conferences) attracted key stakeholders and covered in total virtually all European Union member states and selected third countries:

    i. Paris, France, April 2016, a special event as part of the European Federation of Medical Informatics, Special Topic Conference 2016, with participation from several member states; (conference workshop)

    ii. Madrid, Spain, May 2016, hosted by the Spanish Drug Agency (AEMPS) with participation of EMA, Spanish and Portuguese stakeholders; (national openMedicine workshop)

    iii. Genoa, Italy, June 2016, as part of the International Healthcare Interoperability Conference (IHIC2016) with participation of experts from Austria, Czech Republic, Germany, Netherlands, and the Italian Drug Agency; (national openMedicine workshop)

    iv. Lisbon, Portugal, June 2016, as part of the Portuguese eHealth week with stakeholders and the Portuguese Drug Agency. (national openMedicine workshop)

    v. Munich, Germany, August 2016, as part of the Medical Informatics Europe congress with attendees from most European and several non-European countries; (conference workshop)

    vi. Athens, Greece, October 2016, as part of the Greek and Eastern Mediterranean eHealth Forum with participation from EMA as well as Greek, Croatian, and Moldova drug agencies. Stakeholders from Cyprus, Bulgaria as well as Greek stakeholders; (national openMedicine workshop)

    vii. Berlin, Germany, October 2016, as part of the eCardiology and eHealth congress with participation of many international stakeholders; (conference session)

    viii. Stockholm, Sweden, November 2016, hosted in the Swedish eHealth Agency with participation from Norway, Sweden, Finland, and Estonia drug agencies and eHealth programs (national openMedicine workshop).

- Meetings with national representatives and eHealth Stakeholders:
eHealth stakeholders group, October 2016;
eHealth week, Amsterdam, June 2016;
eHealth Network, Brussels November 2016 (the recommendations of openMedicine were presented and discussed);

Mentioning of the project on Twitter and LinkedIn: >50

Tutorials on ISO/IDMP by CEN TC251/ISO TC215 in Amsterdam and Lillehammer

Meetings with SDOs, (national) agencies, politicians etc. >10 - highlights:
  - HL7 WGM, Orlando Jan 2016, Montreal, May 2016;
  - ISO/TC 215 & CEN/TC251 Meetings, Amsterdam, May 2016;
  - ISO/TC215 & CEN/TC251 Meetings, Lillehammer, November 2016;
  - Meeting with SDO representatives, Oslo, November 19, 2016;
  - PHC-34 & JAseHN meetings.

Scientific papers and newsletters
  - Articles in the HL7 and CEN newsletters reported on the progress of the project
  - Scientific papers reported on research issues of openMedicine

Conference presentations (>20) including:
  - GS1 conference, June 2016;
  - eHealth Forum, Athens October 2016
  - European Society of Cardiology meeting, August 2016

The communication and liaison activities accelerated in the second year of openMedicine to support the consortium in elaborating broadly debated and validated recommendations and roadmap. Multiple meetings and workshops with a range of stakeholders conducted in the spirit of co-creation and consensus building ensured visibility of the project and strong dissemination of project results. Thus, the conclusions of openMedicine are not only scientifically sound, but also discussed and validated by core players and stakeholder groups to maximize update and impact.
2 Glossary

Note: In response to the recommendation of the first annual technical review, the glossary has been moved to the openMedicine portal. In addition, synergies with glossary efforts of SDOs have been pursued.
3 Introduction and Background

3.1 The openMedicine context

openMedicine contributes towards equivocal medicinal product identification. With its final results, the recommendations and the roadmap, it advances the principles of the digital single market in ways that European citizens can benefit. It also facilitates actions that can help advance our awareness of the issues, gaps and barriers, and identify initiatives that can realize high quality cross-border services.

The safety and continuity of treatment for all patients, be it in their home country or when receiving health services across the borders of member states, regions, and organizations was at the core of the efforts of openMedicine. The problem of univocal identification of medicinal products throughout their lifecycle can benefit every aspect of medication use.

Consider a pharmacist dispensing a prescription issued in another country. First of all, s/he must be able to univocally identify the medicinal product prescribed by an authorized person in another country and perhaps also in another language, and match it with the identical product available for dispensation locally.

In case the exact medicinal product prescribed is not available, then for safe dispensation, the pharmacist faces the challenge of selecting among the available medicinal products the one that according to the local regulations can be safely dispensed in place of the prescribed medicinal product.

The approach advocated by openMedicine comprises the identification, validation, and channelling into practical deployment of a common data model, a common vocabulary, supplemented with recommended policies and processes. A roadmap for post-project actions and implementations, along with collaboration events in the EU/US MoU context will support the efforts of openMedicine.

Combining aspects of a support and coordination action, openMedicine has been gathering, collating, and analyzing core information and data, including information on the status quo in global standards, as well as the rules and procedures in effect across member states on prescription and substitution. For these efforts to be successful, openMedicine has actively pursued community building, cooperation and translation of its results across communities and affected stakeholders.

Thus, the communication plan of openMedicine explicitly addressed different stakeholders i.e. SDOs, regulatory agencies, competence authorities in MS, patient advocacy groups, health professionals, USA counterparts, software providers, drug databases, etc., appealing to their needs and values. In all cases, the impact is expressed through concrete examples:

- Patients in any MS can obtain seamlessly at least a medicinal product equivalent to the prescribed MP in any other MS.
- Clinicians can review a foreign referral letter, a patient record or patient summary, and understand fully the medicinal product information contained.
- Pharmacists can pinpoint univocally identify the prescribed medicinal product, and in case it is not available, what is the most appropriate medicinal product in the current member state that fulfils the therapeutic requirements of the MP prescribed abroad.

To facilitate and support all of this, openMedicine engaged in:

- Direct communication with core stakeholder groups: meetings, workshops, expert council.
- Dissemination resources and multipliers: e.g. website, project flyer, webinars, etc. Also social media, Twitter feed, podcasts, YouTube video.
- Modalities to feed outputs into the policy making process and in particular the European and national health policy development, decision making and implementation processes.
3.2 Scope & objectives of WP 7, January – December 2016

At the core of the openMedicine efforts is the adoption of the ISO/IDMP family of standards. Development and adoption of standards, like any consensus-driven process, is time consuming. Technical standards and specifications frequently focus more on technology and less on getting buy-in from stakeholders.

The objectives of WP7 were to:
- Raise awareness about the openMedicine project during the lifetime of the project addressing all actors in the lifecycle of an MP;
- Facilitate cooperation among key players, stakeholders and SDOs;
- Encourage adoption of the recommendations of the roadmap.

Specifically, for the period Jan – Dec 2016, the aims have been to:
- engage the expert council in the meetings of January, June and November 2016;
- disseminate the results of the key deliverables as they are released;
- liaise with activities of the European Medicines Agency and stakeholder networks and initiatives at the European level including the CEF eHealth Digital Services Infrastructure (eHDSI).
- collaborate with FDA and US networks in the context of the MoU.

3.3 Update of the Communication Plan

The updated communication plan maintained the same basic components, each of which is described in a section of D7.1 (Communication Plan): stakeholder registry, dissemination channels, press kit, and indicators of success.

Updates refer to specific activities relating to the concrete deliverables, activities, and results expected in 2nd year of the project.

Following the first annual review, the communication plan was amended to include government agencies and eHealth agencies connecting them with the relevant regulatory agencies and health ministries to discuss identification of medicinal products in cross-border prescriptions.
4 Updated Communication Strategy

4.1 Overview and refinement

The following figure taken from D7.1 presents an overview of the openMedicine communication strategy.

Further to refinements presented in D7.2 with respect to figure 1 below, there have been refinements in communication and liaison activities with respect to:

(a) collaboration with the other PHC34 projects (i.e. eStandards, AssessCT, ValueHealth);
(b) appointment of liaison with JAseHN;
(c) focused dissemination activities with respect to deliverables
(d) more regional and national dissemination meetings and exchange workshops, with a particular focus on Competent Authorities.

Figure 1: Operational dissemination approach (D7.1)

There has been one change resulting in expansion in goals and objectives, actors, structures, processes, and coverage of the communication strategy. Following the recommendation of the reviewers, we refocused the target audience, dissemination items, and channels to member state representatives, specifically their competent authorities.

In dedicated workshops we listened to challenges encountered, gaps perceived, issues noted, and compatibility with national plans. Consistently our efforts were to improve our concrete understanding of challenges at the national and cross-border level, advance awareness of the issues surrounding cross-border ePrescription, and the importance of the European Medicines database.

Working closely with EMA, we have tried to bring closer the eHealth agencies, regulatory (medicines) agencies and political representatives of member states to the issues of univocal identification of medicinal products in cross-border healthcare and other contexts. In workshops dedicated to specific countries or group of countries, we have presented the EMA/FDA roadmap, the draft recommendations developed by openMedicine, and asked how it resonates with national plans. There were 8 workshops, 5 of which were organized in close cooperation with the regulatory and eHealth authorities. Figure 2 shows the revised
communication strategy, where the final conference has been replaced with multiple workshops.

| Conference Workshops, Papers, Posters, and Presentations | Member States
| Workshops |
| Publishable executive summaries from key deliverables | Expert Council |
| Press kit | Participation in SDO activities, Newsletter articles, blogs, etc. |

**Figure 2: Communication channels / modalities in openMedicine remain the same (source: D7.1)**

### 4.2 Evaluation

The openMedicine communication strategy was reassessed regularly. We have gone beyond the “European Commission communication policy requirements”. The impact of the project is tangible, as topics related to it appear in future work programmes. The European Commission recommendations noted in the table below offered important guidance.

**Table 1: European Commission Recommendations on Communication: status**

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| **Within 6 weeks after start of the project or as soon as possible** | 1. **DONE**: website which should at least contain
   - an EU logo of minimum 1 cm with the text "(Co-)funded by the European Union"
   - under this logo you can put a link to our website: http://ec.europa.eu/digital-agenda/en/digital-life/health (sent to Carolien.Nijenhuis@ec.europa.eu)
   - **DONE**: journalistic description of the project
     - understandable for the public meant for EC web pages/ brochures, project website (sent it to Carolien.Nijenhuis@ec.europa.eu)
   - **DONE**: Twitter account
     - other social media is welcome (facebook page, LinkedIn, YouTube) (sent accounts to Carolien.Nijenhuis@ec.europa.eu)
  2. **DONE**: newsworthy story - a news item/press release announcing the project to be sent to Carolien.Nijenhuis@ec.europa.eu; follow @EU_eHealth on twitter
  3. **DONE**: subscribe to the newsletter eHealth in Focus for the latest news of other projects, policy & events.
| **One year to 6 months before the end of the project** | 1. **DONE**: a press release and an updated website with news about the results;
  2. **DONE**: a blog post of the project leader with personal experiences;
  3. Not feasible: if possible a video to make the project understandable for the public;
  4. Done: if possible pictures of users working with the project technology.
  5. **Done**: Inform Carolien.Nijenhuis@ec.europa.eu of any press release, article in the media!
| **Before, during or after the project** | 1. **DONE**: a press release and an updated website with news about the results;
  2. **DONE**: a blog post of the project leader with personal experiences;
  3. Not feasible: if possible a video to make the project understandable for the public;
  4. Done: if possible pictures of users working with the project technology.
  5. **Done**: Inform Carolien.Nijenhuis@ec.europa.eu of any press release, article in the media!
The primary communication objects are project results as reflected in the key deliverables of the project. The communication plan (D7.1) noted several ways that project results can be communicated for effective dissemination. At the end of the second year, as the final deliverables are released, the results were presented in some of the ways presented in the communication plan as noted below:

- Leaflet (YES)
- Brochure (NO)
- Newsletter (YES)
- Press Release (YES)
- News/Magazine (YES)
- Website-Entry (YES)
- Social Network (YES)
- Video (NO)
- Interview (In part as statements)
- Journal Article (YES)
- Book Chapter (NO)
- Conference Paper (YES)
- Other publication – Poster (YES)

4.3 Resources

Resource use in this last period exceeded budget provisions due to the increased requirements of multiple workshops and invited conference sessions. Budget shifts across partners allowed for this unplanned expenditure.
5 Stakeholder Communication & Liaison

5.1 Key stakeholders

The key player and stakeholder groups identified early as part of the medicinal product lifecycle in the communication plan of the project were the target of communication and liaison activities:

- **Market authorization holders – Pharma industry:** communication and liaison through EMA committees and workshops organized by the project. Feedback was provided to the work of the roadmap.

- **Manufacturers in the medicinal product lifecycle:** Associations of pharmaceuticals were invited to the national openMedicine workshops. Strong participation took place in the workshops of Portugal, Spain, and Greece.

- **National regulators:** The openMedicine workshop facilitated direct contact with regulators in several European countries. Representatives of the regulatory agencies in Norway, Sweden, Finland, and Estonia were present in the workshop organized by the Swedish eHealth agency on Dec 20, 2016. The Portuguese drug regulator attended the workshop in Lisbon. Regulators from Moldova, Croatia and Greece attended the workshop in Athens. Regulators from Italy attended the workshop in Genoa. Several other regulators attended the Advisory workshops. The IDMP task force set up by EMA and direct contact with consortium members offered opportunities for liaison, consultation and communication of project results.

- **Commercial/dedicated information brokers:** The openMedicine continued its engagement with Information Brokers and Medical Product dictionary vendors such as First Databank in the US, Z-Index in the Netherlands and Vidal in several countries in Europe and across the globe, during the second year of the project. Information brokers have been represented by VIDAL and Phast in the Expert Council meeting in London and the meeting with FDA in Washington.

- **Patients and their family:** Patient organizations were invited to participate in selected workshops. They are also engaged in related EMA workshops. However, more work is needed in this area to overcome a gap with follow-up projects.

- **Healthcare professionals - prescribers:** Healthcare professional associations were invited in all workshops. The invited section in the 3rd eCardiology and eHealth conference was addressed to health professionals. Health professionals actively participated in the national workshops of Athens Greece, Madrid Spain, Lisbon Portugal, and Stockholm Sweden. The draft openMedicine recommendations were shared with health professional associations at the European level through the eHealth Stakeholder Group.

- **Pharmacists - dispensers:** When pharmacists need to dispense a prescription from another member state, they may have to substitute the prescribed MP with one that is pharmacologically the same and locally available. Implementing IDMP standards will allow correct identification of the products. Using a central database (EMA) can permit a quick check for equivalents to the prescribed medicinal product in the member state of dispensation. Representatives of the Pharmaceutical Group of the European Union (PGEU), the voice of community pharmacists in Europe, took part in both European meetings of the expert council of openMedicine that took place in 2016. In fact, there has been a healthy debate on the letter of the recommendation pertaining to substitution. This showed that it is important to provide an operating model that meets the concerns of the regulators and other authorities. Besides that

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2. http://www.z-index.nl
however, close attention to needs and perception of health professionals is necessary for practical implementation.

- **Healthcare institutions and their management**: Health professionals acting on behalf of their institutions are responsible for dispensing medicinal products as well as issuing prescriptions. Thus, they are obvious stakeholders of better interoperability and safety when admitting or discharging patients from/to another country or health system. Communication to management of health institutions took place indirectly through events and conferences where the openMedicine solution and recommendations were presented as for example HIMSS Europe, MIE2016, and eCardiology and eHealth 2016.

- **Public health and pharmacovigilance bodies**: openMedicine has benefit these bodies by facilitating secondary use of data and engagement of patients and their families in data collection. This is the area where EMA is heavily involved through expert groups and dedicated meetings. Members of openMedicine served on these committees and regularly communicate the results of the project.

- **Healthcare insurance**: openMedicine results have been relevant to insurance companies as they manage medication lists for reimbursable or special products. For the country workshops (e.g. Athens, Stockholm) we invited the organizations that provide ePrescriptions services as IDIKA in Greece. In the workshops, we discussed how the results of openMedicine help them by allowing maintenance of such lists even across member states, to have broad overview of reimbursement programs and medication use. Closer cooperation may be useful in the future.

- **Health IT/eHealth system providers**: openMedicine results will help IT providers identify medicinal products correctly in the cross-border setting, and facilitate interoperability with sufficient information to ensure that medication lists are kept up-to-date in a consistent manner. openMedicine recommendations lead to prescriptions that are ready for cross-border dispensing. Finally, with openMedicine, synchronization and overview of medication treatments for cross-border patients is easy with a single patient medication overview, reconciling medication, and ensuring continuity of treatment across countries. During 2016, openMedicine engaged with health IT system providers in the country workshops but also in conference presentations and workshops.

- **National competent authorities**: National regulatory agencies have a lot to benefit from globally unique identifications for medicinal products as well as direct exchange of structured and semantically consistent information. openMedicine has regular communication with competent authorities in expert meetings and country workshops. In addition, Karl Stroetmann and Jos Devlies delivered presentations to the eHealth Network meeting of November 2016, as well as to meetings of the JAseHN action. The EMA Data board and other EMA committees and working groups provided venues for engagement and synergies. With the start of the eHealth Digital Services Infrastructure project under the Connecting Europe Facility, openMedicine discussed its recommendations and worked towards a change management proposal following the successful workshop in Stockholm.

- **Health professional organizations**: openMedicine results and recommendations need to be accepted and championed by health professional organizations for the change to happen. Thus, we reached out to Medical IT professionals, Pharmacists, Physicians, and Nurses. Conference venues, one-to-one meetings, as well as the eHealth Stakeholder Group of the European Commission (Meeting of October 2016) were used as opportunities for communication and liaison.

- **Advocacy groups (patients)**: Advocacy groups and disease focused patient organisations play a role the clinical side of research and treatment and can support the deployment of IDMP standard. Activities in this area were confined to contacts during conferences and workshops. Moving forward closer cooperation is called for.
5.2 Standards & profile developing organizations:

Standards developing organizations play an important role in directly engaging with the openMedicine project, liaising with relevant standardization projects and reaching out to a broader community. Relevant standards activities include various projects in HL7, ISO/TC215/WG6, GS1, and IHE. Moreover, the JIC of Global Standards Developing Organizations (SDO) health informatics standardization comprising CEN, ISO, HL7, CDISC, IHTSDO, GS1, IHE and DICOM supports the effort.

Members of the openMedicine consortium followed closely the activities of the SDOs, contributing to relevant work items, stimulating development of synergies with openMedicine, and discussing deliverables of openMedicine in their early form looking for comments, corrections, and elaborations. Specifically, the adopted approach was as follows: (a) Definition of discussions to be held (requirements, clarification, guidance, informative materials) from the openMedicine deliverables. (b) Proposing the items to the different working groups, resulting in a calendar for the expectable outcome.

The approach for alignment with SDOs took place on two elements:

- SDOs→openMedicine: Check that SDOs had (or not) guidance or standards relevant for openMedicine, detect, validate and align on any gaps.
- openMedicine→SDOs: Ensure feedback from openMedicine to the SDOs and dissemination across standards, not only on the use of each standard, but also on how other standards were influential to them. Some examples were the need to enhance IDMP awareness and coverage, and to reach a way to exchange product information that is consistent with IDMP.

Throughout the project, there was active engagement with SDOs, with regular participation in conference calls and face-to-face meetings. During the joint ISO/TC 215 and CEN/TC 251 meetings, WG6 organized the ‘IDMP Workshop’, which focused in particular on the IDMP standards and their implementation guidelines. The latter, which form the set of four Technical Specifications, are in the process of being finalized. Publication of the total five specifications are scheduled for end of 2017. The openMedicine project and its relationship with the IDMP standards was presented and discussed in the IDMP Workshop. Experts from around the world attending the venue were invited to participate, increasing the awareness and support for these standards and implementation efforts throughout the world.

5.3 Stakeholders in cross-border care

As noted in deliverable 7.1 and 7.2, key stakeholders in cross-border care are the European Commission, the EMA and the eHealth Network. openMedicine participated in the eHealthWeek 2016, the main event of the EU Dutch presidency held in cooperation with the European Commission DG Sante and DG Connect and HIMSS Europe.

Several committees and WGs of EMA are engaged in cross-border care and members of the openMedicine consortium were engaged in their activities, an engagement that will continue beyond the end of the project:

- **EU Data Board** is part of the EU Telematics action plan setting standards for EMA on how information will be captured.
- **EUNDB** is an advisory body comprising members representing MS and EMA. The programme agreed by the EU Telematics Management Board and Health of Medicines Agency to manage the policies, principles and quality that will ensure access to accurate and risk-free data and information proposing standards, accountabilities and responsibilities

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- **IDMP Task force** established in 2015 includes representatives of terminology organizations, 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 on agreed EU implementation principles.

The volunteer **eHealth Network** (eHN) of national health ministry representatives established under Article 14 of the EU Directive on Patients’ rights to cross-border healthcare. eHN plays a very important role in eHealth policy decisions of the European Union. Liaison activities to the eHN took place directly through members and indirectly through JAseHN. The project draft recommendations were presented to the JasEHN project for input. Furthermore, they were presented to the eHN in a more stable form in its November 2016 meeting.

### 5.4 Transatlantic and global stakeholders

The most prominent among the global stakeholders are the World Health Organization (WHO) which along with SNOMED_CT manages several terminologies. On the global level, there are also FDA, DIA, EFPIA, and ICH.

Through EMA, we fostered the connection to FDA in the Expert Council meetings. The highlight of communication and liaison activities was the EU/US workshop hosted in the premises of FDA in June 2016. The event was attended by a broad set of stakeholders in Europe, Canada and the United States.

### 5.5 Liaison to European projects

There are severable EU co-funded projects that offer important insights to openMedicine and where cooperation has a lot of value. The following project were active during the openMedicine duration: eStandards (www.estandards-project.eu), AssessCT (www.assessct.eu), VALUeHEALTH (www.valuehealth.eu), and JAseHN (www.jasehn.eu). After the Meetings on July 3 with the PHC34 projects and a followup hosted by JAseHN, liaisons were appointed from each project and JAseHN. Furthermore, a Yammer space was set up to share preliminary deliverables and other information of relevance.

The relation of ASSESS CT to openMedicine related to the codification of elements in medication list using SNOMED CT. In some countries, SNOMED CT is used to structure representations of medicinal products. The recommendations of ASSESSCT have been taken into account in openMedicine.

eStandards is synergetic to openMedicine as it aims to define a roadmap toward the collaborative development of standards. IDMP provides case study for the equivocal identification of medicinal products. The eStandards project is organizing a 2-day writing workshop for its draft roadmap in June 2016: Essential standards development, strategic options and policy instruments.

### 5.6 Other relevant work

Other relevant work in Europe related to:
- Falsified Medicines Directive (Directive 2011/62/EU);
- Connecting Europe Facility eHealth Digital Services Infrastructure (CEF eHealth DSI).

Liaison activities and communication of project results were carried out by all members of the openMedicine consortium.

A partial list of relevant and important events appears in section 6.5.
6 Dissemination Report for 2016

Several dissemination channels and communication modes ensured that the message of openMedicine reaches its stakeholders. Different channels were employed: Web site and social media, journals, newsletters, etc.

6.1 Indicators: Website and Broad Dissemination Efforts

The website of the openMedicine project is available since March 2015 in www.open-medicine.eu. The www.open-medicine.eu web site has been active since April 2015 and is regularly updated.

Specific indicators monitored over time for the website are:

- There have been 1833 unique visits, 5251 page views, and 817 document downloads in 2016 (01.01.2016-31.12.2016).
- Publications, events attended and presentations delivered: 4+ publications, about 20 presentations;
- Newsletters and blogposts (including articles supporting the objectives of openMedicine): 3 newsletter articles.
- Mentions of the project on Twitter and LinkedIn and elsewhere: > 50;

The first page of portal appears in the figure below.

![First page of the openMedicine portal](image)

Figure 3: First page of the openMedicine portal

The visit log of the portal appears in the figure below.
6.1.1 Twitter
The twitter handles for openMedicine are as @openmedicine_eu and @openmedicine_eu.
The number of items tweeted (>50) since the beginning of the project has been increasingly used during project events to post pictures and share key statements.

6.2 Scientific publications, presentations in conferences, tutorials, & newsletters
According to openMedicine performance indicators, we assess publications, conference papers and slides:

- paper on “Meeting the semantic challenge of the globally unique identification of medicinal products - the openMedicine approach” was presented at the 4th Global Telehealth Conference 2015 ‘Serving the underserved: Integrating technology and information for better health care’ in Toronto, ON, Canada, May 29-30, 2015
- presentation on “Medicinal products ID and substitution in cross-border healthcare settings” at the Joint EU Member States and stakeholder workshop on Patient

- At the Greek eHealth Forum 2016, Athens, Greece, October 25-26, 2016, a paper was presented on “The univocal identification of medicines – the European added value”
- Presentation at the 10th eHealth Network Meeting, European Commission and Member States, Brussels, Belgium, Nov. 21, 2016, openMedicine together with EMA presented results and opportunities for future actions on “openMedicine and cross border eHealth services – options for the univocal identification of medicinal products”
- Presentation “Gap analysis between Article 57(2) of EC Regulation and the epSOS eP” at the Member States authorities and Competence Centres Engagement Workshop;
- Presentation of Anna Gawronska-Blaszczyk: Presentation during Polish Telemedicine and e-Health Association Conference, Warsaw, September 2016;
- Presentation of Jonas Rennoch at ALPhA final conference: “openMedicine – A European approach to the identification of medicinal products in global contexts”;
- Presentation of Anna Gawronska-Blaszczyk: “I need a medicine while abroad..” during GS1 Healthcare Conference, Geneva, June 2016;
- William Goossen: openMedicine article in the HL7 NL newsletter;
- José Costa Teixeira: openMedicine – One big Step towards Safe Medication, HL7 Europe newsletter, HL7 Europe newsletter #6;
- Short progress reports in the CEN/TC 251 newsletters.
- Tutorial Presentation in the IDMP Workshop, ISO/TC 215 & CEN/TC 251 meetings, Amsterdam, May 2016;

6.3 Engagement with standards and profile organizations and associated WGs

Between January and December 2016, activities have focused on raising awareness on SDOs as in the openMedicine project to check gap in the ongoing work of standards and profiling organizations.

The openMedicine Project was mentioned in HL7 Calls as a project that addresses questions often asked to HL7 about identifying a medicinal product. In several discussions, openMedicine has been mentioned when discussing common use cases (cross-border dispensing) and challenges or solutions (e.g. using ATC and other classifications as a pivot for identifying products).

In the IHE Pharmacy face-to-face meeting in Chania, Greece, on June 18th, it was agreed that openMedicine is influential for the work item "Medicinal product catalogue" in IHE Pharmacy, and therefore it has been suggested to expect for openMedicine to raise some of the use cases and requirements, so that they can be considered also for the scope of IHE work.

In ISO/TC 215/WG6, OpenMedicine was mentioned and its input was considered during the finalization of EN-ISO 17523 – “Requirements for electronic prescription”. The standard is published in 2016.
The Technical Specification CEN-ISO 19293 – “Requirements for a Dispense Record of a medicinal product” – has also been influenced by the results of openMedicine. The project has taken into consideration the needs to identify a product upon dispensing, in cross-border scenarios. In HL7, the discussion to create standard mechanisms to share product information (so that the clinical data flows can be fully aligned with the regulatory data flows, which are covered by HL7 SPL) has started and has been agreed. As a consequence, the new FHIR® standard is accommodating some updates to enable such product information exchange.

Participation in SDO working groups and relevant activities was consistent and engaging. Selected meetings with SDO participation include:

- HL7 Pharmacy meetings in HL7 WGM January 2016 and October 2016
- General discussion on IDMP and HL7 standards SDOs→openMedicine;
  - Presentation on “catalog of medicinal products” openMedicine→SDOs;
  - PSSs for “catalog of items” and “medicinal product catalog entry”
- IHE Pharmacy meetings, 2015, 2016 – in Greece; Switzerland; Austria; Portugal
  - Description of IDMP impact and coordinating across ISO, HL7 and IHE
  - Strategic alignment to check use of IDMP in IHE ePrescriptions
- ISO/TC215 & CEN/TC251 meeting in Amsterdam, Netherlands, May 2016
  - Discussions on IDMP SDOs→openMedicine;
  - Joint WG meetings.
- ISO/TC215 & CEN/TC251 meeting in Lillehammer, Norway, November 2016
  - Presentation on openMedicine-related outcomes. Presentation available on: SDOs→openMedicine;
  - Joint WG meetings.
- Joint ISO/TC 215/WG6, HL7 & IHE Pharmacy experts meeting, May 2016, Paris, France
- CEN/TC 251 plenary meetings, June 2016, Brussels, Belgium
openMedicine – One big Step towards Safe Medication

The ongoing openMedicine project, funded by the European Commission, has the goal to provide guidance concerning the identification of medicinal products across Europe throughout their lifecycle, in a scalable and sustainable way to bridge local, European, Transatlantic, and global perspectives for large scale eHealth deployment.

Identifying medicinal products across borders is essential for continuity of care and pharmacovigilance. This identification must seamlessly cover the complete medicinal product lifecycle, including regulatory and patient care activities. However, such identification poses many challenges: How to identify a substance, or a formulation, or a branded name, while there are no common identifiers for all of these? What to do when brand names are different? Or when a brand name is used in different products in different countries? How to handle clusters, substitution, and prescribing and dispensing rules?

The correct, unambiguous identification of medicinal products is thus a complicated matter.

During 2015, the openMedicine project has provided insight into the subject of medicinal products identification, by providing clarity on the context and goals, by documenting and analysing the issues, and by selecting a candidate standards-enabled data set to support cross-border identification of medicinal products.

6.4 Organization of conference sessions and workshops

The consortium engages in several events, conferences and workshops:

- EFMI Special Topic Conference on April 19, 2016 in Paris: Smart Medications & the Internet of Things, José Costa Teixeira, and Catherine Chronaki (poster);
- EFMI Special Topic Conference on April 19, 2016 in Paris: eHealth Consumers at the age of hyper-personalization: Anne Moen, Morten Bruun-Rasmussen, Rita Mendes, Petter Hurlen, Catherine Chronaki (plenary workshop);
- Communication and liaison activities in the eHealth week 2016
- EU/US Workshop in FDA, June 21, 2016;
- Conference Workshop: Munich, Germany, August 2016, as part of the Medical Informatics Europe congress;
- Conference Session: Berlin, Germany, October 2016, as part of the eCardiology and eHealth congress with participation of local stakeholders; openMedicine session in the 3rd eCardiology and eHealth Congress;
  - Electronic medication prescription in clinical practice -- What do we need? Robert Vander Stichele;
  - Bridging the gap of ePharmacy, pharmacovigilance and mHealth: where do we stand? Kevin Horan, HPRA, Irish Regulatory Agency
An ID-Wallet for open medication management: use cases and enabling standards. Jos Devlies, EuroRec, Jose Teixeira HL7, Anna Gawronska-Blaszczyk, GS1;

Equivalence and Substitution of medicinal products across the European Union: Implication for cross-border services Isabel Lazaro/ Jose Simarro, AEMPS, Spanish Regulatory Agency.

6.5 EU OpenMedicine workshops with EU Member States

Several member state workshops were carried as a result of the recommendation of reviewers.

- Madrid, Spain, May 2016, hosted by the Spanish Drug Agency (AEMPS) with participation of Spanish and Portuguese stakeholders;
- Warsaw, Poland, October 2016, dissemination meeting with the Polish stakeholders;
- Genoa, Italy, June 2016, as part of the International Healthcare Interoperability Conference (IHIC2016) with participation of experts from Austria, Czech Republic, Germany, Netherlands, and the Italian Drug Agency; openMedicine workshop: “Does IDMP fit for the purpose of bridging Clinical Practice with Regulatory Oversight?“;
- Lisbon, Portugal, June 2016, as part of the Portuguese eHealth week with national stakeholders;
- Athens, Greece, October 2016; as part of the eHealth Forum with participation of Croatian, Moldova (observers) as well as local stakeholders;
- Stockholm, Sweden, November 2016; hosted in the Swedish eHealth Agency with participation from Norway, Sweden, Finland, and Estonia.

The agenda for each of these workshops appears in the appendix. Each meeting attracted roughly invited 20-25 experts. With every workshop, our understanding of the local conditions deepened. Each of the member states is different, but understanding of the importance of standards and IDMP in particular is limited. Much more extensive and systematic effort needs to be launched to inform national authorities about the importance of standards and IDMP in particular. Cooperation between drug agencies and national competence centers is limited. The drug agencies that were aware of the need to take action towards a national roadmap for the implementation of IDMP were minority.
### 6.6 Events Calendar

The following table presents more information on events linked to dissemination activities of openMedicine advancing its objectives and their estimated impact:

<table>
<thead>
<tr>
<th>Date from/To</th>
<th>Meeting, conference</th>
<th>Location</th>
<th>Organizer</th>
<th>Target Group, Attendees</th>
<th>Type/Title of Intervention</th>
<th>Impact*</th>
<th>Involvement of OpenMed Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 January 2016</td>
<td>HL7 WGM</td>
<td>Orlando, FL, USA</td>
<td>HL7</td>
<td>SDOs</td>
<td>Presentation of needs to share Product information. General alignment on IDMP</td>
<td>~10 experts</td>
<td>José Costa Teixeira, Giorgio Cangioli (HL7)</td>
</tr>
<tr>
<td>2 February 2016</td>
<td>IHE Pharmacy Meeting</td>
<td>Porto, Portugal</td>
<td>IHE</td>
<td>SDOs</td>
<td>Updated on IDMP</td>
<td>~10 experts</td>
<td>José Costa Teixeira (HL7)</td>
</tr>
<tr>
<td>3 March 2016</td>
<td>openMedicine Expert meeting</td>
<td>Brussels, Belgium</td>
<td>openMedicine</td>
<td>Experts</td>
<td>In-depth review of openMedicine technical and governance aspects</td>
<td>~20 experts, reps</td>
<td>All openMedicine members</td>
</tr>
<tr>
<td>4 April 2016</td>
<td>EFMI STC 2016 Paris</td>
<td>Paris, France</td>
<td>EFMI</td>
<td>Academia, Policy</td>
<td>openMedicine and the internet of things</td>
<td>~70</td>
<td>Academia, Medical Informatics</td>
</tr>
<tr>
<td>5 May 2016</td>
<td>IDMP Workshop at the beginning of Joint ISO/TC215 &amp; CEN/TC 251 WG meetings</td>
<td>Amsterdam, Netherlands</td>
<td>ISO/CEN</td>
<td>SDOs</td>
<td>IDMP and its impact</td>
<td>~50 experts, reps</td>
<td>Paolo Alcini (EMA), Vada Perkins (FDA), José Costa Teixeira (HL7), William Goossen, Christian Hay, Shirin Golyardi (CEN/NEN/ISO)</td>
</tr>
</tbody>
</table>

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5. **Keynote, presentation, poster, distribution of leaflet, short intervention**

6. **Estimated number of attendees (perhaps in steps like: <10, 10-49, 50 – 99, etc.)**
<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
<th>Location</th>
<th>Organization</th>
<th>Description</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2016</td>
<td>Spanish openMedicine Workshop</td>
<td>Madrid</td>
<td>AEMPS</td>
<td>MoH, Spain and Portugal; Stakeholders</td>
<td>Jos Devries, Karl Stroetmann, Catherine Chronaki, Kevin Horan, Jose Simarro</td>
</tr>
<tr>
<td>May 2016</td>
<td>Italian openMedicine Workshop</td>
<td>Genoa</td>
<td>IHIC Conference</td>
<td>Experts: Czech Republic, Greece, Italy (Drug Agency), Italian Regions Germany (Standards DIN); Austria National Program</td>
<td>Catherine Chronaki, Giorgio Cangioli</td>
</tr>
<tr>
<td>15 June, 2016</td>
<td>CEN/TC 251 plenary meeting</td>
<td>Brussels, Belgium</td>
<td>CEN/TC 251</td>
<td>Head of delegations</td>
<td>William Goossen, Christian Hay, Shirin Golyardi (CEN/NEN/ISO)</td>
</tr>
<tr>
<td>June 2016</td>
<td>FDA workshop</td>
<td>FDA, MD, US</td>
<td>FDA, EMA</td>
<td>Experts and governmental agencies (US, Canada, Europe), private companies</td>
<td>All openMedicine members</td>
</tr>
<tr>
<td>June 2016</td>
<td>IHE Pharmacy meeting</td>
<td>Vienna, Austria</td>
<td>IHE</td>
<td>SDOs</td>
<td>José Costa Teixeira (HL7)</td>
</tr>
<tr>
<td>August 2016</td>
<td>EFMI MIE Conference</td>
<td>Munich</td>
<td>MIE/GMDS</td>
<td>Academia, Broad Spectrum</td>
<td>Karl Stroettmann</td>
</tr>
<tr>
<td>September 2016</td>
<td>HL7 WGM</td>
<td>Baltimore, USA</td>
<td>HL7</td>
<td>SDOs</td>
<td>Projects for sharing Medicinal Product information</td>
</tr>
<tr>
<td>Date</td>
<td>Event Description</td>
<td>Location</td>
<td>Panels/Agencies</td>
<td>Activities</td>
<td>Participants</td>
</tr>
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<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>October 2016</td>
<td>South European workshop</td>
<td>Athens</td>
<td>eHealth Forum, Croatian Drug Agency Hellenic Drug Agency Moldovan</td>
<td>Review recommendation Align Greek roadmap Engage with IDMP implementation</td>
<td>Karl Stroettmann, Jos Devlies, Catherine Chronaki, Marcello Melgara</td>
</tr>
<tr>
<td>October 2016</td>
<td>eCardiology and eHealth</td>
<td>Berlin</td>
<td>Europa, Cardiologists and IT</td>
<td>Disseminate openMedicine; review progress</td>
<td>Karl Stroettmann, Jos Devlies, Catherine Chronaki</td>
</tr>
<tr>
<td>November 2016</td>
<td>openMedicine expert meeting</td>
<td>London, UK</td>
<td>EMA, Experts and governmental agencies (US, Canada, Europe), private companies</td>
<td>In-depth review and explanation of openMedicine technical and governance aspects, conclusions and deliverables</td>
<td>Karl Stroettmann, Jos Devlies, Catherine Chronaki, All openMedicine members</td>
</tr>
<tr>
<td>November 2016</td>
<td>Alignment with ePrescription Guidelines</td>
<td>London, UK, and online</td>
<td>EMA, Experts and governmental agencies (US, Canada, Europe), private companies</td>
<td>In-depth review and explanation of openMedicine technical and governance aspects, conclusions and deliverables</td>
<td>Karl Stroettmann, Jos Devlies, Catherine Chronaki, All openMedicine members</td>
</tr>
<tr>
<td>November 2016</td>
<td>IDMP Workshop at the beginning of Joint ISO/TC215 &amp; CEN/TC 251 WG meetings</td>
<td>Lillehammer, Norway</td>
<td>ISO/CEN SDOs, Experts and governmental agencies (US, Canada, Europe), private companies</td>
<td>Presentations on IDMP and its impact on openMedicine, and overall product mater data management in light of openMedicine</td>
<td>Paolo Alcini (EMA), Vada Perkins (FDA), José Costa Teixeira (HL7), William Goossen, Christian Hay, Shirin Golyardi (CEN/NEN/ISO)</td>
</tr>
<tr>
<td>November 2016</td>
<td>Central Europe</td>
<td>Warsaw</td>
<td>GS1, Polish eHealth Agency</td>
<td>Review draft recommendations Awareness in Poland</td>
<td>Anna Gawronska-Blaszczyk, Karl Stroettmann, Jos Devlies, et al</td>
</tr>
</tbody>
</table>
7 Press Kit

The openMedicine press kit includes the Fact Sheet, project presentation, and logos in high quality. These are available as part of openMedicine D 7.1. Updated information material is available via the openMedicine website.
Smart Medications & the Internet of Things

José COSTA TEIXEIRA and Catherine CHRONAKIS

*HL.7 Foundation, Brussels, Belgium

Keywords: Mobile Apps, Medication Systems, Patient-Centered Care, Barcodes

Introduction: In our digital society, where “smart things” become integrated and personalized, digital enhancements can increase safety of medicinal products and help avoid harm for patients. Accurate identification of medicinal products throughout their lifecycle, into prescription, dispensation, and compliance is essential. Wrong use of medication, or use of the wrong medication, can be very harmful. Integrating health information technology with IoT enables among others, individualized drug information, indications of drug-to-drug interaction, allergy alerts, tracking of medication use and effects in wellness and disease, and reporting of adverse events.

Methods: Areas where standards support effective use of medicines are explored. Standards are key to integration of the IoT with eHealth. Creating an ecosystem of ‘smart’ connected health apps and sensors to enhance the use of medication requires standards for semantic and functional interoperability, respecting security and privacy. Healthcare standards support safety and quality in the interaction between the physical medication and the digital world. In one example, standards (GS1 for barcodes and HL.7 for data capture and exchange) support medication identification across borders, and accessing drug databases to deliver personalized patient instructions and alerts. From the prescription, a pharmacist dispenses the medication and confirms it is the right medication using barcodes and accessing the medical history of the patient. The pharmacy uses an HL.7 FHIR ReSTful API (www.HL7.org/FHIR), to obtain the relevant product characteristics, considering the personal context of the patient: contraindications, allergies, interactions with other treatments, wellness data and habits. A “smart” pill box, can help patients and their doctors monitor adherence to the prescribed schedule. OpenMedicine (www.open-medicine.eu) provides a wallet or portfolio of identifiers to enable safe identification of medication throughout their lifecycle. Another case is chronic disease (diabetes) management, where patient monitoring is enhanced using integration standards between several “smart” objects - weight scales, activity monitors, insulin pumps, and medication. Standards-based integration enables a 360° view of the patient treatment. “Feeding” data from the digital world of the IoT to enable responsive treatment. Such dense integration is facilitated by the use of standards and exposes areas for secure trustworthy device and data sharing.

Conclusions: Proper identification of medication across applications and borders is necessary to ensure safety. The IoT provides a lot of data, but this information must be properly captured and managed safely, so that it does no harm and privacy rights are observed. Working at the integration of eHealth and IoT, standards should continue to provide guidance for connecting “smart” things and medication helping people navigate the complexity of interconnected health systems with safety and trust.

1 Corresponding Author

The following work was presented as a plenary panel

eHealth Consumers at the age of hyper-personalization

Anne MOEN¹,² Morten BRUUN-RASMUSSEN³, Rita MENDES⁴, Petter HURLEN⁴,
Catherine CHRONAKI⁴
¹Institute for health and society, University of Oslo, NORWAY
²MEDIQ, Odense, DENMARK
³SPMS - Shared Services for Ministry of Health, Lisbon, PORTUGAL
⁴Akershus University Hospital, Lørenskog, NORWAY
⁵HL7 International Foundation, Brussels, BELGIUM

Abstract. Where the Internet of Things meets healthcare we see a plethora of tools, gadgets, and apps that promise to improve life, health, and independence. However, eHealth consumers frequently find it hard to orient themselves in the unfolding digital reality dominated by fragmented information, data, and knowledge they don’t control. With hyper-personalization, careful selection and use of data provides for more personalized and targeted products, services, and content. For this workshop we are specifically focusing on challenges and opportunities of such hyper-personalization in view of varying eHealth literacy, lifestyle and health goals.

Keywords. Personalization, health data, eHealth literacy, Internet of Things, eHealth Consumers, mHealth

Introduction of the topic

It is well known that citizens employ robust, sophisticated, time relevant and sometimes idiosyncratic strategies to manage their health or keep track of their health information. Internet of Things comes with tools, services and apps that open up for novel and new opportunities for participation and engagement. These mHealth tools and apps also add to the already well-grown body of health related information. When meeting the healthcare system these opportunities are adding to an already fragmented information environment, complicating the eHealth consumer engagement, enactment and empowerment required for sound decision-making and self-care.

In the unfolding digital reality, the eHealth consumers blend general health information and personal health data they may collect by mHealth tools and wellness apps, or access to health record summaries from Medical Doctors, Nurses or other providers in the health service. Hyper-personalization can allow for careful selection and use of person specific data to achieve more targeted and relevant content, products, or services across vendors. However, there is a paucity of comprehensive or integrated support to select and personalize health information to engage meaningfully in recommended or requested health care activities.

¹ Corresponding Author.
Discussion about required skills, capacities or activities the eHealth consumers need to acquire to comprehend all available health information and identify appropriate activities is still in its infancy. The relevant roles and responsibility of the healthcare system is widely debated. More insight to and consensus about capacities, tools and health services that would allow eHealth consumers to engage with resources for their personal health in this unfolding digital reality is needed.

1. Aim of the discussion

For this workshop we are specifically focusing on challenges and opportunities of hyper-personalization, mindful of eHealth literacy and personal goals for life, health and independence, to develop capacities as empowered eHealth consumers that engage with resources to augment and maintain desired health and wellbeing. The overall goal is to discuss a selection of issues to better orient oneself in the fragmented and increasingly complex health information environments, where mHealth tools, opportunities by Internet of Things and traditional myHealthData resources blends. We will invite the audience to elaborate on questions like:

(a) What is eHealth literacy, and can the capacity of consumers to productively use mHealth tools be measured and potentially improved?
(b) Can access to myHealthData personalize the eHealth consumer’s activities?
(c) What strategies for hyper-personalization of health information and tools can effectively support the eHealth consumers to reach their health goals?
(d) What are the research questions that EFMI could address in future workshops at the European and international arenas?

2. Contribution from each speaker

Anne Moen, University of Oslo, Norway will introduce and moderate the workshop. Anne will present the concepts of eHealth literacy and hyper-personalization for eHealth consumers seeking care, preserving their dignity and independence. Then she will engage the audience with our online questionnaire prepared for the workshop.

Rita Mendes, SPMS, Portugal will review determinants and measures of eHealth literacy, relating them to health literacy and eSkills for patients, health providers, and communities. Rita will highlight the importance of socio-demographic profile, personal capacities, educational history, health literacy and computer skills, in creating an effective strategies to facilitate peer learning and allow eHealth consumers to survive the proliferation of mHealth tools and apps capturing, interpreting, and frequently exploiting their health data.

Catherine Chronaki, HL7 Foundation, Brussels will address eHealth literacy in the Internet of Things highlighting the challenges and opportunities coming with hyper-personalization. Catherine will present the important role of standards and interoperability in achieving transparency and allowing citizens to take control of their data and life. She will discuss safety, trust, security and privacy facets of empowerment and activation for eHealth consumers bombarded with suggestions and soon prescriptions of apps, products, and services.

Morten Brun-Rasmussen, Mediq, Denmark will point out some challenges of the non-systematic attention to eHealth literacy in the health system. Morten will address
ways that learning resources can be labeled to address the varied needs and capacities of eHealth consumers and measure the impact of these resources to the health system and the community.

Petter Horlem, Akershus University Hospital, Norway will introduce opportunities of initiatives like myHealthData in the Internet of Things. Petter will discuss the potential role of one’s data in the steering a lifelong eHealth experience and sustained engagement in empowering eHealth consumers to participate in health care decisions.

3. Expected results

The expected result of the workshop is to paint the landscape of engagement, eHealth literacy and hyper-personalization for eHealth consumers where the Internet of Things adds to the exponentially growing body of health related data. The discussion with the audience will contribute and inform research questions and activities that EFMI would address in future work at the European and international arenas.
OpenMedicine Day:
Implementing ISO standards for the univocal identification of medicinal products (IDMP) in Europe - The impact on EU member states/Spain

23rd May, 2016 (Monday)
Ministry of Health,
Paseo del Prado, 18-20, 28014 Madrid (to be confirmed)

Context
Enabling the delivery of safe cross-border healthcare is a policy priority of the European Union. The recently finished epSOS project (Smart Open Services for European Patients; 25 countries participated) developed cross-border services providing physicians access to basic medical data (patient summary, including medication record) when treating patients living temporarily abroad or travelling across Europe, and enabling patients to use a local community pharmacy abroad to obtain their prescription medicines (“ePrescription”). It turned out that dispensing a pharmaceutical prescription poses a specific challenge in this context - the delivery problem of ePrescription. This concerns the univocal identification of the medicinal product (MP), which is noted in a prescription from a given country, by a pharmacist dispensing it in another country.

A prescribed medicinal product can be identified by its attributes in different ways, at least partially depending on its status (authorised, registered, free available...), by its commercial name, package identifier, substance name, composition, and also by its grouping (pharmaceutical class, cluster...).

Dispensing the product may also depend on national regulatory aspects allowing different levels of substitution by the dispensing pharmacist.

openMedicine aims to reach a global consensus in order to describe unambiguously a medicinal and its pharmaceutical product(s). This will facilitate information exchange in a wide variety of applications, like pharmacovigilance, clinical record keeping, prescribing and decision support systems, registration and market authorisation of new products, pharmaceutical data bases. openMedicine closely cooperates with the European Medicines Agency (EMA), the US Federal Drug Agency (FDA), and standards development organisations. The work develops upon and extends the presently available ISO IDMP suite (11615/16, 11238-40) - Identification of medicinal products. An implementation of this suite is now on going by EMA and will be in the short term the reference MP database at EU level for regulatory purposes.

Objectives
It is against this background that openMedicine reaches out to EU member states, their national agencies and stakeholders to increase awareness of the globally ongoing activities in this domain and discuss further steps needed. A particular focus should be on whether the implementation of openMedicine results will be feasible, realistic and useful at the national level. The workshop will

- provide a concise overview of ongoing developments
- explore the implications and potential impacts of implementing global standards for the univocal identification of medicinal products (IDMP) at the national level,
- explore the expected added value for public health, clinical decision support, pharma-
ceoeconomics, pharmacovigilance
- identify challenges and costs of the pending roll-out in EU member states
- explore further steps and activities necessary to fully exploit the benefits foreseen.

**Meeting format**

The small expert meeting is intended as a translational hands-on, pragmatic workshop serv-
ing as a venue for interested national experts and health system stakeholders. It will provide
for a considered exchange of expectations, experience and opinions, and should also lead to
constructive proposals for further activities.

It is envisaged that considerable time will be allocated to intensive discussions. Presenta-
tions should facilitate such discussions, e.g. by identifying issues and challenges of particular
relevance and urgency in the overall context of the workshop.

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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| 14.30 | Welcome  
Brief introduction of participants                                                           | MoH all             |
| 14.40 | openMedicine – The business case for the univocal identification of medicines across Europe   | K. Stroetmann        |
| 14.50 | Regulatory framework and roadmap for national conformance to EU legislation  
- EU regulatory framework  
- structure and process of the information flowing from EMA to national drug agencies, to clinical and pharmacy dispensing systems.  
- status and road plan of the national authorities?  | JM Simarro          |
| 15.20 | Health policy vision for ePrescription/eMedication services  
- Vision of the Ministry of Health on digital health services for ePrescription/eMedication  
- Services and tools to be offered to regions, health agencies and the industry to  
  ✓ address patient safety and  
  ✓ fuel innovation and creativity in eHealth applications.  | Arturo Romero       |
| 15:50 | Global collaborative standards development: the case of IDMP  
- Standards Development organisations (SDOs) cooperation on IDMP – the experience, lessons learned  
- Involvement of international and national regulatory authorities  
- Integrating activities and processes across the standards life-cycle.  | C. Chronaki         |
| 16.00 | Coffee break                                                                               |

**May 23rd, 2016**

**Part 1: Setting the stage**

Chair: Jose Manuel Simarro
<table>
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<th>Time</th>
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| 16:20 | Spanish experience on ePrescription at regional, national, cross-border level  
- Status quo and perspective for ePrescription  
- challenges and problems of scaling up and sustaining deployment  
- epSOS/cross-border experience and needs  
- challenges or gaps in consistent use of value sets and codes  
| Luz Fidalgo |
| 16:35 | Portuguese experience on ePrescription at national & cross-border level  
- Status quo and plans for ePrescription  
- challenges and problems of scaling up and sustaining deployment, challenges or gaps in consistent use of value sets and codes  
| TBA |
|       | The openMedicine approach                                             |
| 16:50 | openMedicine approach: a brief demonstration illustrating the core concepts of openMedicine relevant for implementation at the national level  
| Isabel Lazaro |
| 17:05 | Stakeholder Round Table: Can ISO/IDMP bridge the crossborder and national levels?  
Participants from national level authorities, health professionals, industry and standards development organizations will critically review and explore  
- the expected added value for public health, clinical decision support, pharmacovigilance, pharmacies, and others  
- implementation challenges and costs of the pending roll-out  
- further steps (structures and processes) necessary to fully exploit the benefits foreseen  
| |
| 17:50 | Summary and closing  
Rapporteurs: J. Devlies & J. Simarro |
| 18:00 | End of the workshop |
Does IDMP fit for the purpose of bridging Clinical Practice with Regulatory Oversight?

Villa Giustiniani Camblaso, University of Genoa, June 14th 17:00-18:30

Scope
Learn from several stakeholders what are the current gaps and the bridging opportunities between the regulatory and the clinical worlds. Reflect on IDMP standards and openMedicine proposals.

openMEDICINE (www.open-medicine.eu) is a European Project funded by Horizon 2020 research and innovation programme aiming to advance unique identification of medicinal products and thereby patient safety in cross-border settings. It addresses drug identification and substitution challenges of safely dispensing prescriptions to people no matter where these prescriptions are issued, bridging national, European, transatlantic, and global borders. Main elements of the openMedicine approach are:

- common data models for identification and description of medicinal products, based on the ISO IDMP suite of standards
- a common vocabulary for unambiguous description of medicinal products
- rules to guarantee safe identification of medicinal products:
  - in prescriptions for cross-border dispensing
  - in case that substitution is required
  - in patient summaries as well as adverse event reporting for pharmacovigilance
- a global roadmap for post-project actions and implementation

The work of openMedicine aims to validate of the ISO IDMP suite of standards and their implementation guides for Identification of medicinal products in use cases extending beyond regulatory purposes in Europe and beyond. Meanwhile, each member state has a medicinal product database that is released regularly. openMedicine reaches out to EU member states, their health ministries, national agencies and stakeholders to raise awareness and discuss steps needed to roll out IDMP implementation and benefit from the database of medicinal products that the European Medicines Agency (EMA) is currently developing in collaboration with member states for 2018.

Multi-stakeholder experts from Regulatory agencies, HL7 affiliates, Standards leadership, academia, and national / regional healthcare organizations will present and discuss perceived and experienced gaps between the regulatory and the clinical purposes. Participants will propose and debate bridging opportunities suggesting how the openMedicine project recommendations on implementation of IDMP may help bridge these gaps.

The implications and potential impact for ePrescription/ eDispensation at the national and regional level of implementing IDMP at the European level, will be addressed. The expected added value for public health, clinical record keeping and decision support, pharmacovigilance, industry will be discussed. The opportunities, challenges, and costs of the pending roll-out of IDMP components will be identified along with further steps and activities necessary to fully engage HL7 Affiliates in the process of realizing the benefits of IDMP rollout in a coherent and consistent way across Europe.
Agenda

Introduction / Set up the scene
The aim is to introduce the workshop scope, objectives, and agenda, and present background on the openMedicine project. The role and engagement of the audience will also be clarified.
Speaker: Giorgio Cangioni

The regulatory vision
The scope is to provide the regulatory perspective, form the National and - possibly - from the European point of view, including the IDMP implementation roadmaps.
Speaker: Giovanni Ferretti, AIFA.

The SDO vision
The scope of this session is to provide the SDO perspective. Ed will provide the view of a standard development organization (HL7) that covers both the domains with its standards and whose standards (Common Product Models, SPL, etc) will be likely used for the implementation of IDMP.
Speaker: Ed Hammond, Chair Emeritus, HL7 International

How IDMP can bridge the clinical with regulatory worlds in Healthcare Delivery: national/regional perspectives and openMedicine proposals (Panel)
Jos Devlies will introduce the proposed draft recommendations of openMedicine. Then, the panelists will provide an overview of the current and future state from a national/regional perspective reflecting on the openMedicine recommendations and the role of HL7 affiliates. In view of these proposals, the panelists will address the state of play with drug lists in their country, the underlying processes and added-value services available. They will reflect on supporting EMA requirements and relevant standards for adverse drug reporting and pharmacovigilance.
Moderators: Jos Devlies, openMedicine Roadmap, Custodis, Catherine Chronaki, HL7 Foundation
Panelists:
- Germany: Christof Gessner, Gematik, Immediate past Chair HL7 Germany
- Netherlands: Bert Kabbas, D&A medical group NV, Chair HL7 the Netherlands
- Austria: Stefan Sabutsch, tLGA, Chair HL7 Austria
- Czech Republic: Libor Seidl, MoH, Chair HL7 Czech Republic
- Italy: Stefano Dalmiani, FTGM CNR / Regione Toscana

Wrap Up
Catherine Chronaki
Annex 5: openMedicine Workshop- Lisbon, Portugal, June 2016: questionnaire

openMEDiCine (www.open-medicine.eu) is a European Project funded by Horizon 2020 research and innovation programme aiming to advance unique identification of medicinal products and thereby patient safety in cross-border settings. It addresses drug identification and substitution challenges of safely dispensing prescriptions to people no matter where these prescriptions are issued, bridging national, European, transatlantic, and global borders. Main elements of the openMedicine approach are:

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Tell us what you think...
(1 is low and 5 is high)

Please add your Name and email to inform you of results
ePrescription

Description (optional)

ePrescribing should functionally integrate the PhPID in the prescription document.

1 2 3 4 5
low high

ePrescribing should be able to lookup, retrieve, and integrate the PhPID to the prescription document transparently from...

- national / regional service
- european service
- Other...

Drug databases should make the PhPID available at the point of prescription.

1 2 3 4 5
low high

Drug databases should make other ISO/IDMP identifiers besides PhPID, available to the prescribing system (e.g. SUBID, MPID, PCID)

1 2 3 4 5
low high
eDispensation

Description (optional)

eDispensation should functionally integrate the PhPID in the dispensation document.

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eDispensation should functionally integrate the Package ID in the dispensation document.

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</table>
Electronic Health Records and Patient Summary

EHR applications should enable storage of the PhPID as part of the medication summary

Patient summary should include the PhPID in the medication summary.

Patient summary should use the product ID in the medication summary.

Patient summary should use the MPID to identify a medicinal product in the medication summary
Patient summary specification includes the medication summary. Should it also include the prescription history?

- YES
- NO
- Other.

Please add your own recommendations

Long answer text
OpenMedicine Day:
Implementing ISO standards for the univocal identification of medicinal products (IDMP) in Europe

The impact on EU member states: South - Eastern Europe

25th October, 2016
Athens Megaron, Greece

Context

Enabling the delivery of safe cross-border healthcare is a policy priority of the European Union. The epSOS project (Smart Open Services for European Patients; 25 countries participated) developed cross-border services providing physicians access to basic medical data (patient summary, including medication record) when treating patients living temporarily abroad or travelling across Europe, and enabling patients to use a local community pharmacy abroad to obtain their prescription medicines (“ePrescription”). It turned out that dispensing a pharmaceutical prescription poses a specific challenge in this context - the “delivery” problem of ePrescription. This concerns the univocal identification of the medicinal product (MP), which is noted in a prescription from a given country, by a pharmacist dispensing it in another country.

A prescribed medicinal product can be identified by its attributes in different ways, at least partially depending on its status (authorised, registered, free available, etc.), by its commercial name, package identifier, substance name, composition, and also by its grouping (pharmaceutical class, cluster,...).

Dispensing the product may also depend on national regulatory aspects allowing different levels of substitution by the dispensing pharmacist.

openMedicine aims to reach a global consensus in order to identify unambiguously and to describe a medicine in its different presentation forms. This will facilitate information exchange in a wide variety of applications, like pharmacovigilance, clinical record keeping, prescribing, dispensation, and decision support systems, registration and market authorisation of new products, pharmaceutical data bases. openMedicine closely cooperates with the European Medicines Agency (EMA), the US Federal Drug Agency (FDA), and standards development organisations. The work develops upon and extends the presently available ISO IDMP suite (11615/16, 11238-40) - Identification of medicinal products. An implementation of this suite is now on going by EMA and will be in the short term the reference MP database at EU level for regulatory purposes.

Objectives

It is against this background that openMedicine reaches out to EU member states, their national agencies and stakeholders to increase awareness of the globally ongoing activities in the domain of medicinal product identification and discuss further steps needed. A particular focus should be on whether the implementation of openMedicine results will be feasible, realistic and useful at the national level. The workshop will

- provide a concise overview of ongoing developments
- explore the implications and potential impacts of implementing global standards for the univocal identification of medicinal products (IDMP) at the national level
- explore the expected added value for medicinal care, public health, clinical decision support, pharmacoeconomics, pharmacovigilance
- identify challenges and costs of the pending roll-out in EU member states
- explore further steps and activities necessary to fully exploit the benefits foreseen.
Meeting format

This expert meeting is intended as a translational hands-on, pragmatic workshop serving as a venue for interested national experts and health system stakeholders in South Eastern Europe. It will provide for a considered exchange of expectations, experience and opinions, and should also lead to constructive proposals for further activities.

Considerable time will be allocated to intensive discussions. Presentations should facilitate such discussions, e.g. by identifying issues and challenges of particular relevance and urgency in the overall context of the workshop.

<table>
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<th>October 25th, 2016</th>
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<tr>
<td><strong>Part 1: Setting the stage</strong></td>
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<tr>
<td><strong>Chairs: Karl Stroetmann &amp; Catherine Chronaki</strong></td>
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<td><strong>11:00</strong></td>
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| | - Services and tools for health agencies and industry to:
| | ✓ Enable implementation |
| | ✓ Address patient safety |
| | ✓ Fuel innovation and creativity. | Greek National Organization for Medicines (TBA) |

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<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>11:15</td>
<td>Identification of medicines in ePrescription/eMedication services: Expectations in moving towards digital health services</td>
<td>Tassos Tagaris, IDIA (GR)</td>
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<tr>
<td>11:30-12:00</td>
<td>Coffee Break</td>
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<tr>
<td>12:00</td>
<td><strong>Formulating a transition plan</strong> <em>(Reporters: Jos Devlies, Stephan Schug, Alex Bedes)</em></td>
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<tr>
<td>12:10</td>
<td><strong>Industry and Professional View Points (Panel)</strong></td>
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<td>Transition plan for ISO/IDMP and a EU-wide Drug Database</td>
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<tr>
<td></td>
<td>- What does it take for safe and effective cross-border prescriptions in Europe to happen?</td>
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<td></td>
<td>- What are the costs, challenges, and opportunities of ISO/IDMP adoption in cross-border eHealth?</td>
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<td>- Are health professionals, pharmacies, and the industry ready for the change?</td>
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<td>- What is necessary to health professionals, Pharmacies, and the industry to smoothly adapt?</td>
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<td>- What should openMedicine recommend as part of the transition plan towards ISO/IDMP adoption?</td>
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<td>Input from Pharmacies, Pharmaceutical companies, IT companies, Drug dictionary and additive value services, Electronic Health Record System vendors, Health Professionals</td>
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<td>I. Tsinas, Pharmacist</td>
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<td>E. Fragoalisis, General Practitioner, GR</td>
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<td>G. Nikolaidis, GR</td>
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<td>N. Karanasios, GR</td>
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<td>S. Tsiasos - Tsitaras, Pharmacist, GR</td>
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<td>12:40</td>
<td><strong>Stakeholder Foresight Round Table:</strong></td>
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<td>Bridging Identification Gaps the life cycle of medicines</td>
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<td>- What is the expected added value for clinical care, public health, clinical decision support, pharmacovigilance, pharmacoeconomics of an EU-wide drug database?</td>
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<td>- Can ISO/IDMP and SPOK help create the necessary bridge and be a source of digital health innovation? how? What are the prerequisites?</td>
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<td>- How can Stenaards organisations support and sustain the efforts of EMA and the member states?</td>
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<td>- How can competence centers and academia support the efforts of EMA?</td>
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<td>- What should openMedicine recommend to support digital health innovation?</td>
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<td>Input from research projects and innovative initiatives</td>
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<td>Ch. Lionis, U of Crete</td>
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<td>M. Tsiknakis, FORTH</td>
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<td>D. Koutsouris, NTUA</td>
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<td>G. Fangelos, AUTH</td>
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<td>E. Petelis, U of Crete</td>
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<td>13:10</td>
<td><strong>Summary and closing</strong></td>
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<td>13:15</td>
<td><strong>End of the workshop</strong></td>
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*Attendance by invitation only.*
OpenMedicine Day:
Implementing ISO standards for the univocal identification of medicinal products (IDMP) in Europe - The impact on EU member states – Central Europe
5th October, 2016
Warsaw Poland

Context
Enabling the delivery of safe cross-border healthcare is a policy priority of the European Union. The recently finished eSOS project (Smart Open Services for European Patients; 25 countries participated) developed cross-border services providing physicians access to basic medical data (patient summary, including medication record) when treating patients living temporarily abroad or travelling across Europe, and enabling patients to use a local community pharmacy abroad to obtain their prescription medicines ("ePrescription"). It turned out that dispensing a pharmaceutical prescription poses a specific challenge in this context - the “delivery” problem of ePrescription. This concerns the univocal identification of the medicinal product (MP), which is noted in a prescription from a given country, by a pharmacist dispensing it in another country.

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identify challenges and costs of the pending roll-out in EU member states
explore further steps and activities necessary to fully exploit the benefits foreseen.

Meeting format
This expert meeting is intended as a translational hands-on, pragmatic workshop serving as a venue for interested national experts and health system stakeholders in Poland and surrounding Member States. It will provide for a considered exchange of expectations, experience and opinions, and should also lead to constructive proposals for further activities.

It is envisaged that considerable time will be allocated to intensive discussions. Presentations should facilitate such discussions, e.g. by identifying issues and challenges of particular relevance and urgency in the overall context of the workshop.

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<th>October 5th, 2016</th>
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<tr>
<td>Chair: Karl Stroetmann, Jos Devlies</td>
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<tr>
<td>9:30</td>
<td>Welcome</td>
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<td>Brief introduction of participants</td>
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<td>9:45</td>
<td>openMedicine – The business case for the univocal identification of medicines across Europe</td>
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<td>10:00</td>
<td>Regulatory framework and roadmap for national conformance to EU legislation</td>
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<td>• structure and process of the information flowing from EMA to national drug agencies, to clinical and pharmacy dispensing systems.</td>
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<td>• status and road plan of the national authorities?</td>
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<td>Implementation of e-health services – national perspective</td>
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<td>10:15</td>
<td>Presentation of the programme: &quot;Paperless, cashless Poland&quot;</td>
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<tr>
<td>10:55</td>
<td>Presentation of e-prescription service in Poland</td>
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<tr>
<td>11:25</td>
<td>Presentation of an integrated system aimed at monitoring the flow of medicinal products in Poland</td>
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<td>Industry and Professional View Points</td>
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<td>11:55</td>
<td>• Input from pharmacies</td>
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<td>• Input from pharmaceutical companies</td>
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<td>• Input from IT companies</td>
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<td>• Input for drug dictionaries</td>
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<td>• Input from Electronic Health Record System vendors</td>
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<td>12:15</td>
<td>Coffee break</td>
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<td>The OpenMedicine concept</td>
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<tr>
<td>12:45</td>
<td><strong>openMedicine approach</strong>: a brief demonstration illustrating the core</td>
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<td>concepts of openMedicine relevant for implementation at the national level</td>
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<td>13:15</td>
<td><strong>Practical approach</strong>: a brief demonstration of the OpenMedicine practical</td>
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<td>13:45</td>
<td><strong>Stakeholder Round Table</strong>: Can ISO/IDMP bridge the cross-border and national</td>
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<td>levels?</td>
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<td>14:15</td>
<td><strong>Summary and closing</strong></td>
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<td>14:30</td>
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OpenMedicine Workshop

Implementing ISO standards for the univocal identification of medicinal products (IDMP) in Europe

*The impact on Sweden and Scandinavia*

20th December, 2016

Swedish eHealth Agency, Sankt Eriksgatan 117, 113 43 Stockholm

**Context**

Enabling the delivery of safe cross-border healthcare is a policy priority of the European Union. The epSOS project (Smart Open Services for European Patients; 25 countries participated) developed cross-border services providing physicians access to basic medical data (patient summary, including medication record) when treating patients living temporarily abroad or travelling across Europe, and enabling patients to use a local community pharmacy abroad to obtain their prescription medicines (“ePrescription”). It turned out that dispensing a pharmaceutical prescription poses a specific challenge in this context - the “delivery” problem of ePrescription. This concerns the univocal identification of the medicinal product (MP), which is noted in a prescription from a given country, by a pharmacist dispensing it in another country.

A prescribed medicinal product can be identified by its attributes in different ways, at least partially depending on its status (authorised, registered, free available, etc.), by its commercial name, package identifier, substance name, composition, and also by its grouping (pharmaceutical class, cluster, ...). Dispensing the product may also depend on national regulatory aspects allowing different levels of substitution by the dispensing pharmacist.

openMedicine aspires to health reach global consensus so as to identify and describe medicines unambiguously in their different presentation forms. This will facilitate information exchange in pharmacovigilance, clinical record keeping, prescribing, dispensation, and decision support systems, registration and market authorisation of new products, and archiving in pharmaceutical data bases.

openMedicine closely cooperates with the European Medicines Agency (EMA), the US Federal Drug Agency (FDA), and standards development organisations. The work develops upon and extends the presently available ISO IDMP suite (11615/16, 11238-40) - Identification of medicinal products. An implementation of this suite is now on going by EMA and will be from the end of 2019 the reference Medicinal Product database at EU level for regulatory purposes.

**Objectives**

openMedicine reaches out to EU member states, their national agencies and stakeholders to increase awareness of the globally ongoing activities in the domain of medicinal product identification and discuss further steps needed. Particular focus is on whether the implementation of openMedicine results will be feasible, realistic and useful at the national level, identifying potential challenges and costs. The workshop will:

- provide a concise overview of ongoing developments in medicinal product identification
- raise awareness on the impact of the pending IDMP roll-out in EU member states
- explore the implications and potential impacts of implementing global standards for the univocal identification of medicinal products (IDMP) at the national level
- explore the expected added value for medicinal care, public health, clinical decision support, pharmacoeconomics, and pharmacovigilance
- explore further steps and activities necessary to fully exploit the benefits foreseen.
**Meeting format**

This expert meeting is intended as a translational hands-on, pragmatic workshop serving as a venue for selected national experts and health system stakeholders in Sweden and Scandinavia.

Time will be allocated to intensive discussions on the future of medical product identification and the use of the EMA databases and services. A particular issue is the multiple ways of substance identification that hinders interoperability of clinical and regulatory services and data. Presentations aim to facilitate such discussions, e.g. by identifying issues and challenges of particular relevance and urgency in implementing the necessary changes.

The exchange of expectations, experience and opinions should help validate and refine the recommendations and roadmap of openMedicine proposing concrete steps forward to facilitate stepwise adoption.

### December 20, 2016

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<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>9:00</td>
<td>Welcome Swedish eHealth Agency Brief introduction of participants</td>
<td>All</td>
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<tr>
<td>9:10</td>
<td>The eHDSI: a European digital infrastructure for the cross-border exchange of health data.</td>
<td>Hans Andersson</td>
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<td>9:25</td>
<td>The European Regulatory Network: Implementation of ISO IDMP standards through Substance, Product, Organisation and Referential (SPOR)(^1) master data</td>
<td>Jeff Martin Swedish Medical Products Agency</td>
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<td>10:00</td>
<td>openMedicine – The business case for medication management across Europe</td>
<td>K Stroetmann, Empirica</td>
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<td>10:30</td>
<td>Coffee Break</td>
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### Impact of IDMP and openMedicine

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<th>Time</th>
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<tr>
<td>10:45</td>
<td>openMedicine recommendations, roadmap &amp; consequences</td>
<td>Jes Devlies, Custodix</td>
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<td>11:15</td>
<td>The impact of openMedicine findings for standardization</td>
<td>Giorgio Cangioli, HL7</td>
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<td>11:30</td>
<td>openMedicine proof of concept: brief demonstration of openMedicine concepts pertinent to national implementations</td>
<td>Catherine Chronaki, HL7</td>
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<td>11:45</td>
<td>Roundtable viewpoints on eMedication in Healthcare delivery: national and European perspectives</td>
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<td>• Introduction: Nurmi Harri, TTHL</td>
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<td>• Which service will be affected? E-prescription, Patient Summary, decision support systems and so on.</td>
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<td>• What are the implementation challenges and costs of adopting these new EMA services for member states?</td>
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<td>• Can these services scale globally?</td>
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<td>12:30</td>
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| 13:00 | Formulating a transition plan             | **Roundtable viewpoints on transition plan for ISO/IDMP and a EU-wide Drug Database**  
• What are the key issues for the Nordic countries?  
• What is the experience from other countries?  
• How will this new identification approach affect the Swedish e-Prescription ecosystem?  
• What does it take for safe and effective cross-border prescriptions in Europe to happen?  
• What are the costs, challenges, and opportunities of ISO/IDMP adoption in cross-border eHealth?  
• Are health professionals, pharmacies, and the industry ready for the change?  
• What is necessary to health professionals, Pharmacies, and the Industry to smoothly adopt?  
• What should openMedicine recommend as part of the transition plan towards ISO/IDMP adoption? |
| 14:45 | Coffee Break                              |                                                                                                                                             |
| 15.00 | Roundtable viewpoints on bridging identification gaps on the life cycle of medicines | **All**  
• What is the expected added value for clinical care, public health, clinical decision support, pharmacovigilance, pharmacoeconomics of an EU-wide drug database?  
• Can ISO/IDMP and SPOR help create the necessary bridge and be a source of digital health innovation?  
• How? What are the prerequisites?  
• How can Standards organizations support and sustain the efforts of EMA and the member states?  
• How can competence centers and academia support the efforts of EMA?  
• What should openMedicine recommend to support digital health innovation? |
| 16:00 | Summary and closing                       | **Jos Devlie, CustodiX Catherine Chronaki, HL7**  
Next steps towards a broader implementation oriented discussion                                                                                     |
| 16:15 | End of the workshop                       |                                                                                                                                             |

*Attendance by invitation only.*