DELIVERABLE

Grant Agreement number: **643796**
Project Title: **openMedicine**

D7.2 1st Communication and Liaison Report

Version: 1.0
Status: Final

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**OpenMEDICINE** is a project funded by the **European Commission** in the context of **H2020**.
Revision history, status, abstract, keywords, statement of originality

Revision History

<table>
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<tr>
<th>Revision</th>
<th>Date</th>
<th>Author</th>
<th>Organisation</th>
<th>Description</th>
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<tbody>
<tr>
<td>0.1</td>
<td>Feb 22, 2016</td>
<td>Catherine Chronaki</td>
<td>HL7 Foundation</td>
<td>Final Draft – Including input received from co-authors</td>
</tr>
<tr>
<td>1.0</td>
<td>Feb 29, 2016</td>
<td>Catherine Chronaki</td>
<td>HL7 Foundation</td>
<td>Final</td>
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Date of delivery

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<tr>
<td>Status</td>
<td>final ✓ /draft</td>
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Abstract (for dissemination)
This document presents the 1st Communication and Liaison report of the openMedicine project. It covers the activities carried out in the period July 1, 2015 to Jan 31, 2016 and the events and activities planned for the 2nd year 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This deliverable contains original unpublished work except where clearly indicated otherwise.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 1st Communication and Liaison report aims to provide a report on the communication and liaison activities of openMedicine in months 7-13 of the project, and update the overall communication strategy and dissemination plan.

The objectives of the openMedicine Communication plan are 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) promote adoption of the project recommendations and roadmap.

The communication plan of the project centers around the following key message:

openMedicine addresses the medicine identification and substitution problems with a wallet of identifiers that bridges local, European, and global perspectives.

The openMedicine approach highlights that meaningful exchange and use (i.e. interoperability) of medicinal products (MPs) information across borders is as social good, an aspect of patient safety, driver of innovation and growth. Key elements of the communication plan are:

- 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, transatlantic, 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 project work
- Identify and approach influencers, enablers, policy makers, thought leaders and decision makers.

In accordance with the openMedicine communication plan the last six months we revisited the:

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

The effectiveness of the communication plan has been assessed and adjusted in consultation with the experts involved in project work. According to the specific indicators:

- Visits to the web site: 844; downloads 309; page views 2569
- Publications, Events attended and presentations delivered:
  - Two meetings of the executive council (June 2015 (EMA, London) and January 2016 (CEN, Brussels)
D7.2 Communication & Liaison Report

- Workshops: 1 (3 planned)
  - Medinfo 2015, Sao Paolo, Brazil
- Newsletters and blogposts (incl. articles in support of openMedicine): 3
- Mentions of the project on Twitter and LinkedIn:
- Meetings with SDOs, (national) agencies, politicians etc. (highlights)
  - HL7 WGM, Atlanta October 2015
  - ISO/215 & CEN/TC251 Meeting Bern November 2015
  - ETSI IOT meeting, October 2015
  - PHC-34 & JAseHN meetings

Although the events attended were highly selective, dissemination efforts and communication will be much stronger in the 2nd year of the project, as the project reaches concrete results.

Specific events already planned for the next six months of the project are:

- Publications, Events attended and presentations delivered:
  - executive council (June 2016 (FDA, Bethesda, Dec 2016 (EMA, London))
  - EFMI Special Topic Conference 2016, Poster
- Workshops (planned):
  - IHIC2016, Genoa June 2016
  - EFMI STC2016 Paris, Apr 2016
- Newsletters and blogposts (incl. articles in support of openMedicine):
  - >5
- Meetings with SDOs, (national) agencies, politicians etc.
  - >4

The communication strategy and results will be assessed again in June 2016 and adjusted accordingly for the last 6 months of the project.
2 Glossary

**AI** - **Active Ingredient**: is the ingredient in a pharmaceutical drug or pesticide that is biologically active.

**AHIMA** - **American Health Information Management Association**: an association of health information management (HIM) professionals founded in 1928 to improve health record quality. Serving 52 affiliated US state associations and more than 101,000 health information professionals, it is recognized as the leading source of "HIM knowledge," a respected authority for rigorous professional education and training. AHIMA has played a leadership role in the effective management of health data and medical records needed to deliver quality healthcare to the public. AHIMA hosts the ISO TC215 secretariat. [http://www.ahima.org/](http://www.ahima.org/)

**ATC** – **Anatomical Therapeutic Chemical classification system** according to which drugs are classified into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. The classification system has five different levels. The drugs are divided into fourteen main groups (1st level), with one pharmacological/therapeutic subgroup (2nd level). The 3rd and 4th levels are chemical/pharmacological/therapeutic subgroups and the 5th level is the chemical substance. The 2nd, 3rd and 4th levels are often used to identify pharmacological subgroups when that is considered more appropriate than therapeutic or chemical subgroups.

**CHMP** - **Committee for Medicinal Products for Human Use** approves marketing authorizations in EMA

**CVs** - **Controlled Vocabularies**: ISO Controlled Vocabularies; controlled terminologies; Dictionaries; Lists: A list of structured and maintained information.

**DIA** – Organization established in 1964 as a neutral global membership association dedicated to improving communication and collaboration in drug development that organizes very successful and visible workshops and training events.

**DD** - **Drug Dictionary** is a description of the trade name, contents and manufacturer of the most frequently used drugs in most major drug markets in the world produced by the WHO monitoring center in Upsala.

**EFPIA** - **European Federation of Pharmaceutical Industries and Associations** brings together 33 European national pharmaceutical industry associations, as well as 40 leading companies undertaking research, development and the manufacture in Europe of medicinal products for human use.

**EDQM** - **European Directorate for the Quality of Medicines and Healthcare**: Manages the standard terms for Dosage Forms; Routes of Administration; Containers

**EudraVigilance** is the European Union Drug Regulating Authorities Pharmacovigilance – it’s the European Medicine Agency’s pharmacovigilance system, a system monitoring the post-authorisation safety of medicines through safety reports

**EMA** – **European Medicines Agency** is responsible for the centralized authorization procedure for human and veterinary medicines.

**EMRN** – **European Medicine Regulatory Network** is a partnership between the European Commission, the medicines regulatory authorities in the EU Member States and the European Economic Area (EEA), and EMA that works to ensure that patients in the EU have access to safe and efficacious medicines.

**EML** – **List of Essential medicines**, medicines that satisfy the priority health care needs of a population. They are selected with regard to disease prevalence, safety, efficacy, and comparative cost-effectiveness. They should be available at all times and at accessible prices. WHO publishes a model list of essential medicines that contains a core list and a complementary
Each country is encouraged to prepare their own lists taking into consideration local priorities.

**ePrescription**: a medicinal prescription issued and transmitted electronically.

**EudraVigilance** is a data processing network and management system for reporting and evaluating suspected adverse drug reactions (ADRs) during the development, and following the marketing authorisation of medicinal products in the European Economic Area (EEA). The first operating version was launched in December 2001 [https://eudravigilance.ema.europa.eu](https://eudravigilance.ema.europa.eu).

**EudraCT**: a database containing registrations of clinical trials.

**Eudra Data Warehouse**: data relating to the development, authorization and manufacturing of medicines across Europe.

**eHN – eHealth Network**: volunteer network of representatives of EU member states health ministries established under article 14 of the Directive 2011/24/EU on citizen’s rights to cross border healthcare.

**EPAR - European public assessment report** is published for every human or veterinary medicine that has been granted or refused a marketing authorisation following an assessment by the EMA. For a medicine that is authorised by a Member State, details on the assessment of the medicine are available in a public assessment report.

**EUTCT – European Union Telematics Controlled Terms** a central repository and publication system for controlled term lists used in the European medicines regulatory network;

**EUNDB – European Union Network Data Board** is an advisory body co-chaired by the Head of Business Data and Support Department (EMA) and a National Competent Authority (NCA) representative and comprising members representing Member States and the Agency.

**EU Telematics** is the collective name for a joint endeavor in the context of the regulation of medicines for human and veterinary use between the European Commission, the European Medicines Agency and regulatory authorities in Member States, with the mission to establish ‘A European IT collaboration that will deliver a broad range of cost-effective, efficient and interoperable services to the European Medicines Regulatory Network and to its stakeholders that improve the quality and effectiveness of their business activities’

**EU regulatory network for medicines** comprises the European Commission, the European Medicines Agency and regulatory authorities in Member States.

**EVWEB** the EudraVigilance web portal at EMA where marketing authorization holders enter Medicinal product data.

**Excipient** is a natural or synthetic substance formulated alongside the active ingredient of a medication.

**HL7 International – Health Level Seven International**: Founded in 1987, Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization with the mission to empower global health data interoperability by developing standards and enabling their adoption and implementation. HL7 is supported by more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

**HMA – Heads of Medicine Agencies**

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ICSR – Individual Case Safety Report is report of an adverse event. Now, patients are encouraged to submit directly adverse event reports.

ICH – International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development, so that the benefits of international harmonization for better global health can be realized worldwide. ICH's mission is to achieve greater harmonization to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner – www.ich.org

IDMP - Identification of Medicinal Products refers to five standards created by the International Organization for Standardization (ISO): ISO 11615, ISO 11616, ISO 11238, ISO 11239, ISO 11240. ISO 11615 and 11616 define and differentiate "medicinal products" and "pharmaceutical products" which have "MPID" and "PhPID" numbers. ISO 11238 defines substances. ISO 11239 and 11240 define controlled vocabularies for pharmaceutical dose forms, units of presentation, route of administration, packaging, and units of measurement. The ISO and ICH regions are currently developing Implementation Guides which will further define the details.

IHTSDO - International Health Terminology Standards Development Organisation Manages Snomed CT

INN - International Nonproprietary Name is an official generic and nonproprietary name given to a pharmaceutical drug or active ingredient.

ISO 251 –Health Informatics: Standardization in the field of health informatics, to facilitate the coherent and consistent interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.

LOINC - Logical Observation Identifiers Names and Codes A universal code system for tests, measurements, and observations maintained by Regenstrief.

MA – Market Authorization: A medicinal product may only be placed on the market in the European Economic Area (EEA) when a marketing authorization has been issued by the competent authority of a Member State for its own territory (national authorization) or when an authorization has been granted in accordance with Regulation (EC) No 726/2004 for the entire Union (an Union authorization). The marketing authorization holder must be established within the EEA.

MAH – Marketing Authorization Holder is the company or other legal entity that has the authorisation to market a medicine in one, several or all European Union Member States.

MeDra - Medical Dictionary for Regulatory Activities designed for use in the registration, documentation and safety monitoring of medicinal products through all phases of the development cycle (i.e., from clinical trials to post-marketing surveillance).

MP - Medicinal Product is a substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action or by making a medical diagnosis (src. 2004/27/EC)

MPID - medicinal product id: the IDMP standard specifies a mechanism whereby a medicinal product can be identified uniquely and with certainty in any domain

MS – Member State: refers to the 28 Member states of the European Union

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MSSO- Maintenance and Support Service Organisation: Manages MedDRA

NCA – National Competent Authorities: refers to National Regulatory Agencies, which deliver Marketing Authorization for MP in their jurisdiction

Pharmacoepia (literally, "drug-making"), in its modern technical sense, is a book containing directions for the identification of compound medicines, and published by the authority of a government or a medical or pharmaceutical society. In other words it is reference work for pharmaceutical drug specifications

PhPID - pharmaceutical product id: the IDMP standard specifies a mechanism whereby a pharmaceutical product can be identified uniquely and with certainty in any domain

PF - Pharmaceutical Form refers to the way a medicine is presented, e.g. tablet, capsule, solution for injection, cream, etc.

PI – Product Information refers to documents providing officially approved information for healthcare professionals and patients on a medicine. The product information includes the summary of product characteristics, package leaflet and labelling.

PP - Pharmaceutical Product is in the broadest of terms, a chemical substance that has known biological effects on humans or other animals

Prescription: means a direction usually written for a medical product or for a medical device issued by a member of a regulated health profession within the meaning of Article 3 (1)(a) of Directive 2005/36/EC who is legally entitled to do so in the member state in which the prescription is issued.

RIM - Regulatory Information Management

SmPC – Summary of Product Characteristics4, it is the basis of information for healthcare professionals on how to use the medicinal product safely and effectively.

SPL – Structured Product Labelling HL7 standard specification is a document mark-up standard that specifies the structure and semantics of the content of authorized published information that accompanies any medicine licensed by a medicines licensing authority.

Substances – chemical or biological substances which are used as ingredients in pharmaceutical and medicinal products.

XEVMPD - EXtended EV Medicinal Product Dictionary initially established as EVMPD in 2005 was extended in 2010 (XEVMPD) allowing MA Holders to submit basic details of their MPs to the EMA, either electronically or by manually by entering their data into the Eudra-Vigilance web portal, EVWEB.

WHO World Health Organization: Manages the INN; ATC/DDD Controlled Term Lists

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3 Introduction and Background

3.1 The openMedicine Context

openMedicine contributes towards and enhances through its final results, 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. It will do so, by addressing the problem of univocal identification of medicinal products.

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 used in place of the prescribed medicinal or pharmaceutical product.

The approach advocated by openMedicine comprises the identification, validation, and channeling 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 will gather, collate, and analyze 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. In doing so, openMedicine will actively pursue community building, cooperation and translation of its results.

For the communication plan of openMedicine to be successful, one has to make sure that the project achieves and even surpasses the expected impact as noted in the relevant section of the DoA particularly in relation to engaging stakeholders (i.e. SDOs, regulatory agencies and competence authorities in MS, patient advocacy groups, health professionals, USA counterparts, software providers, drug databases, etc.) appealing to their needs and values. For example, with openMedicine final results:

- 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 summary and understand fully the medicinal product information contained.
- Pharmacists can fully 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 fulfills the therapeutic requirements of the MP prescribed abroad.

Thus, the communication plan remains the same as the original with the following key communication activities:

- 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 WP7, July – Dec 2015

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 are:
- Raise awareness about the openMedicine project during the lifetime of the project addressing all actors in the lifecycle of an MP
- Facilitate cooperation among SDOs
- Encourage adoption of the recommendations of the roadmap.

Specifically, for the period July – Dec 2015, the aims have been to:
- engage the expert council in the meetings of June 2015 and Jan 2016
- disseminate the results for the key deliverables as they are released
- liaise with activities of the European medicines agency and stakeholder networks in the European level
- collaborate with FDA and US networks in the context of the MoU.

3.3 Update of the Communication Plan

The updated communication plan maintains 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 relate only to specific activities relating to the concrete deliverables, activities, and results expected in 2nd year of the project.
4 Updated Communication Strategy

The following figure taken from D7.1 presents an overview of the openMedicine communication strategy. When revisiting it, no major changes were considered necessary.

However, 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.

Figure 1: Operational dissemination approach

There has been no change in goals and objectives, actors, addresses, structures, processes, and coverage of the communication strategy. The target audience, dissemination items, and channels remain the same.

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

The following table relates the openMedicine audience with the results of the project and the dissemination channels. It serves as a draft for discussion and brainstorming.
4.1.1 Communication Objects revisited

The primary communication objects are project results as reflected in the key deliverables of the project. The communication plan noted several ways that project results can be prepared and packaged for dissemination. At the end of the first year as several 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 (NO)
- Book Chapter (NO)
- Conference Paper (YES)
- Other publication – Poster (YES)

Some of the means above that were not used in the first year, are considered more appropriate for the 2nd year.

4.1.2 Resources

Resource use in this period was on track.

4.1.3 Evaluation

The openMedicine communication strategy was assessed in the end of the first year. Results according to “European Commission communication policy requirements” appear in the figure below.

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<th>What</th>
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| **Within 6 weeks after start of the project or as soon as possible** | **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)  
2. **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)  
3. **DONE**: Twitter account

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5 Guidance for the logo specifics for this can be found here: http://ec.europa.eu/research/pdf/eu_emblem_rules_2012.pdf
• other social media is welcome (facebook page, LinkedIn, YouTube) (sent accounts to Carolien.Nijenhuis@ec.europa.eu)

4. 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

5. 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. a press release and an updated website with news about the results;
2. a blog post of the project leader with personal experiences;
3. if possible a video to make the project understandable for the public;
4. if possible pictures of users working with the project technology.

Before during or after the project

5. Inform Carolien.Nijenhuis@ec.europa.eu of any press release, article in the media!
5 Stakeholder Communication & Liaison

In the following sections, we layout the communication & liaison activities carried out or planned in the months 7-12 of the openMedicine. We also list the relevant stakeholders.

5.1 Stakeholders in Medicinal Product Lifecycle

Focusing on the post-market authorization part of the medicinal product lifecycle, we can recognize several important actors presented in the following sections.

5.1.1 Market Authorization Holders – Pharma Industry

Marketing authorization holders (MAH) submit information on medicinal products they hold marketing authorizations optionally using the EVWEB interface. After 2017, marketing authorization holders will submit information in the IDMP format. The ability to uniquely identify medicinal products may be disruptive for the business model of some market authorization holders. As a result, they may be reluctant in engaging with new ways of identifying medicinal products unless the benefit is very clearly articulated.

- In this period no direct communication activities were directed to MAH, even though D2.1 is relevant to then. Some activities directed to Standards Developing Organization are also directed to MAH.
- Communication & Liaison activities were directed through EMA committees and the IDMP task force in particular.
- Planned activities: to be continued in relation with results planned for the 2nd year.

5.1.2 Manufacturers in Medicinal Lifecycle

Manufacturers are involved in the medicinal lifecycle in at three phases/roles: 1) manufacturer of the substances 2) manufacturer of the pharmaceutical product 3) manufacturer of the medicinal product package.

- In this period no specific communication activities were directed to MAH, even though D2.1 is relevant to then. Some activities directed to Standards Developing Organization are also directed to MAH.
- Planned activities: to be continued in relation with results planned for the 2nd year.

5.1.3 National Regulators

National regulators are part of the EU regulatory framework for medicines. They authorize drugs that are not subject to the centralized authorization requirement. The processes vary among regulators and that can present obstacles to achieving the common data model for prescribed medicinal products of openMedicine. An aspiration of openMedicine is to raise awareness and leverage its results and instigate towards implementation among National Regulators.

There are several dictionaries relevant to openMedicine that are maintained by various organizations including regulators. Such dictionaries are MeDra, DD, ATC, Loinc, EDQM, etc. The terms in these dictionaries represent different concepts and there are no unequivocal mappings between them. Sometimes there are even multiple synonyms for the same values. Reaching agreement on which dictionaries to use for what purpose could help advance interoperability, streamline data exchange processes and improve efficiency.

5.1.4 Commercial/Dedicated Information Brokers

Information Brokers are companies that specialize in maintaining up-to-date lists of MPs and providing them to healthcare facilities and private offices as needed thereby facilitating, e.g.
reimbursement. Such companies are e.g. First Databank mainly in the US\(^6\), Z-Index\(^7\) in the Netherlands and Vidal\(^8\) in several countries in Europe and across the globe, etc. Information Brokers would be supporting of openMedicine as their functions are within a contained and contractual scope (a few institutions) but this may be extended or bridged with other scopes for cross-country interoperability.

Medicinal product masterdata dictionaries are (IT) systems that contain the lists and information about medicinal products. One such masterdata dictionary is the XEVMPD in which EMA maintains most recent information focused on the regulatory aspects.

Each country maintains its own national formulae. For GB this the British National Formulary (BNF), while for Ireland it is the Irish national formulae.

Pharmacopoeias are (national) official publications containing a list of medicinal drugs with their effects and directions for their use. In Europe, the European Directorate for the Quality of Medicines and Healthcare (EDQM) of the Council of Europe is maintaining such a reference book.\(^9\) Its European Pharmacopoeia is legally binding in all its member states.

- Information brokers have been represented by VIDAL in the Expert council of EMA (June 25, 2015) and CEN (21-22 January 2016).
- Planned activities: dissemination activities directed towards such dictionaries, pharmacopoeias national formulae will be planned in the 2\(^{nd}\) year of the project.

### 5.1.5 Patients and Family

Patients are important stakeholders and according to recent regulations they are encouraged to directly report an adverse event directly to the EMA database. With the outcome of openMedicine these adverse drug reports can be cross-checked, aggregated and correlated across Europe and perhaps globally in the future, support post market surveillance. Patients and citizens will no doubt benefit from the univocal identification of MPs under any circumstance, whether at home or abroad.

Separate meetings may be considered to advance this purpose. Alternatively, high visibility events or DG Connect eHealth Stakeholders Meeting, may be used to communicate the message of openMedicine to this increasingly important stakeholder group.

- No specific activities towards patients organizations took place in the 1\(^{st}\) year of the project,
- Planned activities: dissemination activities are planned for the 2\(^{nd}\) year of openMedicine once the concrete recommendations are available.

### 5.1.6 Healthcare Professionals: Prescribers

Healthcare professionals, i.e. doctors, nurses etc., may become confronted with prescriptions and medication lists of patients that visit them from another state or country to obtain treatment, or temporary residents like tourists getting involved in an accident or similar unplanned care event. Professionals need to be able to identify the MP referred in those prescriptions or medication lists. A medical doctor may also be confronted with the need to prescribe an identical or an equivalent drug for continuing a treatment started in another country.

The implementation of IDMP in the European Medicine’s database would be particularly helpful in such a context.

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\(^6\) http://www.fdbhealth.com/

\(^7\) http://www.z-index.nl

\(^8\) http://vidal-dis.com/

No specific activities towards health professionals organizations took place in the 1st year of the project.

Planned activities: dissemination activities are planned for the 2nd year of openMedicine once the concrete recommendations are available.

5.1.7 Pharmacist: Dispenser

Pharmacists confront the problem of dispensing a medication which is unknown in their jurisdiction. Actually, when delivering a medicinal product in a cross border setting, pharmacists need to substitute the prescribed MP with another, locally available, even if the dispensed product is pharmacologically the same. In many cases however, pharmacists face considerable difficulties in assessing equivalence.

The main outcome of openMedicine supports definition and implementation of mechanisms that enable safe dispensing of the correct (i.e. appropriate) medicinal product. For example, implementing IDMP standards will allow correct identification of the product, and using a central database (EMA) can permit a quick check for equivalents to the prescribed medicinal product in the member state of dispensation.

Limited activities towards pharmacists took place in the 1st year of the project. Representatives of the Pharmaceutical Group of the European Union (PGEU), the voice of community pharmacists in Europe, took part in both meetings of the expert council of openMedicine that took place in June 2015 (EMA) and January 2016 (CEN).

Planned activities: dissemination activities are planned for the 2nd year of openMedicine once the concrete recommendations are available.

5.1.8 Healthcare Institutions and their Management

Healthcare institutions like hospitals or clinics respectively their professional staff, have the roles of dispensing medicinal products as well as issuing prescriptions. Thus, they are obvious stakeholders of better interoperability.

Additionally, the management of these institutions also benefits from this project: not only in terms of providing better treatment (e.g. by seamlessly continuing a therapy in case of patient admission), but also enabling better operational insight into planning the medication needed, etc.

Limited activities towards health institutions and their management took place in the 1st year of the project.

Planned activities: dissemination activities are planned for the 2nd year of openMedicine once the concrete recommendations are available.

5.1.9 Public Health and Pharmacovigilance Bodies

One very important benefit of openMedicine is its enabling the interoperability of MPs data and thereby the aggregation of data on, e.g., prescribing trends, for reimbursement, management of stocks, or the availability for other. One implicit benefit of openMedicine is its secondary use of data, which can be used for monitoring where openMedicine is supporting the patient continuity of care, and provide insight on the continuation of treatment, adverse drug event reporting for cross-country dispensing, etc.

Activities towards public health bodies and pharmacovigilance bodies that took place in the 1st year of the project, where mostly through expert groups and commitees of the European Medicine Agency (EMA)

Planned activities: further dissemination activities are planned for the 2nd year of openMedicine once the concrete deliverables and the recommendations of the project are available.
5.1.10 Healthcare Insurance Agencies
Statutory as well as private healthcare insurances are managing lists of reimbursable medications. In that respect they are interested in the work of openMedicine. Insurance agencies are managing lists of reimbursable medications. In that respect, the work of openMedicine is relevant to them, since it allows maintenance of such lists even across member states, for a complete overview of the reimbursement programs and medication use.

- limited activities towards insurance agencies took place in the 1st year of the project.
- Planned activities: dissemination activities are planned for the 2nd year of openMedicine once the study on substitution and other relevant deliverables including the final recommendations are available.

5.1.11 Health IT/eHealth System Providers
Providers of health IT systems (developers, vendors, or integrators) must ensure that their systems can identify medicinal products correctly, and that they can provide sufficient information for other systems to correctly identify their medicinal products. While the complexity and the requirements vary, openMedicine project will assist in common challenges:

- List of medications that can be prescribed, and how to ensure that these medication lists are kept up-to-date in a consistent manner.
- How to support issuing prescriptions that are ready for cross-border dispensing.
- How to support dispensing prescriptions from another country.
- How to support synchronization and overview of medication treatments for cross-border patients: Supporting a single patient medication overview, verifying continuity of treatment across countries.

OpenMedicine will provide recommendations and mechanisms for unambiguous identification of medicinal products. As such, vendors and integrators can provide the solutions that will be expected from their customers and users, and they can do so, conforming to a standard, which minimizes diversity, reduces risk and minimizes the effort for integration.

- activities towards health IT and eHealth System Providers took place in the 1st year of the project include the workshop in MedInfo2015 (See Annex 1)
- Planned activities: further dissemination activities are planned for the 2nd year of openMedicine including poster presentation in the EFMI STC2015 conference.

5.1.12 National Competent Authorities
NCA, national regulatory agencies have a lot to benefit from globally unique identifications for medicinal products, taking into account that in some MS NCA’s scope is not limited to MP. They also gain by exchanging information.

- activities towards health IT and eHealth System Providers took place in the 1st year of are relevant to the EMA Data board, its expert committees and working groups
- Planned activities: further dissemination activities are planned for the 2nd year of openMedicine including presentations and joint workshops.

5.1.13 Health Professional Organizations
In promoting the cause of openMedicine, liaison with professional organisations of Pharmacists, Physicians, and Nurses will be established.

- Limited activities towards health professional organizations took place in the 1st year of openMedicine. They were general in general.
- Planned activities: further dissemination activities are planned for the 2nd year of openMedicine including presentations and joint workshops in conferences addressed to
health professionals, such as the European Society of Cardiology and 2nd Conference of eCardiology and eHealth.

5.1.14 Advocacy Groups (Patients)
Advocacy groups, particularly disease focused patient organisations with strong engagement in the clinical side of research and treatment, will be invited to participate and contribute towards supporting the deployment of IDMP.

- Limited activities towards patient advocacy group took place in the 1st year of openMedicine.
- **Planned activities**: further dissemination activities are planned for the 2nd year of openMedicine that would require the formulation of a targeted message towards patients.

5.1.15 Standards & Profile Developing Organizations
There are several stakeholders who are highly relevant for openMedicine to cooperate with that work at the European level and global level. These 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 are following closely the activities of the SDOs, contributing to working items, stimulating the elaboration of working items of relevant to openMedicine, and discussing deliverables of open medicine in their early form looking for comments, corrections, and elaborations.

Specifically, the adopted approach is 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, and a calendar will be fixed for the expectable outcome.

A list of activities and topics to address, as well as the timelines considering the cycles of all SDOs is presented in Annex 2 and 3 and updated according to the progress in the different groups.

- There has been active engagement with SDOs, with regular participation in conference calls and face to face meetings.
- **Planned activities**: further engagement and dissemination activities are planned for the 2nd year of openMedicine including the Spring and Autumn meeting of HL7, the ISO/CEN meeting in Amsterdam, etc.

5.2 Stakeholders in Cross-border Care
There are several stakeholders for openMedicine working on the European level. These are the European Commission which is the one that actually grants the Marketing Authorization once the opinion expressed by EMA is positive. The European Medicines Agency understands the benefit of a European Medicine’s data base.

The EU Data Board is part of the EU Telematics action plan setting standards from EMA on how information will be captured. The EUNDB is an advisory body comprising members representing MS and EMA. It reflects 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. It further propose standards,

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accountabilities and responsibilities, and ensure that data and information usage achieve maximum value to the EU/EEA Regulatory Agencies.

EMA created Task Force to contribute to IDMP implementation in Europe, in early 2015. The IDMP Task Force 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.

- Members of the openMedicine consortium sit on the EU data board and the IDMP task force. They provide regular updates on the progress of the openMedicine project.
- Planned activities: further engagement of the EU data board and ISO IDMP task force are expected in the 2nd year of the project with the dual purpose to disseminate

The volunteer eHealth Network of national health ministry representatives established under Article 14 of the cross-border directive. It plays a very important role in eHealth policy decisions of the European Union. Liaison activities to the eHealth network have been direct through members and indirect through JAseHN. Among the planned activities is the presentation of a discussion paper to the June 2016 meeting.

### 5.3 Global and Transatlantic Stakeholders

The most prominent among the global stakeholders are the World Health Organization, which manages several terminologies. On the global level there are also FDA, DIA, EFPIA, and ICH. FDA is the United States Regulator, which although natural in skype falls within the proposal.

- Through EMA, the connection to FDA has been fostered in the expert council meetings.
- Further dissemination and liaison is planned in June as part of an EU/US workshop planned for late June in the premises of FDA.

### 5.4 Liaison to European Projects

There are several EU co-funded project that offer important insights to openMedicine and where cooperation has a lot of value. The ones currently active are: eStandards (www.estandards-project.eu), AssessCT (www.assessct.eu), VALUeHEALTH (www.valuehealth.eu), and JAseHN. The relation of ASSESS CT to openMedicine relates to existence of a medication list in the comparison of the European and the United States continuity of care records.

eStandards is synergetic to openMedicine in that standards need mature and time/cost impossible these days. After the Meetings in July 3 with the PHC34 projects and Dec 3 hosted by JAseHN liaisons were appointed from each project and JAseHN. Furthermore, a Yammer space has been set up to share preliminary deliverables and other information of relevance. The eStandards project is organizing a 2-day writing workshop for its first roadmap: Essential standards development, strategic options and policy instruments.

### 5.5 Other relevant work

Other relevant work in Europe relate to:

- Falsified medicine initiative" A cooperation has been established with project Alpha11
- Connecting Europe Facility eHealth Digital Services Infrastructure (CEF eHealth DSI)

openMedicine in its second year will review progress to these fronts and hand-over relevant information as required.

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6 Dissemination Channels

Several dissemination channels and communication modes will be used to ensure that the message of openMedicine reaches its stakeholders. It comprises multitude activities, Web site and social media, journals, newsletters, etc. There has been no update on the dissemination channels.

6.1.1 Activities

Participation in SDO working groups and relevant activities at the JIC level. Presentations of openMedicine were carried out in every SDO event. A rich set of liaison activities has been planned.

6.1.2 Website

The website of the openMedicine project, is available since March 2015 in www.open-medicine.eu. The website has been up-to-date. There have been 844 unique visits, 2569 page views, and 309 document downloads. Actual statistics are presented in section 9.

6.1.3 Twitter

The twitter handles for openMedicine are as @openmedicine_eu @@openmedicine_eu

The number of items tweeted since the beginning of the project is 3.

6.1.4 Publications, Conferences and Newsletters

According to the indicators we will be counting publications, conference papers and slides

More than 4 presentations at different workshops of conferences mentioned openMedicine.

1) Nov 20, 2015: European Telecommunication Standards Institute (ETSI): On the 20th of November 2015, the European Telecommunications Standards Institute (ETSI) organised an eHealth Open Meeting on Health and the Internet of Things (HIT) - Use Cases for Standards in Patient-Driven Medicine, in Sophia Antipolis, France. openMedicine was represented by its scientific coordinator, Prof. Dr. Karl A. Stroetmann. Via telecom facility he gave a talk on “Meeting the cross-border challenge of unique identification of medicinal products.”

2) Dec 9, 2015: Expand Final conference Lisbon. The European EXPAND project organised a comprehensive conference and Expandathon on 9 December 2015 in Lisbon. The conference built upon the project’s work on European interoperable, cross border eHealth services based on the legal basis provided by the EU “Patient Rights Directive” relating to their access to planned healthcare in other member states. The goal of the project was to support and facilitate the passage of results and interoperability assets from research to pilots, and from pilots to deployment. It endeavoured to build trust in outcomes and develop capacities for their continued maintenance and support; and cooperation across EU member states. At this meeting, openMedicine was represented by its scientific coordinator Prof. Dr. Karl A. Stroetmann, empirica. In a session of handing over of results across EU projects and future cooperation, he presented the achievements to-date of openMedicine and explored its anticipated impacts and benefits for patient safety, pharmacovigilance and cross-border healthcare across the European Union and beyond.
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 D7.1. There has been no update in the fact sheet since July 2015.
8 Report on Indicators of Success

Specific indicators that will be monitored over time are:

- Visits to the web site: 100
- Publications, events attended and presentations delivered: 2 publications, 3 presentations
- Newsletters and blogposts (including articles supporting the objectives of openMedicine): 1 newsletter
- Mentions of the project on Twitter and LinkedIn and elsewhere: 3
- Meetings with SDOs, (national) agencies, politicians etc.: regular participation in meetings, presentation of openMedicine results in every opportunity, engagement of the SDOs workgroups.
9 Dissemination Report [Jul-Jan 2016]

9.1 Activities Carried out

9.1.1 Articles, Presentations, Newsletters

Several presentations in SDO and stakeholder meetings, a conference presentation and a number of newsletters enhanced the visibility of openMedicine in this period. These include:

- HL7 Pharmacy meetings in HL7 WGM Oct, 2015 and Jan 2016 (see Figure 3)
- IHE Pharmacy meetings, 2015
- ISO/TC215 & CEN/TC251 meeting in Bern, Switzerland
- Medinfo workshop “Information to the point of action – opportunities for medication management?” (see annex 1)
- MedInfo workshop “Tools for interoperability – Time for eStandards?” (see annex 2)

Figure 3: HL7 WGM Meeting materials.

- HL7 Pharmacy meetings in HL7 WGM Oct, 2015 and Jan 2016 (see Figure 3)
- IHE Pharmacy meetings, 2015
- ISO/TC215 & CEN/TC251 meeting in Bern, Switzerland
- Medinfo workshop “Information to the point of action – opportunities for medication management?” (see annex 1)
- MedInfo workshop “Tools for interoperability – Time for eStandards?” (see annex 2)

Figure 4: Newsletter articles in HL7 Newsletter of and HL7 Europe News respectively raising awareness on the OpenMedicine Project and its objectives.
9.2 Planned activities for the next six months

Several activities are planned for the next six months, including:

- EFMI Special Topic Conference on April 19, 2016 in Paris: Smart Medications & the Internet of Things, José Costa Teihera, 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 panel)

- Activities in the eHealth week – possibly with the rest of the PHC34 projects

- Targeted messages for specific stakeholders

- EU/US Workshop in FDA, June 21, 2016


- 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 (TBA)
  - An ID-Wallet for open medication management: use cases and enabling standards Jos Devlies, EuroRec, Jose Texeira 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
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>17 Jun 12, 2015</td>
<td>Second ISO IDMP Task Force meeting</td>
<td>London, UK</td>
<td>EMA</td>
<td>Standards and Profile developing organizations; National Reps</td>
<td>Discussion of IDMP implementation relevant to openMedicine</td>
<td>~20 experts</td>
<td>Christian Hay (ISO/CEN/NEN)</td>
</tr>
<tr>
<td>21 Jun 25, 2015</td>
<td>openMedicine Expert Council</td>
<td>London, UK</td>
<td>EMA</td>
<td>Expert council members, project representatives</td>
<td>Discussion of progress and direction for the project</td>
<td>30 participants, very high impact</td>
<td>On file</td>
</tr>
<tr>
<td>22 Jul 3, 2015</td>
<td>JAsEHN, PHC34 coordination meeting</td>
<td>Brussels, Belgium</td>
<td>European Commission</td>
<td>EU project, H2020 PHC34 DG Sante, Cnnt Connect /JA</td>
<td>Presentation of openMedicine</td>
<td>High, leads to better synergy</td>
<td>Jos Devlies (Custodix) Paolo Alcini (EMA)</td>
</tr>
</tbody>
</table>

12 Keynote, presentation, poster, distribution of leaflet, short intervention

13 Estimated number of attendees (perhaps in steps like: <10, 10-49, 50 – 99, etc.)
9.2.1 Focus on Standards and Profile organizations

Between January and June 2015, dissemination activities have focused on raising awareness on the openMedicine project and checking gaps in the ongoing work of standards and profiling organizations.

The openMedicine Project was mentioned in HL7 Calls as a project that addresses relevant 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 (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 catalog" 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 WG6, OpenMedicine was mentioned and its input was considered during the finalization of ISO 17523 – "Requirements for ePrescription". A final review is expected for early August 2015.

ISO 19293 – “Dispense Record” - may also be influenced by the results of openMedicine, and as such the project is in its radar. Actions need to be taken, pending further progress in openMedicine, to facilitate a consistent approach.

9.2.2 Website

The www.open-medicine.eu web site has been active since April.

The first page of portal appears in the figure below.

![Figure 5: First page of the openMedicine portal](Image)

The visit log of the portal appears in the figure below.
844 visits

3 min 15s average visit duration

43% visits have bounced (left the website after one page)

3.6 actions (page views, downloads, outlinks and internal site searches) per visit

0.52s average generation time

2,569 pageviews, 1,863 unique pageviews

12 total searches on your website, 1 unique keywords

309 downloads, 273 unique downloads

104 outlinks, 97 unique outlinks

37 max actions in one visit

Figure 6: Visit statistics for the open-medicine.eu portal.
Annex 1: MedInfo 2015 Workshop I

Information to the point of action – opportunities for medication management?
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Abstract
Available, updated information at the point of action is a core premise for quality care, patient safety and professional accountability. However, numerous reports in the research literature, examples of personal experiences and “wisdom of the consumer crowds” demonstrate that despite the efforts over time or deploy ICT-functionality, inadequate information at the point of action prevails. These challenges serve as a backdrop for exploration of facilitators and barriers for real change by ICT-enabled services. In this workshop we will choose one important, problematic topic: medication management and information exchange for updated medication overview and medication reconciliation.

The aim of this workshop is to engage the audience in discussing opportunities for problem resolution, challenging the previously suggested approaches and collaboratively explore a way forward that takes advantage of evolving technological development, transitioning professional jurisdictions, and consumer involvement for safe, high quality services. The topic for discussion is therefore the role of emerging technology in relation to existing and future workflow trends, the inherent complexities of medication management, contemporaneous medications, drug-drug interaction, and problem of side effects or allergies that may or may not be successfully transmitted and shared.

The intended audience includes researchers, consumers, practitioners, software vendors, and policy makers involved in cross-level service design, development, implementation and management.

Keywords:
Participatory health, consumer engagement, system interoperability, socio-technical research, medication reconciliation

Workshop Description

Among the significant challenges to the provision of efficient, effective and comprehensive care is access to information at the point of action. The seminal IOM report “to Err is Human” [1], drew global attention to the interconnectedness of patients’ safety, appropriate information for care and professional accountability. However, numerous reports in the research literature as well as anecdotal evidence like personal experiences and accumulated “wisdom of the consumer crowds” demonstrate that despite the efforts over time to understand the problems(s), suggest solutions or deploy ICT-functionality, the problem of valid information for participatory health and consumer engagement at the point of action persists. Achievements and opportunities in handheld and mobile devices, i.e. tablets, smartphones, and attached sensors, come with expectations for change [2].

In the Nordic countries, national prescription databases are implemented, and there are also emerging national medication records [3, 4]. Unfortunately these approaches do not address the problems of multiple professionals involved in and subsequently responsible to contributing to updated records, how to maintain integrity data or how these initiatives can support transnational mobility. Despite such broad national initiatives, problems causing harm are still too frequent.

Still, 15 years after the seminal IOM report, the problems of medication misadventures, i.e. suboptimal drug use, medication errors and adverse drug events (5) continues. Equally important is accurate and updated information about the prescribed and actually taken medication. Information about the various elements in the medication management process; e-prescribing, transmission and exchange of information in the prescriptions to involved entities, medication overview and drug use need more attention. Also, issues of professional accountability, task shifting and responsibilities should be addressed when the GP, local specialists, home care and several hospitals are all involved in various aspects of complex cases.

Of specific concern are inadequate tools and systems for information sharing and access to accurate, up-to-date information at the point of action, e.g., in transitions between hospital departments, levels of care, regional, state or country borders. Additionally, information lost in interaction of increasing number of collaborating providers, multi-disciplinary perspectives, deteriorating health or increasing severity of illness, challenge communication practices [6]. In these health and illness trajectories near misses or medication-related errors are still too common. Justifications of new approaches accepting participation and building on engagement of the consumer carry potential for error reduction and likelihood of up-to-date medication overview and regular medication reconciliation. Support for community, safety and collaboration in these patient trajectories call for rethought, and probably the disruption of digital technology to provide information for medication management, at the point of action.

Attention to this complex and multi dimensional problem often comes under the umbrella of poly-pharmacy and failed medication reconciliation. In the context of informatics, amplification of unexpected vulnerabilities when information systems are introduced in the chain of activities, can inform major changes for real reduction of multiple opportunities for near misses or errors at the point of action. Therefore we set out to engage the audience in discussions to unpack the string of actions in information exchange from prescription of a chosen medication, the prescription is filled to the pharmacy, prepared for the person who needs the medications and the necessary overview for safe medication management.

Following the ePSOS large scale pilot, the European Commission has funded a number of support actions aiming to unpack
issues related to standardization and interoperability in the face of large scale eHealth deployment. In parallel, the European Medicines Agency offers health consumers direct access to adverse reporting and is the process of developing a European wide medications database. These policy developments have concrete short term and long-term implications for consumers, the industry, and the society as a whole. The aim of this workshop is to engage the audience in discussing opportunities for problem resolution, challenging the previously suggested approaches and exploring ways forward that take advantage of evolving technological development, transitioning professional jurisdictions, and consumer involvement for safe, high quality services.

Workshop Speakers

Anne Moen will introduce research into prevalence of adverse events or near misses and experiences with medication management by the consumer in a call for rethinking the process of medication reconciliation and addressing challenges for information access at the point of action. Here are inspirations for informatics support as safety nets based on information exchange, and consumer governance. She will moderate the workshop.

Petter Hulten will discuss the problem of accurate information at the point of action from a professional and patient perspective. Specifically, he will use experiences from the clinical field where information exchange at significant transition points in and across levels of care calls for innovative ICT support for access to information at the point of action.

Catherine Chronaki will provide a more detailed account of specific health information exchange activities, where challenges associated with increased mobility, calls for advancements of interoperability efforts supported by European funding, e.g., Standards, OpenMedicine, and the HL7 supported FHIR approach to facilitate cross-border information exchange and ensure updates and correct information about medication at the point of action.

Ross Koppel will take a socio-technical perspective, and point out differences prescription regulations across the 50 US states and other countries as a start for consolidation and change. The problem with e-prescribing creates unequal access to medications and prescription processes with related opportunities for near misses or even errors in the chain of activities. He will suggest areas for immediate action and longer-term changes and improvements.

Workshop Structure and Arguments

The questions to discuss will include:

1. What are the problems, future trends and developments needed to support mobility and information access to take advantage of opportunities for change?

2. What are the facilitators and barriers for real change by ICT-enabled services?

3. What are areas of activity for immediate action and longer-term changes and safety improvements?

4. What are the expectations for standards and profile developing organizations, e.g., HL7, IHE, ISO?

5. Is it time to revisit the interoperability discourse engaging health consumers and their rights?

The action items will be elicited and circulated to the attendees interested in follow-up conclusion of the workshop.

Specific Educational Goals

The workshop will provide the attendees with the following valuable opportunities:

- A global perspectives to understand and appreciate new opportunities for participation and information access at the point of need, where the case of medication management can demonstrate challenges and articulate possible solutions for the future

- The opportunity to contribute to the establishment of international, research initiatives and network opportunities with colleagues from around the world

Expected Attendees

The intended participants are researchers, professional practitioners, software vendors, and policy makers with interest or responsibility for patient safety, IT service design, implementation and management.

If workshop is accepted, all presenters agree to be present at the conference.

References


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Annex 2: MedInfo 2015 Workshop II

Tools for interoperability – Time for eStandards?

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¹CEN/TC 251, Brussels, Belgium; ²HL7 Foundation, Brussels, Belgium; ³MEDIQ Odense, Denmark; ⁴Heitmann Consulting and Services, Germany; ⁵HL7 International, United States

Abstract

This workshop revisits tools for standards-based interoperability aiming to update participants on recent developments in Health Level 7 (HL7) and stimulate discussion with the audience on advances in tools for requirements analysis as well as creation and deployment of standards and reusable interoperability assets challenging the traditional notion of standards in print. Best practices using tools for HL7 Clinical Document Architecture (CDA) like Art Decor and Model Driven Health Tools, and inspired by the early work of the OpenEHR foundation based on EN ISO 13606 address the interplay of tools for standards and their profiles with interoperability assets through general descriptions and concrete examples. Emerging standards like Fast Healthcare Interoperability Resources (FHIR) and renewed interest in quality management for interoperability testing in a use case oriented iterative process of co-producing are catalyzing eHealth ecosystems locally, nationally, and globally.

Keywords: Interoperability testing, tools, eHealth standards, Clinical Document Architecture, HL7, FHIR, EHR

Workshop Description

Large-scale deployment of eHealth demands consistent and accelerated implementation of standards at a lower cost. This workshop aims to engage the audience in a discussion on the future of standards for interoperability across eHealth ecosystems with interoperability tools, shared interoperability assets, and quality management, at the backdrop of the eStandards initiative funded by the European Commission.

The European eStandards project has been proposed by HL7, CEN/TC 251, and EHE, leading organizations for eHealth standards and specifications, supported by the European eHealth Network, ISO/TC 215, GCH, IHE/SDO, IEEE, EIML, and EMA, to advance eHealth interoperability and global alignment of standards and specifications. The two-year project aims to join up with stakeholders in Europe and globally to build consensus on creating interoperability across different (possibly overlapping) eHealth standards, accelerate knowledge-sharing, and promote wide adoption of standards. In an evidence-based Roadmap, eStandards targets alignment, iterative consolidation, and broad acceptance of eStandards, elaborating the European eHealth Interoperability Framework use cases with clinical content modelling for different paradigms and embedding a Quality Management System for interoperability testing & certification of eHealth systems. The project team will collect evidence and will provide guidance on the coexistence of competing or overlapping standards in large-scale eHealth deployment, whether regional, national or cross-border.

Interoperability tools play a critical role in this context as they hold promise of optimizing the entire interoperability standards lifecycle as introduced in the eHealth Interop report [1]:

- Identification of a use case or set of requirements
- Selection of supporting interoperability standards, with the selection of options
- Implementation, conformance testing, certification
- Deployment in projects, which closes the feedback loop from the real world.

The interoperability tools presented and discussed in this workshop address mainly the process of exposing requirements, creating specifications, testing and revising them cultivating a Quality Management Culture and integrating evidence that can support large-scale eHealth deployment (see Fig. 1).

Figure 1: Integrating evidence and cultivating a culture of quality management in eStandards.

The speakers will present indicative tools for functional profiles of health record systems used to elicit requirements as the functional health record profiling tool, and drive specification, testing, and implementation with the Model driven Health Tools and Art Decor. Also we will be looking at
future directions for Health Information Technology (HIT) standards in the FHIR initiative. This workshop aims to engage the participants in productive discussions on how the different pieces fit together and how to drive innovation and quality improvement across health systems.

Instrumental to this process is exploring socio-economic aspects of eHealth interoperability, revisiting the language for user-vendor interaction that embodies “co-making” in trust, collaboration and long-term engagement. The eStandards Roadmap and associated evidence base, a white paper on the need for formal standards, and two guidelines addressing how to work with clinical content in profiles and competing standards in large-scale eHealth deployments will detail key pragmatic steps toward alignment and convergence.

The workshop hopes to engage ModInfo2015 participants and catalyze evidence, experiences, evidence, and best practices that will catalyze the process of innovating in HIT standards.

**Workshop Speakers and Topics**

**Towards eStandards, Catherine Chronaki, HL7 Foundation, Brussels**

Catherine Chronaki will co-chair the workshop with Robert Stegwee. She will introduce the main theme and objectives of the workshop at the backdrop of eStandards, a project funded by the European Commission to create an evidence driven roadmap for building bridges between standards and to support large scale deployment of standards in Europe.

Catherine is the Secretary General of the HL7 Foundation. She has been engaged in eHealth projects since the early 90’s. She is an avid promoter of interoperability standards and is deeply convinced that the use of international HIT standards can drive innovation, quality and patient safety.

**Roadmap for eStandards – Questionnaire Robert Stegwee, CEN/TC 251**

Robert Stegwee will present the white paper Standards-based Interoperability and will layout the principles and questions for the eStandards Roadmap, setting the stage for the presentations rethinking the use of different (possibly overlapping) standards from different angles.

Robert Stegwee, PhD is the chair of HL7 the Netherlands and CEN/TC 251. He has been actively promoting the use of standards based interoperability at a local, regional and global level and helps to create the necessary governance and education to achieve these objectives.

**How tools can help on developing functional profiles: the Italian Experience of the Fascicolo Sanitario Elettronico (FSE), Giorgio Cangioni, Italy**

The realization of Regional interoperable EHR systems is part of the plan for the Italian Digital Agenda. In order to mitigate the risk of deploying systems with functional incompatibilities and fragile unreliable components, a Functional Profile for the FSE based on HL7 ISO 10781 EHR-S Functional Model Release 2 (EHR-S FM R2) [2], was defined and published as an IL7 Italy standard. A tool for modeling the functional profiles in UML - developed by Results 4 Care B.V. as part of the tooling strategy of HL7 International - was used. The presentation will show how the tool helps users ensure consistency with the EHR-S FM R2 standard. The aim of the discussion is to show how tools can contribute to the consistent expression of system functionality enabling beyond profile development, comparison of profiles for consistency and reuse of artifacts.

**Model Driven Health Tools, Dr. Amnon Shabo (Shvo), Israel**

The Genetic Testing Report (GTR) Implementation Guide of CDA was one of the first end-to-end examples created using Model Driven Health Tools (MDHT) [3]. GTR addresses a constantly growing number of genetic testing types yielding new result formats less familiar to the receiving party. The challenge is to define a universal implementation guide (template) that accommodates common data requirements of genetic testing reports, which can be further refined to GTR specializations for research and healthcare as well as to specific genomic technologies or regional/realm requirements. The MDHT tool supports this type of specialization ensuring that each sub-template of GTR will be consistent with its parent template. To this end, MDHT supports the definition of abstract templates. Additionally, an abstract entry-level template, i.e. clinical docimenic statement, was created to represent discrete data elements. The clinical docimenic statement template is further refined to create specialized clinical docimenic statement types for describing specific genotype-phenotype associations. Finally, refinement is also done by binding to different terminologies, both static binding, as well as dynamic binding, such as linking to external genomic ontologies.

**Using Art-Decor to close the cycle of specification, testing and deployment, Dr Kai Heitmann, MD, Germany**

Kai Heitmann will present recent developments on the Art-Decor tools [4], which facilitate cooperative development, implementation and testing of clinical documents in the HL7 CDA format. In particular, Dr. Heitmann will introduce a use case example and go through the typical phases by highlighting specification aspects, how implementers are supported by the tool while building interfaces and what is important about testing and validation.

Dr. Kai Heitmann, MD, is an independent consultant for healthcare IT and is involved in education, specification and implementation projects mainly throughout Europe. He is member/contributor of several standardization organizations such as HL7 and ISO and author of several standards.

**HL7 Standards looking into the future, Prof. Charles Jaffe, MD, PhD**

Since the advent of the Fresh Look Task Force in 2011, Health Level 7 has placed increasing emphasis on the needs of the implementation community. Fresh Look envisioned a new approach to interoperability that leveraged some of the best elements of Version 2, Version 3, and CDA, while supporting modern web technologies and advances in clinical information modeling. Both FHHR [5] and CIMI (Clinical Information Modeling Initiative) [6] emerged from those efforts. The US Department of Health and Human Services (HHS) released the JASON Report [7], which promoted open APIs as the future of interoperability. The JASON Task Force subsequently leveraged this concept in a significant departure from traditional approaches to interoperability, which resonated with the HL7 FHIR initiative already underway. The Argonaut Project [8], comprised of leading private sector organizations and healthcare systems, has given promise to the evolution of FHIR as a global interoperability platform. Concurrent efforts

The following poster was accepted:

Smart Medications & the Internet of Things

José COSTA TEIXEIRA 1 and Catherine CHRONAKI

1 HL7 Foundation, Brussels, Belgium

Keywords: Mobile Apps, Medication Systems, Patient-Centred Care, Barcode

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 (OSI for barcodes and HL7 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 HL7 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 treatment, 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 need 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 accepted as a plenary panel.

eHealth Consumers at the age of hyper-personalization

Anne MOEN\textsuperscript{a1}, Morten BRUUN-RASMUSSEN\textsuperscript{b}, Rita MENDES\textsuperscript{c}, Petter HURLEN\textsuperscript{d}, Catherine CHRONAKI\textsuperscript{e}

\textsuperscript{a}Institute for health and society, University of Oslo, NORWAY
\textsuperscript{b}MEDIQ, Odense, DENMARK
\textsuperscript{c}SPMS - Shared Services for Ministry of Health, Lisbon, PORTUGAL
\textsuperscript{d}Akershus University Hospital, Lørenskog, NORWAY
\textsuperscript{e}HL7 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 orientate 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.

\textsuperscript{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 our 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 to the varied needs and capacities of eHealth consumers and measure the impact of these resources to the health system and the community.

Potter Hurlen, Akerhus University Hospital, Norway will introduce opportunity of initiatives like myHealthData in the Internet of Things. Potter will discuss the potential role of one’s data in the storing 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.
## Annex 6: Calendar of Events

**openMedicine - calendar of relevant events**

<table>
<thead>
<tr>
<th>2015</th>
<th>July</th>
<th>13-15</th>
<th>2015</th>
<th>OMICS</th>
<th>Asia Pacific Pharma Congress</th>
<th>Beijing</th>
<th>China</th>
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<tr>
<td>July</td>
<td>20-22</td>
<td>OMICS</td>
<td>2015</td>
<td>World Congress on Pharmacology</td>
<td>Brisbane</td>
<td>Australia</td>
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<tr>
<td>July</td>
<td>27-29</td>
<td>OMICS</td>
<td>2015</td>
<td>International Congress on clinical trials</td>
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<tr>
<td>August</td>
<td>3-5</td>
<td>OMICS</td>
<td>2015</td>
<td>5th International Conference on Pharmaceutical affairs</td>
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<tr>
<td>August</td>
<td>10-12</td>
<td>OMICS</td>
<td>2015</td>
<td>4th International Conference Pharmacovigilance &amp; Clinical Trials</td>
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<td>UK</td>
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<td>August</td>
<td>10-12</td>
<td>OMICS</td>
<td>2015</td>
<td>Global Pharma Summit</td>
<td>Philadelphia</td>
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<tr>
<td>August</td>
<td>11-13</td>
<td>OMICS</td>
<td>2015</td>
<td>International Conference Drug Discovery &amp; Designing</td>
<td>Frankfurt</td>
<td>Germany</td>
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<tr>
<td>August</td>
<td>19-23</td>
<td>Medinfo</td>
<td>2015</td>
<td>Medinfo2015 - 15th World Congress on Medical and Health Informatics</td>
<td>Sao Paulo</td>
<td>Brazil</td>
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<td>25-27</td>
<td>OMICS</td>
<td>2015</td>
<td>European Pharma Congress</td>
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<tr>
<td>Aug/Sept</td>
<td>30-06</td>
<td>EMBC</td>
<td>2015</td>
<td>37th Annual International Conference</td>
<td>Milan</td>
<td>Italy</td>
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<tr>
<td>September</td>
<td>26-30</td>
<td>AHIMA</td>
<td>2015</td>
<td>AHIMA 2015 Annual Convention</td>
<td>New Orleans</td>
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<tr>
<td>October</td>
<td>4-9</td>
<td>HL7</td>
<td>2015</td>
<td>29th Annual Plenary &amp; WG</td>
<td>Atlanta</td>
<td>USA</td>
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<td>October</td>
<td>6-8</td>
<td>IHF</td>
<td>2015</td>
<td>39th World Hospital Congress</td>
<td>Chicago</td>
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<tr>
<td>October</td>
<td>12-16</td>
<td>GS1</td>
<td>2015</td>
<td>GS1 Global Standards Event (Autumn)</td>
<td>Warsaw</td>
<td>Poland</td>
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<tr>
<td>Month</td>
<td>Date</td>
<td>Year</td>
<td>Event</td>
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<tr>
<td>October</td>
<td>17-23</td>
<td>2015</td>
<td>WHO-FIC WHO - Family of International Classifications meeting</td>
<td>Manchester, UK</td>
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<td>October</td>
<td>19-22</td>
<td>2015</td>
<td>GS1 GS1 Global Healthcare Conference (Autumn)</td>
<td>Budapest, Hungary</td>
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<td>October</td>
<td>25-30</td>
<td>2015</td>
<td>IHTSDO IHTSDO October Business Meeting &amp; SNOMED CT Expo 2015</td>
<td>Montevideo, Uruguay</td>
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<tr>
<td>November</td>
<td>02-06</td>
<td>2015</td>
<td>ISO/TC215 ISO/TC215 Health Informatics Plenary (with JIC meeting included)</td>
<td>Bern, Switzerland</td>
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<tr>
<td>November</td>
<td>09-13</td>
<td>2015</td>
<td>CDISC CDISC International Interchange 2015</td>
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<td>November</td>
<td>14-18</td>
<td>2015</td>
<td>AMIA AMIA 2015 Annual Symposium</td>
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<td>December</td>
<td>7-9</td>
<td>2015</td>
<td>OMICS 3rd International Conference on Clinical Pharmacy</td>
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<td>January</td>
<td>10-15</td>
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<td>HL7 WG meeting</td>
<td>Orlando, USA</td>
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<td>February</td>
<td>22-26</td>
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<td>GS1 GS1 Global Forum 2016</td>
<td>Brussels, Belgium</td>
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<td>Feb/March</td>
<td>29-04</td>
<td>2016</td>
<td>HIMSS US HIMSS16 Annual US Conference</td>
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<td>17-20</td>
<td>2016</td>
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<td>TBC, TBC</td>
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<td>08-13</td>
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<td>HL7 WG meeting</td>
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<td>June</td>
<td>25-29</td>
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<td>Geneva, Switzerland</td>
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<td>September</td>
<td>18-23</td>
<td>2014</td>
<td>HL7 30th Annual Plenary &amp; WG</td>
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<td>15-20</td>
<td>2016</td>
<td>AHIMA AHIMA 2016 Annual Convention</td>
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<tr>
<td>October</td>
<td>17-21</td>
<td>2016</td>
<td>ISO/TC215 ISO/TC215 Health Informatics Plenary (with JIC meeting included)</td>
<td>Malaysia</td>
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Overview of OMICS conferences
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<td>2016</td>
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