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Abstract (for dissemination)

This document presents the communication plan of the openMedicine Project. It provides the core elements of its strategy to engage the stakeholders in the lifecycle of medicinal products by developing material and language that appeals to their values bridging local, EU, transatlantic, and global perspectives. This strategy will evolve in the course of the project through consultation with the expert advisory council and in collaboration with the EC, EMA, WHO, eHN in: (a) developing and maintaining a stakeholder registry; (b) executing targeted communication activities with quality assured content; (c) using networks and targeted communication and publicity kits to increase impact and outreach; (d) working with SDOs to maintain and promote artefacts created in this project in a pre-coordinated way; (e) presenting the interoperability of pharmaceuticals products as social good, an aspect of patient safety, and a driver of innovation and growth in policy circles.

The communication plan aims to be actionable, inclusive, targeted and agile focusing on stakeholder engagement identifying influencers, enablers, policy makers, thought leaders and decision makers. It shows how using the stakeholder registry, openMedicine will establish and nurture liaison activities that will ensure wide exploitation of project results by relevant stakeholders. Liaison activities include endorsement of conferences, presentations in workshops, panels. A set of indicators assessing the results of individual activities is also presented.

Keywords

Dissemination, Liaison, Stakeholders

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This deliverable contains original unpublished work except where clearly indicated otherwise.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

The objectives of the openMedicine Communication plan are:

(a) to raise awareness on the openMedicine project especially addressing the medicinal product (MP) lifecycle community including pharma industry, pharmacists, prescribers, health authorities, national and European drug agencies, pharmacovigilance institutes, hospital associations and healthcare facilities, healthcare providers, social workers, advocacy groups, health software vendors;

(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 one central key message. The key message of the project is as follows:

*openMedicine aims to solve the medicine identification and substitution problems in Europe (and hopefully globally), in a scalable and sustainable way that bridges local and European, transatlantic 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 and promote artefacts created in this project in a pre-coordinated way
- Identify and approach influencers, enablers, policy makers, thought leaders and decision makers.

The design elements of the communication plan are as follows:

- 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](http://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 plan will be monitored in six month intervals and adjusted in consultation with the experts involved in project work. This document presents primarily the communication strategy and plan over the lifecycle of the study, including a report on activities during the first 6 months of the project.
Specific indicators that will be monitored over time are:

- Visits to the web site
- Publications, Events attended and presentations delivered
- Newsletters and blogposts (including articles supporting the objectives of openMedicine)
- Mentions of the project on Twitter and LinkedIn
- Meetings with SDOs, (national) agencies, politicians etc.
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.

**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 list\(^1\). 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.

**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 inter-operable 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**

**ICSR – Individual Case Safety Report** is report of an adverse event\(^2\). 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](http://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

**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

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Pharmacopoeia (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 EudraVigilance web portal, EVWEB.

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

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 comprises 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 and Objectives of WP7 (Communication & Liaison)

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.

To secure this buy-in, the communication WP focuses on the targeted stakeholders namely mainly the national drug agencies as well as stakeholders involved in the production, prescription and dispensing of MPs. Additionally, openMedicine will reach out and cultivate relations with expert organizations and user representatives linked to numerous research activities, while liaising with their US counterparts in the industry but also in policy, deployment, and academia.

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.

3.3 Structure of the Communication Plan

The structure of the communication plan includes the following components, each of which is described in a section of this report: stakeholder registry, dissemination channels, press kit, and indicators of success.

In a separate section we present the dissemination activities for the first 6 months of the project i.e. January to June 2015.

The appendices provide information forms for the consortium members to report events.
4 Communication Strategy

4.1 Generic Elements of a Communication Strategy

In this section we sketch the openMedicine communication strategy that will be refined, enriched, elaborated, and potentially adapted in the course of project execution across the following dimensions that are outlined in specific sections of this report:

- goal, objectives
- actors
- addressees
- structures
- processes
- communication channels, modalities
- communication objects
- resources
- evaluation

4.2 OpenMedicine Strategy

The following figure presents an overview of the openMedicine communication strategy.

![Figure 1: Operational dissemination approach](image)

4.2.1 Goals and Objectives

The main goal of the openMedicine strategy is to promote the results of the project and share the main aspiration of openMedicine as outlined below:
openMedicine aims to solve the medicine identification and substitution problems in Europe (and hopefully globally), in a scalable and sustainable way that bridges local and European, transatlantic, and global perspectives.

Following the letter of the contract with the European Commission §38 the project will promote the action and visibility of EU funding by providing information to multiple including the media and the public in a strategic and effective matter following the guidance of the EC5. In that spirit, this report presents a comprehensive communication plan that address the "public policy perspective" with their communication activities at a measure proportionate to the scale of the action, which will be coordinated by openMedicine WP7.

4.2.2 Actors

The main actors of the communication strategy are project partners and by virtue of the nature of the project, SDOs, the EMA, and the Expert Council.

4.2.3 Addressees

Addressees of the communication strategy are the stakeholders listed in the stakeholder registry. Analysis of the broad stakeholder categories appears in section 5. In the initial phase of the project our emphasis is with the regulatory bodies of the member states starting with the members of the consortium and the relevant groups established by EMA.

4.2.4 Structures

The main structures driving the openMedicine strategy, to be regularly evaluated in the course of the project are:

- Web site team at empirica: makes sure the [www.open-medicine.eu](http://www.open-medicine.eu) website is up-to-date
- Communication team comprising all partners in WP7: refines, directs, and keeps tract of the operational communication activities
- Expert Council: advise the communication strategy highlighting potential gaps and opportunities

Topics of relevance to the communication strategy are addressed in meetings of these groups.

4.2.5 Processes

The openMedicine Communications team touches base monthly and addresses all aspects of the project including those of the communication strategy. All partners contribute their communication activities which are updated by the web site team on [www.open-medicine.eu](http://www.open-medicine.eu).

The communication team chaired by the WP7 leader meets regularly to prioritize dissemination activities based on the resources available.

4.2.6 Coverage

In terms of coverage, the expectation is to cover different levels in parallel, as shown below:

- International
- European
- National

Regional

4.2.7 Target Audience, Dissemination Items and Channels

The following figure presents the generic tools that will be employed by the openMedicine communication strategy and be evaluated based on the indicators set by the relevant project structures.

![Main communication channels / modalities framework](image)

Figure 2: Main communication channels / modalities framework to be employed in openMedicine

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.

In the legend: +++ very relevant to – not relevant.

Table 1: Relevance to dissemination items to different target audience

<table>
<thead>
<tr>
<th>Dissemination Items &amp; modalities/channel</th>
<th>Target Audiences</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>openMedicine community</td>
</tr>
<tr>
<td>News of Project</td>
<td>+++</td>
</tr>
<tr>
<td>Explanation of purpose, goal, outputs</td>
<td>+++</td>
</tr>
<tr>
<td>Call for Experts</td>
<td>+++</td>
</tr>
<tr>
<td>Invitations to meetings</td>
<td>+++</td>
</tr>
<tr>
<td>Videos</td>
<td>+++</td>
</tr>
<tr>
<td>Draft Roadmap</td>
<td>+++</td>
</tr>
<tr>
<td>Final Roadmap</td>
<td>+++</td>
</tr>
</tbody>
</table>
4.2.8 Communication Objects

The primary communication objects are project results as reflected in the key deliverables of the project. There are different ways that these objects will be prepared and packaged for dissemination, e.g.:

- Leaflet
- Brochure
- Newsletter
- Press Release
- News/Magazine
- Website-Entry
- Social Network
- Video
- Interview
- Journal Article
- Book Chapter
- Conference Paper
- Other publication

4.2.9 Resources

OpenMedicine dedicates 8.5 person months to the communication and liaison workpackage. However the actual investment is higher since the project relies in other tasks and resources for the management of the website and the communication with the expert council.

4.2.10 Evaluation

Every six months the openMedicine communication strategy will be reevaluated on the basis of the indicators set up in the relevant section of this report and in conformance to the guidance of the European Commission communication policy requirements. The relevant checklist to be reported in the biannual updates appears in the table below.

<table>
<thead>
<tr>
<th>European Commission communication policy requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When</strong></td>
</tr>
</tbody>
</table>
| Within 6 weeks after start of the project or as soon as possible | 1. website which should at least contain
   - an EU logo of minimum 1 cm with the text "(Co-)funded by the European Union"⁶
   - under this logo you can put a link to our website: http://ec.europa.eu/digital-agenda/en/digital-life/health
   - link of the website to be sent to Carolien.Nijenhuis@ec.europa.eu |
|                                                       | 2. 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. Twitter account |

⁶ Guidance for the logo specifics for this can be found here: http://ec.europa.eu/research/pdf/eu_emblem_rules_2012.pdf
<table>
<thead>
<tr>
<th>Time Frame</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>One year to 6 months before the end of the project</td>
<td>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.</td>
</tr>
<tr>
<td>Before, during or after the project</td>
<td>5. Inform <a href="mailto:Carolien.Nijenhuis@ec.europa.eu">Carolien.Nijenhuis@ec.europa.eu</a> of any press release, article in the media!</td>
</tr>
</tbody>
</table>

- other social media is welcome (facebook page, LinkedIn, YouTube)
- sent accounts to Carolien.Nijenhuis@ec.europa.eu

4. newsworthy story - a news item/press release announcing the project to be sent to Carolien.Nijenhuis@ec.europa.eu

5. follow @EU_eHealth on twitter

6. subscribe to the newsletter eHealth in Focus for the latest news of other projects, policy & events.
5 Addressees of the Strategy: Stakeholder Registry

5.1 Medicine Lifecycle

The medication lifecycle includes a large number of actors, most of which interact with the regulatory sphere and not health care information technology per se. However, lately more and more the pharma industry realises the added-value from eHealth and ICT applications and services as key enablers to streamline and improve the life cycle of medicinal products.

Figure 3: Lifecycle of a new drug, showing the many actors involved\(^7\). The figure mentions FDA, however a similar process would apply in Europe with EMA, FDA’s European counterpart.

Figure 3 shows key parts in the lifecycle of a medicinal product comprising of preclinical and clinical research, data analysis, approval and post-approval testing and monitoring. In each phase a different group of stakeholders kicks in. For openMedicine to succeed engagement in as many phases of drug development as possible is relevant to its long term impact.

Figure 4 takes a more comprehensive stand and links the investigation, consumption, and disposal, including the environmental impact, of medicinal products.

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\(^7\) [http://www.grant Thornton.com/Issues/Library/Articles/Life-Sciences/2013/12-13-Deductions-Can-Lighten-Life-Sciences-Startup-Costs.aspx](http://www.grant Thornton.com/Issues/Library/Articles/Life-Sciences/2013/12-13-Deductions-Can-Lighten-Life-Sciences-Startup-Costs.aspx)
Figure 4: The lifecycle of medicinal products according to the noPILLS in Waters initiative at the Dutch National Institute for Public Health and the Environment.

The life cycle aspect of adverse event reporting is highlighted in the following graph:

Figure 5: Actors in involved in the part of the medicinal product lifecycle concerned with adverse event reporting.

Figure 5 shows, in the context of post market surveillance most actors involved in reporting an adverse event: the patient, the doctor/pharmacist, the monitoring center, and the relevant regulatory body (s).
Through these different viewpoints, it is evident that medicinal products significantly impact our lives, and the ability to uniquely identify them, is key not only to patient safety and quality care of the individuals, but also to the people connected directly or indirectly.

5.2 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.

5.2.1 Market Authorization Holders – Pharma Industry

The European Medicines Agency is responsible for the centralized authorization procedure for human and veterinary medicines across the Union. This procedure results in a single marketing authorization that is valid in all EU countries, as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway. For some advanced medicines centralized authorization by EMA resulting in a single market authorization is compulsory. This is the case for:

- human medicines for the treatment of human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS), cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases;
- veterinary medicines for use as growth or yield enhancers;
- medicines derived from biotechnology processes, such as genetic engineering;
- advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;
- officially designated 'orphan medicines' (medicines used for rare human diseases).

For medicines that fall outside the scope of the centralized procedure, national authorization procedures lead to marketing authorization within a specific territory.

Marketing authorization holders submit information on medicinal products they hold marketing authorizations optionally using the EWEB interface. After 2016, marketing authorization holders will submit information in the IDMP format.

Thus, they are an important stakeholder of the work to be undertaken in openMedicine.

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.

5.2.2 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.

5.2.3 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.

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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.

5.2.4 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\(^9\), Z-Index\(^{10}\) in the Netherlands and Vidal\(^{11}\) 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. In that role they participated in the openMedicine expert council that convened at EMA, in London on 25 June 2015.

5.2.5 Medicinal Product Masterdata

Medicinal product masterdata dictionaries are (IT) systems that contain the lists and information about medicinal products. These masterdata can vary in scope of action, the process covered (relating to what is described in section Fehler! Verweisquelle konnte nicht gefunden werden.), etc., for other member states.

One such masterdata dictionary is the XEVMPD in which EMA maintains most recent information focused on the regulatory aspects.

5.2.6 National Formulae

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

5.2.7 Pharmacopoeias

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.\(^{12}\) Its European Pharmacopoeia is legally binding in all its member states.

5.2.8 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.

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\(^9\) http://www.fdbhealth.com/
\(^{10}\) http://www.z-index.nl
\(^{11}\) http://vidal-ds.com/
\(^{12}\) See https://www.edqm.eu/en/european-pharmacopoeia-8th-edition-1563.html: “The European Pharmacopoeia (Ph. Eur.) defines requirements for the qualitative and quantitative composition of medicines, the tests to be carried out on medicines and on substances and materials used in their production.”
D7.1 Communication Plan

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.

5.2.9 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.

5.2.10 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.

5.2.11 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.).

5.2.12 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.

5.2.13 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.
5.2.14 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.

5.2.15 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.

5.2.16 Health Professional Organizations

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

5.2.17 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.

5.2.18 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 are:

- HL7 is launching FHIR, a new standard for interoperability and continuously maintaining and supporting existing HL7 v2, and HL7 v3 standards and CDA templates.
- ISO TC 215 WG6 is defining a standard for electronic prescription and technical specifications for “medicinal product dictionaries systems for health care” and “dispense record”.
- GS1 is providing guidance for the identification of medicinal product packaging in the context of the implementation of the “Falsified Medicines Directive” 2011/62/EC
- IHE is improving and defining new profiles for prescription and dispensing as well as informative materials.
The JIC of Global health informatics standardization comprising CEN, ISO, HL7, CDISC, IHTSDO, GS1, IHE and DICOM supports the effort.

Given the asynchronous balloting cycles of these SDOs and profiling organizations, it imperative that primary requirements, work in progress, and well as completed work are effective and timely communicated bilaterally between openMedicine and the SDOs and profiling organizations.

The approach is the following:

- First agreement on eventual collaboration, given that openMedicine team members participate in the groups
- Definition of discussions to be held (requirements, clarification, guidance, informative materials) from the openMedicine deliverables.
- 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 Appendices 5 and 6 and updated according to the progress in the different groups. It is envisioned that these appendices will be regularly updated in the course of the project. However, in many ways, ISO IDMP is the centrepiece of the relevant openMedicine work as shown in Figure 6.

**Figure 6:** International activities and IDMP (slide presented by Jean-Francois FORGET at the Joint ISO/HL7/IHE Pharmacy meeting of May 2015.)
5.3 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 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.

5.3.1 EU Network Data Board (EUNDB)

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

5.3.2 EMA/ISO IDMP Task Force

Early 2015, EMA has called a Task Force to contribute to IDMP implementation in Europe. The Task Force includes 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 based on agreed EU implementation principles.

5.4 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 Regulato, which although natural in skype falls within the proposal.

5.5 Related European Projects

There are serval EU co-funded project that offer important insights: eStandards, AssessCT, VALUeHEALTH, SALUS, JAseHN, and EXPAND are presented below.

5.5.1 eStandards: eHealth Standards & Profiles in Action for Europe and Beyond

The eStandards CSA was by HL7, CEN TC251, & IHE, leading Standards Organizations (SDOs), and is supported by the eHealth Network, ISO TC215, GS1, IHTSDO, IEEE11073, and IMIA to advance eHealth interoperability and global alignment of standards with seven objectives: The eStandards CSA is proposed by HL7, CEN TC251, & IHE, leading Standards Organizations (SDOs), and is supported by the eHealth Network, ISO TC215, GS1, IHTSDO, IEEE11073, and IMIA to advance eHealth interoperability and global alignment of standards with seven objectives:
1. Join up with Stakeholders in Europe and globally to build consensus on eHealth standards, accelerate knowledge-sharing, and promote wide adoption of standards.

2. Deliver an evidence-based Roadmap for alignment, iterative consolidation, and broad acceptance of eStandards that is endorsed by SDOs, the eHealth Network, the providers, and the Industry.

3. Contribute to the eHealth Interoperability Framework use cases focusing on clinical content modelling for different paradigms and embed a Quality Management System for interoperability testing & certification of eHealth systems.

4. Collect evidence and provide guidance on the coexistence of competing or overlapping standards in large-scale eHealth deployment nationally and cross-border.

5. Participate in EU/US MoU roadmap actions as the international patient summaries standard.

6. Explore socio-economic aspects of eHealth interoperability, revisiting the language for user-vendor interaction that embodies ‘co-making’ in trust, collaboration and long-term engagement.

7. Align across PHC-34 to nurture innovation, sustainability & growth under CEF and beyond contributing to Key actions of the Digital Agenda 2020.

The eStandards’ ambition is to strengthen Europe’s voice and impact, while reinforcing the bridges established with the EU Patient Summary guideline across the Atlantic in Trillium Bridge and among MS with epSOS, eSENS, Antilope, and EXPAND. The eStandards Roadmap and associated evidence base, a white paper on the need for formal standards, and two guidelines addressing how to work with: (a) clinical content in profiles and (b) competing standards in large-scale eHealth deployments will be pragmatic steps toward alignment and convergence.

Relation to openMedicine

eStandards is synergetic to openMedicine in that standards need mature and time/cost impossible these days.

The EC has organized on June 3, a PHC-34 Coordination meeting with participation of PHC34 coordinators, project officers, and key persons of JAsfeHN Joint action supporting the eHealth Network. openMedicine was represented by J. Devlis from Custodix (WP6 lead). A follow up meeting is tentatively planned for November 2015.

5.5.2 ASSESS CT

ASSESS CT will contribute to better semantic interoperability of eHealth services in Europe, in order to optimize care and to minimize harm in delivery of care. In a joint one-year effort, the ASSESS CT consortium will investigate the fitness of the clinical terminology SNOMED CT as a potential standard for EU-wide eHealth deployments, scrutinizing clinical, technical, financial, and organizational aspects. Unbiased towards SNOMED CT adoption, the ASSESS CT project will employ established evaluation approaches from social science. It will scrutinize adoption against two alternative scenarios: to abstain from actions at the EU level, or to devise an EU-wide semantic interoperability framework without SNOMED CT.

ASSESS CT will review the current state of SNOMED CT through survey and focus group, regarding its use by IHTSDO members and the fulfillment of semantic interoperability use cases, the relationship with EU-wide recommendations, known technical and organizational drawbacks, and maintenance of the terminology. A series of studies using sampled clinical data will provide new evidence about conceptual and term coverage for selected languages, as well as technical fitness in manual and automated semantic annotation scenarios. The consortium will also analyze the impact of SNOMED CT adoption from a socio-economic viewpoint, encompassing management, business, organizational, and governance aspects.
Validation of all working tasks, both political and domain-specific, will be secured through four large workshops with a list of distinguished experts assembled in an Expert Panel, Committee of MS Representatives, and national focus groups. Sufficient budget is reserved, also for coordination across the parallel H2020 Call PHC-34 projects. Concrete strategy recommendations will be delivered to both MS, the EC, and SDOs about how SNOMED CT can scale up successful adoption and contribute to building a EU eHealth Interoperability Framework.

**Relation to openMedicine**

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.

ASSESS CT participated to the PHC-34 coordination meeting on June 3rd, previously reported.

### 5.5.3 VALUeHEALTH

VALUeHEALTH is a Research and Development project within the Horizon 2020 Framework Programme and is funded by the European Union. The project will demonstrate how interoperability of health information can consistently create, deliver, and capture value for all stakeholders, in order to justify sustainable investments in scaling up interoperability across Europe.

VALUeHEALTH will establish how eHealth interoperability can create, deliver, and capture value for all stakeholders, to justify a sustainable market in scaling up cross-border interoperability. An evidence-based business plan for sustainable interoperability, with sustainable revenue streams for developing and operating self-funding priority pan-European eHealth Services beyond 2020.

This will not only include the costs and revenues, and their timelines, but the strategies needed to derive value from them - which is vital to justify sustainability. One important context is substantial investment in Europe through the CEF in establishing a pan-European digital services infrastructure covering multiple public sectors. This investment provides a unique opportunity and momentum to define and deliver a more strategically sound, value driven, business plan to realize sustainable eHealth interoperability. The CEF will offer a time window of European funding in generic services, and for some specialized eHealth specific services, that eHealth can take advantage of. CEF (public) funding is not a long-term solution, but an important enabler. The permanent solution is to construct a value chain that maintains a perpetual cycle of investments in interoperability that become embedded within the larger ecosystem of the health care delivery and health ICT sectors, and indeed bring sufficient benefit to enhance those sectors. VALUeHEALTH will demonstrate how this critical value chain can be constructed and optimized by developing an evidence-based business plan for sustainable pan-European services.

Thus the goals for VALUeHEALTH are:

1. VALUeHEALTH aims to produce a prioritised list of use cases, whose relevance has been determined by Member States on the basis of cross-border and within border health service priorities and business needs.
2. VALUeHEALTH will use a business model reference framework to define multiple stakeholder Value Propositions for European scale interoperability, define the multisided market which needs to sustain investments in interoperability services, perform state of the art Cost Benefit Assessment and from this develop a strategic plan for sustainability.
3. VALUeHEALTH will collate the experience gained so far across Europe in success strategies for promoting the adoption (creation and use) of high-quality structured and coded health records, and of organisational changes needed to capitalize on the benefit of richly
interoperable, computable health information, to produce a roadmap of scale-up adoption strategies including recommended incentives and who should fund them.

4. VALUeHEALTH will examine the European digital services that are needed to deliver the prioritised use cases, the interfaces, standards and platform services and tools to deliver them, and from this derive a design and deployment roadmap which prioritizes the key services needed for the prioritised use cases. It will differentiate generic services from those specifically needed by health care, by tracking the evolution of the DSI specifications. We will include a gap analysis of standards, technical specifications and translations together with an indication of their urgency and estimated costs.

5. Finally, VALUeHEALTH will pull all of these results together to create a definitive business plan and sustainability strategy for taking forward public and private investment in digital eHealth services, to provide clear guidance to the CEF on how it may construct its digital service infrastructure (DSI) in relation to health, in order to ensure maximum value and optimal sustainability. This will be detailed, and not only include the costs and revenues, and their timelines, but the strategies needed to derive value from them - which is vital to justify their sustainability.

**Relationship to VALUeHEALTH**

At this point relationship of VALUeHEALTH to openMedicine need some additional analysis.

VALUeHEALTH participated to the PHC-34 coordination meeting on June 3rd, previously reported.

**5.5.4 SALUS**

Pre-approval clinical trials cannot possibly ensure that a drug will not have disastrous side effects once it arrives on the market. Post-approval safety data gathering was put in place to address this problem, but as implemented, it has not proven to be as effective as hoped. This is due to the fact that, current post market safety studies largely depend on the submission of spontaneous case reports where underreporting is a major problem.

The need for a proactive approach is apparent, where safety data from multiple sources are actively monitored, linked and analyzed. Effective integration and utilization of electronic health records (EHR) can help to improve post-market safety activities on a proactive basis. There are prototype studies to monitor EHRs for simplifying ADE reporting, and also for signal detection by screening multiple EHRs, however these tools are directly built on top of EHR/EMR systems through proprietary interfaces. It is apparent that the promise of proactive, continuous monitoring of multiple sources cannot be achieved through such proprietary integrations. To facilitate wide scale proactive post market safety studies, there is a need for a new capacity enabling accessing the data locked in multiple different heterogeneous EHR systems. In SALUS project, we aim to provide a standard-based interoperability framework that will enable execution of safety studies for mining and analyzing real-time patient relations data in communication with disparate heterogeneous EHR systems. SALUS will provide:

- Functional interoperability profiles enabling exchange of EHRs
- Semantic interoperability solutions enabling meaningful interpretation of the exchanged EHRs
- Security and Privacy mechanisms ensuring EHRs are shared in an ethical and safe way
- A novel framework for open-ended temporal pattern discovery for safety studies on top of EHR Systems
Implementation of high potential use cases enabling secondary use of EHRs for post market safety studies

Relationship to openMedicine

Identification of medicinal products for additional use cases, pharmacovigilance, assessed in Task 1.2, and consequent decisions in WP2 could take advantage of the experience gained in SALUS.

There is potential for synergies to be further discussed and clarified.

5.5.5 JAseHN - Joint Action to support the eHealth Network

The overall ambition from MS is to better include eHealth into health policy and better align eHealth investments to health needs. A central aspect is the transferability of health data across borders of MS and therefore the organizational, technical, semantic and legal interoperability of eHealth. In order to ensure progress and to bridge the gaps between the governance, strategy and operational levels, a dedicated mechanism for eHealth at EU level has been established: The eHN was formally established in 2011 through the Commission’s Implementing Decision 2011/890/EU based on Art. 14.3 Directive 2011/24/EU and represents the highest decision-making body at EU political level. At a European level, there is a strong need to maintain this mechanism and to ensure further common political leadership and ongoing integration of eHealth into health policy in order to continue developing eHealth services responding to the needs and health objectives of health systems. This is the framework for the eHN JA, which is led by the EU MS and co-financed by the European Commission (EC).

Hence, the general objective of the action is to act as the main preparatory body for the eHN. By doing so, the JA aims to develop political recommendations and instruments for cooperation in the four specific priority areas that are specified in the eHN’s MWP and that were adopted by the eHN in May 2014: (1) interoperability and standardisation, (2) monitoring and assessment of implementation, (3) exchange of knowledge and (4) global cooperation and positioning. The content-related work packages (WP) of this JA have been articulated in a way that they can address the majority of the needs linked to these four priority areas.

Thereby, the JA functions also as a platform for operational and strategic cooperation between MS on eHealth including their relationship with numerous eHealth stakeholder groups and standardization organizations. Within this framework, the eHN, the EC and the MSs will discuss and agree on political and strategic issues related to eHealth, in accordance with Art. 14 Directive 2011/24/EU, including political prioritization. To ensure coordination, coherence and consistency between the political level (the eHN) and the operational level (experts working in the WPs of the JA), the eHN shall provide guidance as well as feedback for the work of the JA as appropriate. The overall work that will be done by the JA shall lead to quality securing and shall result in the continuity, safety and efficiency of healthcare provided with the support of ICT.

Relation to openMedicine

In the July 3, 2015 PHC-34 co-ordination meeting, it was agreed to identify “meeting points” between the JAseHN and the openMedicine workplan so as to raise awareness in the eHN of the openMedicine results and recommendations.

5.5.6 EXPAND Thematic Network

The aim of the EXPAND Thematic Network is to address the challenge of moving from a set of point-solution pilots to a large-scale deployment of cross-border facilities that support
Member States (MS) in delivering their local eHealth plans and providing cross-border care. In particular, the objective of EXPAND is to launch a process through which it will be possible to harness the available resources and to act as a catalyst for their operational use on a large scale. While this process shall cater to cross border eHealth services in general, the initial focus of EXPAND shall be to secure the sustainability and expandability of the epSOS pilot services including the proper handover, up to the launch of the Connecting Europe Facility (CEF).

EXPAND will in particular focus on demonstrating expansibility and scalability, as well as the potential of accelerated deployment through re-using eHealth assets created by both EU and national initiatives. In order to meet this overarching objective, the network will focus also on establishing an assessment scheme through which maturity, usability and hence appropriateness, for this purpose, can be determined of the assets which have been, or are being, developed by standardization bodies and EU projects. Such assets will be primarily those contributing to the establishment of an EU wide infostructure.

EXPAND is expected to:

Maintain and further develop interoperability assets which have a European scope,
Integrate any relevant recommendations and decisions taken by the eHealth Network and report to the eHN on the deliverables of EXPAND.
Foresee a proper handover strategy from the successful proposal to the CEF
Bring together a wide range of relevant stakeholders with expertise in the development, implementation, assessment, maintenance, dissemination and use of the elements of an EU wide infostructure.

EXPAND activities address four main components as follows:

a) A vision concerning the activities of the EXPAND project will be described. This vision will be in line with the decision made by the eHealth Network, and uses the cross-border directive as its basis.

b) Documentation of re-usable Assets. The aim is to build on the outputs of the many eHealth projects in order to re-use the assets. The task is in two parts: to define an assessment framework (criteria of usability and readiness) and then, based on this the identification of useful assets from EU projects at EU level suitable for potential adoption within the infostructure. There will be twin deliverables from this activity: an assessment framework, and a consolidated list of assets.

c) Interoperability needs. Tools will be needed to help multiple classes of user to identify individual resources or resource bundles that are targeted at particular interoperability needs. Some examples of these tools and services will be designed by SHN for semantic interoperability. EXPAND will pick up from that work and extend the scope to the wider range of interoperability resources and also it will aim to specify a workplan through which the main features of an Infostructure could be implemented.

d) Handing over to CEF is the main focus of the TN through the development of the specifications for a web-based distribution channel for interoperability assets which will contribute to the EU-wide infostructure under the auspices of CEF. These specifications can be used to set up a working information service. This distribution channel will essentially be conveying elements from the epSOS developments and additional elements from other EU-funded projects that may be considered valuable.

There is a deliberate overlap with epSOS, with its terminus on June 2014, as it serves to further guarantee continuity of work, expanding from epSOS to CEF some of existing MS operations and ideally maintaining and expanding assets made available over time.
Relation to openMedicine

Although EXPAND will finish on December 31st, 2015, synergies have been already put in place between the two projects.

For example, the assessment of the EC Guidelines in ePrescription have been included in D1.1 on the assessment epSOS issues on eP, together with the recently adopted change request to ePrescription specifications, to allow eP piloting in Northern MS. On the other hand, the assessment of the possibility to adopt EMA Art. 57 database for pharmacovigilance, triggered in EXPAND after indications from EC and eHN, were performed in openMedicine.

The results have been returned to EXPAND, in order to prepare a formal communication to eHN on potentialities and decisions to be taken by MS.

Further achievements from openMedicine will be, as far as possible, taken into consideration for inclusion on EXPAND revised epSOS specifications, to be handed over to EC and CEF.

After the end of EXPAND, this mechanism would probably be transferred between openMedicine and JAseHN.

5.6 Other relevant work

The European Union "Directive on the application of patients' rights in cross-border healthcare" (DIRECTIVE 2011/24/EU)\(^\text{13}\) stipulates in Article 11 the "Recognition of prescriptions issued in another Member State" for dispensation in any other Member State. It mandates the adoption of non-binding guidelines supporting Member States in developing the interoperability of ePrescriptions without prejudice to national rules.

In order to prepare such guidelines for Member States, the Executive Agency for Health and Consumers (EAHC) of the Directorate General for Health and Consumers (DG SANCO) (Link: [http://ec.europa.eu/dgs/health_food-safety/index_en.htm](http://ec.europa.eu/dgs/health_food-safety/index_en.htm)), European Commission issued a European-wide tender to draft such guidelines. A contract was awarded to empirica and its associates to prepare draft guidelines on interoperable ePrescriptions. Research on this cross-border ePrescription study proceeded in two steps.

Firstly a comprehensive feasibility analysis phase, which gathered broad evidence on the status and processes of national ePrescription services in Member States where such systems exist or were under implementation. This also involved assembling experts across the Union to analyse this knowledge for its relevance to develop evidence-based guidelines indeed meeting the perceived needs of Member States. The second step focused on the concrete formulation of draft guidelines and their extensive validation. This work was complemented by a detailed socio-economic impact analysis of estimated implementation costs associated with guidelines translation into national initiatives.

However, based on the "ePrescription draft guideline proposal" as prepared by empirica and submitted by the EC to the Member States for comment in early 2014, the eHealth Network of Member State representatives further developed and adopted these guidelines. They were published as “Guidelines on ePrescriptions Dataset for Electronic Exchange Under Cross-Border Directive 2011/24/EU. Release 1 – 18 November 2014”\(^\text{14}\).


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.

6.1.1 Activities
Participation in SDO working groups and relevant activities at the JIC level.

6.1.2 Website
The website of the openMedicine project, is available since March 2015 in www.open-medicine.eu.

6.1.3 Twitter
The twitter handles for openMedicine are as
@openmedicine_eu #openmedicine_eu

6.1.4 Publications, Conferences and Newsletters
According to the indicators we will be counting publications, conference papers and slides
7 Press Kit

The openMedicine press kit includes:

- Fact sheet (presented in the appendix),
- Presentation (presented in the appendix)
- Logos in high quality

The press kit will be updated regularly based on progress in the execution of the project and based on feedback from the work carried out and the events underway.
8 Indicators of Success

Specific indicators that will be monitored over time are:

- Visits to the web site
- Publications, events attended and presentations delivered
- Newsletters and blogposts (including articles supporting the objectives of openMedicine)
- Mentions of the project on Twitter and LinkedIn and elsewhere
- Meetings with SDOs, (national) agencies, politicians etc.
9 Dissemination Report [Jan-Jun 2015]

9.1 Activities Carried out

9.1.1 Articles, Presentations, Newsletters
Several presentations in SDO and stakeholder meettings, a conference presentation and a number of newsletters enhanced the visibility of openMedicine in this period. These include:

- 28th May, 2015: openMedicine presented by Jos Devlies at the annual Eudravigilance expert working group workshop of EMA (partnership with SALUS)
- eStandards kick off meeting, Jos Devlies presented

Figure 7: HL7 WGM Meeting materials.
- HL7 Pharmacy meetings in Q1, 2015
- IHE Pharmacy meetings, Q1, 2015
- CEN Management meeting, June 17, 2015
- Newsletter article in HL7 Europe News, May 2015 (see Figure 8: )
- Medical Informatics Europe workshop on “Tools for interoperability: making standards digital?” Madrid, Spain, May 27-29, 2015. The workshop had attendance of 30 people, who were very interested in the notion of employing tools to accelerate standards development and adoption. The topic of medicinal product identification was mentioned as an example and through that openMedicine.

Global Telehealth 2015, Toronto Canada, May 29-30, 2015, Karl Stroetmann presented the scientific paper: Meeting the semantic challenge of the globally unique identification of medicinal products – the openMedicine approach

eHealth Week Riga (11 to 13 of May)

- openMedicine was presented as one of the PHC34 projects in relation to eStandards presentations in (a) EU/US MoU Assembly; (b) in the speakers corner.
  - Attendance was 150-200 people in total.

ISO meeting WG6 San Francisco, April 17-23, 2015

JIC face to face meeting, San Francisco, April 17, 2015

EU Data network meeting, June 2015, Paolo Alcini presented the project.

EC PHC34 and JaseHN coordination meeting, Jos Devlies, July 3, 2015
Figure 8: Newsletter articles in HL7 News 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:

- **Aug 2015:** MedInfo2015 workshop on tools, Sao Paolo Brazil, 19-24 August, 2015. Two relevant workshops are planned were awareness will be raised on openMedicine:
  - “Tools for interoperability – Time for eStandards?”
  - “Information to the point of action – opportunities for medication management?”
- **Sep 2015:** openMedicine, Technical project meeting in Ireland
- **Oct 2015:** HL7 WGM Atlanta, US
- **Nov 2015:** ISO TC251 meeting in Bern, Switzerland, 3rd project executive meeting in Milan, 6th eHN meeting in Brussels. H2020 PHC34 Coordination meeting.
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&lt;sup&gt;16&lt;/sup&gt;</th>
<th>Impact&lt;sup&gt;17&lt;/sup&gt;</th>
<th>Involvement of OpenMed Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Jan 14, 2015</td>
<td>openMedicine kick-off meeting</td>
<td>Bonn, Germany</td>
<td>empirica</td>
<td>Key project contact persons</td>
<td>Full agenda, partner presentations, overall and WP schedule</td>
<td>High attendance Good start</td>
<td>Project Management Committee</td>
</tr>
<tr>
<td>3 Feb 3, 2015</td>
<td>AssessCT kickoff meeting</td>
<td>Bonn, Germany</td>
<td>Empirica</td>
<td>EU projects H2020 PHC34</td>
<td>Information sharing</td>
<td>~20 project participants</td>
<td>Karl Stroetman (empirica) Catherine Chronaki (HL7)</td>
</tr>
<tr>
<td>5 April 17, 2015</td>
<td>Joint Initiative Council on Global SDO Health Informatics Standardization</td>
<td>San Francisco, CA, USA</td>
<td>AHIMA</td>
<td>Standards Developing Organizations</td>
<td>Presentation of openMedicine</td>
<td>~30 experts</td>
<td>Catherine Chronaki (HL7) Robert Stegwee (CEN) Christian Hay (GS1)</td>
</tr>
</tbody>
</table>

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<sup>16</sup> Keynote, presentation, poster, distribution of leaflet, short intervention

<sup>17</sup> Estimated number of attendees (perhaps in steps like: <10, 10-49, 50 – 99, etc.)
## D7.1 Communication Plan

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
<th>Location</th>
<th>Organisation/Contact Person</th>
</tr>
</thead>
</table>
| April 21, 2015 | Member States authority and Competence Centres Engagement Workshop\(^{18}\) | Luxemburg, Luxembourg    | SPMS, eHealth Policy Makers | OpenMedicine, H2020, PHC34, N° 643796, August 17, 2015
| April 29, 2015 | VALUEHealth kickoff meeting                                                      | Brussels                  | EuroRec                     | Information sharing | ~100 | Giorgio Cangioli (HL7) Paolo Alcini (EMA)
| May 6-7, 2015 | eStandards kickoff meeting                                                       | Amsterdam, Netherlands    | Nictiz                      | Information sharing | ~30 experts | Catherine Chronaki (HL7)
| May 12, 2015 | HL7 Spring WGM, Policy Summit                                                     | Paris, France             | HL7                         | Information sharing | ~20 experts | Jos Devlies (Custodix)
| May 11-15, 2015 | HL7 Spring WGM                                                              | Paris, France             | HL7                         | Information sharing | ~20 people per WG | Girgio Cangioli, Jose Texeira (HL7), Panagiotis Telonis (EMA) William Goosen, Christian Hay (CEN/ISO/NEN)
| May 13, 2015 | eHealth Week                                                                      | Riga, Latvia              | Latvian Presidency, European Commission EHCA alliance | Information sharing | ~30 people | Catherine Chronaki (HL7)
| May 19-20, 2015 | Project Executive Board F2F meeting                                              | Amsterdam, NL             | GS1                         | Information sharing | ~20 people | (on file)

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<tr>
<th>Date</th>
<th>Event Description</th>
<th>Location</th>
<th>Organisation</th>
<th>Notes</th>
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<tbody>
<tr>
<td>May 26-29, 2015</td>
<td>Medical Informatics Europe 2015</td>
<td>Madrid, Spain</td>
<td>Spanish Health Informatics Society</td>
<td>Health informatics community References to openMedicine as part of workshops on Tools for standards development and adoption ~30 participants Catherine Chronaki, Giorgio Cangioli, Charles Jaffe (HL7)</td>
</tr>
<tr>
<td>May 28, 2015</td>
<td>Eudra Vigilance - Expert Working Group of EMA</td>
<td>London, UK</td>
<td>EMA</td>
<td>National Drug Agencies Presentation of openMedicine ~100 experts Jos Devlies (Custodix)</td>
</tr>
<tr>
<td>Jun 25, 2015</td>
<td>openMedicine Expert Council</td>
<td>London, UK</td>
<td>EMA</td>
<td>Expert council members, project representatives Discussion of progress and direction for the project 30 participants , very high impact On file</td>
</tr>
<tr>
<td>Jul 3, 2015</td>
<td>JAsenH, PHC34 coordination meeting</td>
<td>Brussels, Belgium</td>
<td>European Commission</td>
<td>EU project, H2020 PHC34 DG Sante, Cntt Connect /JA Presentation of openMedicine High, leads to better synergy Jos Devlies (Custodix) Paolo Alcini (EMA)</td>
</tr>
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</table>
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 9: First page of the openMedicine portal

The visit log of the portal appears in the figure below.
D7.1 Communication Plan

Figure 10: Visit statistics for the open-medicine.eu portal.
Appendix 1: Stakeholder Registry

For each of the stakeholders mentioned in WP4 we keep the information presented in the table below.

<table>
<thead>
<tr>
<th>Name</th>
<th>Email</th>
<th>Tel</th>
<th>Fax</th>
<th>Stakeholder Category</th>
<th>Comment</th>
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## Appendix 2: Calendar of Events

<table>
<thead>
<tr>
<th>openMedicine - calendar of relevant events</th>
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<tr>
<td><strong>2015</strong></td>
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<td><strong>January</strong> 14</td>
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<td>February 09-14</td>
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Appendix 3: Project Presentation

7/30/2015

D7.1 Communication Plan

Enabling the univocal identification of medicinal products
- Objectives, outcomes and benefits -

Goals

- Enhance the safety and continuity of cross-border (and national level) healthcare through interoperable ePrescriptions
- Propose concrete solutions to the delivery problem: “The challenge in ePrescription is how medicines can be communicated in the cross border setting”
- Univocal identification of a medicinal product dispensed in another country
- If and where substitution is permitted or required, dispensation of an equivalent or similar product in line with national regulations

European Union policy priorities

A Digital Single Market Strategy for Europe
- Digital interoperability & standardisation in the health domain as a means to boost competitiveness

Conceptual approach - Unique identification and description of medicinal products (MPS)

The overall concept to overcome the challenges identified is to develop concrete solutions in a global context:

- A consensus data model (set of common conceptual, logical and implementable data models) – expanding upon the ones developed byodyC and existing ISO 15420 standards
- A common vocabulary (set of codes and identification system for the pharmacological definitions, descriptions and identification of medicinal and pharmaceutical products throughout Europe and globally)

Concerted approach - Interoperability framework

- Application domains: cross-national, regional health systems, healthcare provider organisations
- Business domain: processes, management
- Governance & Legal domain: law, rules, regulations
- Policy domain: policies, strategies, support

Identification levels from substance to cluster

Data Access & Exchange Domain
- Interoperability level 3 (e.g., integration language, message format)
- Structure interoperability level (e.g., data fields, semantics)
- Business interoperability level (data model)
D7.1 Communication Plan

Purpose is...
- NOT to...
  - regulate on how to prescribe a branded medicinal product
  - standardise prescribing and administering medicines
  - define the content and structure of a comprehensive drug database
  - define how to...
    - handle investigational medicines
    - conduct clinical trials
    - manage pharmaceutical information
    - do pharmaceutical research, pharmacoeconomic research
- But to address the identification of the product in each of these applications and for each kind of product

Related standards (1)
- No standard is addressing only the identification issue
  - IDMP suite
    - 16604: for the unique identification and exchange of... product information
    - 16605: for the unique identification and exchange of... measurement
  - 16390: for the unique identification and exchange of... substances
  - 16391: for the unique identification and exchange of... pharmaceutical active... forms, units of presentation, routes of administration and packaging
  - 16402: for the unique identification and exchange of... measurement

Related standards (2)
- Competing “standards” to IDMP
  - IME profile on exchange of prescriptions
  - HI2 (v3) medication domain
  - QPOS specifications
  - What about article 57 EMA?
  - What is needed?
  - Documentation of pros and cons
  - Decision on where we want to travel
  - Motivated decisions
  - Agreement on steps for implementation (roadmap)

Defining substitution
Therapeutic substitution
- Substitution with a chemically different drug. The substituted drug belongs to the same pharmacologic class, but to a different therapeutic class
- (WHO International drug substitution list)
- Substitution with a BP different from the one prescribed for the specific person (e.g., availability of prescribed drug, but not within the same therapeutic class)

Generic/economic substitution
- For a generic substitution, a generic drug is substituted for a brand-name drug. Both drugs have the same active chemical ingredient, same dosage strength and same therapeutic form
- Due to financial reasons a cheaper generic drug, which is not necessarily a copy of the original, is substituted.

Meeting the substitution challenge
- QPOS Member States agreed to adopt a relatively simple substitution approach with the lowest risk of a negative impact on patient safety
- Only two levels of substitution were patented:
  - Substitution of the medicine itself is allowed only if the package size can be changed
  - The substitution of the medicine is allowed as long as the outer packaging and the strength are the same, i.e., the brand name can be changed
  - Differences in substitution are assumed to be in the dosage strength and in the active ingredient level
  - Once a better, global capability of describing/identifying medicinal products commercially is available, the probability that a given substitution can be filled in another country increases

Different levels of substitution
- Package level (different size of package, e.g., 56 tablets instead of 91 tablets)
- Name level: same product with a different name
- Dosage level: same product with a different dosage
- Strength level: same product with a different strength
- Substance level: same active ingredient, different substance (different salt)
- Active ingredient level: e.g., ibuprofen instead of paracetamol (but still the same therapeutic class)
- Complete substitution: different therapeutic class (e.g., bioprophylactic instead of succinate)
D7.1 Communication Plan

Study process

- Concentrate on and give priority to the concepts and data elements related to Medicinal Product Identification for e-prescribing and e-dispensing, and additional use cases (Pharmacovigilance, ...)
- Address the process to validate medicinal descriptions
- Address process and architectural impacts of adopted solution on eHealth cross-border Interoperability Infrastructure (National contact points for eHealth – NCPs – and national infrastructures)
- The dataset is related to administration (preparation, instructions for preparation, instruction for the patients) will only be considered as far as they are used for identification of the medicinal pharmaceutical product

Workflow

Timeline (subject to change)

Coordination and partners

Stakeholder groups/experts

Outcomes

- Common datamodel
- Common vocabulary
- Report on substitution
- A set of recommendations
- Roadmap for implementation
Outcomes

Practical solution to identify, validate, and feed into practical deployment

Benefits

- Safety dispensation to patients of a medicine at least equivalent to the one prescribed in another country
- Easier understanding for medicinal therapy information contained in foreign patient’s summary
- Pharmacists and hospital staff involved in the administration of the medicine can gain knowledge of the product’s “proprieties”
- Simplification and speeding up of the registration of new MPS
- Improvement in communication

Acknowledgements

The ideas, insights and information presented are partially derived from the openMedicine Coordination & Support Action, which received funding from the European Commission Directorate General for Communications Networks, Content and Technology under Grant Agreement No 643796 - support which is gratefully acknowledged.

Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use of the information contained in this document. The views expressed are solely those of the author(s) and do not necessarily reflect those of the European Commission or any other organisation.

We are most grateful to colleagues at the participating organisations as well as external experts who contributed and critically reviewed project work.
D7.1 Communication Plan

OpenMedicine Fact Sheet

Meeting the challenge of open access to medicinal products across the Union

OpenMedicine addresses drug identification and substitution challenges of safely dispensing prescriptions to people no matter where these prescriptions are issued, bridging national, European, transatlantic, and global borders.

Objectives of the project
Identification and substitution of medicinal products
Large scale eHealth implementations of the patient summary and ePrescription services are a policy priority of the eHealth Network of European Union Member State representatives. This requires scalable and sustainable solution of two problems:

First, how can medicinal products be identified so that they are safely dispensed across border in another Member State and globally?

Second, if substitution of medicinal products for therapeutic and/or economic reasons is permitted in a Member State, how are the relevant medicinal products identified when the original prescription comes from another Member State?

OpenMedicine advances the unique identification of medicinal products and the safety of cross-border healthcare through focused actions to deliver:

- a common data model for prescribed medication based on global standards
- an unambiguous vocabulary for description and identification of medicinal and pharmaceutical products
- robust rules to regulate and gradually harmonize concepts and practices of therapeutic and economic substitution
- a global implementation roadmap to realise interoperable and safe eHealth services across local, state, and International borders
- coordination of OpenMedicine practical solutions and policy recommendations with the EU/US roadmap process for eHealth cooperation.

Case Study: Paolo, a retired businessman, technology savvy, suffers from hypertension, likes traveling for recreation, and feels safe while abroad as he is actively involved in managing his health using online tools and gadgets. He works closely with his personal physician, who adjusts Paolo’s medication and dosage to keep his hypertension under control. Paolo meticulously monitors his blood pressure symptoms and adverse events online in his personal health record that supports the European Patient Summary Guideline. While on travel in Poland, Paolo lost the bag with his new prescription medication package, and needs a new one. The patient has a patient summary uploaded and consults a local physician to get a prescription. The local physician identifies the local equivalent medicinal product using appropriate services. The pharmacist dispenses the medicinal product based on that prescription. They are thankful to European COMMANDER, the European Medicinal Products Database.

Project Description
Pushing the envelope for interoperable ePrescription

OpenMedicine addresses the reliable selection/prescription and the safe dispensation of medicines. Accurate identification of medicinal products is critical when the country of prescription differs from the country of dispensing, as in the epSOS ePrescription use cases. Substitution for economic or therapeutic concerns is a related challenge when it is allowed to dispense a different medicinal product than the one prescribed. Substitution is common practice in some countries, but also a reality in emergencies or “on duty” dispensing.

OpenMedicine activities reflect these considerations starting with extending the epSOS cross-border ePrescription use cases (WP1). Work on identification issues (WP2, 3, 4) and substitution (WP5) proceeds in parallel. Recommendations, Roadmap, Validation (WP6) engage external experts and stakeholders. Communication & Liaison (WP7) focuses mainly on national drug agencies, stakeholders in production, prescription and dispensing of medicinal products, but also patients and other players as health IT industry.

Towards a European Medicinal Product Database for reliable and safe border-proof
Expected Benefits and Societal Impact

The impact and benefits of openMedicine for patients, clinicians, pharmacists, regulators and the pharma industry will be significant:

- Patients will obtain seamlessly medicine equivalent to that prescribed to them in another country.
- Clinicians reviewing the patient summary of a foreign patient will fully understand the medication section.
- Pharmacists can safely identify appropriate medicinal products that fulfill the therapeutic requirements of the medicine prescribed abroad, in accordance with local laws and substitution rules.
- Medical trials spanning multiple countries can meaningfully exchange data and care information on medicinal products.
- Identifiers of medicinal products help access "properties" of a medicinal product anywhere, creating opportunities for services supporting patients today and tomorrow.
- Cost of maintaining up-to-date medication lists is reduced.
- Bridges between pharma and health care are reinforced.
- Registration of new products is more efficient.
- Recruitment for clinical trials involving patients in multiple countries will be easier.
- Pharmacovigilance activities are more effective, advancing patient safety and improving health care.

Work in this domain started in 2008, when Standards Development Organizations (SDOs) cooperated globally to develop the identification of Medicinal Product (IDMP) and the adverse event reporting standards (ICSR). Here EMA, the US FDA and other regulators, together with global manufacturers represented through the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) worked together, driven by collaborative spirit and a shared vision. Advancing this work and streamlining implementation based on a validated roadmap is an opportunity for immense global impact.

Moving forward, an effective Governance and regulatory framework adopted by European and national regulatory agencies is essential. It should be translated into the daily practice of feeding and maintaining the data of the common data model, including updates along the life cycle of medicinal products.

The ambition of openMedicine is to push the envelope for open access to medicinal product identification and directly impact safety and quality of care, enabling innovation and supporting economic substitution where appropriate.

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Appendix 4: Reporting from Dissemination events

Event Report

Objective
The objective of this report is to capture and advance the potential of an event prior to it as well as report back after the event.

Prior to the event
1. What is the name and dates of the event?
2. What is the potential engagement of OpenMedicine?
3. What is the overall attendance to the part of the venue?
4. Which are the main OpenMedicine Stakeholders represented?
5. What is the cost of our participation?
6. What are the success measures for this event?
7. Was OpenMedicine presented in the event?
8. Is it mentioned in a publication associated with the event?
9. What is key feedback for Openmedicine for this event?
Appendix 5: Working Items of relevance to openMedicine in Standards and Profile Developing Organizations

<table>
<thead>
<tr>
<th>SDO / Org</th>
<th>Work Group</th>
<th>Activity</th>
<th>Status</th>
<th>Impact / needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>HL7</td>
<td>Pharmacy</td>
<td>FHIR Pharmacy resources (MedicationOrder, MedicationDispense, MedicationStatement)</td>
<td>DSTU / In preparation</td>
<td>Review resources as an aid to modeling, and check for coverage of cross-country dispensing (D2.2)</td>
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<tr>
<td>HL7</td>
<td>Pharmacy</td>
<td>CDA templates</td>
<td>Normative</td>
<td>Review templates as an aid to OpenMedicine modeling (D2.2)</td>
</tr>
<tr>
<td>HL7</td>
<td>Pharmacy</td>
<td>HL7 v3</td>
<td>Normative</td>
<td>Review RIM and V3 messages as an aid to OpenMedicine modeling (D2.2)</td>
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<tr>
<td>HL7</td>
<td>Pharmacy</td>
<td>H7 v2 messages</td>
<td>Normative</td>
<td>Review CH04 messages as an aid to OpenMedicine modeling (D2.2)</td>
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<tr>
<td>ISO</td>
<td>TC215 WG6</td>
<td>IDMP</td>
<td>Final</td>
<td>Use guidance and concepts for product identification</td>
</tr>
<tr>
<td>ISO</td>
<td>TC215 WG6</td>
<td>ISO 17523 - Requirements for e-prescription</td>
<td>In preparation</td>
<td>Cross-Review between ISO and OpenMedicine</td>
</tr>
<tr>
<td>ISO</td>
<td>TC215 WG6</td>
<td>ISO 19256 - Medicinal Product Dictionaries</td>
<td>In preparation</td>
<td>Cross-Review between ISO and OpenMedicine</td>
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<tr>
<td>ISO</td>
<td>TC215 WG6</td>
<td>ISO 19293 - Dispense Record</td>
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<td>Cross-Review between ISO and OpenMedicine</td>
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<tr>
<td>GS1</td>
<td>GS1 Healthcare</td>
<td>EANCOM / XML standards</td>
<td>Final</td>
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<td>GS1</td>
<td>GS1 Healthcare</td>
<td>Guidelines for product identification cc Falsification</td>
<td>Final</td>
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<tr>
<td>IHE</td>
<td>Pharmacy</td>
<td>Community Pharmacy profiles</td>
<td>Published for Public Comment</td>
<td>Cross-Review between IHE and OpenMedicine</td>
</tr>
<tr>
<td>IHE</td>
<td>Pharmacy</td>
<td>Medication Lists content</td>
<td>Published for Public Comment</td>
<td>Check for impact in OpenMedicine (Medication Overview)</td>
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<tr>
<td>IHE</td>
<td>Pharmacy</td>
<td>Common Pharmacy profile</td>
<td>Started</td>
<td>Check for coverage of cross-country dispensing</td>
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<tr>
<td>IHE</td>
<td>Pharmacy</td>
<td>Supply of Products for healthcare</td>
<td>Started</td>
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<td>Hospital Pharmacy profiles</td>
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<td>Pharmacy</td>
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<td>Medication Formularies</td>
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<td>HL7</td>
<td>Pharmacy</td>
<td>FHIR Supply resources</td>
<td>DSTU</td>
<td>(check if any overlap and review / influence)</td>
</tr>
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</table>
## Appendix 6: Collaboration with Standards and Profiling Organizations

### Dependencies and cross-work between OpenMedicine and SDOs

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Detailed description</th>
<th>Initiator</th>
<th>Notes</th>
<th>SDO / WG</th>
<th>OM WP</th>
<th>Originator</th>
<th>Assignee</th>
<th>Status</th>
<th>Expected by</th>
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<tbody>
<tr>
<td>1</td>
<td>Share plan and list of deliverables</td>
<td>Share project description, plan and list of deliverables for common awareness</td>
<td>OM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>José Costa Teixeira</td>
<td></td>
<td>42217</td>
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<tr>
<td>1</td>
<td>Explicitly model standard levels of identification in HL7</td>
<td>&quot;given the fact that codes at different levels of precision can be used to specify medication, do the differences between these levels have to be explicitly modelled?&quot;</td>
<td>OM</td>
<td></td>
<td>HL7 Pharmacy</td>
<td>D1.3</td>
<td>William Goossen (OM)</td>
<td>William Goossen</td>
<td>Final version of D1.3</td>
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<tr>
<td>2</td>
<td>Review ISO 17523</td>
<td>Review e-Prescription standard within OpenMedicine, to check alignment and coverage gaps</td>
<td>ISO</td>
<td></td>
<td>ISO TC215 WG6</td>
<td>Paolo Alcini (ISO)</td>
<td>José Costa Teixeira</td>
<td>Mid August 2015</td>
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<td>3</td>
<td>Review of D1.3</td>
<td>Review of D1.3 Initial openMedicine infostructure</td>
<td>OM</td>
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<td>ISO, HL7, IHE</td>
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<td>M9</td>
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<td>Review of D2.1</td>
<td>Review of D2.1 Report on standards based identification and description enabling dispensing equivalent medicinal products</td>
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<td>ISO, HL7, IHE</td>
<td>M9</td>
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<td>Review of D2.2</td>
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<td>Review of D2.3</td>
<td>Review of D2.3 openMedicine final identifying and descriptive attributes</td>
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<td>Review of D3.2</td>
<td>Review of D3.2 Identification and description of special products</td>
<td>OM</td>
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<td>Review of D4.1</td>
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<td>Review of D5.1</td>
<td>Review of D5.1 Meeting the substitution challenge: Member State regulations and</td>
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</table>


| Review of D5.2 | Review of D5.2 openMedicine substitution: options and roadmap | OM |
| Review of D6.3 | Review of D6.3 openMedicine Recommendations and Roadmap for Implementation | OM |
| Review of D7.3 | Review of 2nd Communication and Liaison Report | OM |