



# REPORT

on

## European Semantic Interoperability in eHealth

### Document Information:

<b>Document status:</b>	For adoption by the members of the eHealth Network at their 12th meeting on 28 November 2017
<b>Approved by JAseHN sPSC</b>	Yes
<b>Document Version:</b>	v1.9
<b>Document Number:</b>	D5.5
<b>Document produced by:</b>	Joint Action to support the eHealth Network <ul style="list-style-type: none"> <li>• WP 5 Interoperability and Standardization</li> <li>• Task 5.5 Semantic Interoperability</li> </ul>
<b>Author(s):</b>	Vanja Pajić (External), Luc Nicolas (External) Michiel Sprenger and Merik Seven, Nictiz (Netherlands)
<b>Member State Contributor(s):</b>	ATNA (Austria), THL (Finland), NICTIZ (Netherlands), MSSSI (Spain), SEHA (Sweden), HSCIC (UK)
<b>Stakeholder Contributor(s):</b>	PwC, SEMIC, ISA Unit, DG INFORMATICS

## TABLE OF CHANGE HISTORY

VERSION	DATE	SUBJECT	MODIFIED BY
V0.1	24-02-2017	FIRST PROPOSAL OF DOCUMENT SCOPE, CONTENT AND TIMING	LUC NICOLAS (EXTERNAL)
V0.11	27-02-2017	ALIGNMENT OF PART 4. ADDING OF METHODOLOGY.	LUC NICOLAS (EXTERNAL)
V0.12	28-02-2017	COMMENTS, ADDITIONS, ETC	MICHIEL SPRENGER / MERIK SEVEN
V.0.13	21-03-2017	MINOR CHANGES FOLLOWING SPSC REVIEW	LUC NICOLAS (EXTERNAL)
V1.0	29-03-2017	FIXED AS PRELIMINARY 1.0, SENT TO SPSC	MICHIEL SPRENGER, NICTIZ
V1.1	21-04-2017	REFERRED PROJECTS DATES ADDED. TIMING ADAPTED.	LUC NICOLAS (EXTERNAL)
V1.1	21-04-2017	CHECKED AND APPROVED	MICHIEL SPRENGER, WPL
V1.2	22-09-2017	FINALIZED THE DOCUMENT & SENT FOR SEMANTIC EXPERTS (NICTIZ) FOR REVIEW	VANJA PAJIĆ (EXTERNAL)
V1.3	06-10-2017	FINALIZED THE DOCUMENT AFTER SEMANTIC EXPERT'S REVIEW	VANJA PAJIĆ (EXTERNAL)
V1.4	09-10-2017	SENT FOR SPSC+WP3+WP4 FOR REVIEW	VANJA PAJIĆ (EXTERNAL)
V1.5	10-10-2017	WP3 QUALITY CHECK	RADU PIRLOG (BBU) ANDREEA MARCU (BBU)
V1.6	09-10-2017	FINALIZED THE DOCUMENT ACCORDING TO WP3 QUALITY CHECK	VANJA PAJIĆ (EXTERNAL)
V1.7	25-10-2017	FINALIZED THE DOCUMENT ACCORDING TO SPSC 1 <sup>st</sup> REVIEW AND SEND FOR 2 <sup>ND</sup> REVIEW	VANJA PAJIĆ (EXTERNAL)
V1.8	06-11-2017	FINALIZED THE DOCUMENT ACCORDING TO SPSC 2 <sup>nd</sup> REVIEW	VANJA PAJIĆ (EXTERNAL)
V1.8.1	08-11-2017	SMALLER ADAPTATIONS OF THE DOCUMENT WITH REGARDS TO THE DISCUSSION DURING SPSC MEETING	VANJA PAJIĆ (EXTERNAL), MICHIEL SPRENGER, WPL
V1.9	09-11-2017	WP3 QUALITY CHECK	RADU PIRLOG (BBU) ANDREEA MARCU (BBU)

## LIST OF ABBREVIATIONS

ACRONYM	DEFINITION
AMDS	ASSET DESCRIPTION METADATA SCHEME
ATC	ANATOMICAL THERAPEUTIC CHEMICAL CLASSIFICATION
CALLIOPE	CALL FOR INTEROPERABILITY
CDA	CLINICAL DOCUMENT ARCHITECTURE
CEF	CONNECTING EUROPE FACILITY
CEN	EUROPEAN COMMITTEE FOR STANDARDIZATION
CPT	CURRENT PROCEDURAL TERMINOLOGY
EC	EUROPEAN COMMISSION
EDQM	EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES
EHGI	EHEALTH GOVERNANCE INITIATIVE
EHN	EHEALTH NETWORK
EHR	ELECTRONIC HEALTH RECORD
EMA	EUROPEAN MEDICINES AGENCY
ESCO	EUROPEAN SKILLS/COMPETENCES, QUALIFICATIONS AND OCCUPATIONS
EU	EUROPEAN UNION
GMDN	GLOBAL MEDICAL DEVICE NOMENCLATURE
HIMMS	THE HEALTHCARE INFORMATION AND MANAGEMENT SYSTEMS SOCIETY
HL7	HEALTH LEVEL 7
ICD	THE INTERNATIONAL CLASSIFICATION OF DISEASES
ICF	INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY AND HEALTH
ICNP	INTERNATIONAL CLASSIFICATION FOR NURSING PRACTICE
ICPC	THE INTERNATIONAL CLASSIFICATION OF PRIMARY CARE
ICT	INFORMATION AND COMMUNICATION TECHNOLOGY
IDMP	IDENTIFICATION OF MEDICINAL PRODUCTS
IHTSDO	INTERNATIONAL HEALTH TERMINOLOGY STANDARDS DEVELOPMENT ORGANISATION (NOW SNOMED CT INTERNATIONAL)
ISO	INTERNATIONAL STANDARDS ORGANISATION
LOGD	LINKED OPEN GOVERNMENT DATA
LOINC	LOGICAL OBSERVATION IDENTIFIERS NAMES AND CODES
MEDRA	MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES
MESH	MEDICAL SUBJECT HEADINGS
MPD	MEDICINAL PRODUCT DICTIONARIES
MPID	MEDICINAL PRODUCT IDENTIFIER
MS	MEMBER STATE OF THE EUROPEAN UNION
MTC	MASTER TRANSLATION CATALOG
MVC	MASTER VALUE CATALOG
PARENT	PATIENT REGISTRIES INITIATIVE
PCHA	PERSONAL CONNECTED HEALTH ALLIANCE
PHPID	PHARMACEUTICAL PRODUCT IDENTIFIER
SDO	STANDARDS DEVELOPMENT ORGANISATION
SEMIC	SEMANTIC INTEROPERABILITY COMMUNITY
SNOMED CT	SYSTEMATIZED NOMENCLATURE OF MEDICINE – CLINICAL TERMS
SPOR	SUBSTANCE, PRODUCT, ORGANISATION AND REFERENTIAL MASTER DATA
TR	TERMINOLOGY RESOURCE
WHO	WORLD HEALTH ORGANIZATION

## TABLE OF CONTENTS

1.	Scope of JaseHN Task 5.5 .....	6
2.	Aim of this report.....	6
3.	Internal dependencies.....	6
4.	Methodology.....	7
5.	Introduction .....	7
	5.1 Semantic Interoperability.....	7
	5.2 Semantic Interoperability Levels.....	8
	5.3 Terminologies, Ontologies, Interfaces & Clinical Models.....	9
	5.4 Semantic Interoperability Projects.....	10
6.	Findings .....	10
	6.1 Common Ontologies, Terminologies and Interfaces.....	10
	6.2 Common Training and Education of Health Professionals .....	11
	6.3 Common Approach to Standards .....	12
	6.4 Cooperation between Member States .....	12
	6.5 Reusing Semantic Projects’ Deliverables .....	12
	6.6 Building of Expert Semantic Communities.....	12
	6.7 The Question of Using SNOMED-CT .....	13
7.	Recommendations .....	13
	<b>RECOMMENDATION #1: Endorse a Common EU-Level Semantic Interoperability Tooling Strategy by Adopting an Implementation Roadmap.....</b>	<b>13</b>
	<b>RECOMMENDATION #2: Use the outcomes of previous semantic projects as a key foundation of that strategy.....</b>	<b>14</b>
	<b>RECOMMENDATION #3: Create a reasonably stable ecosystem of terminologies by connecting EU-level aggregation terminologies, reference direct healthcare provision terminologies, and national user interface terminologies .....</b>	<b>14</b>
	<b>RECOMMENDATION #4: Develop content and services for training and education of end users in order to support “Semantic Literacy” on the Member State national level.....</b>	<b>15</b>
	<b>RECOMMENDATION #5: Start by doing - Select a Promising Use Case/Set and achieve Tangible Semantic Interoperability for that Use Case/Set. ....</b>	<b>15</b>
8.	Final considerations .....	16
	Appendix A: State of play regarding semantic interoperability in the EU .....	18
	A1 Semantic Health (2008).....	18
	A2 Calliope Network (2008 - 2011) .....	19
	A3 SemanticHealthNet (2011 - 2015).....	20
	A4 Antilope Project (2013 - 2015).....	21

<b>A5 ASSESS-CT (2015 - 2016)</b> .....	22
<b>A6 openMedicine (2015 - 2016)</b> .....	24
<b>A7 Semantic Interoperability Community (SEMIC)</b> .....	27
<b>Appendix B: Other relevant projects</b> .....	29

## 1. Scope of JAseHN Task 5.5

The goal of JAseHN's Task 5.5 is to analyse the project deliverables elaborated by dedicated EU funded projects whose objective was to provide a semantic reference point for all key stakeholders in Europe.

The overall objective of this task is thus to provide the eHN with a consolidated analysis of proposals made by national and EU projects which can provide significant inputs in this domain.

JAseHN T5.5 will also make sure that its objectives are aligned with JAseHN tasks 5.3, 5.4, 5.6, 6.1, 6.2 and 7.5, respectively.

## 2. Aim of this report

This report aims at analysing the state of play in EU semantic interoperability with regards to healthcare.

Its main purpose is to provide the eHealth Network with a compilation of recommendations that are based on an analysis of previous semantic interoperability projects' experiences and thus builds upon an already existing body of knowledge and recommendations that have previously not been connected into a coherent list.

The summary of relevant project's recommendations is an important step in achieving synergy towards a common strategic Member State approach to semantic interoperability for both national and cross-border use cases.

## 3. Internal dependencies

eHMSEG established a Semantic Task Force with working groups on legal, architectural and semantic issues. Contact has been established in order to make sure that the key outputs of the task force which is supporting the CEF eHDSI deployment are duly taken on board.

Members of this task force have recently expressed the need to support a longer term vision which goes beyond the more incremental adaptation of the epSOS/EXPAND legacy, but to build up on the results of epSOS/EXPAND.

The first Semantic Boot Camp was organized in March 2017 with as a key objective to allow Member States to show what they are ready to share and also learn from each other's best practices, experiences, and mistakes. Information provided at this occasion was also fed into this report.

The second Semantic Boot Camp was organized in May 2017 where additional sharing of information and training activities took place.

Within eHMSEG, a proposal was made by Switzerland to consider making an EU terminology server (CTS) available for everyone in an Open Source distribution; thus establishing an OpenCTS platform to complement the OpenNCP. The EU would thus directly support Member States in their respective efforts to establish semantic interoperability at national levels. In addition, using a terminology management solution at

Member State level would arguably achieve a higher level of semantic interoperability at the EU level.

Collaboration with other JAseHN tasks such as 5.3, 5.4, 5.6, 6.1, 6.2 and 7.5 has been established in order to ensure proper alignment and avoid overlaps in writing this deliverable.

## 4. Methodology

This report will perform a review of ongoing and past projects, initiatives and strategies both at the EU and Member State level in order to provide the eHN with an updated state of play with regards to semantic interoperability.

Based on these analyses, this report will provide the eHN with a set of recommendations on the next steps that need to be taken in order to ensure semantic interoperability across EU.

The proposed methodology is:

Step 1: Analyse selected deliverables of key projects on semantic interoperability and summarize them according to their most important findings and recommendations. The projects were chosen on the basis of their perceived importance for semantic interoperability across the EU.

Step 2: Formulating proposals of general recommendations for the eHealth Network based on Step 1. These recommendations will summarize and prioritize all the relevant recommendations from relevant projects on semantic interoperability.

## 5. Introduction

### 5.1 Semantic Interoperability

In healthcare, interoperability can be defined as the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged<sup>1</sup>.

Two information systems are considered to be semantically interoperable only if each system can carry out the tasks for which it was designed using concept meanings taken from the other as seamlessly as using its own data and information<sup>2</sup>.

The lack of semantic interoperability between European e-Government systems is one of the major obstacles in the provision of cross-border and cross-sector digital public services.

Semantic interoperability and cross-systems preservation of meaning are therefore a crucial precondition for achieving meaningful communication between healthcare systems today.

Semantic Interoperability should enable the various systems to combine received information with other information resources and to process it in a manner that preserves meaning. It

---

<sup>1</sup> HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations, 2nd Edition, 2010, Appendix B, p190, original source: Wikipedia.

<sup>2</sup> Ceusters W, Terminology and Ontology in Semantic Interoperability of Electronic Health Records, <http://www.who.int/classifications/terminology/ceusters.pdf>

aims at the mental representations that human beings have of the meaning of any given data. To put it in one simple sentence: “what is sent is the same as what is understood”.

In the eHealth context, the reference is made to semantic interoperability as the systems’ capacity, with the support of ICT applications, to exchange, understand and act upon data related to a citizen/patient and other health data, information and knowledge between clinicians, patients and other actors/systems using diverse languages and information coding systems within and between health systems.

In order to sustain the key objectives related to patient security and quality of care, to support chronic patients collaborative/integrated care, to develop home care and to reinforce the empowerment of the patient, the clinical meaning (data, information, knowledge) needs to be expressed in a consistent way which will allow e.g.:

- To share and combine health data between heterogeneous health actors/systems
- To permit the integration and the secured use of protocols, alerts and clinical paths by the EHR systems.
- To support cross-border exchange of information
- To guarantee the necessary quality and consistency of data in order to make possible secondary uses of longitudinal and heterogeneous data to support public health, research or health services management objectives.
- To link EHR data with reference Evidence Based textbooks and educational material in order to maximize patient (and his family/helpers) involvement and to contribute to a digital health literacy.
- To indirectly contain costs and optimise reimbursement

A key component of operational semantic interoperability is to have semantic assets. One needs to differentiate between different types and categories of semantic assets although the same semantic asset can sometimes be classified in different categories:

- What one means (Ontology)
- How one says it (Languages, Terminologies and Code Systems)
- How one finds it (Interface)

## 5.2 Semantic Interoperability Levels

According to HIMMS<sup>3</sup>, in order to advance the effective delivery of healthcare for individuals and communities within eHealth systems, one has to account for three distinct levels of health information technology interoperability:

*“Foundational” interoperability allows data exchange from one information technology system to be received by another and does not require the ability for the receiving information technology system to interpret the data.*

*“Structural” interoperability is an intermediate level that defines the structure or format of data exchange (i.e., the message format standards) where there is uniform movement of healthcare data from one system to another such that the clinical or operational purpose and meaning of the data is preserved and unaltered. Structural*

---

<sup>3</sup> HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations, 3rd Edition, 2013, p. 75.



*interoperability defines the syntax of the data exchange. It ensures that data exchanges between information technology systems can be interpreted at the data field level.*

*“Semantic” interoperability provides interoperability at the highest level, which is the ability of two or more systems or elements to exchange information and to use the information that has been exchanged. Semantic interoperability takes advantage of both the structuring of the data exchange and the codification of the data including vocabulary so that the receiving information technology systems can interpret the data. This level of interoperability supports the electronic exchange of patient summary information among caregivers and other authorized parties via potentially disparate electronic health record (EHR) systems and other systems to improve quality, safety, efficiency, and efficacy of healthcare delivery.<sup>4</sup>*

Therefore, the development of semantic resources is an incremental process consisting of “layers” and necessitates the creation of terminologies, ontologies and meaningful interfaces.

### **5.3 Terminologies, Ontologies, Interfaces & Clinical Models**

In order to achieve semantic interoperability, the systems involved must refer to an agreed authority, typically a terminology that clearly defines the meanings of the items carrying the information.

The use of controlled terminologies, and controlled mapping tables and mapping rules for any transformation promises sufficient reliability. These controlled terminologies and mapping tables, also in their representations as taxonomies, ontologies, thesauri are usually referred to as semantic interoperability assets.

Formal ontologies can support the automatic recognition and processing of such heterogeneous expressions. In the SemanticHealthNet Network of Excellence a semantic framework is being built which addresses the goal of semantic interoperability by proposing a generalized methodology of transforming existing resources into “semantically enhanced” ones.<sup>5 6</sup>

These aspects all refer to the representation of clinical values and concepts. A separate category of activities deals with bringing structure to the information landscape. This is mostly referred to as Clinical Modeling. The aim of these models is to bring several relevant values together in a small clinical model describing an entity that is use case and technology neutral but understandable for health professionals. Examples are Blood Pressure, Smoking

---

<sup>4</sup> HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations, 2nd Edition, 2010, Appendix B, p190, original source: HIMSS Electronic Health Record Association.

<sup>5</sup> Schulz S., Martínez-Costa C. (2013) How Ontologies Can Improve Semantic Interoperability in Health Care. In: Riaño D., Lenz R., Miksch S., Peleg M., Reichert M., ten Teije A. (eds) Process Support and Knowledge Representation in Health Care. Lecture Notes in Computer Science, vol 8268. Springer, Cham

<sup>6</sup> Traditionally, classification systems from the World Health Organisation (WHO) were used to support data entry on mortality, morbidity, symptoms, reasons for encounter and processes. The International Classification of Diseases (ICD) is used for mortality and morbidity registration, and is a longstanding tool for epidemiological and public health policy research. The International Classification of Primary Care (ICPC) is used in general practice for episode-oriented registration of reasons for encounter, symptoms, prevalent diseases, and processes. The International Classification of Functioning, Disability and Health (ICF) is focussed on the impact of diseases. Other examples are Logical Observation Identifiers Names and Codes (LOINC) for laboratory test results or Anatomical Therapeutic Chemical Classification (ATC) for medicinal products. Historically, the bulk of medical data has been classified with these classifications. It is likely that these systems will continue to be used in the next decade, so mapping to any new reference terminology to be developed for semantic interoperability will be necessary, at least for legacy conversion reasons.

Behaviour, Patient, etc. Activities of this kind are e.g. the Archetypes (from openEHR, CIMI or others), the Detailed Clinical Models (DCM) and the Health and Care Information Models (HCIM) as deployed by several MS. The common practice is to use these models to construct larger information sets for a specific use case.

#### **5.4 Semantic Interoperability Projects**

There has been a number of EU projects in semantic interoperability in the previous years. Unfortunately, many of their findings did not have influence outside the projects themselves and thus their reuse in the “real world” was limited.

This paper will therefore analyse the findings from these projects (listed in Annex A) in order to provide a summary of conclusions for the future of semantic interoperability in the EU.

### **6. Findings**

Based on the analysis of the projects in semantic interoperability (see Appendix A), several common themes were identified which will make the basis of this recommendation.

#### **6.1 Common Ontologies, Terminologies and Interfaces**

Terminology and ontology tools are the basis of services that make content accessible to users. The term Terminology Resources (TRs) denotes systems that provide standardized meaning of domain terms, like thesauri (e. g. MeSH or MedDRA), which relate terms using close-to-language semantic relations, classifications (like ICD-10), with single hierarchies and non-overlapping classes, and others.

Ontologies categorize domain entities and axiomatically describe how they are related. TR types are not mutually exclusive: e. g. SNOMED CT is based on a thesaurus with an ontological underpinning. TRs can be furthermore divided into core vs. specialised TRs, TRs of global relevance against TRs restricted to a certain jurisdiction. Different TRs focus either on clinical documentation vs. biomedical (& clinical) research.

Cross-border interoperability critically depends on the availability of multilingual content. This is a major bottleneck, due to the resources needed for content translation. Translation of preferred terms or fully specified names only is not sufficient for many use cases that require concept retrieval or machine processing of clinical narratives. These use cases also require large repositories of interface terms, which vary with dialects, institutions and clinical specialties. For most European languages, translations only exist for very few TRs, e. g. ICD; and large, non-proprietary interface term repositories are missing altogether.

For terminologies, this will best be achieved by starting with areas where there is a high degree of consensus on both the content and the need. Key areas are likely to be sensitivities and adverse drug reactions, translational medicine, and large scale public health and population research initiatives such as bio-banking.

Although the overall conclusion of the ASSESS-CT project was that the “adopt scenario”<sup>7</sup> should prevail, the main key lessons learnt are to be found elsewhere. For the same set of data, results proved indeed to be sometimes very different for reasons not necessarily linked to the terminology itself but rather to other factors such as the (lack of precision of the) testing methodology itself, the initial competence of the tester and the acceptance of the tester to comply with the requested protocol.

The creation and maintenance of user interface terminologies cannot depend on a top-down approach only. The newly generated terms need to be constantly checked against the terminology, and gaps need to be filled. User-, language-, and domain-specific user interface terms have to be accounted for. This suggests a distributed, bottom-up development of user interface terminologies. Robustness, agile updating and responsive maintenance methods and processes become critical in this area.

All evidence supports the position that neither SNOMED CT nor any other terminology can be the unique solution. However, numerous experts maintain that any solution excluding SNOMED CT would be incomplete and would become irrelevant. Multiple terminologies are needed and SNOMED CT was suggested as a good candidate for the cross-border exchange of data assuming EU license issues are resolved, since a majority of MS are already members of IHTSDO. However, reference terminologies should be related to national and international aggregation/classification terminologies to support secondary use and administrative processes. In this context, the role of SDOs is critical in reducing conflicts and gaps among terminologies, enabling collaborative use of standards.

It should be noted here that, on the international level, the aggregation/classification terminologies seek to be harmonized with SNOMED CT. Recent examples are the International Classification for Nursing Practice (ICNP), Orphanet, Current Procedural Terminology (CPT), Global Medical Device Nomenclature (GMDN) and ICD-11

Overlaps between ontologies and information models may give rise to conflicting representations, requiring sophisticated mitigation strategies. The very same complex information can be represented to different proportions in clinical ontologies and clinical information models which is known to create semantic interoperability problems.

As needs and use cases increase, so does the need to develop interface terminologies, which start from the language used by patients, physicians and scientists and reduces the burden of concept selection and validation.

## **6.2 Common Training and Education of Health Professionals**

Specialists customize data acquisition tools based on TRs (e. g. on clinical models) and require in-depth knowledge of the TRs. This also applies to dataset validators, guideline creators, architects of clinical registries, decision support systems, and other systems that depend on semantically explicit content.

---

<sup>7</sup> ASSESS-CT researched the adoption of SNOMEDCT against two alternative scenarios: to abstain from actions at the EU level, or to devise an EU-wide semantic interoperability framework alternative without SNOMED CT.

A common approach to training is therefore needed in order to enable a common practice of using TRs for everyday application. This remains an unfulfilled task of many of the currently ongoing semantic interoperability initiatives.

### **6.3 Common Approach to Standards**

Although advocated in 2004 already, a joint evolution of TRs and information models is not sufficiently endorsed by the SDOs involved. Support is needed for accepting compositional expressions into clinical models (e. g. CDA Templates), which relies on highly sophisticated reasoning.

Consequently, investment in an operational semantic interoperability roadmap still remains a low priority for policy makers. Furthermore, the weight of legacies within administrations and other organized bodies requires a well-planned strategy in order to break resistance to change. Return of investment can appear to be slow and uncertain and thus politically risky. Investment thus remains often limited to the referencing and public diffusion of TRs.

### **6.4 Cooperation between Member States**

Policies should be established to increase Member State and SDO alignment on the approach to advancing common semantic interoperability.

The policies that increase the cooperation between Member States have a direct impact on cost sharing, pooling of resources, exchanging expertise and best practices, taking advantage of internationally agreed definitions of concepts, and leveraging cooperation in developing pragmatic subsets for end-user.

### **6.5 Reusing Semantic Projects' Deliverables**

The main issue from all the analysed projects in semantic interoperability (as is arguably the case in other interoperability domains as well) is lack of follow-up and proper alignment both during the project duration and afterwards. The reuse of project deliverables and lessons learned is low and thus provides little value for the overall approach to semantic interoperability.

The value of building upon previous projects in semantic interoperability is in the rational reuse of resources, avoidance of work duplication and learning upon past mistakes.

In the present context, any translational or cross-domain use of evidence of quality for systems certification remains unrealistic.

### **6.6 Building of Expert Semantic Communities**

There are some notable examples of establishing a community of semantic experts which would contribute to the overall semantic interoperability such as the not-for-profit European institute created as a result of the Semantic Health Net - The European Institute for Innovation through Health Data also known as i~HD.

Although such endeavours are recommendable, they are quite recent and still need to demonstrate their added value. They are also research oriented which seriously impact their practical applicability in “real-life” situations. The objective to set up a European network of

excellence or a network of national centres to facilitate the use of archetypes and use of multilingual terminology resources has not yet materialized.

There is a need for collaborative and specialised semantic communities that would contribute significantly to the semantic interoperability effort by standardising terminologies for local purposes.

## 6.7 The Question of Using SNOMED-CT

Before the formal establishment of the eHealth Network under the Directive on the application of patients' rights in cross-border healthcare, the role of SNOMED-CT has been discussed periodically within the auspices of the former i2010 sub-group on eHealth.

The results and recommendations from the ASSESS-CT project highlight the fact that SNOMED CT have received increased attention and has been selected a key strategic terminological resource by a number of Member States but actual use and implementation in concrete projects has been limited<sup>8</sup>.

The approach proposed (demonstration of a semantically sound and quality-assured reformulation of an accessible collection of subsets of SNOMED CT in order to provide evidence for long term decisions on the role of SNOMED CT in Europe) has not been followed as such but holds promises for the future eHDSI implementation within CEF. More evidence will be required for quantitative, qualitative, cost and technology innovation aspects.

## 7. Recommendations

Based on the analysis performed and with the active support of participating countries, this report proposes a number of recommendations associated with short (a), medium (b) and long term (c) actions to the eHealth Network.<sup>9</sup>

### **RECOMMENDATION #1: Endorse a Common EU-Level Semantic Interoperability Tooling Strategy by Adopting an Implementation Roadmap**

Actions to be undertaken:

- a) Support ongoing EU and MS initiatives that aim at adopting and implementing terminology resources and other semantic standards. Support the use of structured primary documentation by encouraging software vendors and healthcare providers to implement better support for entering coded information ideally entered at the point of care.

---

<sup>8</sup> For more information on the use of SNOMED-CT in EU, see the ASSESS-CT WP1 D1.3 Current and Future Use of SNOMED CT (Interim Report); [http://assess-ct.eu/fileadmin/assess\\_ct/deliverables/assess\\_ct\\_d1.3\\_current\\_and\\_future\\_use\\_of\\_snomed\\_ct.pdf](http://assess-ct.eu/fileadmin/assess_ct/deliverables/assess_ct_d1.3_current_and_future_use_of_snomed_ct.pdf)

<sup>9</sup> Most of the recommendations outline a need for the support of either ongoing or future activities. Support here is meant both on the policy, organizational and funding level.

- b) Elaborate a shared catalogue of semantic assets used and developed in the EU and abroad and identify user groups and use cases for semantic interoperability in the EU public and private domain.
- c) Support the development of an open source, publicly available service that provides access to the core terminologies / terminology server (e.g. SNOMED CT, ICD Classifications, ISO IDMP model and terminologies, WHO ATC, LOINC). The continuity of use of HL7 V3 - CDA and a formal evaluation of HL7 FHIR is also recommended. Also, develop a framework for measuring adoption and actual use of semantic standards at EU, MS, and regional levels of granularity.

### **RECOMMENDATION #2: Use the outcomes of previous semantic projects as a key foundation of that strategy.**

Actions to be undertaken:

- a) Collect best practices originating from or described in previous semantic interoperability projects, catalogue their main findings and recommendations and systematically monitor ongoing projects in order to identify best practices regarding the practical use of semantic resources and information models. Apart from the more theoretical projects listed in this paper, significant learnings of best practises can also be found in the practical projects that have been carried out in the last 10 years e.g. epSOS, EXPAND, e-SENS, and now from the Semantic Taskforce of the CEF eHealth.
- b) Classify and prioritize the use of semantic resources and information models with regards to the use cases defined in the EU semantic interoperability strategy. In order to allow for the exploration of clinical information for purposes other than direct care, such as for quality indicators, clinical research use e.g. Clinical Queries as recommended by eStandards project<sup>10</sup>, i.e. a methodology which allows a health care professional and or a health care analyst to search for and retrieve structured and coded discrete clinical information from systems that store patient information.
- c) After reusing past project components, continue with the existing activities and perform a follow-up with a new cycle of semantic interoperability projects in order to up-keep the creation of reusable semantic assets and information models.

### **RECOMMENDATION #3: Create a reasonably stable ecosystem of terminologies by connecting EU-level aggregation terminologies, reference direct healthcare provision terminologies, and national user interface terminologies**

Actions to be undertaken:

- a) Endorse the creation of MS terminology centres in charge of creating semantic resources and establish mechanisms for EU-wide dissemination in order to ensure the semantic interoperability following a “bottom up” approach to implementation. Identify and build-

---

<sup>10</sup> [http://www.estandards-project.eu/eSTANDARDS/assets/File/deliverables/eStandards%20D3\\_5-3%20Roadmap%20Components%20F02%2020170731.pdf](http://www.estandards-project.eu/eSTANDARDS/assets/File/deliverables/eStandards%20D3_5-3%20Roadmap%20Components%20F02%2020170731.pdf)

up the existing resources without creating new ones and making use of the already established informal networks of semantic experts to support the reuse and sharing of semantic resources. There should be no need to create new “bodies” for semantic interoperability as the build-up of national competence centres for semantic resources to act as a single point of contact for EU semantic interoperability issues should suffice.

- b) Support the creation and evolution of a semantic ecosystem that will maintain semantic resources on the EU level. As the national code systems and nationally defined value sets based on international code systems are managed by national terminology centres and/or within the IT maintenance organizations of national/regional/local IT Systems. The suggestion is to recommend sharing and reusing existing terminology resources, as well as other semantic assets, and collaborate internationally in the development of new assets. The recommendation could then also include mechanisms for publishing/sharing resources from national initiatives to an EU repository.  
Inviting the SDOs to participate in this ecosystem, i.e. those institutions which stand behind the terminologies used in the MVC as well as inviting those organisations that are responsible to maintain and release terminologies on the national level, as in these two groups the highest expertise is to be expected, would benefit the ecosystem significantly.
- c) Propose and introduce new semantic resources from the “top down” by introducing mechanisms for EU semantic resources management.

#### **RECOMMENDATION #4: Develop content and services for training and education of end users in order to support “Semantic Literacy” on the Member State national level**

Actions to be undertaken:

- a) Establish national education/training services associated with the use of terminologies, ontologies and interfaces. Ensure a transfer of knowledge from Member State terminology experts to other stakeholders involved in the continuum of care such as healthcare decision makers, local authorities and agencies.
- b) Endorse Member State efforts in continuously collecting and analysing user needs in relation to terminologies, ontologies and interfaces. Build-up national competence centres for semantic resources to act as single point of contact and share knowledge with other Member States.
- c) In order to improve semantic consistency with regards to terminology resources, establish common reusable catalogues of interface terms for both natural and clinical languages and share them between Member States.

#### **RECOMMENDATION #5: Start by doing - Select a Promising Use Case/Set and achieve Tangible Semantic Interoperability for that Use Case/Set.**

Actions to be undertaken:

- a) Select the most promising use case set/information model/value set<sup>11</sup> to achieve MS semantic interoperability in practical terms. Example use case sets may include product-related allergies (substances), body structures or medical devices. Be aware of the pitfalls attributed to drugs, diagnoses and procedures as these may require an in-depth analysis, beyond the use of aggregation classifications for representing direct care data in individual patients. Agree to use clinical modelling for representing and sharing clinical data structures across the EU, select an approach out of the several that exist.
- b) Acquire rights from SNOMED International to use the required value sets across the whole EU and harmonize/translate the value sets in national languages. Publish these resources within SNOMED CT and then use the value set in the selected Use Cases with sufficient guarantee of continuity. Create ontology bindings to archetypes in order to use a validated subset of SNOMED-CT to test alternative representation for a specific use case and to test bindings between terminologies and information models in order to create a framework for aggregation of EHR data for public health use.
- c) Evaluate the process and report on the gained added value.

## 8. Final considerations

Semantic interoperability is not the endpoint in itself, since it is a path to attain cognitive interoperability and generalized improvements of health services. Nevertheless, it is arguably a significant challenge for public administrations in the EU. More specifically, it is a constraint on the benefits of cross-border provision of eHealth services within the EU.

Public administration in some Member States are still using their legacy system which are created to be used in local languages which creates the plethora of incompatible terminologies that are in use today.

Therefore, semantic assets such as ontologies, terminologies, data models, data dictionaries, and code lists have been and are still being organized with a silo mentality, thus the change towards standardized, shared and collaborative solutions is slow and often cumbersome. Lack of training on semantic interoperability issues is still a major hurdle. A tendency to reinvent the wheel and also a déjà vu effect begins to be evident on semantic interoperability project developments and deliverables.

Also, the widespread use of free text<sup>12</sup>, unstructured data, and a lack of adoption of unique resource identifiers for commonly used values are still the norm in many EHR systems already implemented. Regardless of their significance, standards and semantic assets from EU projects are not organized to support easy finding and re-use.

A decision regarding a central EU authority is still missing for management and maintenance of semantic assets and for giving guidance on the adoption of semantic interoperability assets in a way that would benefit the Member States in an EU Unique Market.

---

<sup>11</sup> SNOMED Use case sets; Information Paper “Making use of SNOMED-CT: Key questions and status as of September 2013”; [https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev\\_20131119\\_co5\\_3\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20131119_co5_3_en.pdf)

<sup>12</sup> as was found in JAseHN’s D7.5 FINAL Report On EU state of play on patient access on eHealth data



Multiple roadmaps have been drawn and proposed since semantic interoperability became a priority. What is missing is a clear global vision on the future of semantic interoperability in eHealth, and the strategy to convincingly describe the crucial use cases and services that need to be implemented in order to establish interoperable systems.<sup>13</sup>

Without a clear decision on the roadmap to follow, it is often difficult to convince stakeholders on the benefits of interoperability which can stimulate its further development. There are arguably still some differences in the maturity status and scope of semantic assets between Member States in terms of compliance to data standards.

The key impetus for public administrations and also business sectors to make semantic interoperability and adherence to a set of commonly used standards a reality will require commitment to develop a corpus of legal obligations. As the political awareness on the importance of semantic interoperability is growing, more and more policy decisions and legislative requirements will develop to include the establishment of semantic interoperability in public administrations.

In addition, the portability regulations the legal support for sharing of data across EU will be an important driver for semantic interoperability and standardization as notable examples from other domains have shown already (e.g. the geospatial domain).

The establishment of a clearer strategy on EU semantic interoperability in eHealth, support and reuse of EU projects deliverables and assets, with their integration into a larger ecosystem of semantically interoperable systems, the continuous collaboration with SDOs and the development of mechanisms for support, training, tooling and education of end users are landmarks of the way forward.

---

<sup>13</sup> A similar conclusion was presented in the ASSESS CT project, as part of its recommendation that an European terminology strategy should... be part of an overarching European eHealth strategy

## **Appendix A: State of play regarding semantic interoperability in the EU**

In this Appendix a summary will be provided of notable EU-level projects having to do with semantic interoperability.

This summary is by no means an extensive one and its aim is to provide a general overview of relevant EU projects in semantic interoperability, their purpose, results and most important conclusions. It tries to capture the essence of the projects in semantic interoperability and outline their importance for future initiatives in European semantics.

Every project is explained in three sections – Introduction, Main Findings and Recommendations. “Introduction” explains the goals of the project, “Main findings” lists the crucial components of the projects with implications for future semantic interoperability initiatives and “Recommendations” lists the projects’ conclusions.

The Recommendations from each of the projects listed here were taken into account for the overall recommendations to the eHealth Network.

### **A1 Semantic Health (2008)**

#### **A1.1 INTRODUCTION**

The purpose of this EU funded project was to describe a short and medium-term Research and Deployment Roadmap for Semantic Interoperability in eHealth. It started by defining 2 levels on short and mid/long term (operational deployment and research) and 3 dimensions (Electronic Health Records, ontologies & terminologies and terminologies for public health) for Semantic Interoperability.

The vision was to reconcile the needs for the direct patient care safety, biomedical and clinical research and for public health by the reuse of direct care data: from gene to individuals and populations. Milestones for the short and mid/long terms were set.

#### **A1.2 MAIN FINDINGS**

On terminology aspects, the most relevant convergence efforts have been mainly driven by SNOMED International (former International Health Terminology Standards Development Organisation - IHTSDO) have been taking place but progress within the EU has been much slower than expected while final results remain fragile due to a lack of consistent policies and financial support of some involved parties.

The complexities and the barriers to achieve effective semantic interoperability were discussed in the 2nd and 3rd eHealth Network meeting while in November 2013, during its 4th meeting, an Information Paper - Making use of SNOMED CT<sup>14</sup> - key questions and status as of September 2013 prepared by the eHealth Governance Initiative (eHGI) was submitted.

The European Commission also presented an information paper: Information paper EC - EC activities on SNOMED CT - Semantic interoperability<sup>15</sup> which detailed the two actions that

---

<sup>14</sup> [https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev\\_20131119\\_co5\\_3\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20131119_co5_3_en.pdf)

<sup>15</sup> [https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev\\_20131119\\_co5\\_2\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20131119_co5_2_en.pdf)

the EC intended to take, namely to conduct an assessment of SNOMED CT as a core terminology to solve semantic interoperability issues – through Horizon 2020 work program 2014 to 2015 to enter into discussion with SNOMED International (then IHTSDO) to ensure licensing to SNOMED CTE for EU projects and programs.

The project ASSESS-CT is thus the concretisation of this action plan. It aims thus officially at investigating the fitness of the clinical terminology SNOMED CT as a potential standard (a core terminology) for EU-wide eHealth deployments, scrutinising clinical, technical, financial, and organisational aspects.

Although the focus is on EU-wide deployments and given the strong linkages between cross-border and national/regional use cases, most of the project analysis is of course largely applicable to national deployment.

### A1.3 RECOMMENDATIONS

Aside from the creation of a network of excellence, some of the key short term recommendations of this initial roadmap included to agree to use archetypes (ISO 13606) for representing and sharing clinical data structures across the EU and work parallel on ontology bindings to archetypes, to use a validated subset of SNOMED-CT to experiment alternative representation for a specific use case and to test bindings between terminologies and information models and to create a framework for aggregation of EHR data for public health use. A specific emphasis was put on the critical need of development of open source tools such as archetype editors and aggregation tools.

More information on the Semantic Health project:  
<https://www.ncbi.nlm.nih.gov/pubmed/18487802>

## **A2 Calliope Network (2008 - 2011)**

### A2.1 INTRODUCTION

The Calliope Network created a structured and open forum to support the implementation of interoperable eHealth infrastructures and services across Europe.

The purpose of CALLIOPE was to review and advance the EC interoperability recommendation, add value to eHealth standardisation initiatives and propose an EU-level roadmap for eHealth interoperability.

The Calliope Roadmap proved to be a necessary step in order to obtain the preliminary buy-in of the decision makers. By nature, it was not however capable to provide the supporting global governance and infrastructure necessary to support Member States in the development and use of critical semantic resources directly related to national and European Roadmaps which would encompass multiple environments and use cases (including those related to secondary use of data).

Calliope Roadmap encouraged the use of definition of appropriate quality standards for data in medical records and other electronic medical data/documents which are to be shared across borders while also addressing the challenges of multilingual semantic mapping.

### A2.2 MAIN FINDINGS

Although the CALLIOPE roadmap has certainly contributed to a much better understanding of the strategic issue of semantic interoperability- beyond the “experts” niches- it has been produced at a time when most European countries had not yet put in place their eHealth – be it basic- architecture. It thus certainly succeeded to increase the global eHealth awareness in Europe and contributed to its upscaling on political agendas but it did not lead to a concrete plan of action.

### A2.3 RECOMMENDATIONS

Calliope Roadmap recommended that the EU eHealth High Level Group, together with European Commission consider the area of semantic interoperability as an area largely catering to multinational collaboration and empower a collaborative governance framework that will facilitate collaboration of the various stakeholders, incl. international SDOs and relevant industry bodies at all three layers: steering, strategic and empirical.

Calliope Roadmap suggested that in order to provide strategic direction, use cases need to be prioritized based on high priority diseases common to all MS.

It was also recommended to support co-ordination of work of national and European professional associations to engage into the development of terminology and translation services developed together with data structures and linked to the development of respective care pathways.

More information on the CALLIOPE Interoperability Roadmap (2010): <http://www.chgi.eu/Download/European%20eHealth%20Interoperability%20Roadmap%20%5BCALLIOPE%20-%20published%20by%20DG%20INFSO%5D.pdf>

## **A3 SemanticHealthNet (2011 - 2015)**

### A3.1 INTRODUCTION

The aim of SemanticHealthNet was to develop a scalable and sustainable pan-European organisational and governance process for the semantic interoperability of clinical and biomedical knowledge in order to ensure that EHR systems are optimised for patient care, public health and clinical research across healthcare systems and institutions.

### A3.2 MAIN FINDINGS

In SemanticHealthNet it was foreseen that the project would end by establishing a virtual organisation to connect the stakeholders who had contributed to the development of semantic interoperability assets during the project. This virtual organisation would sustain the network of excellence and promote the ongoing development of further semantic interoperability assets.

The project has instead proposed that the European Institute for Innovation through Health should become the European organization of reference for guiding and catalysing the best, most efficient and trustworthy uses of health data and interoperability, for optimizing health and knowledge discovery.

### A3.3 RECOMMENDATIONS

The project has elaborated 12 recommendations which aim at describing what should be the role of Health Ministries.

It states in particular that MS should define the use cases but avoid to develop standards. Governments should purchase rights for royalty-free use of standards developed by SDOs while the standards need to be agreed upon at European level.

According to the project, semantic interoperability needs to be widely understood as a business model for investment in building and maintaining the necessary infrastructure, information structure and services.

More information on SemanticHealthNet:

<http://www.semantichealthnet.eu/index.cfm/news/>

## **A4 Antilope Project (2013 - 2015)**

### A4.1 INTRODUCTION

The aim of Antilope project was to drive eHealth interoperability in the EU and abroad.

Antilope project created, validated and disseminated a common approach for testing and certification of eHealth solutions and services in the EU.

Based on the eEIF study, the Antilope project offered practical tools that can be used in solving interoperability problems across EU.

Together with the corresponding testing tools, Antilope has given regional, national and international projects practical guidelines to converge their eHealth platforms and practices.

### A4.2 MAIN FINDINGS

Antilope project provided a portfolio of testing tools that would be sufficient for testing the recognized profiles from the eEIF, and developed an inventory of recommended existing open source testing tools.

Although Antilope project did not specifically tackle the semantic interoperability issue, it proposed a set of 8 use cases whose implementation is described by the corresponding realization scenarios which are linked to a selection of Integrating the Health Enterprise (IHE) and Personal Connected Health Alliance (PCHA) profiles.

Each individual profile is an implementation guidance specification for the underlying standards for a concrete and interoperable implementation.

Antilope project also provided organizational models, concrete examples and guidance that can be implemented both at the European level and at the national/regional level to preserve consistency at each level.

### A4.3 RECOMMENDATIONS

WHO actively promotes Antilope project's deliverable reuse by all Member States in the WHO European Region as best practice for developing a national approach to eHealth interoperability.

In particular, the eHealth European Interoperability Framework and the use case approach developed by Antilope are considered by WHO to provide a useful methodology for solving interoperability issues at the national level so their take-up is expected in all interoperability initiatives in the future.

Antilope's resources are available here: <https://data.ihe-europe.net/antilope/resources/>

## **A5 ASSESS-CT (2015 - 2016)**

### **A5.1 INTRODUCTION**

The project ASSESS-CT aim is the investigation of the fitness of using the clinical terminology SNOMED CT as a potential standard (a core terminology) for EU-wide eHealth deployments, scrutinising clinical, technical, financial, and organisational aspects.

Although the focus is on EU-wide deployments and given the strong linkages between cross-border and national/regional use cases, most of the project analysis is of course largely applicable to national deployment.

### **A5.2 MAIN FINDINGS**

The final project report considers SNOMED CT as currently the best available core reference terminology for cross-border, national and regional eHealth deployments in the EU but states that it should be part of a wider global terminologies eco-system and proposes a use case based gradual implementation.

With regards to the use of SNOMED CT, three groups of countries could be identified: high use (UK), medium use (Sweden, Malta, Netherlands, Denmark, Finland), and low use (Estonia, France, Germany, Greece, Austria, Italy, Belgium, Croatia, Luxemburg).

The main reported use of SNOMED CT is as reference terminology. Only the UK and Malta use SNOMED CT as reference, aggregate, and interface terminology.

The 9 countries that reported use of SNOMED CT employ pre-coordinated concepts, while only three use the additional descriptive power of SNOMED CT. Introduction of SNOMED CT follows a project or use case based approach in the early start-up phases, with some countries e.g. UK, NL, gradually moving towards a mixed or centrally managed approach. UK, Sweden, Spain, and Denmark use the full SNOMED CT core with national extensions. Estonia, Netherlands, Portugal, Malta, and Belgium follow an approach based country specific subsets. The translation and the collection of synonyms are nationally coordinated in most countries recognizing the need for international cooperation.

The eventual choice of terminologies is sometimes only partially driven by the “fitness for purpose”, and may depend on “non-functional” dimensions such as terminology availability in that setting.

Full translation of SNOMED CT was not considered a precondition to rollout SNOMED CT, and the urgency of maintaining the epSOS vocabularies for the eHealth DSI was stressed.

Also the need for education but also the right of patients and physicians to express themselves in their language was largely expressed.

### A5.3 RECOMMENDATIONS

The Recommendations of ASSESS-CT project were summarized in 5 points.

I Decisions about the adoption and role of terminological resources, including SNOMED CT, must be part of a wider, coherent and priority-driven strategy for optimising the benefits of semantic interoperability in health data, and of the overarching eHealth strategy of the European Union and its Member States. A European terminology strategy should be part of an overarching European eHealth strategy. The strategy should support the principles of collecting clinical data once and using them multiple times, wherever allowed and required. Thus, administrative, public health and research information should almost always be derived from routinely collected clinical information. This strategy should have Member State commitment and should consider human and financial resource implications, incentives, as well as technical and semantic requirements.

II SNOMED CT is the best available core reference terminology for cross-border, national and regional eHealth deployments in Europe. A main advantage is its content coverage, which is superior to any other single terminology, making it the most complete point of reference for health related concepts. Another advantage of SNOMED CT over a set of other clinical terminologies is its principled ontology-based architecture, with a logic-based coordination syntax.

III SNOMED CT should be part of an ecosystem of terminologies, including international aggregation terminologies (e.g., the WHO Family of Classifications) and user interface terminologies, which address multilingualism in Europe and clinical communication through multidisciplinary professional language and lay language. No country sees SNOMED CT as a stand-alone solution, but rather as an important part of the national terminology infrastructure.

IV The adoption of SNOMED CT should be realised incrementally rather than all at once, by developing terminology subsets that address the interoperability requirements for priority use cases, and expanding these sets over a of number years. Such incremental use, across all Member States, might be subject to specially negotiated licences on behalf of the whole of European Union. Solutions must be in place for legacy conversion, guaranteeing the continued exploitation of historical data, for user interface terminologies, and for assuring the continuation of global mortality and morbidity statistics.

V Mechanisms should be established to facilitate and co-ordinate European Member State co-operation on terminology and semantic interoperability, including common areas of governance across national terminology centres, eHealth competence centres (or equivalent national bodies).

The recommendations above are expected to maximise the value of Member State and SDO alignment on the approach to advancing semantic interoperability, including the implementation and deployment of SNOMED CT.

More information on the ASSESS-CT recommendations for using SNOMED-CT: [http://assess-ct.eu/fileadmin/assess\\_ct/final\\_brochure/assessct\\_final\\_brochure.pdf](http://assess-ct.eu/fileadmin/assess_ct/final_brochure/assessct_final_brochure.pdf)

## **A6 openMedicine (2015 - 2016)**

### A6.1 INTRODUCTION

The goal of openMedicine was to enhance the safety and continuity of cross-border (and also national level) healthcare through interoperable ePrescriptions, and to develop concrete solutions to remaining challenges.

The project aimed to reach a global consensus in order to univocally identify and describe unambiguously medicines, resulting in the delivery of the appropriate medicinal product to the patient.

openMedicine was also considering issues and challenges in the clinical context, like recording medicinal products in the ePatient Summary as well as in electronic health records and other clinical documents, like in the prescription history or the active medication list.

### A6.2 MAIN FINDINGS

Harmonising the identification of medicines in regulatory processes, in ePrescriptions, eDispensation reports as well as in clinical messages, records and decision support systems is a European challenge, particularly also when considering the fundamental importance of high quality and safe provision of cross-border prescription and dispensation services. It impacts on pharmacovigilance, the tracing of data across the life cycle of a medicinal product, the aggregation of information for public health purposes and many other health domains. And it promises a substantial European added value.

Across the EU, differences in names of medicinal products and active substances, variations in strength and box size prevail, and the availability of a specific medicinal product varies considerably across member states. This situation necessitates substitution of the prescribed product at the point of dispensation in many instances if a patient is to be timely served in a pharmacy. The EU-wide implementation of ISO IDMP standards as under way by EMA for pharmacovigilance is a route to mitigate many of these problems. However, presently, national ePrescription and medicines data bases are not supporting the Medical Product Identifier (MPID) or Pharmaceutical Product Identifier (PhPID) attributes and codes, because at the national level there are few direct benefits from solving cross-border identification and semantic issues.

To fundamentally increase the probability, e.g., that a cross-border ePrescription can indeed be dispensed in another Member State, it is mandatory to have the pharmaceutical product identification number (PhPID) available respectively automatically included from national sources or a central EMA data base, in order to identify medicinal products locally available which are equivalent to the one identified in the prescription. This also applies *mutatis mutandis* to other clinical or regulatory records and contexts.

In the medium term, it will be mandatory to link the EMA IDMP (SPOR) DB with national drug DBs (or use NCPeH procedures) to have identifiers and identifying attributes



automatically included into software systems which have to make use of such input for prescribing and other clinical systems. This will also improve and harmonise reporting of adverse drug events and pharmacovigilance.

This requires creating an EU approach to further improve, implement and maintain the EMA SPOR data bases and the supporting coding efforts, thereby also facilitating regulatory processes, and even Big Data applications. A common approach and operating model needs to be developed, including common processes for validation of contents, error mitigation, of linking from central hubs to national and regional levels, updates and mappings to other systems. Harmonisation of prescribing and dispensation practices could be a further focus. A sustainable migration process from the present situation to the ISO IDMP / SPOR adoption should be also addressed.

For cross-border health services, when a prescriber specifies an innovator or generic brand name, or an active substance and further attributes, it must be assured that any local ePrescription system will be able to automatically look up equivalent products available in the dispenser's country by filtering making use of any coded identifier or the identifying attributes reported in the prescription.

### A6.3 RECOMMENDATIONS

The project proposes 12 recommendations which should lead in the medium/long term to the univocal identification of medicinal products in cross border ePrescriptions, eDispensing reports and Patient Summaries in Europe and beyond based on the implementation of a set of ISO standards, namely, the ISO IDMP – Identification of Medicinal Products implementation standard.

In the short term, unique Pharmaceutical Product ID should be created within the EU and built by using the Article 57 (2) substance standard data base as currently made available through the SPOR project. Effective piloting is described as possible from mid-2017 on.

In order to improve the likelihood that a medicine specified in a cross-border ePrescription can indeed be fully identified and dispensed (or substituted), it should be considered to use for the time being the publicly available EMA substances data base and code system as an additional value set of the Master ValueSet Catalogue (MVC).

Use of different levels of detail to identify medicinal products is justified by the different needs observed in each of the numerous use cases described. A medicine should be defined by its attributes, or identified by at least one of the identifiers as defined in the IDMP standards (i.e. Pharmaceutical product (s) – PhPID(s), medicinal product - MPID, package - PCID).

Each ePrescription, eDispensation, or medication record in an ePatient Summary should contain (an automatically added) pharmaceutical product identifier, preferably the global PhPID assigned by EMA, once available. An authorised mapping to the PhPID should be available in case of using proprietary identifiers. Each ePrescription, eDispensation or medication record in an ePatient Summary may contain additional IDMP compatible identifiers.

Future support is also needed for cooperation across Standards Developing Organisations (SDOs) to integrate and agree on standards for medicinal products, pharmacovigilance, usage of these data in the clinical context, for messaging like ePrescription, eDispensation, in ePatient Summaries, clinical electronic records like EHR systems. This may also include the setting up of cross-border pilots to assess and validate the proposed approach in virtual environments with test data.

As a further step towards IDMP implementation, MSs involved in CEF may want to assess and validate the suitability, efforts and risks involved in mapping the data elements needed for ePrescription and electronic Patient Summary, and for creating a PhPID from the presently available EMA Art. 57 data base.

When recording in care process documents (prescribing, dispensing, administration/billing, reports) both in electronic systems and when sharing that information, the structures used for supporting information (e.g. for dosage instructions) should have standardised definitions/codes and be populated with globally recognised controlled terminologies like European Directorate for the Quality of Medicines - EDQM codes.

Future work should be done to identify in a cross-border context adjuvants and excipients of pharmaceutical or medicinal products which may cause allergic reactions or intolerances, or are otherwise contraindicated.

The ISO IDMP suite of standards should be usable and used throughout the complete lifecycle of a medicine. This requires assigning a globally unique PhPID to each pharmaceutical product already at the development stage.

Regarding the harmonisation of terms & concepts, the recommendation OpenMedicine Expert Council 201611-25, SDOs and other stakeholders should update the terms and their definitions (concepts) used with respect to identifying, describing and recording medicines in order to harmonise them.

Medicinal Product Dictionaries (MPD) as well as clinical applications for recording and processing medicinal information should meet a set of quality criteria like being correctly coded, compliant in structure and content with EMA and national specific standards, and completeness and persistence of information regarding meanwhile withdrawn medicines. Completeness should encompass every product that can be prescribed.

Further work should also include an assessment of impacts based on benefits and costs to be anticipated. Such an assessment should not only deal with regulatory impacts, impacts on setting global standards and best practice, and impact on clinical data quality and interoperability, but also spill-over effects to pharmaceutical companies, data base producers and competitive advantage of European companies. Newly marketed medicinal products should have a distinct name that differs from any other medicinal product name in the EU.

Regarding the sustainability of the authoritative source data, it is recommended that sufficient resources should be allocated to make available in a timely fashion the IDMP compatible central European Medicines Database for cross-border health services. Its long-term maintenance needs to be assured as openMedicine project suggested.

Also, the Member State national rules on substitution of medicinal products at the point of dispensation, when specified in a cross-border prescription, should be harmonised

More info on openMedicine's objectives and results: <http://www.open-medicine.eu/objectives-results.html>

## **A7 Semantic Interoperability Community (SEMIC)**

### A7.1 INTRODUCTION

**Semantic Interoperability Community (SEMIC)** is a European Commission initiative aiming to improve the semantic interoperability of interconnected e-Government systems.

It was funded under the [Action on Promoting semantic interoperability amongst the European Union Member States](#) of the [Interoperability Solutions for European Public Administrations \(ISA<sup>2</sup>\) Programme](#).

### A7.2 MAIN FINDINGS

SEMIC focuses on the development and promotion of e-Government core vocabularies and the development and promotion of the Asset Description Metadata Schema (AMDS)

The e-Government Core Vocabularies are simplified, re-usable and extensible data models that capture the fundamental characteristics of an entity, such as a person, a business, a location or a public service, in a context-neutral way. They can then be used by public administrations to attain a minimum level of semantic interoperability for e-Government systems.

The Asset Description Metadata Schema (ADMS) is a vocabulary to describe and document reusable interoperability solutions, such as data models and specifications, reference datasets, and open-source software. The objective of ADMS is to facilitate the discoverability of reusable interoperability solutions, in order to reduce the development costs of cross-border and/or cross-sector e-Government systems.

### A7.3 RECOMMENDATIONS

SEMIC encourages EU-wide the provision of “data as a service” and supports the vision of the Web as an open ecosystem where data owners, data publishers, and data consumers can interconnect and integrate disparate datasets.

SEMIC explores the potential of linked open government data (LOGD), from a business and a technical point of view, as an enabler to the flexible integration of data coming from different e-Government systems.

According to the SEMIC website, the main driver for the use of LOGD is that it allows for flexible data integration; this helps to increase data quality by allowing cross-references to authoritative data to be included and may drive future development of new services. It is claimed that the use of LOGD increases the efficiency of the internal operation of the data provider and allows them to fulfil their public task more effectively and efficiently. LOGD is currently applied most successfully in reference data, such as in the case of the Named

Authority Lists of the Publications Office<sup>16</sup>, Eurovoc thesaurus<sup>17</sup> and European Skills/Competences, qualifications and Occupations (ESCO)<sup>18</sup>.

It is mentioned that LOGD makes future upgrades of data models much easier, for example to include new data or connect data from different sources together. URIs allow an easy to follow navigation structure that provides better navigation through complex data. Also, LOGD is mostly provided free of charge and under open licences which enables further use and reuse of data.

The eHealth domain still remains to be explored within the SEMIC framework but it opens huge possibilities of linking data, the creation of interconnected data models in the public domain and the extension of core vocabularies to the healthcare-specific ones.

More information on SEMIC: <https://joinup.ec.europa.eu/community/semic/description>

---

<sup>16</sup> Named Authority Lists of the Publications Office, <http://publications.europa.eu/mdr/authority/index.html>

<sup>17</sup> eurovoc.europa.eu, <http://eurovoc.europa.eu/>

<sup>18</sup> European Skills/Competences, qualifications and Occupations, <http://ec.europa.eu/social/main.jsp?catId=1042>

## Appendix B: Other relevant projects

The EU has funded a number of research projects which have put to the test the semantic interoperability challenge. Although limited in scope and not operational, they have delivered a number of lessons and recommendations which are worth analysing, focusing mainly on those which have an impact on policy level.

Among the projects worth mentioning and without any claim for completeness one can cite : [DebugIt](#) (2008 - 2011), [Ponte](#) (2010 - 2013), [EHR4CR](#) (2011 - 2016), [EURECA](#) (2012 - 2015), [SALUS](#) (2012 - 2015), [OpenPhacts](#), [Linked2Safety](#) (2011 - 2014), [eTRIKS](#) (2012 - 2017), [p-Medicine](#) (2011 - 2015), [Transform](#) (2010 - 2015), [Emif](#) (2013 - 2017) and [BioMedBridges](#) (2012 - 2015).

Other major European Joint Actions and projects such as RENEWING HEALTH (2010 – 2013), PARENT (2012 – 2015), SUSTAINS (2012 - ) and PALANTE (2012 – 2015) have also been somewhat associated with semantic interoperability but not exclusively. Further convergence of these projects is needed in order to support an EU-wide semantic interoperability synergy.

### B1 Links to other relevant projects

1. DebugIt (More info here: <http://www.debugit.eu/>),
2. Ponte (More info here: [http://www.ponte-project.eu/index.php%3Fpage=european\\_commission.html](http://www.ponte-project.eu/index.php%3Fpage=european_commission.html)),
3. EHR4CR (More info here: <http://www.ehr4cr.eu/>),
4. EURECA (More info here: <http://eurecaproject.eu/>),
5. SALUS (More info here: [http://cordis.europa.eu/project/rcn/100716\\_en.html](http://cordis.europa.eu/project/rcn/100716_en.html)),
6. OpenPhacts (More info here: <https://www.openphacts.org/>),
7. Linked2Safety (More info here: [http://cordis.europa.eu/project/rcn/100765\\_en.html](http://cordis.europa.eu/project/rcn/100765_en.html)),
8. eTRIKS (More info here: <http://www.etriks.org/>),
9. p-Medicine (More info here: <http://www.p-medicine.eu>),
10. Transform (More info here: <http://www.i-hd.eu/index.cfm/resources/ec-projects-results/transform/>),
11. EMIF (More info here: <http://www.emif.eu/>),
12. BioMedBridges (More info here: <http://www.biomedbridges.eu/>),
13. PARENT (More info here: <http://parent-ror.eu>),
14. SUSTAINS (More info here: <https://ec.europa.eu/digital-single-market/en/news/results-sustains-pilot-patients-accessing-their-health-data>),
15. PALANTE (More info here: [http://cordis.europa.eu/project/rcn/191916\\_en.html](http://cordis.europa.eu/project/rcn/191916_en.html)),
16. RENEWING HEALTH (More info here: [http://cordis.europa.eu/project/rcn/191719\\_en.html](http://cordis.europa.eu/project/rcn/191719_en.html)).