



REPORT

on

Inventory of eHealth Specifications

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LIST OF ABBREVIATIONS

ACRONYM	DEFINITION
API	Application Programmable Interface
CAMSS	Common Assessment Method for Standards and Specifications
CCOW	Clinical Context Object Workgroup
NGO	Non-governmental organisation
PHR	Personal Health Record
SDO	Standards Developing Organisations
UML	Unified Modeling Language
URL	Universal Record locator

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1. Purpose

This report forms part of Task 8.2 of the Joint Action on eHealth. The Description of Work describes the task as follows: “there is much to be gained from awareness of different approaches to specifying the requirements, and how to enable Member States MS in Europe to benefit from the experience of others. This task will source eHealth specifications from across the world, with a view to understanding developments and priorities in different countries, identifying lessons learned and examples of good practice”.

The deliverables from this task are as follows:

D8.2.1 Inventory of eHealth specifications - (initial month of delivery: M7, November 2015);

D8.2.2 Evaluation and good practice guide for eHealth specifications - (initial month of delivery: M19, November 2016).

This document is D8.2.1 and describes the purpose and structure of the inventory.

The sub-tasks include the establishment of a repository of specifications and also a good practice guide. The current intention is to use the repository created in EXPAND and now maintained by i-HD. This may be found at

<http://www.i-hd.eu/index.cfm/resources/interoperability-asset-register/>

2. Scope

The primary focus of the Task is to support Member States and health and care organisations for whom they have a responsibility. In a number of countries this includes National Competence Centers - permanent administrative support structures created or expanded to also cover eHealth infrastructure requirements. Examples include *gematik* (Society for Telematic Applications of the Health Card) in Germany, *ASIP* - Agence pour les Systèmes d'Information de santé Partagés in France, and *THL* National Institute for Health and Welfare in Finland. Annex B provides a list of potential source organisations.

The publication of specifications such as interfaces (APIs) to national infrastructure may assist suppliers by opening up the market to new entrants and new application possibilities.

The types of specification might include interoperability, systems, non-functional requirements. The application areas involved will be informed by what is available – for instance, eHealth in a home or community setting, and other mhealth applications, are likely to represent a growing area.

There is a major overlap with the creation, in Expand, of an asset repository. Whilst the scope and intended use differ in detail, nevertheless, there is sufficient commonality to recommend a joint approach. This is reflected, therefore, in both the descriptors and the criteria being applied.

The types of artefact are considered in chapter 2, but might include high-level vision, “user stories” (as in an agile process), detailed functional requirements, technical design. The sources would include national centres, SDOs and academic units. It will be necessary to consider how to capture and make available the information. It is expected that the repository will include both applications (see chapter 3) and standards (chapter 4) documentation. The good practice guide will discuss processes for development and types of artefact and will propose evaluation criteria for “good” requirements and standards.

This work should provide a basis for strategic decisions on eHealth standardization on the level of eHN and also for the member states. The aim is to be inclusive, so SDOs and others will be invited to contribute, notwithstanding the concerns about balancing interests (governmental, inter-governmental actors, national/international companies, individuals/NGOs), lines on IP policies and licensing and knowledge transfer. Annex C provides an initial list of potential artefacts.

3. Requirements

3.1 Development of requirements

This section considers the development of requirements, the products or artefacts thus created. The development of requirements continues throughout a project, from early visioning to implementation and review. The process starts early in the lifecycle. Before embarking on an information gathering exercise, it is important to establish the scope. Taken together with the Stakeholder Business Model and Business Information Model, these determine the breadth of the analysis work to be accomplished.

3.2 Requirement Artefacts

Figure 1 below illustrates resulting artefacts and the relationship between them:

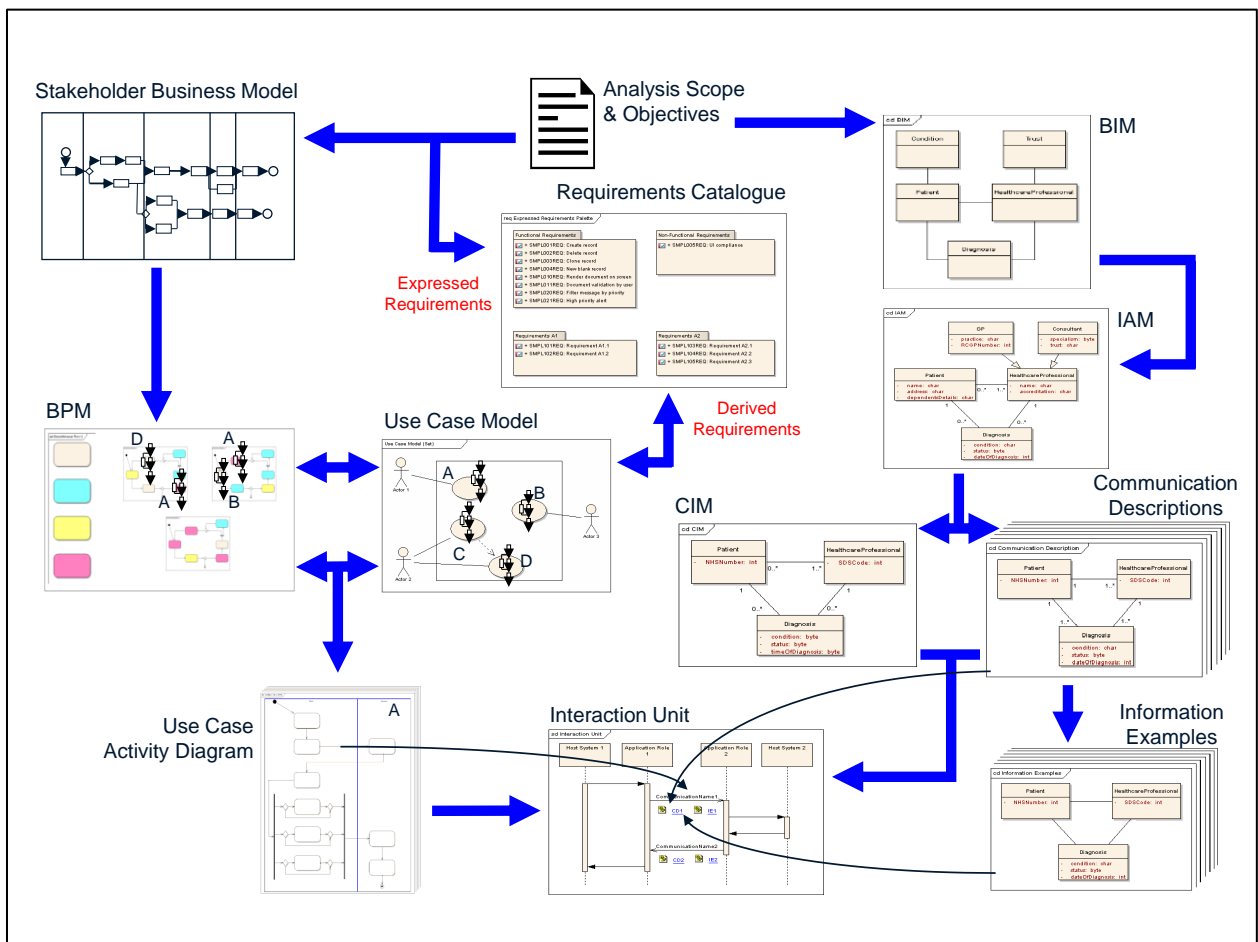


Figure 1. Requirements Artefacts

As the scope is established, the capture, categorisation and prioritisation of Requirements are sourced through a variety of consultations, particularly with Stakeholders. It is expected, as well as important to keep them fully involved in the development of Requirements over the lifecycle of a project. These consultations may take the form of workshops, interviews and

questionnaires. Inputs for Requirements can also be gathered from a wide range of other sources. Having a group of key stakeholders upon whom to draw is critical to supporting the activity of Requirements gathering. These may include domain experts, clinicians and users, as well as other analysts. These individuals should be able to directly provide information or identify key reference sources.

Scenarios can also be a useful additional tool for identifying Requirements, particularly to:

- help gather and refine Requirements in a user friendly way
- encourage more creative and innovative thinking
- encourage team review
- ensure that Requirements are captured in an accessible and intuitive way
- ease the process, by applying Requirements to real-life situations

By the end of this process, Analyst and Stakeholders should be satisfied that they have a sufficient set of validated Expressed Requirements.

The Artefact Definitions to support the development of Domain Analysis Projects are summarised in Table 1 overleaf. These include (the content also provides access to related sub-Definitions, Adopted Notations and Product Description).

<p><i>UML-derived Artefacts</i> □ These are created as part of the Model using the UML Modelling Approach:</p>	<p><i>Non-UML Artefacts</i> created as part of the Model using adopted modelling approaches:</p>
<ul style="list-style-type: none"> • Stakeholder Business Model (SBM) • Business Information Model (BIM) • Business Process Model (BPM) • Information Analysis Model (IAM) • Use Case Model Artefact (UCM) <ul style="list-style-type: none"> ○ Use Case Catalogue ○ Actors Catalogue Package (Model-wide store for Actor Elements) ○ Use Case Model Package ○ Use Case Diagram ○ Use Case Activity Diagram (UCAD) • State Diagram Artefact • Additional Artefact development content: <ul style="list-style-type: none"> ○ Class Model Artefacts, and ○ Class Elements Usage <ul style="list-style-type: none"> ▪ Splitting Large Class Diagrams ▪ Constraints (including Datatypes) ○ Use Case Elements on ○ Use Case Artefacts ○ Activity Diagram Artefacts 	<ul style="list-style-type: none"> • Requirements Artefacts: • Requirements Catalogue • Requirements Catalogue Palette Diagram • Requirements Diagrams including: • Requirements Elements • Requirements Associations • Non Diagrammatic Requirements Outputs

Table 1. The Artefact Definitions to support the development of Domain Analysis Projects

4. Specifications

4.1 Assets

The purpose of the inventory is to provide a resource that is searchable and structured so that contents may be accessed and, where appropriate, re-used.

The EXPAND project developed a register of interoperability assets [1], to become a publicly available resource to enable individuals and organisations establishing new interoperability use cases and information flows to identify relevant assets that may be suitable and can be re-used.

The EXPAND project has developed a list of descriptors for providing information about an interoperability asset [2]. These descriptors were designed not to provide a detailed specification of the asset, which is normally available through other claims of supporting documentation, but rather to enable insight to a potential downstream user about how well suited the asset might be to their needs, especially with regard to scaling up the use of that asset to additional contexts and geographies. The EXPAND register is intended to provide enough information to enable such users to make an informed decision of whether to invest time and effort in obtaining and appraising the asset formally [3].

For the Joint Action task, a specification has been seen as potentially relating to functional and non-functional areas, and not just for interoperability purposes. In this context, such a specification will typically be intended for one or more use contexts in clinical or administrative activities (*functional* viewpoint), one or more integration contexts in relation to organizational and activity boundaries (*organizational activity system* viewpoint), and often based on one primary "interoperability mode" in a systems implementation context (*interoperability paradigm* viewpoint). These viewpoints provide support for quick screening, grouping, and location of specification from viewpoints of the identified user groups [4,5].

4.2 Functional classification

Functional classifications are based on different functional areas of health care activities. The main division used in the interface map is between administrative and clinical domains, and both of these main classes can be further classified according to different administrative or clinical areas of activity. In addition, there are specifications which do not distinguish between whether they are used in clinical or administrative activities (generic domain). Examples include:

- Administrative

- Patient admission and discharge specifications
- Patient and organization billing interfaces
- Diagnosis-related group (DRG) grouping service interfaces
- Appointment scheduling specifications
- Clinical
 - Electronic Patient Record Documents
 - Laboratory Orders and Results
 - Clinical and Radiology Imaging interfaces
 - Clinical Decision Support interfaces
 - Transfer of Care (referral, discharge)
 - Personal Health Records
- Generic
 - Generic messaging specifications

The aim is to be inclusive, and as new application areas emerge (e.g. mhealth) so they will be incorporated.

4.3 Organizational activity system and interoperability classification

Organizational activity system classification is driven by distinction between different types of integration needs. It especially focuses on *boundaries of activities in organizational context*. Interoperability needs and solutions are observed in terms of what kind of organizational or activity boundaries are faced in the integration effort in relation to the activity system. These aspects often have very profound effects on the architecture, security requirements, availability of shared infrastructure, and the level of detail of needed agreements for interoperability. The categories and examples of interoperability specifications in each category are as follows:

1) Interoperability internal to one activity: support for work of an *individual user or group*. Examples include synchronization of applications using clinical context integration solutions such as those based on HL7 CCOW standard (e.g. selection of a patient in one application and communication of patient context to other simultaneously used applications), portal integration, user-based integration between scheduling or ePrescription system with EPR

application, single sign-on, etc. This category also includes interfaces between devices and professional systems within an activity.

2) Interoperability between *activities within an organization*, typically between core clinical care activities or units and supporting activities and services. Examples include re-request-reply interactions between clinics and laboratories or between wards and radiology departments.

3) Interoperability between *activities along the service chain or inter-organizational care pathway*. Examples include electronic referral and discharge messages, support for ePrescription processes between care providers and pharmacies, or disease-specific system integrations, support the care pathway of diabetes patients, for example.

4) Interoperability solutions for *information sharing between organizations* participating in the service spectrum, with-out tying the integration points to any particular processes or pathways. For example, regional or national document sharing infrastructures or shared EPR repositories are included in this class.

5) Interoperability for *electronic services and self-management* for patients and clients. These kinds of solutions include integrated or provider-tethered PHRs, patient / provider shared care and communication systems and integration between home measurements and professional care provision systems, for example.

6) Interoperability for *management, public health and statistics* which is not directly related to client-facing services. Such interoperability solutions include public health.

4.4 Metadata for specifications

There are various metadata templates for requirements and standards catalogues, such as the HL7 product brief templates. These are simple worksheet listings of standards and their key attributes. Such metadata typically include administrative and intended use data, and may also contain classifications. Consistent metadata promotes comparability and consistency within the standards catalogue. Building on the EXPAND set, the data items in Table 2 overleaf may be recorded for each specification.

Data item	Meaning
Name	Complete name of the specification
Version	Version information included in repository
Identifier	Universal identifier of the specification e.g. OID, URI, official abbreviation or id
Date	Year or timestamp of publications
Link	Location of the specification (e.g. URL)
Status	Level of official acceptance, e.g. normative, draft, etc.
Document type	e.g. pdf, word, excel, other
Scope	Scope statement as stated in specification
Organization	Organization responsible for maintenance of the specification.
Functional class	(see section "Functional classification")
Organizational class	(see section "Organizational activity system classification")
Interoperability paradigm class	(see section "Interoperability paradigm classification")
Summary	Brief free format description of the main contents of the specification
Relationships	Key relationships to other specifications such as base standards, dependencies, etc.
Additional information	Other relevant key information about the specification.
Version history	Previous versions of the specification (including links if applicable)

Table 2. Metadata for specifications

5. Inventory

5.1 Overview

Key Task 8.2.1 is titled “inventory of specifications”. The eHN will be able to access the inventory, but the focus of the work to date has been on the scope, structure and data elements needed to make the inventory useful. Once established, the inventory itself is expected to grow steadily as additional specifications are sourced and captured.

The Interoperability Asset Register is an online register and discovery service for interoperability assets. Interoperability assets are documents, templates, term lists, clinical models, technical specifications, software, multi-media resources that support the design, implementation or adoption of interoperability of health data. Examples of such assets include:

- Legal and regulatory interoperability assets, such as Directives and Regulations, legal frameworks, agreement templates...
- Organisational interoperability assets, such as policies, adoption guidelines and care pathways, training resources...
- Semantic interoperability assets, such as clinical models, terminology subsets...
- Technical interoperability assets, such as information models, XML schema...

Each asset is documented using a standard set of descriptors, developed through an examination of many current methods and metadata specifications for assets, complemented by a wide consultation with many experts, initiatives, SDOs and profile development organisations.

5.2 Design approach for the inventory

The primary objective of the inventory is to be a single central point of reference for the discovery of assets that can contribute to the successful analysis, design, implementation, adoption or benefits realisation of information systems and services within an eHealth environment which might be as small as a city or region or as large as Europe and beyond. The concept of discovery does not automatically equate with the function of curation.

The actual assets themselves may be held by the same trusted party maintaining the register, and be directly accessible through the register. In other cases the register will act more as a signpost, and refer the user to another web portal where the asset may be described in even greater detail and acquired. This will occur, for example, for international standards that are published individually by each SDO.

The starting point for the design of the EXPAND interoperability assets register was to identify the appropriate characteristics of quality that an interoperability asset should have in order to be suitable for wider use and reuse. Important inputs to this were the deliverables of epSOS, of eSENS and Deliverable 5.1 of SemanticHealthNet (Quality criteria and proposals for certification of semantically interoperable resources and systems). This last deliverable in turn drew on deliverables from the Q-REC project and from the EuroRec criteria for EHR systems, which includes criteria on interoperability. The Common Assessment Method for Standards and Specifications (CAMSS) was also examined as a source of potential quality descriptors. A set of dimensions was derived from these various input sources, by which an asset might be classified in order to support indexing and discovery, and the selection or comparison of assets against uniform (quality) selection criteria. These dimensions included the use cases supported by an asset, the components within an eHealth architecture the asset supports interoperability of or between, the type of asset it is and its present level of endorsement (such as a standard, a publication from a recognised body, a research project output).

All of these aspects apply equally well to the JAseHN specification inventory. The goal of the inventory is to provide insight into those different dimensions of maturity rather than to offer a formal assessment of fitness for (any particular) reuse purpose.

5.3 Potential Descriptors

In the next stage of Key Task 8.2.2, work will focus more on the assessment of “what makes a good requirement?”. The issues of tooling, management and re-use will be explored further, alongside further consideration of criteria for both applications and standards documentation. The conclusions from this exercise will inform a review of the list from EXPAND.

The descriptors defined in Section 4 have been implemented in a spreadsheet tool alongside the quality criteria in order to be able to easily test this framework for asset evaluation. The designed spreadsheet form can allow users to evaluate their assets by using a familiar application. The spreadsheet form will be used to evaluate the proposed domains, descriptors and graphical representation, before being implemented as an online register and database.

This spreadsheet is organised in 11 domains that are classified into two groups:

- **Domains to support asset discovery and provenance information.** This group includes three domains, represented in a white background colour. They include the description of the purpose and recommended usage, enabling new users external to the asset’s development team to determine if the specific asset is suitable to be reused in their

projects and systems. Additionally, these descriptors provide information about access to the asset, detailing the organisation that developed the asset and the one that now hosts the asset.

5.3 Planned developments

In its early versions, the JAseHN specification inventory will support searching through the values of its asset descriptors. A later development will be to enrich the search function to support a user looking to find a collection of potentially diverse assets that may be used in combination to deliver specific interoperability functions. These "asset bundles" may comprise a mixture of asset types covering legal, organisational, technical, semantic and other dimensions of interoperability that all need to be in place in order to ensure success of that interoperability function.

During EXPAND, as a result of pilot testing and stakeholder workshop, some specific development areas were identified:

- To enrich the information provided about IP and licensing, to indicate if the asset has an IP owner (who might not be the curator), if the asset is in the public domain, if there is a formal license whether this permits new IP to be created using the asset and what licensing rules might apply to that.
- To make some descriptors mandatory and to convert those that are currently in free text to offer more structured (controlled vocabulary) entries. These will in particular be those that are considered to be the most important determinants of quality.
- Status and history of editing of the assets including quality assurance. This will include the ability for downstream asset users and maintainers to also update the register with adoption guidance, feedback on use, issues etc.
- Improvement of user profiles (administrators, editors, readers).
- Online collaboration, a team that edits, comments and finalises an asset entry.

Tracking the lifecycle of the register entry, as well as of the assets.

Annex A: References

- [1] EXPAND: D4.1 Classification of, and inclusion criteria for, European eHealth interoperability resources, WP 4 Assessment model, 14-11-2014 , Version 1.0
- [2] EXPAND: D4.2 Quality labelling criteria for European eHealth interoperability resources, WP 4 Assessment model , 10-08-2015
- [3] EXPAND: D4.3 Functional characteristics of a European eHealth Interoperability Infostructure, WP 4 Assessment model, 15 February 2016, Revision 1.0
- [4] Virkanen H, Mykkänen J, Tuomainen M. Interface Map as a User-Driven Interoperability Standards Portfolio. In: Lehmann CU, Ammenwerth E, Nohr C, eds. Medinfo 2013. Stud Health Techn Inform 192, pp. 407-411
- [5] Mykkänen JA, Tuomainen MP. An evaluation and selection framework for interoperability standards. Inform Software Tech 2008;50(3):176-197
- [6] [http://9001quality.com/wp-content/uploads/2014/02/ISO-9001-4.2.4-contro of records documentation pyramid.bmp](http://9001quality.com/wp-content/uploads/2014/02/ISO-9001-4.2.4-contro%20of%20records%20documentation%20pyramid.bmp)
- [7] European Commission Communication on ICT Standardisation (COM(2009)324) <http://ec.europa.eu/transparency/regdoc/rep/1/2009/EN/1-2009-324-EN-F1-1.Pdf>

Annex B: Asset Descriptors

The table below lists the asset descriptors developed in EXPAND.

ID	Description
	Description of asset
100	Purpose and usage
101	Asset name
102	Asset type
103	Use cases supported
104	Scope/purpose
105	Domain coverage
106	Targeted user groups
106	Language
700	Relationship with other assets
701	Belongs to the following bunch of assets
702	Alignment and usability with other assets
703	Misalignment and usability with other assets
704	Implementation of another asset
705	Sub-component of another asset
706	Incorporates another asset
707	Extends another asset
708	Supports adoption of another asset
709	Provides evidence for another asset
710	Supersedes another asset
800	Access information
801	Originating project or initiative
802	Current custodian/curator
803	Current release version and date
804	Enquiry and access channels
805	Register information provider

All domains include multiple descriptors corresponding to the most representative metrics that are useful to support decision for adopting, reusing or modifying the selected asset. Descriptors are evaluated with a drop-down list that details multiple options ordered according to their level of fulfilment.

Annex C: Potential Sources

Specification artefacts are being gathered from the following:

- NEHTA, Australia
- Canada Health Infoway
- HSCIC, UK
- ONC, US
- European Interoperability Framework
- HL7
- IHE
- Continua Alliance
- Antilope refined the eHealth interoperability framework and offered an inventory of relevant standards, quality management approaches, testing tools, and labelling processes. The process was broadly inclusive and involved all relevant players in eHealth interoperability (including IHE and Continua), and was validated in events with many Member States representatives in 2014 and January 2015. It would be regrettable if that body of work were not in some way reflected here. See <http://www.antilope-project.eu/resources/>
- An extensive study on eHealth interoperability was funded by the German Ministry of Health and is published here: <https://publicwiki-01.fraunhofer.de/Planungsstudie-Interoperabilitaet/index.php/Hauptseite>
- There is a comprehensive list of publications on the subject on the wiki of HL7 Germany: <http://wiki.hl7.de/index.php?title=Kernpublikationen>

Annex C: Competence Centres

Countries		Web page
Australia	NEHTA	www.nehta.gov.au
Austria	ELGA GmbH	www.elga.gv.at
Austria	Federal Ministry of Health	www.bmg.gv.at
Austria	Gesundheit Österreich GmbH	
Belgium	Service Public Federal Sante Publique	www.health.fgov.be
Bulgaria	Bulgarian Executive Agency of Transplantation	www.bgtransplant.bg
Bulgaria	Ministry of Health	www.mh.government.bg
Bulgaria	National Centre for public Health and Analysis	
Canada	Health Infoway	www.infoway-inforoute.ca
Croatia	Croatian health Insurance Fund	www.hzzo.hr
Cyprus	Ministry of Health	www.moh.gov.cy
Czech Republic	Institute of Health Information and Statistics of the Czech Republic	www.mzcr.cz
Denmark	Danish National Board of Health	www.ssi.dk
Estonia	ehealth agency	www.e-tervis.ee
Estonia	Ministry of Social Affairs of Estonia	www.sm.ee
Finland	Ministry of Social Affairs and Health	
Finland	National Institute for Health and Welfare	www.stm.fi
Finland	THL	www.thl.fi
France	ASIP Santé	www.sante.gouv.fr
France	Ministry of Health	
France	Ministry of social affairs, health and women rights	www.sg.social.gouv.fr
Germany	Gematik	
Germany	Gesellschaft für Telematikanwendungen der Gesundheitskarte mbH	www.gematik.de
Germany	Institute for Medical Documentation and Information	
Germany	Ministry of Health of Germany	www.bmg.bund.de
Greece	Third(3'D) Hellenic Health Region, Directorate of Informationstechnologie	www.3ype.gr
Hungary	Nationale Institute for Quality- and Organizational Development in HealthCare and Medicine	www.acek.hu
Hungary	Semmelweis Egyetem	www.semmelweis-univ.hu
Ireland	Department of Health	www.health.gov.ie
Ireland	HSE	

Joint Action to support the eHealth Network

Italy	Ministry of Health	-
Italy	Ministry of Health	www.sanita.it
Latvia	National Health Service	www.vmnvd.gov.lv
Lithuania	National Health Insurance Fund Under The Ministry Of Health Of The Republic Of Lithuania	www.santa.lt
Lithuania	Vilnius University Hospital Santariskiu Klinikos	www.vlk.lt
Luxembourg	Agence eSanté - Agence nationale des informations partagées dans le domaine de la santé	www.agence-esante.lu
Malta	Ministry of Health-Government of Malta	www.gov.mt
Netherlands	Ministry of Health, Welfare and Sport	www.minvws.nl
Netherlands	Nederlands Instituut voor ICT in de Zorg	www.nictiz.nl
Norway	The Norwegian Directorate of Health	www.helsedir.no
Poland	National Center for Health Information Systems	www.csioz.gov.pl
Portugal	Ministry's of Health Shared Services	www.spms.min-saude.pt
Romania	Babes-Bolyai University Cluj-Napoca-Center for Health and Public Health	www.ubbcluj.ro
Romania	Head Office of National Contact Point from the National Health Insurance House	www.publichealth.ro
Slovenia	Ministry of Health of the Republic of Slovenia	www.gov.si
Spain	Ministry of Health, Social Services and Equality	
Spain	Ministry of Health	www.msssi.es
Sweden	Public Health and Health Care Division, Ministry of Health and Social Affairs Government Offices	www.ehalsomyndigheten.se
Sweden	Swedish ehealth Agency	www.gov.se
United Kingdom	Department of Health	www.dh.gsi.gov.uk
United Kingdom	Health and Social Care Information Centre	www.hscic.gov.uk
United States	Office of the national co-ordinator	www.healthit.gov
	European Commission	www.ec.europa.eu
	European Health Telematics Association	www.ehtel.eu

Annex D: Links to documents

Countries	Links to Specification Doc
Australia	https://www.nehta.gov.au/news-and-events/news/923-implementation-resources-updated-clinical-document-specifications-clinical-documents-integration-toolkit-august-2015-release
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1135-2010
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1224-2011/NEHTA-0794-2011
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1224-2011
Australia	https://www.nehta.gov.au/implementation-resources/ehealth-foundations/EP-1543-2013/NEHTA-1542-2011
Australia	https://www.nehta.gov.au/implementation-resources/ehealth-reference-platform/EP-2134-2015/NEHTA-2112-2015
Australia	https://www.nehta.gov.au/implementation-resources/ehealth-foundations/EP-1880-2014/NEHTA-1894-2011
Australia	https://www.nehta.gov.au/implementation-resources/ehealth-reference-platform/EP-2106-2015/NEHTA-2107-2015
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1135-2010/NEHTA-1136-2010
Australia	https://www.nehta.gov.au/get-started-with-ehealth/what-is-ehealth/features-of-the-ehealth-record-system/ehealth-foundations
Australia	https://www.nehta.gov.au/implementation-resources/national-infrastructure/EP-1514-2012/NEHTA-1118-2012
Australia	https://www.nehta.gov.au/implementation-resources/national-infrastructure/EP-1514-2012/NEHTA-1119-2012
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1414-2013/NEHTA-1417-2013
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1414-2013/NEHTA-1244-2013
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1414-2013/NEHTA-1415-2013
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1387-2013/NEHTA-1395-2011
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1387-2013/NEHTA-1389-2011
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1387-2013/NEHTA-1394-2011
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-0938-2010/NEHTA-1381-2013
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1142-2011/NEHTA-0806-2011
Australia	https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1094-2011/NEHTA-1226-2011
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Denmark	https://sundhedsstyrelsen.dk/en/.../sale/.../extended-storage-period
Denmark	https://sundhedsstyrelsen.dk/.../Kontrol%20af%20laegemidler%20med%20indholdsstoffet%20strep...
Denmark	https://sundhedsstyrelsen.dk/en/.../notification-of-prices-and-range
Denmark	https://sundhedsstyrelsen.dk/en/.../safety/danish-drug-interaction-databases
Denmark	https://sundhedsstyrelsen.dk/.../tender-for-secondary-standard-dosimetry-laboratory-ssdl
Denmark	https://sundhedsstyrelsen.dk/.../D351DCAA2DB4463498724643F4E876C6 . ashx
Germany	http://www.bmg.bund.de/fileadmin/dateien/Downloads/Gesetze_und_Verordnungen/GuV/M/MPG_english.pdf
Germany	http://www.bmg.bund.de/fileadmin/redaktion/pdf_gesetze/amg-engl.pdf
Germany	http://www.bmg.bund.de/fileadmin/dateien/Downloads/Gesetze_und_Verordnungen/GuV/M/Medicinal_Products_Act_28052010.pdf
Germany	http://www.bmg.bund.de/fileadmin/dateien/Downloads/Gesetze_und_Verordnungen/GuV/A/AMG_English_Version_130115.pdf
Italy	http://www.salute.gov.it/portale/temi/documenti/dispositiviMedici/C_17_pagineAree_1678_listaFile_itemName_5_file.ppt
Spain	http://www.mssi.gob.es/organizacion/sns/planCalidadSNS/docs/Laboratorio_Clinico_EyR.pdf
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