



D3.1 EXPAND Vision

WP 3.1 eHealth interoperability assets

02-07-2014

Version 1.0

This is an evolving document; it follows the discussions and development of common concepts in the project, which is developing in a highly dynamic environment. It is a high level document aiming to maintain a common vision across all work packages and work teams of the project, which remains consistent with the evolving external environment to the project, within the boundaries of its Technical Annex. This is the first version leading up to the May 2014 EXPAND workshop. The next version will be issued before the end of 2014.

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Acronyms

Acronym	Description
ANTILOPE	Advanced eHealth Interoperability
CALLIOPE	Call for Interoperability
CAMSS	Common Assessment Method for Standards and Specifications
CEF	Connecting Europe Facility
CIP/PSP	Competitiveness and Innovation Programme/Policy Support Programme
DoW	Description of Work
EC	European Commission
eHGI	eHealth Governance Initiative
eHN	eHealth Network
epSOS	European Patient Smart Open Services
eSENS	Electronic Simple European Networked Services
EU	European Union
FP7	Framework Programme 7
ICT	Information and Communication Technologies
LSP	Large Scale Pilot
MS	Member States
PS	Patient Summary
SDOs	Standards Development Organizations
SHN	Semantic Health Net
WP	Work Package

Executive Summary

This document is prepared in the form of an evolving concept paper with the aim to simultaneously serve the purpose to assist EXPAND in reaching out and communicating common objectives to other projects of interest. At the same time, this document is expected to serve the purpose of establishing and maintaining a common vision across all EXPAND working groups at all times.

EXPAND will operate in the gap between piloting and deployment of epSOS cross border services and will go beyond the epSOS scope in the following ways. Its main objective is a successful handover of the current pilot cross border eHealth services to an environment of sustainable cross border eHealth services established at EU level by the Connecting Europe Facility (CEF) and at national level through deployment of appropriate technical and legal interfaces and gateways coupled with interoperable national infrastructures and services. While the Description of Work (DoW) of EXPAND describes a work plan to address these challenges, this vision document aims to consolidate the main concepts, including those associated to dealing with the wider use of assets developed within different projects, the values and principles.

EXPAND will also aim to demonstrate expandability beyond the epSOS eHealth services to planned care services as described in the cross-border Directive (2011/EU/24). This is pursued primarily through establishing a framework for appraisal of assets to be applied in first instance operations to the epSOS assets but also to assets developed in other projects that contribute to cross-border services supporting healthcare. These assets will be provided to the CEF for consideration for use in the deployment of eHealth services. The implementation of new services exploiting such assets is out of scope of EXPAND and it is expected that it will be assigned to future projects.

The work hypothesis for EXPAND is therefore that it is possible to swiftly **expand** the portfolio of available cross border eHealth services by exploiting “appropriate” eHealth assets, developed in various international or national/regional initiatives. In order to test this hypothesis, EXPAND will define what “appropriate assets” means in this transferrable assets context and elaborate a comprehensive framework for assessment of eHealth assets, including criteria for acceptance and quality labeling of resources. Eventually, by doing so, the project will be expanding on the current epSOS concept of unscheduled care use case for the exchange of medical summaries, to examine scenarios of planned care of different kinds.

For this purpose the project will produce a number of publicly available reference and repository tools. They will enable users to access the core information. EXPAND will thus play an important role in distribution of assets, while it will not maintain and evolve them. This “hand-over” work of EXPAND will be based on the thorough assessment of assets produced by other projects according to the EXPAND’s criteria proposed and validated within the project.

EXPAND will define a set of quality labeling criteria that can be applied to different classes of interoperability assets, derived from existing work in several European projects including epSOS, SHN, e-SENS, and from quality processes already used by relevant SDOs. An operational model for this quality labeling process will be defined, which may include a mixture of self declaration and formal independent quality assurance. The publication environment (infostructure) will make quality labels visible to end users, and enable users to search only for quality labeled assets if appropriate.

1. Introduction

The EU has been funding through its CIP/PSP, Public Health and FP7 programmes a large number of projects which aim to address particular challenges of sharing health information across the MS, the health professionals and other stakeholders. Despite the successful development of such projects, experience shows that the passage from research projects to pilots and from pilots to deployment in general and in the context of cross border eHealth services in particular, has several challenges such as: appraisal of projects' results; building trust in outcomes and capacities for their continued maintenance and support; and interdependencies across MS priorities. The latter has been particularly addressed through involvement of national health authorities in policy support actions such as epSOS, CALLIOPE, the eHGI and most recently EXPAND.

While the Description of Work (DoW) of EXPAND describes a work plan to address these challenges, a deeper analysis of the main concepts, including those associated to dealing with assets developed within different projects, the values and principles and eventually an EXPAND vision is needed.

This document is prepared in the form of a concept paper with the aim to simultaneously serve the purpose to assist EXPAND in reaching out and communicating common objectives to other projects of interest. At the same time, this document is expected to serve the purpose of establishing and maintaining a common vision across all EXPAND working groups at all times.

1.1. Background

EXPAND is defined by means of a number of key words, delimiting its scope: the project is about *interoperable, cross border, EU, eHealth services* based on the legal basis provided by the "*Patient Rights Directive*" relating to their access to *planned care abroad*. It will *maintain, update and upraise epSOS assets* and prepare them for their *hand over to CEF*, but will go beyond epSOS, by exploiting opportunities and *assets produced in other projects and initiatives*.

Directive 2011/24/EU aims to provide clarity with respect to the rights of European citizens to cross border care by establishing rules for facilitating access to safe and high-quality cross-border healthcare in the Union. Continuity of care is recognized as one of the major objectives and as such it is supported by several legal provisions such as for recognition of prescriptions and for increased co-operation between Member States (MS) expressed in the form of European Reference and Health Technology Assessment Networks. Cross border eHealth and eHealth interoperability (legal, organizational, technical and semantic) are also considered as one of the major enablers of cross border health care.

Article 14 of the Directive established the voluntary eHealth Network (eHN). The overall objective of the eHN ("the Network") is to work towards delivering sustainable health, social and economic benefits of European eHealth systems and services, including interoperable applications. The eHN adopted in November 2013 *Guidelines on patients summary set of data for cross border electronic exchange* and within the next months it is expected to adopt *Guidelines on e-Prescriptions, Guidelines on Legal Interoperability* and e-Identification and authentication measures to support the above services.

It is noted that both of these cross border services have been successfully developed, tested and piloted in epSOS within a secure and legally sound environment. This project has thus delivered a number of assets in the form of interoperability specifications, semantic assets, architecture and

basic service building blocks, open source code and legal agreements, that collectively made the provision of services possible on a pilot basis. It is important however to fully appreciate the **scope limitations of epSOS**:

- Firstly, epSOS is a Large Scale Pilot (LSP), which was conceived as a proof-of-concept of the EC Recommendation on Interoperability of electronic Patient Records¹; it started in June 2008 and will finish end of June 2014. Its mission has been to develop and test pilot services for cross-border data sharing to support patient care delivered to European citizens outside their usual state of residence by means of a shareable electronic Patient Summary and ePrescription. **Deployment** of these services is out of scope of epSOS and would require further legal measures, co-ordination mechanisms and adoption by the ICT marketplace.
- Secondly, the epSOS LSP has focused primarily on unplanned care/emergency situations. Directive 2011/24/EU however, is supporting **planned care** especially in cases where the opportunities arising from European co-ordination and cross border care have the maximum impact on efficiency and quality of care, examples being the treatment and development of clinical knowledge in the areas of rare and of chronic diseases. Planned care has additional requirements with respect to the clinical/semantic information to be transferred.
- Thirdly, there is a **gap** between the pilot phase and the deployment phase, the latter having to cope with a number of associated EU level and national challenges. In this context, epSOS has delivered recommendations for **sustainability** after its closure mid-2014, which foresee also “survivability” of the developments on course to full, sustainable deployment.

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:190:0037:0043:EN:PDF>

2. EXPAND Vision

2.1. The EXPAND Remit

EXPAND is a project that will operate in the gap between piloting and deployment of epSOS cross border services and will go beyond the epSOS scope in the following ways.

Its main objective is a successful handover of the current pilot cross border eHealth services to an environment of sustainable cross border eHealth services established at EU level by the Connecting Europe Facility (CEF) and at national level through deployment of appropriate technical and legal interfaces and gateways coupled with interoperable national infrastructures and services. In doing so,

- (i) it will secure the continuing operation of the *organizational* structures developed in epSOS that will allow for the maintenance and updating of assets used in the current pilots;
- (ii) EXPAND will also aim to demonstrate expandability beyond the epSOS eHealth services to priority planned care services of the Directive. This is pursued primarily through establishing a framework for appraisal of assets to be applied in first instance operations to the epSOS assets but also to assets developed in other projects.
- (iii) if and to the extent needed, it will ensure adoption of EXPAND proposals by its participating health authorities and their continuing commitments to the running pilots, thus reducing the risk of reverting to bilateral contracts between MS which inevitably will threaten the currently established levels of interoperability. It should be however mentioned that coordination of national policy is out of scope of EXPAND and this activity will be strictly limited to what is needed for carrying out the project's specific objectives and to the extent they fall outside the eHN's work plan of activities².

These assets will be handed over to CEF for their use in the deployment of eHealth services. The implementation of new services exploiting such assets is out of scope of EXPAND and it is expected that it will be assigned to future projects.

For this purpose the project will produce a number of publicly available reference and repository tools. They will enable users to access the core information. EXPAND will thus play an important role in distribution of assets, while it will not maintain and evolve them. This "hand-over" work of EXPAND will be based on the thorough assessment of assets produced by other projects according to the EXPAND's criteria proposed and validated within the project.

2.2. The EXPAND work hypothesis

The work hypothesis for EXPAND is that it is possible to swiftly **expand** the portfolio of available cross border eHealth services by exploiting "appropriate" eHealth assets, developed in various international or national/regional initiatives. Such expansions may be for example in the form of extending the PS data set, to align it with the evolving EC PS Guidelines and to include elements that are deemed necessary to support exemplary cases of planned care, through incorporating

² The work to be carried out by EXPAND is not fully in scope of the eHN priorities at this stage and as per its 2012-2014 Multiannual Work Plan (MWP). Its next MWP is currently under development, hence this requirement for EXPAND will be reviewed and revised as necessary

validated semantic assets developed outside epSOS; expansions may also be in the direction of new or updated technical specifications for eHealth services.

In order to test this hypothesis, EXPAND will define what “appropriate assets” means in this transferrable assets context and elaborate a comprehensive framework for assessment of eHealth assets, including criteria for acceptance and quality labeling of resources. Eventually, by doing so, the project will be expanding on the current epSOS concept of unscheduled care use case for the exchange of medical summaries, to examine scenarios of planned care of different kinds.

EXPAND does not have the resource capacity to implement neither a complete new Infostructure, nor a sustainable system in the form of a repository of semantic and other assets, that but will aim to specify the features for such Infostructure and asset management tools and a work plan through which these main features could be evolved and maintained by the CEF.

The assets themselves will be developed and maintained by a multitude of initiatives and projects at EU and at national level. As such the ownership of these assets will usually remain with their initial creators. EXPAND will foster a signposting approach paradigm by bringing together and publishing or referencing a body of interoperability assets derived from multiple projects, including epSOS, and by offering these in a way that is organized by use case and clinical scenario. In fact, the proposed SemanticHEALTH Institute aims to develop the infostructure that EXPAND will contribute designs for. The project will therefore aim to explore ways through which appropriate mechanisms that may be established as part of the CEF governance framework in the near future will be able to ensure, and offer an assurance to future end-users of these assets, that they are fit for purpose, have been well-designed and meet appropriate requirements including their governance.

2.2.1 Working Approach

In supporting the current epSOS pilots, and in preparing epSOS assets for assessment within EXPAND and their eventual hand over to CEF, EXPAND will continue to “consolidate specifications”³, EU level standard interfaces, open source code and collaborative models and procedures developed in epSOS and will integrate experience from the Semantic Health Net (SHN), e-SENS and the other projects that it will engage in collaboration with. It will also continue to provide guidance for the associated national implementations.

In order to address the expandability challenge, EXPAND will initiate at the start of the project - and maintain throughout its duration - a close working relationship with relevant projects and stakeholders. Globally three groups are envisaged:

- EU collaborative projects within the ICT for Health area of activity supported by CIP/PSP and FP7. Semantic assets in particular have been developed in several projects and many of them concern care situations and diseases that relate much closer to the planned care situations e.g. data sets for chronic diseases developed within the SHN, NEXES and Renewing Health;
- Clinically driven, EU collaborative projects within the public health area of activity focusing on the definition of clinical data sets and their semantic representations in specific disease

³ It is noted that the scope and work involved vis-a-vis available resources will need further analysis within WP5

areas supported by the Public Health Programme; such projects have for example focused on the adoption by clinicians, of treatment data sets for a multitude of rare diseases.

- SDOs, national and regional initiatives.

As a first step, these potential contributors will be identified and invited to the first EXPAND workshop to take place in May 2014, in association to the high level eHealth Conference 2014 in Athens, with a key objective to explore the existing potential of expandability by appropriately exploiting existing assets. This first workshop will also support an open process for the collection of input towards the definition of the assessment framework.

Defining such a framework will need be an iterative process:

- Firstly, EXPAND needs to identify amongst the different projects, possible candidate assets beyond the epSOS ones. The first EXPAND workshop will focus on identifying potential contributors of assets and will initiate a discussion and a collaboration with interested external parties and stakeholders.
- In a second stage, EXPAND will propose an assessment framework for candidate assets and will make available an assessment mechanism. This framework will be validated through its first use for the purposes of the assessment of assets of projects and stakeholders contributing to this challenge.
- Subsequently, EXPAND will work together with a small group of contributors of assets, selected through this collaboration and following the successful assessment of their assets, in order to explore the functional characteristics of a European eHealth Infostructure, which will include version managed repositories, with distribution and publishing capability, as well as functions for supporting the maintenance of individual resources. A second workshop will cater to supporting this objective.
- The project will provide the move from the working example of - primarily but not exclusively - epSOS to a proof of concept of generally usable and applicable assets of projects in the shape of an interoperability assets information repository.

EXPAND will define a set of quality labeling criteria that can be applied to different classes of interoperability assets, derived from existing work in several European projects including epSOS, SHN, e-SENS, and from quality processes already used by relevant SDOs. An operational model for this quality labeling process will be defined, which may include a mixture of self declaration and formal independent quality assurance. The publication environment (infostructure) will make quality labels visible to end users, and enable users to search only for quality labeled assets if appropriate.

The e-SENS project in the eGov domain is developing and testing a framework for assessment of re-usable interoperability resources based on the Common Assessment Method for Standards and Specifications (CAMSS) methodology. EXPAND will benefit from this experience and apply such methodologies where appropriate; however the major contribution of EXPAND will be in the domain of semantic assets where the relevance of CAMSS is insignificant, while of great significance to eHealth.

Last but not least, EXPAND will promote the importance and value of interoperability of eHealth solutions. The aim with regard to dissemination is to make end users (health professionals) and the main profiteers (citizens/patients) aware of current developments in order to generate a need and demand for cross-border eHealth services across Europe. The project ideas will be made

public and the results and findings available for all the stakeholders and users. The assets which will be successfully assessed by EXPAND will be referenced to in publicly available systems and therefore their re-usability further enhanced.

3. Final Remarks

This first version of the EXPAND vision, has successfully served its purposes, being primarily (i) to provide a background document to support the project kick-off meeting discussions and (ii) be the basis for communication outside the projects leading to the 1st EXPAND workshop.

The environment around EXPAND is however quickly evolving and many basic assumptions are evolving as well.

In May 2014, the eHealth Network adopted a set of priority services to be prepared for the CEF. This adoption is one of the major inputs into the scoping of assets to be prioritized by EXPAND. During the same meeting, the eHealth Network established a Subgroup of MS for the upkeep of epSOS services. A total of 15 MS signed up with a keen interest to continue piloting. This new reality raises also new questions as to the role of EXPAND in support this group. It also raises questions as to a possible role of EXPAND in creating convergence with other projects such as eSENS, Antilope and SHN towards maximising the value and usage of their resources for the purposes of supporting the post epSOS operation of the eHealth pilots.

It is therefore envisaged that the preparation of the 2nd version of the EXPAND vision will be initiated immediately after the WP5 kick-off in July 2014, will be prepared in close co-operation with WP1 and WP5 where several aspects and stakeholder commitments will be further clarified. This next version will incorporate a number of new elements including but not limited to:

- a new section on the Role of EXPAND in supporting the eHN subgroup for upkeep of cross border services;
- a section on the role of EXPAND in producing convergence with other running cross border projects with overlapping objectives towards supporting the continuation of services;
- updated descriptions concerning assessment of assets and signposting following the very insightful discussions at the workshop and the collection of the first round of assets.

ANNEX 1. EXPAND Vision Document for External Use



Expanding Health Data Interoperability Services

Collaboration with relevant projects and initiatives

Preamble

The EU has been funding through its CIP/PSP, Public Health and FP7 programmes a large number of projects which aim to address particular challenges of sharing health information across the MS, the health professionals and other stakeholders. Despite the successful development of such projects, experience shows that the passage from research projects to pilots and from pilots to deployment in general and in the context of cross border eHealth services in particular, has several challenges such as: appraisal of projects' results; building trust in outcomes and capacities for their continued maintenance and support; and interdependencies across MS priorities. The latter has been particularly addressed through involvement of national health authorities in policy support actions such as epSOS, CALLIOPE, the eHGI and most recently EXPAND.

1. Background

EXPAND is defined by means of a number of key words, delimiting its scope: the project is about *interoperable, cross border, EU, eHealth services* based on the legal basis provided by the "*Patient Rights Directive*" relating to their access to *planned care abroad*. It will *maintain, update and upraise epSOS assets* and prepare them for their *hand over to CEF*, but will go beyond epSOS, by exploiting opportunities and *assets produced in other projects and initiatives*.

Directive 2011/24/EU aims to provide certainty with respect to the rights of European citizens to cross border care by establishing rules for facilitating access to safe and high-quality cross-border healthcare in the Union. Continuity of care is recognized as one of the major objectives and as such it is supported by several legal provisions such as for recognition of prescriptions and for increased co-operation between Member States expressed in the form of European Reference and Health Technology Assessment

Networks. Article 14 of the Directive established the voluntary eHealth Network. The overall objective of the eHealth Network ("the Network") is to work towards delivering sustainable health, social and economic benefits of European eHealth systems and services, including interoperable applications. The eHealth Network adopted in November 2013 *Guidelines on patients summary set of data for cross border electronic exchange* and within the next months it is expected to adopt *Guidelines on e-Prescriptions*, *Guidelines on Legal Interoperability* and e-Identification and authentication measures to support the above services.

In fact **EXPAND** will ensure that there is a successful handover of the current pilot cross border eHealth services to an environment of sustainable cross border eHealth services established at EU level by the Connecting Europe Facility (CEF) and at national level through deployment of appropriate technical and legal interfaces and gateways coupled with interoperable national infrastructures and services.

2. The EXPAND Remit

EXPAND will also aim to **demonstrate expandability beyond the epSOS eHealth services to priority planned care services** of the Directive. This is pursued primarily through establishing a framework for appraisal of assets to be applied in first instance operations to the epSOS assets but also to assets developed in other projects.

These assets will be handed over to CEF for their use in the deployment of eHealth services. The implementation of new services exploiting such assets is out of scope of EXPAND and it is expected that it will be assigned to future projects.

The project will produce a number of publicly available reference and repository tools. They will enable users to access the core information. EXPAND will thus play an important role in distribution assets, while it will not maintain and evolve them. This "hand-over" work of EXPAND will be based on the thorough assessment of assets produced by other projects according to the EXPAND's criteria proposed and validated within the project.

3. The EXPAND work hypothesis

The work hypothesis for EXPAND is that it is possible to swiftly **expand** the portfolio of available cross border eHealth services by exploiting "appropriate" eHealth assets, developed in various international or national/regional initiatives. Such expansions may be for example in the form of extending the Patient Summary data set, to align it with the adopted PS Guidelines and to include elements that are deemed necessary to support exemplary cases of planned care, through incorporating clinically validated semantic assets developed outside epSOS; expansions may also be in the direction of new or updated technical specifications for eHealth services.

In order to test this hypothesis, EXPAND will define what "appropriate assets" means in this transferrable assets context and elaborate a comprehensive framework for assessment of eHealth assets, including criteria for acceptance and quality labeling of resources. Eventually, by doing so, the project will be expanding on the current epSOS concept of unscheduled care use case for the exchange of medical summaries, to examine scenarios of planned care of different kinds.

EXPAND does not have the resource capacity to implement neither a complete new Infostructure, nor a sustainable system in the form of a repository of semantic and other assets, that but will aim to specify the features for such Infostructure and asset management tools and a work plan through which these main features could be implemented in CEF.

The assets themselves are developed and maintained by a multitude of initiatives and projects at EU and at national level. As such the ownership of these assets will remain with their initial creators. EXPAND will foster a signposting approach paradigm by bringing together and publishing or referencing a body of interoperability assets derived from multiple projects, including epSOS, and by offering these in a way that is organised by use case and clinical scenario.

In fact, the proposed SemanticHEALTH Institute⁴ aims to develop the infostructure that EXPAND will contribute designs for. The project will therefore aim to explore ways through which appropriate mechanisms (that may be established as part of the CEF governance framework in the near future) will be able to ensure, and offer an assurance to future end-users of these assets, that they are fit for purpose, have been well-designed and meet appropriate requirements including their governance.

4. Working approach

In order to address the expandability challenge, EXPAND will initiate at the start of the project - and maintain throughout its duration - a close working relationship with relevant projects and stakeholders. Globally three groups are envisaged:

- EU collaborative projects within the ICT for Health area of activity supported by CIP/PSP and FP7. Semantic assets in particular have been developed in several projects and many of them concern care situations and diseases that relate closely to the planned care situations.
- Clinically driven, EU collaborative projects within the public health area of activity focusing on the definition of clinical data sets and their semantic representations in specific disease areas supported by the Public Health Programme; such projects have for example focused on the adoption by clinicians, of treatment data sets for a multitude of rare diseases.
- SDOs, national and regional initiatives.

As a first step, these potential contributors will be identified and invited to the **first EXPAND workshop to take place in May 2014** in association to the high level eHealth Conference 2014 in Athens. This will be **a consultation workshop with a key objective to explore the existing potential of expandability** through the contributions of projects with a specific kind of tangible output within the thematic scope of EXPAND. ***The ultimate objective of the workshop will be to establish a common understanding and driving principles for the elaboration of quality labelling criteria for interoperability assets and assessment processes for such assets.***

⁴ Proposal by the SemanticHealthNet NoE <http://www.semantichealthnet.eu/>

In a second stage, EXPAND will propose an assessment framework for candidate assets and will make available an assessment mechanism. This framework will be validated through its first use for the purposes of the assessment of assets of projects and stakeholders contributing to this challenge.

Subsequently, EXPAND will work together with a small group of contributors of assets, selected through this collaboration and following the successful assessment of their assets, in order to explore the ***functional characteristics of a European eHealth Infostructure***, which will include version managed repositories, with distribution and publishing capability, as well as functions for supporting the maintenance of individual resources. A second workshop will cater to supporting this objective.

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