



DG SANTE
Unit Information systems (A4)

Non-paper Workplan and budget 2016

eHealth DSI

Date: 06/05/2016
Doc. Version: 03

TABLE OF CONTENTS

1 GLOSSARY	3
2 INTRODUCTION	4
2.1 Objective of the document.....	4
2.2 eHealth background	4
2.3 Overview of the scope and roadmap of eHealth DSI.....	5
3 SOLUTION DESCRIPTION	5
3.1 Legal Basis.....	5
3.2 Benefits.....	6
3.3 Scope and deliverables	6
3.3.1 Core and Generic services.....	6
3.4 Planning for 2016.....	7
3.5 Budget for 2016	8
4 TABLE OF REFERENCES.....	9

1 GLOSSARY

Acronym	Definition
epSOS	Smart Open Services for European Patients. epSOS aims to design, build and evaluate a service infrastructure that demonstrates cross-border interoperability between electronic health record systems in Europe.
EXPAND	Expanding Health Data Interoperability Services
e-SENS	Electronic Simple European Networked Services. e-SENS will develop the digital infrastructure for improving the quality of public services in EU by: <ul style="list-style-type: none"> • making it easier for companies to set up business electronically • enabling electronic procurement procedures for businesses • creating seamless access to EU legal systems • making it easier to use healthcare services abroad in cases of emergency
Stork	Secure Identity Across Borders Linked. EU-wide system for the recognition and authentication of electronic identity (eID via electronic cards or other means). It will enable businesses and citizens to securely use their national electronic identities and get help from public administrations in any Member State they live in or travel to.
CEF	Connecting Europe Facility Digital Service Infrastructures (DSIs) delivering networked cross-border services for citizens, businesses and public administrations. These projects are to contribute: <ul style="list-style-type: none"> • to improving the competitiveness of the European economy, • to promote the interconnection and interoperability of national, regional and local networks, and • Access to such networks, thus supporting the development of a Digital Single Market.
Trillium Bridge	The EU-funded Trillium Bridge project wants to align the use of standards between the EU and the US to share basic patient data between health professionals. Of course only when the patient has given his consent.
IHE	Integrating the Healthcare Enterprise (IHE) is an ISO liaison forum where Healthcare Professionals work together with industry to specify and test interoperability solutions that answers their needs. They develop common framework based on profiles that enables seamless health information exchange within and between organizations.

2 INTRODUCTION

2.1 Objective of the document

The objective of this document is to provide eHealth Network visibility to the implementation of eHealth DSI core services. The production of this document was agreed in the eHealth Network meeting on 23rd of November 2015 and it will be given to eHealth Network for approval on annual basis.

2.2 eHealth background

eHealth DSI aims to offer seamless healthcare to European citizens by setting up the necessary infrastructure to enable the exchange of Patient Summaries, ePrescription and eDispensations of medicines across borders. eHealth DSI therefore contributes to the improvement of the quality and safety of healthcare for citizens when travelling to another European Union (EU) Member State.

eHealth DSI finds its origin in the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

eHealth DSI has been preceded by a large scale pilot project, epSOS (Smart Open Service for European Patients), which developed specifications for cross-border interoperability of health information between EU Member States and which also set-up the supporting ICT infrastructure enabling secure access to patient health information.

The pilot implemented effectively 2 uses cases¹:

- Patient Summary, allowing the Healthcare Professional of the visited country (country different than the country of origin of the patient) to consult the Patient Summary of the home country of the patient, when the patient is seeking for healthcare either in occasional or in planned visit;
- ePrescription, allowing the dispensation of medicine(s) in the visited country when the medicine(s) has been prescribed in the patient's home country, where the patient has a valid identification in terms of health care.

The objective of this pilot was to test the feasibility and acceptance of the proposed solution from different interoperability standpoints: functional, organizational, technical (including security) and legal.

The epSOS pilot having demonstrated its maturity (scalability and extensibility), it has been selected to be funded by Connecting Europe Facility (CEF)² to be deployed at a larger scale. The purpose of eHealth is therefore to make the ICT infrastructure designed by epSOS operational at Member States' level and to implement the 2 uses cases³ that were considered mature enough to be financed by CEF work programme 2015.

The pilot project epSOS which ended in July 2015 has been extended through the project EXPAND (Expanding Health Data Interoperability Services). EXPAND focusses on maintaining the epSOS pilot services, making the bridge between the pilot and eHealth operational services.

¹ Additional uses cases were designed in term of specifications but never implemented: Patient Access, Medication Related Overview, Health Care Encounter Report, 112 Emergency, European Health Insurance Card

² The Connecting Europe Facility (CEF) finances projects which fill the missing links in Europe's energy, transport and digital backbone, in line with the Europe 2020 strategy.

³ Cross-border patient summary and exchange of ePrescription/eDispensation

2.3 Overview of the scope and roadmap of eHealth DSI

eHealth DSI will focus in a first instance on the implementation of the Patient Summary and the ePrescription/eDispensation *services*. The implementation of other uses cases might follow in the future.

Where appropriate and to the extent it is feasible, the eHealth DSI will expand the services developed by re-using mature assets (called Digital Service Infrastructure building blocks) from CEF or pilot projects like the eID developed by the project Stork⁴, or the EU/US standards patient data defined by the project Trillium Bridge⁵.

A Memorandum of Understanding on operational activities for the CEF eHealth Digital Services Infrastructure (DSI) between DG CONNECT, DG SANTE and DG DIGIT is defining the respective roles of the different DGs in the implementation of the cross-border services (Patient Summary and ePrescription):

- DG SANTE will be responsible of the implementation, support and operation of eHealth central services⁶ and of the evolution of the OpenNCP open source platform used in the Member States' implementation of eHealth;
- DG DIGIT will analyse how some DSI building blocks (like eID/eSignature etc.) may be re-used in eHealth, from a technical perspective.

The project EXPAND which ends on 31/12/2015 will maintain, update and upraise epSOS assets and prepare them for their hand over to eHealth, it will also explore opportunities and assets produced in other projects and initiatives.

The eHealth DSI governance was adopted in the eHealth Network on 23 November 2015.

3 SOLUTION DESCRIPTION

3.1 Legal Basis

The eHealth Network was established in the Directive on patient's rights and the main focus of the work should derive from the provisions of Article 14, which institutes the legal policy cooperation on eHealth at EU level.

Article 14 sets the following objectives of the eHealth Network:

- work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare;
- draw up guidelines on patient summaries and effective methods for enabling the use of medical information for public health and research;
- support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

⁴ http://ec.europa.eu/information_society/apps/projects/factsheet/index.cfm?project_ref=224993

⁵ <http://www.trilliumbridge.eu/>

⁶ Central services are services support the National Contact Points in exchanging patient information and which are constituted of the configuration and of the terminology services, ensuring respectively that the national configurations are up to date and that the information exchanged can be translated and is understandable for the other party of the communication.

3.2 Benefits

The main benefit of eHealth is to offer a secure peer-to-peer⁷ network allowing the exchange of Patient Summary and ePrescriptions, improving the possibilities to receive healthcare across the EU Member States for EU citizens.

This peer-to-peer network could also be extended in the future to other healthcare domains or to other countries outside the European Union.

3.3 Scope and deliverables

DG SANTE and DIGIT will host and operate the central services (configuration server and terminology services) needed by the Member States to operate.

Horizontal Digital Service Infrastructure (DSI) building blocks from DIGIT⁸ for e-ID (Mutual recognition of electronic identification), e-Signature (Creation and validation of e-signatures) and e-Delivery (Transport layer for delivering electronic documents and data in general) will be analysed and used where applicable.

The following sub chapters will describe the scope in more detail, after having briefly introduced it in the below section, using CEF terminology (Core and Generic).

3.3.1 Core and Generic services

Core services and generic services are terms from the CEF terminology.

- Core services are central hubs of digital service infrastructures aiming to ensure trans-European connectivity, access and interoperability and which are open to Member States and may be open to other entities;
- Generic services are gateway services linking national infrastructures to core service platforms or other national infrastructures.

The following table gives an overview of the distribution of the responsibilities from different aspects (legal, organizational, coordination, semantic and technical), and following the CEF terminology (Core vs. generic).

	Core	Generic
Legal	Implications of the EU law	Member state responsibility
Organizational	CEF Governance explained in the eHealth Network document of 23 November 2015	Organization needs are explained in JAseHN D5.1.1.
Coordination efforts	Orchestration of the different implementation phases of the generic service components accessing and using core services	Coordination in MS level. Participation to CEF expert groups.
Semantic	<ul style="list-style-type: none"> • Hosting of terminology services (including terminology repository): terminology server hosting and running. • Terminology synchronization provider: Component to synchronize NCP 	<ul style="list-style-type: none"> • Manage exchanged content: data objects, terminology, structures, transformation. <p>In particular manage MVC⁹/MTC: National Semantic experts manage the terminology and translations.</p>

⁷ From the NCP perspective

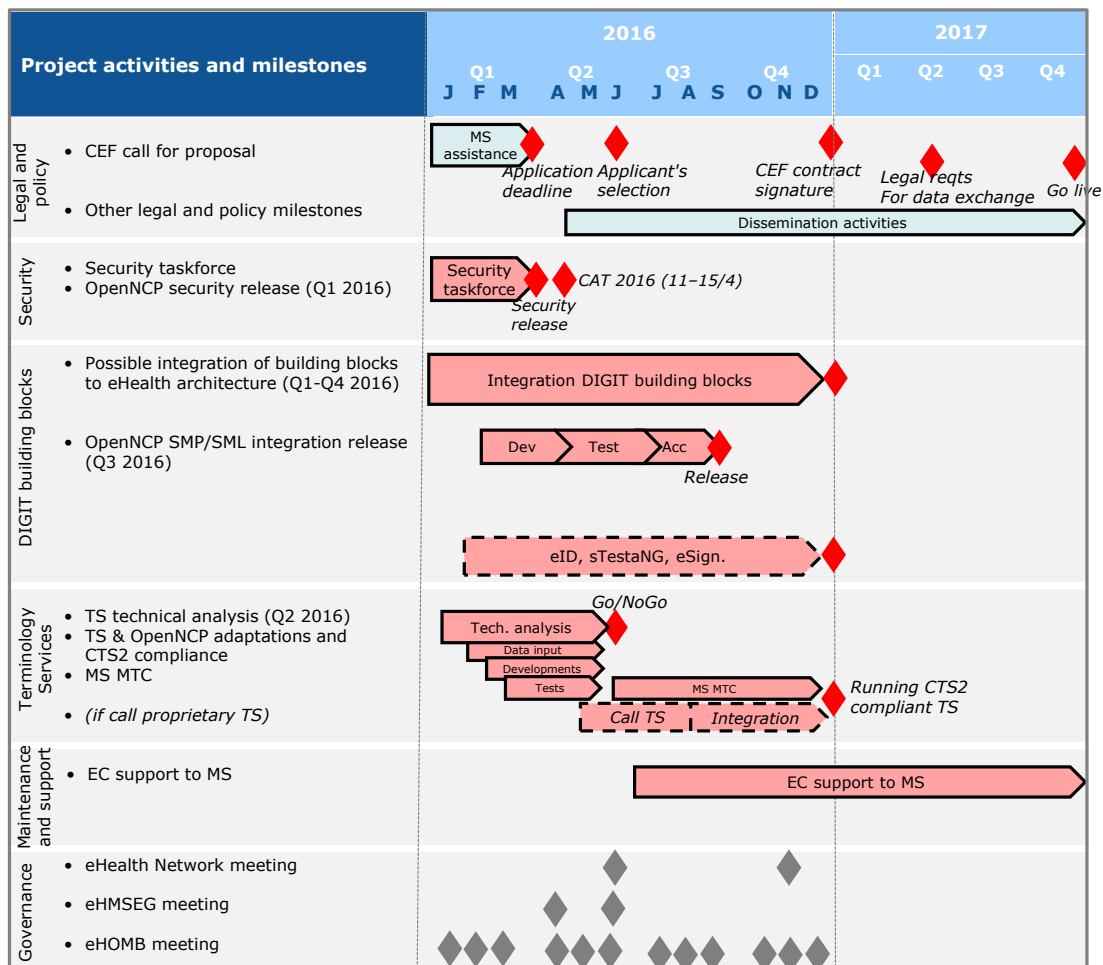
⁸ DSI building blocks are basic infrastructural capability that is ready to be (re)used as software or as central service.

⁹ MVC: Master Value Catalog; MTC: Master Translation Catalogue

	configuration and terminology repository.	<ul style="list-style-type: none"> Request synchronization: download terminology data from the Central Services repository into the local database
Technical	<ul style="list-style-type: none"> Coordinate Open NCP community. Release management for Open NCP software Host tools used in developments and knowledge sharing: Source code repository, continuous integration tools, issues management tool, wiki etc. Installation assistance: Assist MS in the installation of their Open NCP and integrating national infrastructure with Open NCP. Configuration and security services: Certificate & trust service synchronization provider. Integrating CEF building blocks 	<ul style="list-style-type: none"> Participate and contribute in the Open NCP community. Integrate <i>NCPeH</i> to national infrastructure Install and operate <i>NCPeH</i> synchronizing <i>NCPeH</i> with central services (configuration/semantic) Provide a user interface for the end users of Patient Summary and ePrescription services in the Member State level

3.4 Planning for 2016

The following figure illustrates major activities and milestones:



3.5 Budget for 2016

The following table provides an indication of the repartition of the budget per activities and per year for the eHealth DSI¹⁰, based on the information indicated in the 2 Memorandum Of Understanding (MOU)¹¹ agreed amongst DG CNECT, DG SANTE and DG DIGIT.

Amounts are indicated in EUR



(*) The figures of MOU2 exclude Activity 8 ERN: 2.500.000 €

Solution Implementation Costs		2015/2016	2017	2018	2019	Totals
DIGIT						
MOU1	Activity 1 eID feasibility study	250.000				
MOU1	Activity 2 SMP/SML eDelivery impact PKI Impact assessment	120.000				
MOU1	Activity 3 Testa NG feasibility study	50.000				
MOU1	Activity 4 eSignature requirements elicitation	50.000				
MOU1	Activity 5 Hosting of the central services (configuration server and terminology services)	100.000	100.000	100.000	100.000	
Total MOU1						870.000
MOU2	Activity 6 Adaptation of the eID, eSignature and eDelivery building blocks in order to support the eHealth DSI	200.000				
	6.1 Implementation of SMP for eHealth, PKI-based trust model of eDelivery	200.000				
	6.2 Implementation of eID					
	6.3 Implementation of eSignature					
	6.4 Implementation of eDelivery BB					
	Activity 7 OpenNCP Collaborative platform	40.000				
Total MOU2						240.000
Total DIGIT (MOU1+MOU2)		810.000	100.000	100.000	100.000	1.110.000
SANTE						
MOU1	Activity 1 Configuration services: Handover, maintenance and evolution of the central configuration for the first two years	150.000	150.000	50.000	50.000	
MOU1	Activity 2 Terminology services: Handover, evolution and operationservice for the central Terminology services	200.000	100.000	50.000	50.000	
MOU1	Activity 3 OpenNCP platform: Handover, maintenance, evolution and operation-support	200.000	150.000	75.000	75.000	
MOU1	Activity 4 Policy coordination & governance	22.500	22.500	22.500	22.500	
Total MOU1						1.390.000
MOU2	Activity 5 Adaptation of the central services (configuration and terminology services), OpenNCP for the subsequent years. Operations, support and maintenance	835.000	605.000	530.000	530.000	
	5.1 Adaptation of configuration services	155.000	50.000	50.000	50.000	
	5.2 Maintenance, support and operations of configuration services	70.000	70.000	70.000	70.000	
	5.3 Adaptation of terminology services	175.000	100.000	50.000	50.000	
	5.4 Maintenance, support and operations of terminology services	70.000	70.000	70.000	70.000	
	5.5 Adaptation of OpenNCP	175.000	125.000	100.000	100.000	
	5.6 Operations, support and maintenance of OpenNCP	70.000	70.000	70.000	70.000	
	5.7 Other costs (Auditing...)	120.000	120.000	120.000	120.000	
Total MOU2 (*)						2.500.000
Total SANTE (MOU1+MOU2)		1.407.500	1.027.500	727.500	727.500	3.890.000
GRAND TOTAL (*)		2.217.500	1.127.500	827.500	827.500	5.000.000

¹⁰ Excluding "Activity 8 ERN" (2.500.000€)

¹¹ The 2 MoU are available in section "[Table of references](#)"

4 TABLE OF REFERENCES

	Document name	
1	MoU 1: Memorandum of Understanding (MoU) on operational activities for the CEF eHealth DSI between the Directorate-General for Communications Networks, Content and Technology (DG CNECT) and the Directorate-General for Health and Food Safety of the European Commission (DG SANTE) and the Directorate-General for Informatics of the European Commission (DG DIGIT)	 MoU 1.pdf
2	MOU2: Memorandum of Understanding (MoU) on operational activities for the CEF eHealth DSI between the Directorate-General for Communications Networks, Content and Technology (DG CNECT) and the Directorate-General for Health and Food Safety of the European Commission (DG SANTE) and the Directorate-General for Informatics of the European Commission (DG DIGIT)	 Mou 2.pdf