



eHealth Network

Governance model for the eHealth Digital Service
Infrastructure during the CEF funding

Updated version 2016

eHealth Network

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth. The Joint Action supporting the eHealth Network (JAseHN) provides scientific and technical support to the Network.

Adopted by the eHealth Network, Brussels, 21 November 2016

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Introduction

The eHealth Digital Service Infrastructure (eHDSI or eHealth DSI) is the initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility (CEF). eHDSI sets up and starts deploying the core and generic services, as defined in the CEF, for Patient Summary and ePrescription. The generic services are the necessary implementation of data exchange at country level, the core services at EU level¹. These together enable the provision of Cross Border eHealth Information Services² (CBeHIS).

The eHDSI is financed by the Member States and the European Union through the CEF programme. The core services are set-up and deployed by the European Commission using its own resources and through calls for tender financed by CEF. The generic services are funded from the national sources and supported by grants from the CEF through a call for proposals.

The grant agreements for generic services will be managed by Innovation and Networking Executive Agency (INEA).

The 2015 work programme³ of CEF defines Patient Summary and ePrescription/eDispensation as the scope of the eHDSI, the amendment added the core services of European Reference Networks. The duration of action is 4 years (2015–2019). Future calls are expected in 2017 and possibly later during the duration of the CEF programme until 2020.

The provision of generic services in the Member State under the eHDSI means the preparation, setting-up, deployment and operations of the National Contact Point for eHealth (NCPeH) for provision of CBeHIS. A national or regional network connecting a wide range of healthcare providers to each other is a prerequisite for connecting them to a European network through the NCPeH.

The governance and operating principles of the NCPeHs are covered in the Guideline⁴ on an Organisational Framework for eHealth National Contact Point adopted by the eHealth Network.

Need for robust governance of the eHDSI

The eHDSI needs a robust governance model to succeed as a health policy and initial deployment and operation of service. The governance also needs to assure an overall coherence of the European Interoperability ecosystem⁵ which is being built.

epSOS was a large-scale research and development project under 7th Framework Programme, with an appropriate project organisation. The project exchanged a limited amount of test data.

¹ The CEF Telecom guidelines define digital service infrastructures (DSIs), which are composed of 'core service platforms' – central hubs which enable trans-European connectivity – and 'generic services' which link national infrastructures to the core service platforms. 'Building blocks' are basic DSIs which enable the more complex digital service infrastructures to function properly.

² http://ec.europa.eu/health/ehealth/docs/ev_20151123_co01_en.pdf

³ Amended CEF 2015 Work Programme is here:

https://ec.europa.eu/inea/sites/inea/files/c_2015_7381_f1_annex_en_v3_p1_828057_cef_telecom.pdf

⁴ http://ec.europa.eu/health/ehealth/docs/ev_20151123_co01_en.pdf

⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ%3AJOL_2014_086_R_0014_01&from=EN

The eHDSI is a move from a project to deployment phase of cross-border exchange of health data (CBeHIS). A new governance model is needed, which has strong steering elements addressing both policy and technical issues.

When real patient data is exchanged, the NCPeH must be in conformity with the agreed principles as adopted by the eHealth Network (eHN). These principles include - but are not limited to - the Guidelines for an Organisational Framework of National Contact Point for eHealth⁶, the future agreement between National Authorities responsible for National Contact Points for eHealth on participation in cross-border eHealth information services⁷, and Guidelines on Patient Summary and ePrescription.

The eHDSI stage is expected to last at least until 2019. The governance structure as presented in this document will be in operation during the financing and deployment of the NCPeHs under CEF.

It is expected that towards 2019, the EU's cross-border health data exchange starts to be an accepted practice of the national healthcare systems and that an increase in the patients served by the CBeHIS will be noticed. At that stage, the building up phase of core services is over and many countries have their NCPeH in routine operation, as well some groups of countries show a routine exchange of patient data. This coincides with the finishing of the first CEF funding round for generic services.

Beyond 2020, a new, permanent governance structure is needed for operation and maintenance of CBeHIS.

The permanent governance model is outside the scope of this document.

The European Reference Networks (ERN) will have their governance structures. However, the CEF financing will be under the umbrella of the eHDSI. Many legal, organisational, semantic and technical issues of eHDSI will be the same. The ERNs are in the building phase and the links of eHDSI-ERN to the eHDSI-PS/eP are still unclear and needs to be considered in the near future. At national level the NCPeH may have a role, and at EU level the eHealth Network may get involved in policy decisions.

The governance of the eHDSI-ERN is outside the scope of this document.

Review of the document

The eHDSI governance model, as presented in this document, was originally adopted by the eHealth Network on 23 November 2015, [and revised on 21 November 2016]. It can be subject to revision if needed by the eHN.

⁶ http://ec.europa.eu/health/ehealth/docs/ev_20151123_co01_en.pdf

⁷ Under discussion the eHealth Network, scheduled for adoption in June 2017

Key elements of the governance model

The governance model presented in this document stems from the general CEF governance model⁸. This document adds the ehealth policy structures and adapts the CEF model to the specificities of the health sector taking into account existing actors, structures and bodies.

The eHDSI governance model consists of bodies dealing with

- Policy governance
- IT governance
- Secretariat functions
- Stakeholder liaison

The governance model seeks not to set up new structures but associate the eHDSI tasks to existing bodies to the extent possible.

An audit function is necessary to ensure that NCPeH compliance can be established, maintained and reinforced. The audit process is as described in Section 4.1 of the Guidelines for an Organisational Framework of National Contact Point for eHealth⁹.

The organisation of the audit is outside the scope of this document.

⁸ Non-paper on the IT Governance of CEF Building Block Digital Service Infrastructures (DSIs). See [here](#). The governance model is based on The European Commission PM² Project Management Methodology Guide 2.5 Edition.

⁹ http://ec.europa.eu/health/ehealth/docs/ev_20151123_co01_en.pdf

Description of governance bodies and functions

Policy governance bodies and secretariat

Governance body or function	Who is involved?
eHealth Policy Owner	eHealth Network, as set up by Directive 2011/24/EU
eHealth Policy Secretariat	European Commission, DG SANTE (B3)
Member States Policy Support	Through appropriate Joint Action ¹⁰ Work Packages, such as JAseHN WP 5 Interoperability and Standardisation; Task 5.5 Semantic Interoperability; Task 5.6 CEF Operational Support; Task 6.2 Legal Interoperability.

IT governance bodies and secretariat functions

Governance function or body	Who is involved?
DSI Owner	SANTE (Directorate B)
DSI Co-Owner	CNECT (Directorate H)
Operational Management Board	DG SANTE (B3, A4), CNECT (H3), DIGIT Chair and co-chairs of eHMSEG
Member States Expert Group	Managers responsible for implementing the eHealth National Contact Point, nominated by the participating MS.
DSI Solution Provider	SANTE (A4), DIGIT (A3, B4)
Member States Operational Support	National Contact Points for eHealth in view of their responsibility for contribution towards the eHDSI at EU level, through the community set up in the eHDSI.

¹⁰ "Joint action" in this document refers to the Joint Action supporting the eHealth Network (JAseHN) running 2015-2018, or possible later joint actions working towards similar aims.

Stakeholder liaison

Who is involved?	Liaison modality
Patient, professional, industry and other stakeholders	Mediated by Commission through the eHealth Stakeholders Group. Stakeholders take part in joint action processes according to agreed principles.
Standardisation bodies	[To be decided – Could be mediated by JAseHN through its Standardisation Platform if set up.]
DSI community	Liaison with OpenNCP community through SANTE A4

Interaction processes between the eHDSI governance bodies

The eHDSI governance bodies strive at the full transparency in their operations, for example by circulating or publishing the minutes of their meetings and reporting to each other actively.

The eHDSI governance bodies will invite experts to attend the meetings when beneficial for the handling of the matters being discussed. .

The work plans and other decisions will define in more detail the business relationships and the division of development, implementation and operational tasks between the various eHDSI bodies, within the framework of this decision.

The composition and tasks of the main bodies in the eHDSI governance

eHealth Policy Owner - the eHealth Network

Main function: The eHealth Network steers the policy relevant to the DSI. It is assisted by the Joint Action supporting the eHealth Network (JAseHN).

Tasks

1. Set the priorities of the eHDSI, and oversee its operation. Decide on guidelines for the operation of the eHDSI and the strategy on standards used.
2. Seek and ensure funding for the eHDSI and its future components
3. Consider solutions for legal issues.
4. Admit¹¹ the National Contact Points to become operational in CBeHIS
5. Approve the annual work plan and financial plan for the eHDSI.

Composed of: Representatives of Member States

¹¹ The decision to admit a Member State NCPeH could be taken by the participating members alone. However, during eHDSI, the broad consensus and transparency on the joining is important and the decision should be taken in full transparency involving the all Members of the eHealth network, keeping in mind that all Member States are also prospective members in the CBeHIS and thus have an interest.

eHealth Network

Chaired by: Co-Chairs of the Network (Director General of DG SANTE and a Member State representative)

Secretariat: eHealth Policy Secretariat

Meeting frequency: Twice a year

eHealth Policy Secretariat - European Commission, DG SANTE Unit B3

Main function: To prepare the meetings of the eHealth Network and support its work, and ensure the liaison between the eHealth Network, eHDSI IT governance and various Commission services.

Tasks

1. Overall policy planning and coordination for eHDSI
2. Contacts with CNECT on the CEF Work Programme preparation, budget and liaison with the CEF Telecom Committee.
3. Prepare the eHDSI-related topics for the eHealth Network.
4. Liaison with the joint action assisting the eHealth Network.
5. Work closely with the DSI Solution Provider in preparing the meetings of eHMSEG and eHOMB.
6. Supports eHOMB and eHMSEG with their necessary interactions and communication.

Team Leader: Head of Unit SANTE B3

Team: Staff in SANTE B3

eHealth Operational Management Board (eHOMB)

Main function: To oversee the provision of service, make tactical and operational decisions about the eHDSI, and coordinate with other DSIs. Oversee the building of core elements and maintain the close links to Member States and NCPeH. It reports to the eHealth Network and the Member State Expert Group.

Tasks according to the IT governance processes:

1. Lifecycle management. Management of the lifecycle of software and services: changes, releases. Create a Service Level Agreement with DSI Solution Provider.
2. Architecture management. Management of the DSI's architecture
3. Risk and issue management. Management of risks, opportunities and issues
4. Configuration management. Track configuration of software and services
5. Propose the annual work plan and financial plan to the eHealth Network.
6. MS and stakeholders liaison. Management of the consultations of Member States and stakeholders
7. Reporting and escalation. Report to the CEF in view of it monitoring the progress of the eHDSI.

Composed of: DSI Owner and Co-owner
eHealth Solution Provider
Core Building Blocks Solution Provider
Chair and Co-Chairs of the eHealth Member States Expert Group

Chaired by: DSI Owner

Meeting frequency: 4-8 times a year depending on the need

eHDSI Member States Expert Group (eHMSEG)

eHMSEG is a group representing the participating Member States¹². eHMSEG coordinates the technical and organisational implementation of the NCPeH to ensure that they are fully interoperable. It gives advice to the eHealth Network and eHOMB on core elements and provides a link to building of the national elements. eHMSEG is duly informed about and consulted on solutions for the eHDSI, and asked to contribute to the lifecycle of the eHDSI's core services.

It can set up working groups composed of its members and (external) experts on specific topics. The eHDSI Solution Provider will support the working groups. Working groups report to the eHMSEG and interact with the Solution Provider.

Tasks

1. Provide assistance and expert advice on:
 - a. The management of the lifecycle of the DSI's software and services.
 - b. The management of risks and opportunities, including existing or emerging service management issues, that affect the DSI;
 - c. The definition of architecture guidelines for the DSI
 - d. Consult with the joint action and its WP leaders as appropriate.
2. Monitor and support the national implementation, such as:
 - a. Compliance with legal agreements and provisions in force;
 - b. Compliance with agreed technical solutions and specifications, in line with the guidelines adopted by the eHealth Network;
 - c. Address semantic issues relates to the use of terminologies and national translations.
3. Evaluate the initial audit¹³ report of a National Contact Point and prepare a proposal for admission to the eHN, and prepare a proposal for follow up of subsequent follow-up audits, in agreement with the DSI Owner.
4. Report to the eHealth Network on the eHDSI.
5. Initiate further activities or interactions in order to foster cooperation of Member State in preparations, implementation and operations of the eHDSI.

Composed of:	Managers responsible for implementing the NCPeH, nominated by the participating MSs
Chaired by:	Chair and two Co-Chairs elected from the Member State representatives
Secretariat:	eHealth Solution Provider, jointly with the eHealth Policy Secretariat
Meeting frequency:	On average 4 times per year

¹² The participating Member States are those, who express their intention to join the permanent CBeHIS and the network being built through the eHDSI. They thus join the Expert Group and participate in the deployment and operation in the CBeHIS. Normally this means also participation in the call for the CEF funding for the generic services.

¹³ The framework for conducting the initial and follow-up audits will be decided by the eHealth Network.

eHealth DSI Solution Provider - European Commission, DG SANTE Unit A4

Main function: To build the eHealth DSI specific software and services; advise and assist Member States on setting up the generic services, and ensure that they are linked to the core services (technical and semantic interoperability). eHealth DSI Solution Provider is responsible for the provision of core services.

Tasks

1. Technical planning and programming of the DSI's software and services
2. Implement the eHealth specific building blocks according to a Service Level Agreement
3. Liaison with DIGIT on core DSI building blocks
4. Manage contracting for core eHealth building blocks and contribute to the calls for proposals on generic services
5. Prepare and organise the meetings of eHOMB and eHMSEG
6. Coordinates the activities of the OpenNCP Community

Team Leader: Head of Unit SANTE A4

Team: eHDSI project manager and other IT staff in A4

The DSI Solution Provider for Building Block services (eID, eDelivery...) to the eHealth domain is DIGIT.

DSI community - Open NCP Community

The open NCP community is coordinated by the DSI solution provider and it is composed of developers from DSI solution provider, the Member States and private companies. The OpenNCP community implements technically the decisions made by the Operational Management board related to the DSI's software and services.

Liaison with patient, professional, industry and other stakeholders

The liaison is mediated by Commission through the eHealth Stakeholders Group and stakeholders take part in JAseHN processes according to agreed principles.

The exchange and input will be through different levels, eHealth Network and its operational arm JAseHN as well as through the Expert group and Operational Management Board.

Liaison is supported by the eHealth Policy Secretariat.

Liaison with standardisation bodies

eHDSI needs to maintain liaison with the standardisation bodies, such as the Multi-Stakeholder Platform on ICT standardisation, and other structures active in standardisation in eHealth.

[The arrangements in JAseHN to be decided.]