

Proposal for an Organisational Framework of eHealth National Contact Point

7th Meeting of the eHealth Network For discussion by the eHealth Network

April 27th, 2015
Draft version 06

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Version	Date	Subject	Modified by
0.1	10.04.2015	Basic draft document	Licinio Mano (SPMS)
0.2	13.04.2015	Draft proposal	Henrique Martins (SPMS)
0.3	14.04.2015	Enriched proposal with “Initial Considerations for the Framework”	Henrique Martins (SPMS) Licinio Mano (SPMS)
0.4	21.04.2015	Task members (Review comments) + EXPAND Workshop discussions	Licinio Mano (SPMS)
0.5	24.04.2015	Informal evaluation from eHN JA members	Licinio Mano (SPMS)
0.6	27.04.2015	Review EC commission eHN JA PSC members	Licinio Mano (SPMS)

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1 Purpose of this document

Propose an organisational framework to prepare, establish and govern eHealth National Contact Points in the scope of cross border care services deployed under the Connecting Europe facilities work plan.

2 Introduction

One of the main challenges in supporting the eHN ambitions on sustainability policies regarding assets in the field of cross border interoperability is the linkage between the policy level of thinking and deciding (eHN), and the more operational development, deployment and maintenance of assets (e.g. like standards, guidelines and agreements) level (member states and SDOs).

The main architectural foundation for cross border interoperability relies on National Contact Point (NCP). These NCP enable the country interoperability gateway (beyond technical and semantic, the NCP embrace the other Key Interoperability Layers) that assure the overarching responsibilities:

- Interfacing with other Member States;
- Interfacing with National Infrastructure;

Having in consideration the crucial role played by NCPs, the work being done under the eHN-JA includes a proposal for an organisational framework of eHealth NCPs which states the role, tasks and responsibilities of the eHealth NCP and their “national architecture”. This work will deal additionally with, supporting a “localization strategy” for the elaboration of guidelines adopting the necessary legal and/or contractual arrangements between different countries’ eHealth NCP.

One of the major reference materials for the proposed for the Organisational Framework of eHealth NCP is the ***Framework Agreement on National Contact Points in the context of the epSOS (epSOS FWA)***. In epSOS FWA we may find some of the best-suited organisational pillars for the framework, namely:

- Creation of the eHealth National Contact Point (NCP);
- Core Characteristics of the eHealth National Contact Point (NCP);
- General Duties and responsibilities of the eHealth NCP;
- eHealth NCP duties and responsibilities towards other eHealth NCPs;
- Duties and responsibilities concerning eHealth Patient Consent;
- Duties and Responsibilities of the eHealth MS under the Cross Border Care Services Security Policy
- Relationship between eHealth NCP and Points of Care, Health Professionals and Healthcare Providers
- Dispute resolution and applicable law

This paper is built upon several reference materials, beyond epSOS FWA, provided by several EU eHealth projects. The following list provide an exhaustive identification of the materials considered until the present version of the document:

- Framework Agreement on National Contact Points in the context of the epSOS (epSOS FWA)
- epSOS Interoperability Framework and Key Interoperability Layers (D.3.3.3)
- epSOS National Pilot Set Up and Deployment Guide (D3.8.2)
- epSOS FINAL SECURITY SERVICES SPECIFICATION DEFINITION (D.3.7.2.), namely the SECTION III SUITABILITY ANALYSIS.
- epSOS Testing Methodology, Test Plan and Tools (D3.9.2)
- epSOS Recommendations (D2.2.7)
- Antelope Refinement Definition document (D1.1)
- EXPAND Scope and transferability of key outcomes of epSOS and corresponding actions for transferability and scale up (D5.1 Draft)

As well as reuse and enhance project pilot tools that can be reshaped and adapted for Large Scale Services, like:

- epSOS Participating Nation Pilot Plan;
- epSOS Requirements and Recommendations – Check List;
- epSOS Participating Nation Member State Progress Report;
- epSOS Participating Nation Initial Audit Report
- epSOS D4.D.3 Report on readiness to pilot

The following diagram provides a high lever overview on the foundational baselines considered (on the left) and the Organisational Framework materialisation (on the right).



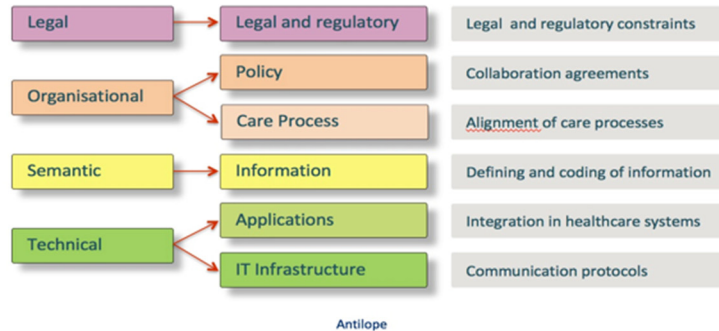
Topics on both sides of the diagram will be explained along the current document. At this stage of maturity the detail and specificity level provided aim to establish the fundamental concepts and structure from which the complete framework will be built upon.

3 Key Interoperability Layers

For this paper we will follow one specific aspect from the ReEIF, namely the description of the different interoperability layers that need concerted action by different actors in order to achieve interoperability. Accordingly, on each layer, discussion on Organizational Framework on eHealth NCPs can be started.



- ✓ Builds upon the current eEIF model
- ✓ Reflects organisational / functional levels
- ✓ Avoids technical terms



In previous figure, the core picture of the Antilope deliverable is shown, the layers are:

1. **Legal and regulatory:** here we do not see any action needed from the SDO platform to be established under the eHN-JA.
2. **Policy:** this is the main area of interest for the eHN itself, which has an interest and a need for standards.
3. **Care processes:** this is the place where guidelines are usually developed for health professionals on how to act in a specific care situation. In standards developing, on this abstraction layer use cases are described as the standard care process expected, on which the other standards must provide an answer.
4. **Information:** This is the abstraction layer for the description of the information (structure, coding, content) needed in the specific care process / use case. This is described agnostic of implementation.
5. **Applications:** this is the layer of health specific applications (EHRs, electronic prescription systems, apps, etc), which needs standards for the implementation of the information described in level 4. Especially interoperability requires much effort here: applications of totally different nature and origin (e.g. a hospital based EHR and a community pharmacy based IT environment) must be brought to exchanging information in a meaningful way.
6. **Technology:** this is in ReEIF the layer of not-healthcare specific technology: networks, web services, storage, etc. This is by definition not an area for development by the health sector, but the health sector has great interest in these developments as such, and for standards to be available timely and correctly for healthcare to use.

4 Underlying Principles

As a consequence of the above framework a number of principles can be announced in relevance to the process of establishing interoperability in the eHealth NCPs context. Those principles act as constraints when it came to decide the level of interoperability to impose on European cross border health services.

Underlying Principle 1: Security and Privacy

Patients and Health care professionals must be assured that they interact with eHealth systems in an environment of trust and in full compliance with the relevant regulations, e.g. on privacy and data protection. This means that eHealth services must guarantee that the privacy of patients and the confidentiality of information provided by businesses are respected.

This principle is enforced most specially Identity management and Security specifications in regards to the usage of technological standards and protocols, notably with specifications of the Audit trail.

Underlying Principle 2: Transparency

Within the necessary security constraints, patients and Health Professionals should have the right to verify the information national and/or European systems have collected about them and to decide whether this information may be used for purposes other than those for which it was originally supplied.

Patients and HCPs should be able to understand administrative and business processes. They should have the right to track procedures that involve them and have insight into the rationale behind decisions that could affect them.

Underlying Principle 3: Preservation of Information

Medical records and information in electronic form held by national and/or European infrastructures for the purpose of documenting procedures and decisions must be preserved. The goal is to ensure that medical records and other forms of information keep their legibility, reliability and integrity over time and can be accessed taking into account security and privacy.

In order to guarantee long-term preservation of all electronic records and information, formats should be selected so as to ensure long-term accessibility, including preservation of associated electronic signatures and other electronic certifications.

For medical information sources owned and managed by national infrastructures, the preservation is a purely national matter. For European eHealth Services (like Patient summary and ePrescription) and for information that is not purely national preservation should become an European issue and the necessary "preservation policy" has to be foreseen, notably towards codes and translations for semantic mapping.

Underlying Principle 4: Openness & Reusability

Interoperability involves the sharing of information and knowledge between organisations, hence implies a certain degree of openness.

Specifications, software and software development methods that promote collaboration and the results of which can freely be accessed, reused and shared are considered open and lie at one end of the spectrum while non-documented, proprietary specifications, proprietary software and the reluctance or resistance to reuse solutions lie at the other end. Re-use is key to the efficient development of European eHealth Services. Re-use means that organisations confronted with a specific problem seek to benefit from the work of others by looking at what is available, assessing its usefulness or relevancy to the problem at hand, and decide to use solutions that have proven their value elsewhere.

Underlying Principle 5: Technological Neutrality and Adaptability

When establishing European eHealth Services, organisations should focus on functional needs and defer decisions on technology as long as possible in order to avoid imposing specific technologies or products on their partners and to be able to adapt to the rapidly evolving technological environment.

Member states should render access to eHealth services independent of any specific technology or product. This is the purpose of choosing standards and protocols when deciding the interoperability framework.

5 Initial considerations for the Framework

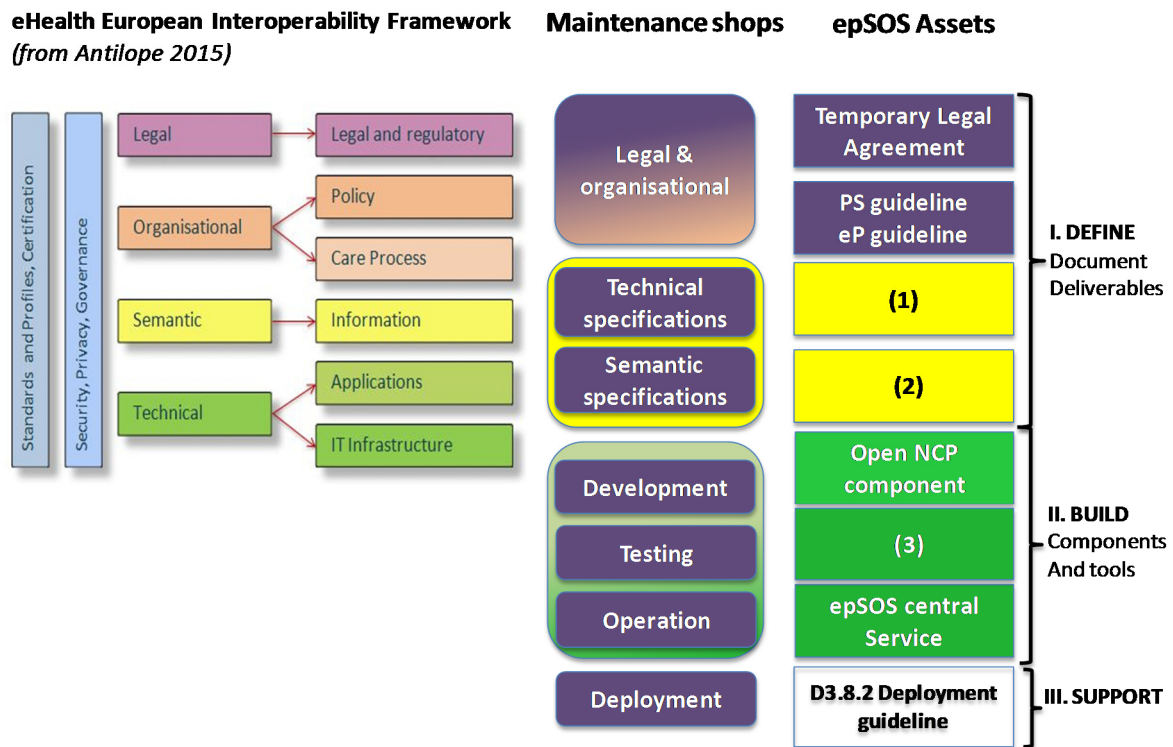
Establishing a Health NCP Organisation Framework, at this point in time, may benefit tremendously with the significant experience gained and lessons learned on previous large scale health pilots at European level, regarding the successes and complexities of cross-border health information exchange. The following table provides a detailed insight on the epSOS Final Recommendations (D2.2.7) that were envisaged as actions to be taken forward by a combination of European Commission, the eHealth Network (supported by the eHGI-JA), Member States and other organizations (e.g. Standards Developing Organisations (SDOs) such as CEN, IHTSDO) as well as follow up projects (e.g. EXPAND, e-SENS, Trillium Bridge).

A	Legal
A.1	On the EU eHealth Governance:
1	It is recommended that a sustainable trusted environment is established between MS for the provision of cross border services
2	It is recommended that while the new EU legal framework is expected to diminish the needs addressed by the epSOS Framework Agreement, until this framework is fully in place and complete, deployment of cross border eHealth services would require a common MS legally binding framework, based on agreements with an EU wide applicability and acceptance
3	It is recommended that in order to create conditions for legal and organizational interoperability, such MS agreements or Acts may be modified during transposition into local legal and organizational frameworks and guidelines only in so far as it is necessary to do so in order to comply with local law or custom
4	It is recommended that each country or region is represented in the cross border eHealth context by its National Contact Point for cross border eHealth (NCPeH) which may be a different that the NCP foreseen under Directive 2011/24/EU. A national or regional NCPeH acts as a communication gateway and maintains compliance to normative interfaces in terms of structure, behaviour and security policy
5	It is recommended that agreements should also define criteria for preparedness of MS to join cross border services, check points for MS self assessment against legal, organizational and technical requirements as well as a process for notification of accession to the cross border eHealth services common environment
6	It is recommended that the EU governance framework should include provisions for the supervision of the Agreements spanning over all active parties in the data sharing. It should also include provisions for Arbitration
7	It is recommended that liability of cross-border operational services is a matter of importance and should be clarified in a dialogue of providers with national and EU level authorities
8	It is recommended that the European Commission and the MS should foster the further adoption and development of eHealth services through mutual assistance actions, as well as collection and publishing of cross-border eHealth services information and statistics
A.2	On Data Protection and confidentiality:
9	It is recommended that all data contained in medical documentation, in electronic health records and in EHR systems are “sensitive personal data” and therefore subject to Article 8 of the Data Protection Directive
10	It is recommended that the processing of healthcare data must have a clear legal basis. In the absence of other legitimate grounds, this can be the data subject’s two-step explicit consent
11	It is recommended that the processing of personal data is strictly limited to the minimum which is necessary for the fulfilment of any specific cross border eHealth services which must be specified, explicit and legitimate
12	It is recommended that MS consider appropriate duration of storage of data in the log files for litigation purposes
13	It is recommended that the NCPeH is assigned the role of data controller when receiving and further processing personal data from abroad (National implementations may differ between MS depending on the national context and the national law)

A.3	On Information to Patients:
14	It is recommended that the NCP foreseen by the Directive 2011/24/EU should include information the specific rights of data subjects, conditions and practicalities on privacy and confidentiality aspects, according to the different legislations of each Member State
15	It is recommended that MS adopt measures at the local and regional level to improve patient knowledge and education on cross border eHealth aspects relating to their ability to exercise rights in the visited country that they would be able to exercise at home, such as a right to mask certain information rules
16	It is recommended that patients are provided access to cross border audit trails
17	It is recommended that in the event of emergency access to health data without consent, the patient or person acting on behalf of the patient is informed about the override of consent upon leaving the Point of Care (PoC) including details of access
18	It is recommended that privacy and confidentiality are embedded in the design of all eHealth cross border services. Examples of such facilities include encryption between NCPs, mandatory components for patient consent and access to audit trails and notification in case of emergency access (consider end-to-end encryption)
A.4	On Information Security:
19	It is recommended that MS should include cross border specific safeguards into their national information management systems and compliance requirements
B	Organizational
20	It is recommended that healthcare professionals are appropriately engaged in specification updates and other clinical issues to be addressed in moving to mature implementation
21	It is recommended that training materials and activities be provided to support improved deployment of the service
22	It is recommended that the non-functional requirements (e.g. relating to performance and reliability) be formally reviewed to form the basis for Service Level Agreements (SLAs) for live, at-scale operation of national and central services
23	It is recommended that a platform of NCPeHs is established to deal with on-boarding of new PNs, periodic auditing and general operations of the epSOS infrastructure
24	It is recommended that dissemination activities for other projects, initiatives and the policy domain continue beyond the end of the project
25	It is recommended that Member States continue to disseminate at national level the results and experiences of piloting
26	It is recommended that the lessons from the epSOS pilot evaluation are followed up to ensure that commitments are put into practice
27	It is recommended that the specifications from epSOS be updated, in the light of pilot experience, to reflect changes such as terminology versions, and taking into account usability of the functions
28	It is recommended that good practices within the piloting PNs are shared for cross-border eHealth convergence within the EU in order to promote and diffuse the value of the epSOS design
C	Semantic
29	It is recommended that work on the requirements for the maintenance, QA and provision of central terminology services be specified
30	It is recommended that the review of the datasets uses a similar set of selection criteria derived in epSOS for identifying fields, and supporting coding schemes
31	It is recommended that discussions are progressed with SDOs (e.g. in relation to licensing, approach to translations) prior to the development of the semantic work
32	It is recommended that formal tooling be used to document dataset selection decisions, including versioning control to have the full change log and traceability, and to maintain a central repository
33	It is recommended that, with SDOs, minimum common import format of the code systems should be adopted, based on International standards
34	It is recommended that each SDO generate a minimum Meta-information containing necessary supporting guidance for a value set including information of how the value set was created
35	It is recommended that a use-case based approach is taken to specifying requirements (e.g. for MVC) which is therefore dependent on business needs
36	It is recommended that the development of requirements for semantic interoperability services should

	consider both cross-border and national scenarios
37	It is recommended that further work be undertaken to address the issue of the identification of medicinal products
D	Technical
38	It is recommended that the specifications from epSOS are maintained as assets, and improved where possible to be more suitable for use by industry partners. An appropriate approach might be to formalize the status of the specifications (e.g. as Publically-Available Specifications)
39	It is recommended that a structured, iterative process be followed when documenting and evaluating the design/specifications, to assist evaluation and improve the value of the design
40	It is recommended that, as specifications and standards are updated, the profiles are maintained, and implementation guidance uplifted
41	It is recommended that the Open Source components be maintained and updated (as appropriate) with governance arrangements in place to ensure integration testing, on-going support and new developments where appropriate (e.g. for new use cases)
42	It is recommended that arrangements be put in place for testing facilities, to enable testing of cross-border activities, but also to enable individual Member States to test their own facilities
43	It is recommended to ensure that, as the legal and regulatory requirements become clear, the supporting security requirements are updated, together with mechanisms for assuring compliance

These recommendations have been scrutinised by EXPAND partners (since the project early beginning) and have been used as the basis for structuring the ongoing work in this European project, namely by inspiring the creation of “EXPAND Maintenance Shops” dedicated to the upkeep, maintenance and maturing of cross border care assets to be fit for purpose on each of the Key Interoperability Layers. The EXPAND Maintenance Shops (EXP-MtnShops) follow the Antilope refined eHealth European Interoperability Framework (ReEIF). The following picture (source: EXPAND 5.1 draft version) presents the map between the EXP-MtnShops and the ReEIF.



Taking in consideration i) epSOS Recommendations, ii) Antilope refined eHealth European Interoperability Framework and iii) EXPAND Maintenance Shops ongoing work, a clear

understanding on the **overarching structure** and **complexities** associated with the eHealth National Contact Points organisational environment can be achieved.

The debate and discussion of such evidence-oriented materials should be included on the scope of the work to be performed by the eHN-JA WP5 Task 5.1. From that debate is expected to result awareness and knowledge, enriched by an evidence-based approach, that will drive the design of the aimed Organization Framework of eHealth NCP.

5.1 Legal and Organizational Considerations

The main epSOS Legal and Organizational Assets, namely: i) the Framework Agreement (FWA) and the ii) Baseline Security Profile (BSP) serve as skeleton for the Framework. To provide support for ongoing activity namely up keeping epSOS services and supporting piloting in LSPs such as e-SENS and STORK2, the existence and official nature of “groups” of member states representatives is key. This was achieved through the eHealthNetwork subgroup for upKeeping Services and, from November 2014 onwards, the eHN Subgroup for eHealth DSI Implementation.

This Legal and Organizational matrix is key to ensure that there are mechanisms of interaction with other LSPs, and even to start live services, for example:

- Temporary Legal Agreement TLA (for upkeep of epSOS services) which was prepared from the epSOS Framework Agreement (FWA) to the TLA. Which can then be used by members states for bilateral/multilateral consolidation, but guaranteeing a univocal text.
- Issuing concept notes on eHealth participation in and with LSPs

In order to complete this L&O matrix the following activities need to be completed:

- Revision of the epSOS BSP; Adoption at the CEF eHealth DSI governing body.
- Ensuring that the support e-SENS WP3 (eHealth business use case), WP4 (Legal aspects) and WP5.2 (eHealth piloting) happen in alignment with overarching Framework.

5.2 Semantic and ValueSet coordination Considerations

Be capable of incorporating the outcomes of EXPAND semantic Maintenance shop. This aims at reviewing epSOS semantic assets and “prepare” them to be CEF assets by updating them and, when possible, including improvements and alignments that can be done within the resources and time schedule of the EXPAND project. The specific goals are:

- In the short-term: to face detected issues
- In the medium-term: improvement and alignment following different criteria (end user perspective, adherence to guidelines, etc)

Now, while EXPAND is not a mandated decision body, the group cannot ensure agreement on any big changes, it can just work on limited improvements, or presented evidence/quality labelled support for changes to be proposed to eHN Joint Action for

further analysis/discussion or to a decision body, namely close to the CEF eHealth DSI governance body.

What these activities mean and prove, is that while there is usability of epSOS assets, in this case semantic assets, further work is needed to expand their use into other use-cases, as well as into adapting them to ongoing evolution in terms of adopted guidelines, such as Patient Summary, ePrescription/eDispensation and the unstoppable evolution of more sophisticated vocabularies and catalogues.

This also highlights the need for a central “governance” of these semantic rules, which is not to be found in either SDOs per se, nor in each respective country. Thus, this will remain a core function that needs to be part of the Organizational Framework for eHealth NCP, since at national level semantic experts need to have a single source of information for determining certain adaptations to their national infrastructure or the way in which it links back into the NCP.

Likewise it is very difficult to avoid the discussion of a functional framework without clarifying the role and existence or not of a central reference terminology server. While the type, form and the mechanisms of implementation are still open to analysis and debate, it seems certain aspects are initial considerations upon which decisions need to be taken.

1. Countries should have the interfaces compliant to the sub-set of the HL7 CTS2 specifications, identified in epSOS and revised in EXPAND
2. The system should be declared Open Source according to accepted license models (EUPL, ASL V2, GSL V3)

Finally a mechanism to ensure proper link between use-cases, centred on patient care and value-sets, making use of the relevant, valid and quality labelled semantic assets/catalogues is critical. This is a sort of coordination role at EU level for value-set governing.

Both for eP/eD as well as patient summary, eventually more in the latter case, the adoption of MVC 1.9 and MTC in epSOS was a way to centrally coordinate the exact value-set exchanged as well as the corresponding translations. While there is significant ongoing work by SDOs and IHE, the coordination and central adoption of an exact value-set valid at a certain time, with which all NCPs are in sync is a necessity.

This should not be mistaken with: ***Guidelines on how national centres responsible for semantics should work***, but relates to how they should work vis-à-vis cross-border exchange of health data;

When is this needed? This is needed now, during CEF (Jan 2016-dez 2020) and beyond CEF (Jan 2021- onwards).

Regarding the last period - beyond CEF – how such service should be catered in discussions that will take place in the ValueHealth project. This can detail a proposal and a sustainable business model for such core function like any other core service. For now, EXPAND Maintenance shop can analyze MVC 1.9; as well as MTC, and, as suggested, propose

improvements and upgrades, the issue in this phase is the process of members states' endorsement, perhaps via the endorsement of the member states officially represented in the eHealth Network subgroup for implementation?

Finally during CEF, an expected annual review of the catalogues, and respective endorsement and acceptance process by member states need to happen. Issues like translation costs and official value. Use of translations for projects like Trillium, or personal (patient mediated access to Patient summary) is still open and need a definition. Finally, what value sets to choose from which semantics catalogues (e.g. SNOMED CT, ICD, etc) and the process of choice and adoption and adaptation need to become a core service, clear, secured and staffed so that the sustainability of this service is guaranteed.

Some of these issues were raised by the Expand Coordination in the eHealth Network subgroup for Implementation meeting in 16th march and a proposal by the EC for the subgroup to bring about a discussion paper to be presented to the eHealth Network was made. Based on this some of the ongoing work of the semantics maintenance shop as well as handing over to CEF in respect to semantics will thus take the form of this discussion paper.

5.3 Technical Considerations

At a technical level significant work is undergoing in line with EXPAND WP5, namely on the Orchestration and Operation of OpenNCP Community, enabling the community with the needed steering, governance and empower to work towards the major eHealth piloting projects that can benefit from the reuse of the OpenNCP as a bundle or as set of components that can be adopted for establish eHealth ICT interoperability gateways at different levels beyond cross border (e.g. national wide, or inside an organisation).

EXPAND as also been working on concrete CEF requirements for an eHealth DSI with Core and Generic Services, provide recommendations on how the call requirements should be organized and structured underlying the Core Services and Generic Services framework which has been used by other CEF DSI.

6 The Process

The following process, to be accepted by the eHN, describes a method for ensuring that trust between the eHealth NCPs can be established, maintained and reinforced, through the pre-defined set of activities and responsibilities:

- a) How to check and endorse eHealth NCP legal and operational readiness for starting a certain service;
- b) How to create a peer-to-peer process for auditing organizational arrangements between countries;
- c) How to fulfil the eligibility criteria for CEF allocation of funds to generic services;
- d) How to create regular reports on activities related to the use of CEF funding in generic services.

One of the key building blocks for the Organization Framework of eHealth NCP will, most probably, be a process through which Member States can progress in their strategies regarding the deployment of cross border care services. For that purpose, and taking in consideration the epSOS process towards evaluation a Member State readiness to pilot with real patient data, a depicted set of steps (to be enhanced and refined) is proposed at this stage, having in consideration the fundamental difference between large scale deployment and large scale pilots – the need for a long term sustainability methodology that can drive service operation under high levels of demand, liability and efficiency, that are expected to emerge as requirements for the mainstream usage of this health information services.

Process Steps

Preparation

- Member State Service Deployment - PLAN
- Member State Requirements and Recommendations - CHECKLIST;
- Member State Preparation Progress - REPORT
- Member State Service Readiness - REPORT
- Member State Service Initial Audit - REPORT

Operation

- Member State Service Operation - PLAN
- Member State Service Operation Monitoring - REPORT
- Member State Service Operation Audit – REPORT
- Member State Service Operation Evaluation – REPORT

7 Proposed next steps

In order to provide the final version of the current document in November 2015, the following steps are proposed:

- 1) Preparation phase for eHN JA task 5.1 members (May, June)
First this activity should result in achieving a common knowledge base between the task 5.1 members regarding **Cross Border Healthcare Interoperability Framework** in general and the **Organisational Framework of eHealth NCP** in particular.

Secondly this step should result in a common understanding, perspective and expectation of the eHN JA task 5.1 and agreement on the task distribution and planning.
- 2) Developing the handing over process of the Organisational Framework of eHealth NCP to permanent governing body
In order to assure a sustainable adoption of the WP 5 task 5.1 outcomes, it is crucial to agree on the handing over process as well as to correctly identify roles and responsibilities that need to be addressed for long-term sustainability.
- 3) Construct final deliverable for eHN November 2015 (Oct)
Based on the debate, maturation and refinement eHN-JA task 5.1 should be able to deliver a solid proposal for the **Organisational Framework of eHealth NCP**.
- 4) eHN decision on eHN Organizational Framework of eHealth NCP (Nov)
In the eHN meeting in November the WP 5 task 5.1 deliverable will be provided for decision.
- 5) Support eHN adopting the **Organisational Framework of eHealth NCP** (permanent)
The handing over of the WP 5 task 5.1 outcomes should also include the possibility of support the eHN applying the **Organisational Framework of eHealth NCP**.

This paper is meant to give a start to the realisation process of the proposed **Organisational Framework**, in order to have a discussion in the eHN meeting of May, 2015.

The information can be used to reflect and discuss on the topic and should be used for adjustments and approval for further proceedings towards a final decision on the establishment of **Organisational Framework of eHealth NCP** foreseen for the eHN meeting of November 2015.