EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Secretariat of
eHealth Digital Service Infrastructure

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NOTE ON THE eHDSI INFRASTRUCTURE:

SYSTEMS DEVELOPED FOR EUROPEAN REFERENCE NETWORKS

AND FOR THE CROSSBORDER EXCHANGE OF ePRESCRIPTION AND PATIENT SUMMARY

The eHealth Digital Service Infrastructure is one of the Connecting Europe Digital Service Infrastructures (DSIs). All DSIs are currently co-financed by the Connecting Europe Facility (CEF) Programme but in the long-term they will need to become a part of sustainable Member State and European infrastructures.

Directive 2011/24/EU on patients' rights in cross-border healthcare promotes cooperation and the exchange of information among Member States. The Directive also aims at delivering sustainable eHealth services and providing interoperable applications at European level. The Directive set up the eHealth Network, which is a voluntary network connecting national authorities responsible for eHealth.

In 2014, the eHealth Network endorsed starting to work on four eHealth services and asked financing from the CEF[1]: ePrescription and eDispensation, Patient Summary, European Reference Networks, and Patient Registries (the work hasn't yet begun). The request resulted in setting up the eHealth Digital Service Infrastructure in the CEF Work Programme 2015.

Formally the eHealth DSI under the CEF consists of two parts. The system enabling the cross-border exchange of ePrescriptions and Patient Summaries for unscheduled care is commonly referred to as the eHDSI. The second part consists of IT tools enabling the co-operation and clinical work of the European Reference Networks of highly specialised clinical centres. This ERN IT Platform allows pooling of knowledge, improvement of diagnosis and care in medical domains where expertise is rare, and helps Member States with low number of patients to provide highly specialised care.

Due to their different objectives, scope and characteristics both parts are governed and developed in a separate way. They have separate budgets for the core services provided by the Commission, however implemented by the same unit (the Solution Provider). The funding of

[1] https://ec.europa.eu/inea/sites/inea/files/c_2017_696_f1_annex_en_v3_p1_875665.pdf

generic services under the CEF is also divided into two parts as the beneficiaries in the eHDSI are the Member States and in the ERN IT Platform are the European Reference Networks.

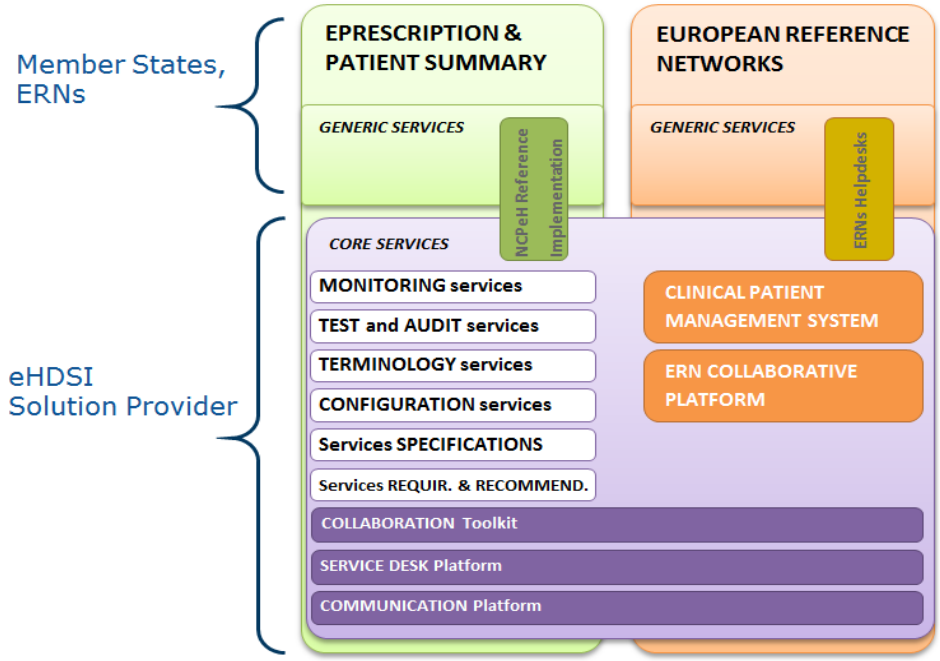

Figure 1 eHDSI Service Offering - Solution Provider perspective

GOVERNANCE OF EUROPEAN REFERENCE NETWORKS AND THE ERN IT PLATFORM

The general rules regarding governance of the European Reference Networks were defined by the Commission implementing decision in 2014[2]. The decision invited the Member States set up a Board of Member States which shall decide whether or not to approve the proposals for Networks and their members. The Board also coordinates the work of the Member States and provides guidance to the ERNs. The Commission provides the secretariat of the Board of Member States.

The Board on Member States has set up an IT Advisory Board consisting of the representatives of the Board, the European Reference Networks, and the relevant Commission departments.

The Networks themselves are allowed to have different organisation models but are required choose one of their Members as the coordinating Member. The coordinating Member shall appoint one person acting as the coordinator of the Network. In the IT matters, the Network Coordinators are assisted by a Board and supported by an IT coordinator.

[2] Commission implementing decision (2014/287/EU) of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

GOVERNANCE OF EHDSI FOR THE CROSS-BORDER EXCHANGE OF EPRESCRIPTION AND PATIENT SUMMARY

In order to succeed in preparing, setting up, deploying and operating the network of the National Contact Points for eHealth (NCPeH) of Member States, a robust governance model has been put in place. The governance structure comprises of 3 bodies.

- The eHealth Network steers the policy relevant to the eHealth DSI. The eHealth Network decides on the admission of an NCPeH to join the Cross Border eHealth Information Services, on the basis of the initial audit report of an applicant NCPeH.
- The eHealth Member State Expert Group brings together the project managers of the participating Member States. The eHMSEG coordinates the technical and organisational implementation of the NCPeHs to ensure that they are fully interoperable. It advises the eHealth Network and the Commission on core elements and provides a link to building of the national elements. The eHMSEG is consulted on solutions for eHDSI and asked to contribute to the lifecycle of the core services.
- The eHealth Operational Management Board's main function is to oversee the provision of service, make tactical and operational decisions about the eHDSI, coordinate with other DSIs, oversee the building of core elements and maintain the close links to Member States and the NCPeHs.

CHARACTERISTIC OF SYSTEMS DEVELOPED FOR EUROPEAN REFERENCE NETWORKS

The Commission delegated decision[3] in 2014 sets requirements on the exchange of expertise, information systems and eHealth tools of the ERNs. They should be able to foster the use of telemedicine and other e-health tools within and outside their facilities, by fulfilling the minimum interoperability requirements, using agreed standards and recommendations.

Interoperable and semantically compatible information and communication technology systems facilitate the exchange of health data and patients' information, and the establishment and maintenance of shared databases and registries.

To enable this cooperation the European Commission together with European Reference Networks has set up the ERN IT Platform under the eHealth Digital Service Infrastructure. With support of funds from Connecting Europe Facility, DG SANTE has developed two IT systems necessary for ERN proper cooperation. Those systems are the ERN Collaborative Platform and Clinical Patient Management System.

European Reference Networks Collaborative Platform (ECP)

The ERN Collaborative Platform (ECP) is a restricted online space to share, organise, contribute and discuss. Only people affiliated with one of the ERNs can obtain an access to the ECP. Users are clearly informed that ECP should not contain patient personal case information.

In the ECP, the members can upload files (Library), publish news (All Activity), discuss (Forum), schedule (Agenda), vote (Poll), endorse (Like). These serve to share information and knowledge with other members of the network.

[3] Commission delegated decision of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil (2014/286/EU).

Clinical Patient Management System (CPMS)

The objective of Clinical Patient Management System (CPMS) is to support European Reference Networks in the diagnosis and treatment of rare disease or low prevalence complex disease or conditions across national borders.

The CPMS is configured on multiple physical servers with redundancy so that in the case of a hardware failure the system will remain operational. The physical server structure allows for increasing hardware as the demand increases, i.e. increasing the number of Web-Application Servers or Database Servers. The CPMS is web-based and cross-platform accessible for end-users and is backward compatible with the most common operating systems, devices (computer, tablet, smart phone) and web-browsers (Firefox, Safari, Chrome, Internet Explorer). It respects the W3C Web Content Accessibility Guidelines.

CPMS collects the following information securely:

- structured patient general information (e.g. name, date of birth, gender), clinical data using international standard ontologies including ORDO, HPO and in a format compatible with different guidelines (e.g. dysmorphic features, allergies, current medical problems, medical implants, major surgical procedures during the last six months) and a list of current medication (including prescribed medicines), and confirms with the guidelines (in particular the patient summary) approved by the eHealth network;
- upload of digital medical images through Picture Archive and Communication Systems (PACS) in multiple formats for ultrasound (US), magnetic resonance (MR), nuclear medicine imaging, positron emission tomography (PET), computed tomography (CT), endoscopy (ES),
- mammograms (MG), digital radiography (DR), computed radiography (CR), histopathology, for all uploaded images and artefacts there must be a provision to add annotations (e.g. comments boxes) by members of multidisciplinary teams;
- anatomical pathology data (macroscopic, microscopic, biochemical, immunologic and molecular examination of organs and tissues);
- genetic and genomic information and pedigree/family history in line with international standards, such as those agreed by the Global Alliance for Genomics and Health (GA4GH) and IRDiRC employing widely used bioinformatics tools to exchange the data.

The CPMS pseudonymises patient data (at both the level of the patient/clinician and at the level of the researcher). The CPMS encrypts and stores the data in a relational database which however provides for the possibility create reports. After the case is closed, the data is stored in a low accessibility database. With a specific consent, the patient can allow an ERN to collect and export data for potential future use in clinical decision-making tools, protocols, guidelines, case library or research.

The logical architecture of the systems consists of many components, such as: Clinical Portal, PACS, Integration Engine, Video Conferencing, Deployment and Design. The Clinical Portal

is composed of separate applications, which provide a mechanism to encapsulate business logic, security rules and data.

The CPMS is the tool to be used by ERN multidisciplinary healthcare team on daily basis. The main high-level use cases are:

- Treating healthcare provider requires support to diagnose or treat a patient,
- Treating healthcare provider enrols patient in the CPMS and creates a new Panel,
- The Panel Lead invites other specialists to the panel to make their contribution,
- Panel members can collaborate effectively using the CPMS,
- Treating healthcare provider can attach DICOM images from their local disk and from the healthcare provider organization to the Panel,
- Treating healthcare provider can attach CDA files from their local disk and from the healthcare provider organization to the Panel,
- Data can be shared with research participants (invited panel members),
- The system monitors participation and reports against Key Performance Indicators,
- The System Administrator manages the system,
- The ERN Coordinator manages the data.

CHARACTERISTIC OF THE SYSTEM FOR THE CROSS-BORDER EXCHANGE OF EPRESCRIPTIONS AND PATIENT SUMMARIES

The goal of the eHealth DSI is to enable European health data exchange between healthcare professionals in a seamless manner for the benefit of citizens. The current eHealth DSI architecture enables the cross-border interoperability of Patient Summaries and ePrescriptions.

The primary purpose of electronic Patient Summary in eHealth DSI is to provide the healthcare professional with the key health information at the point of care to deliver safe patient care during unscheduled care and planned care, having its maximal impact in the unscheduled care. The purpose of the PS information is to support the coordination and continuity of healthcare in a European-wide mobility of citizens.

The ePrescription service is made up of electronic prescribing and electronic dispensing. ePrescribing is defined as prescribing of medicines in software by a legally authorized healthcare professional for dispensing at a pharmacy, once it has been electronically transmitted. eDispensing is defined as the act of electronically retrieving a prescription and giving out the medicine to the patient as indicated in the corresponding ePrescription.

The eHealth DSI is implemented as a set of interacting National Contact Points for eHealth built on top of internet based technology. Each NCPeH agrees to exchange medical data under a mutual circle of trust. The exchange of data is enabled by the core services set up by the Commission.

The National Contact Point for eHealth is the single national gateway for eHealth DSI services. It guarantees the compliance of all eHealth DSI services with the eHealth DSI information governance. The eHealth DSI interfaces are normative for the NCPeH. The NCPeH is a participant in the eHealth DSI services network only if it is compliant with

normative eHealth DSI interfaces in terms of structure, behaviour and security policy. The main part of these services is related to exchange but some common utility services (i.e. Central Configuration Services; Central Terminology Services) are centralized.

The National Interfaces are services provided and used by the NCPeH within the national infrastructure. The implementation of these interfaces depends on the specific characteristic and standard adopted by the national infrastructure.

The internal NCPeH service architecture defines a structure of sub-components and its relative internal interfaces. This set of specifications supports the realization of Common Components and can be viewed as a facility for the eHealth DSI.

The NCPeH Reference Implementation (usually known as the OpenNCP) is a flexible framework of common components that can be used by a country to fulfil the requirements regarding the eHealth DSI transactions. The common components are developed by the Commission together with the OpenNCP Community.

Each country is responsible for its own and unique implementation of the NCPeH gateway. It's assumed that for reducing the costs, each country will try to use as many common components as possible. Nevertheless a reasonable part of the NCP gateway remains nation specific and therefore cannot be specified nor jointly developed by eHealth DSI.

The Commission is responsible for the design, implementation and operation of the eHDSI core services. These services range in nature (e.g. guidelines, normative specifications, IT services, open source software) and in function (e.g. enable services operation, define interoperability specification and facilitate the NCPeH development).

Terminology Services (which include the Terminology Server, the Master Value Catalogue and the clinical document Implementation Guides) are the key elements for achieving a Europe-wide harmonization of clinical data representation. Together, they provide a way for exchanging clinical data without distorting meaning or endanger patient safety. Tremendous progress has been done some far, by moving from a commercial solution (e.g. terminology Server) to the Commission sourced solution addressing the core requirements for Master Value Catalogue and Master Translation Catalogue handling.

The complete list of the service offering from the eHealth Digital Service Infrastructure is given in an Annex.

ANNEX. COMPLETE SERVICE OFFERING FROM EHDSI

SERVICE	TYPE	DESCRIPTION
COMMUNICATION services	Web Page	Web site publicly available to any stakeholder to promote eHDSI official dissemination content (e.g. new, discover, how it works, services, communities).
SERVICE DESK services	Platform	Issue driven platform to gather and track End-Users requests for assistance or support.
COLLABORATION services	Platform	In order to boost collaborative work, the toolkit provide, at least, the following tools: – Knowledge Sharing through the use of wiki pages (e.g. documentation, meeting minutes, discussions, files management) and a powerful search engine to assist find content. – Work Orchestration by providing mechanisms to describe, assign and monitor work tasks to be performed. – Teleconferencing facilitating the organisation of remote meetings by providing audio, video and screen sharing.
Services REQUIREMENTS	Guideline	In order to be able to accurately point and trace back requirements from specifications, implementation, test and audit, there is the need for having the following instruments in place: – Requirements Source Blueprint – Requirements List – Requirements Management
Services SPECIFICATION	Normative Specifications	Fundamental design information that map requirements into clear indications on what is to be built.
CONFIGURATION services	IT Service	In order to set up and keep functional the NCPeH Service Network, there is the need for Dynamic Service Location and Capability Lookup services that allow the NCPeH to discover each other and establish trusted communication.
TERMINOLOGY services	IT Service	In order to achieve semantic interoperability there is the need for a common vocabulary (Master ValueSet Catalogue – English by default) to describe the clinical data. The MVC should be presented to the End-Users in the MS desired language and code systems. For that, MS should be able to translate, map and transcode (creating the Master Translation/Transcoding Catalogue MTC) according to their national policies.
TEST AND AUDIT services	Framework	Entering the Operational NCPeH Service Network (Go Live) requires a specific level of Conformance and Trust. In order to reach that level the NCPeH (organisation and technical gateway) must undergo specific Test and Audit procedures to gather evidence to fundament the Readiness Statement each MS presents to the eHN when seeking approval to Go Live.
MONITORING services	Framework	Performance monitoring is crucial to understand effective usage of the services and detect defects. In order to achieve performance monitoring it is needed to have in place mechanisms able to collect and report specific performance data. These services (that may come as Specifications, Software or Services) should ease the burden of MS on reporting tasks.
NCPeH Reference Implementation	Software	The NCPeH technical gateway is one of the core nodes in the Service Network. Since each MS need to deploy an NCPeH based on the same specifications, it was agreed between EC and MS that a reference implementation should be jointly developed, so that knowledge shared and effort distributed among the participating MS.