



eHealth Network

POLICY PAPER

on

**How to Assess Member States Overall Readiness
to Go Live**

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 consensus by the eHealth Network, Saint Julian's, Malta, 9 May 2017

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LIST OF ABBREVIATIONS

ACRONYM	DEFINITION
CBeHIS	CROSS-BORDER eHEALTH INFORMATION SYSTEMS
eHDSI	eHEALTH DIGITAL SERVICE INFRASTRUCTURE
MS	MEMBER STATES
NCPeH	NATIONAL CONTACT POINT FOR eHEALTH
SP	eHDSI SOLUTION PROVIDER

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1. Executive Summary

This paper provides an overview of the Policy Papers and Technical Annexes linked to the “Go Live” process of Cross-border eHealth Information Systems (CBeHIS) implementation for Member States (MS). It explains the rationale behind the documents jointly provided by JAseHN (i.e. Policy Papers) and the eHealth Digital Service Infrastructure (eHDSI) Solution Provider (SP) (i.e. Technical Annexes) for guiding the MS through the process of Going Live.

2. Introduction

Each MS must undergo the CBeHIS implementation stages as foreseen in the Guideline on an Organisational Framework of National Contact Points for eHealth: Preparation, Deployment and Operation. During these implementation stages, the MS need to test their services and conduct an initial audit before Going Live.

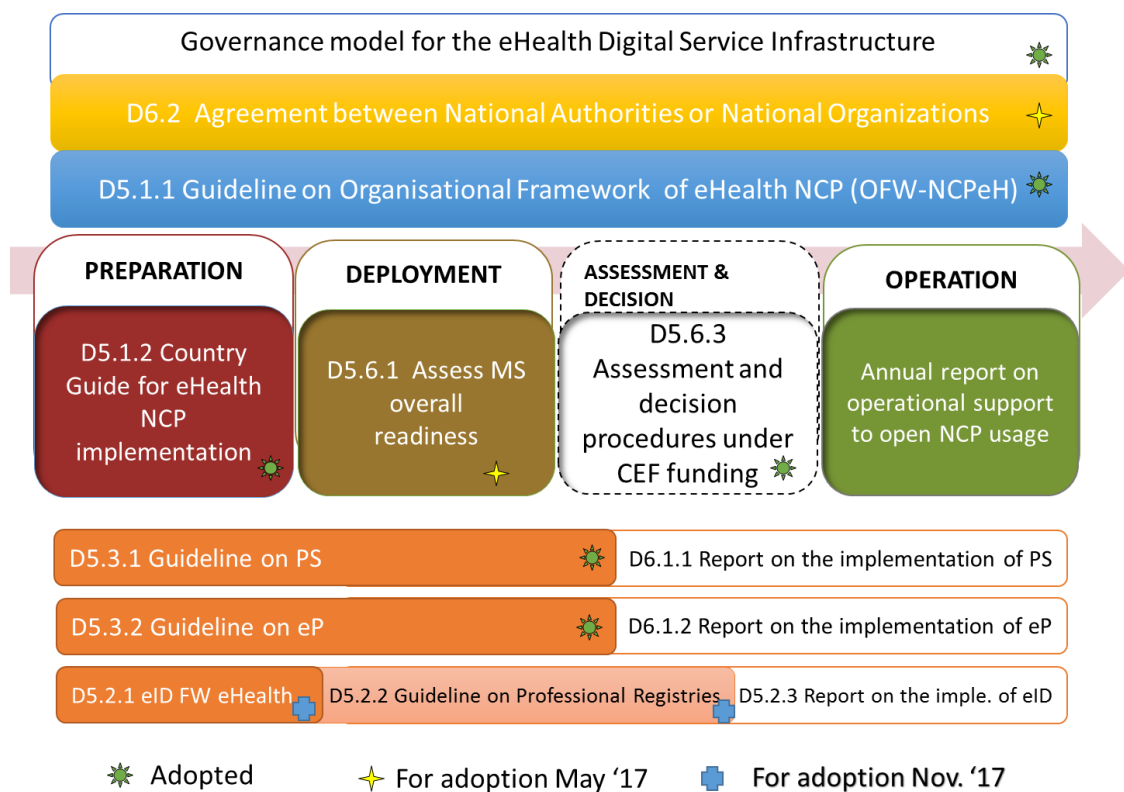


Figure 1: The status of each of CBeHIS implementation stages as well as the relation of the overall linked documents that represent and define the common basis for the overall CBeHIS process including the documents that relate to each stage

3. Overview of key documents for assessment of MS Overall Readiness to Go Live

During the CBeHIS implementation, each MS is assessed against criteria listed in the technical documents provided by the eHDSI Solution Provider. The assessment of the MS' overall readiness to Go Live is thus supported by following requirements provided in the documents listed in Figure 2: Yellow boxes contain the overall Policy Papers provided by JAsEHN to the eHN and green boxes contain Technical Annexes mainly provided by the eHDSI SP¹. Both are assigned in each stage of CBeHIS implementation to specific bodies listed in the blue boxes. The Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross Border eHealth Information Services is a legal requirement that must be followed by each MS intending to Go Live while the Organizational Framework of eHealth NCP (OFW-NCPeH) describes the overall process from Preparation to Operation stages of CBeHIS implementation.

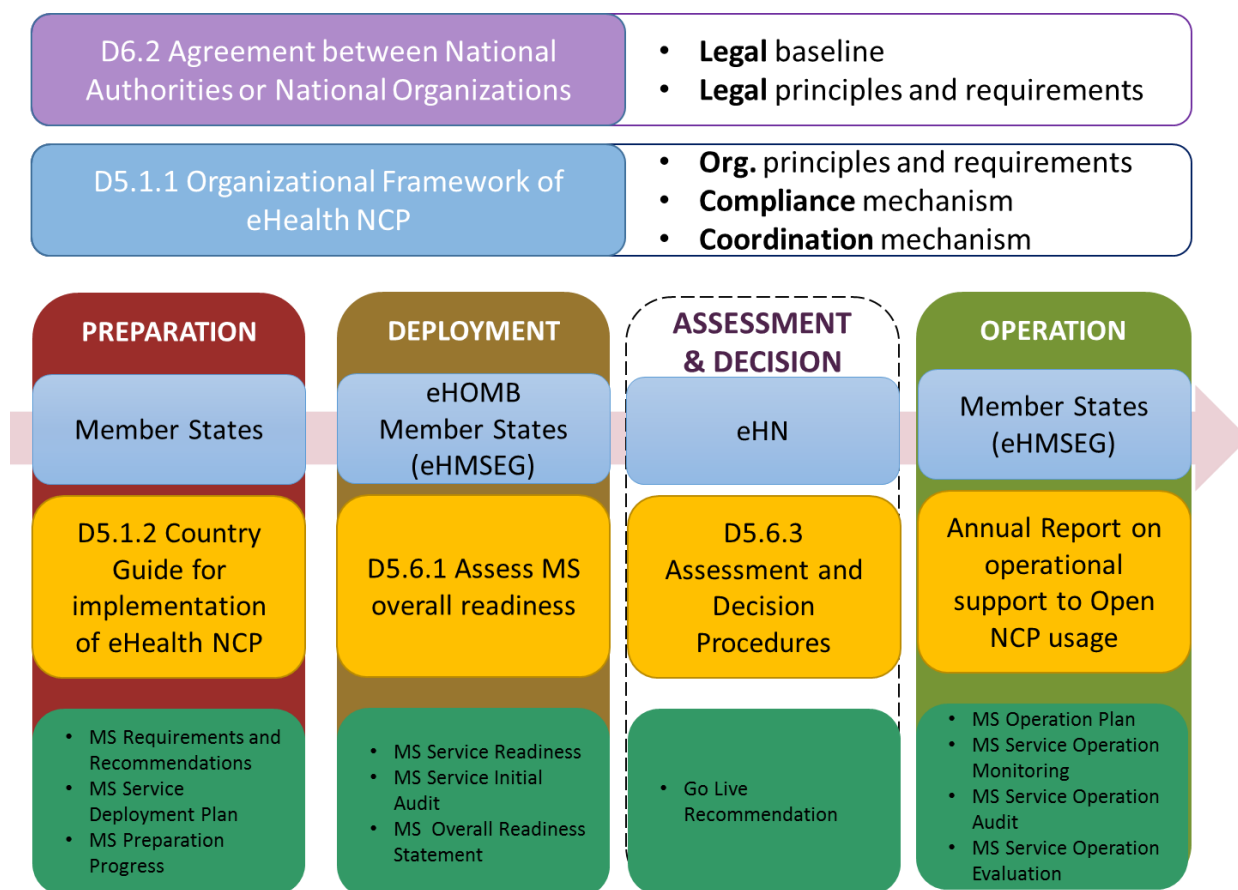


Figure 2: Interdependencies of technical and policy documents with respective responsibilities and implementation stages

¹ Recommendation to the eHN in JAsEHN D5.6.3 Policy Paper on Assessment and Decision Procedures under CEF Funding

The Technical Annexes for assessment of MS Overall Readiness to Go Live are described below.

3.1 MS Requirements and Recommendations

Explanation: This document provides all necessary criteria related to the CBeHIS implementation that shall be followed by each MS intending to join the eHDSI during Preparation stage.

Source: See Annex 1

3.2 MS Service Deployment Plan and MS Preparation Progress

Explanation: This document describes the individual MS plan for the implementation of CBeHIS services describing the preparation activities for NCPeH deployment in a structured, common and comparable way. The MS Service Deployment Plan is an appendix of the eHDSI NCPeH Deployment Guide, produced and maintained by the eHDSI Solution Provider. The MS Service Deployment Plan also represents the first deliverable of every country participating in the eHDSI. The MS Preparation Progress is a follow-up to the MS Service Deployment Plan and is used for frequent reporting. Whereas the MS Service Deployment Plan is produced only once, the MS Preparation Progress is produced on a quarterly basis by each MS.

Source: See Annex 2

3.3 MS Service Readiness and MS Service Initial Audit

Explanation: MS Service Readiness and MS Service Initial Audit are parts of the Audit Framework. The Audit Framework is elaborated and maintained by the eHDSI SP with an annual release plan in March. The main purpose of the Audit Framework is to provide guidance to the Auditing Body on how to plan, execute and evaluate the adherence by MS to the Readiness Criteria.

- The MS Service Readiness is represented by the Readiness Checklist which is an annex of the Audit Framework. The purpose of the Audit Checklist has to elaborate specific questions for the NCPs, and facilitate understanding of how controls match between the standard and what the NCPs would need to have in place regarding internal policies, processes and controls. It is based on the ISO 27002:2013 standard.
- The MS Service Initial Audit is represented by the Audit Report Template which is an annex of the Audit Framework. The Audit Report details the audit findings based on the implementation level of the Readiness Criteria.

Source:

- Audit Framework: See Annex 3
- Audit Checklists: See Annex 4
- Audit Report Template: See Annex 5

3.4 MS Overall Readiness Statement

Explanation: MS Overall Readiness Statement is a declaration statement by every MS applying to Go Live. It formally declares that a country is ready to Go Live with the respective services and shall therefore be signed by an authorized person representing the MS. A template to be filled-in by every country is provided by eHDSI Owner.

Source: See Annex 6

3.5 Go Live Recommendation

Explanation: The Go Live Recommendation is a report being the main basis for the eHN members to make the Go Live decision for an applicant MS. The Go Live Recommendation is based on the Go Live Recommendation Report Template, which will be elaborated by eHMSEG². The Go Live Recommendation Report lists the main findings of the Test Report, Audit Report and includes a Risk Assessment for each MS applying to Go Live.

Source: See Annex 7

4. Policy processes

In order to implement CBeHIS, there is a need for monitoring MS progress through different implementation stages. Therefore, a common timeline was established in order to ensure alignment and compliance to the above listed document before (and after) Going Live. The overall process of CBeHIS implementation, from the Preparation stage to the Operation stage, is depicted in Figure 3.

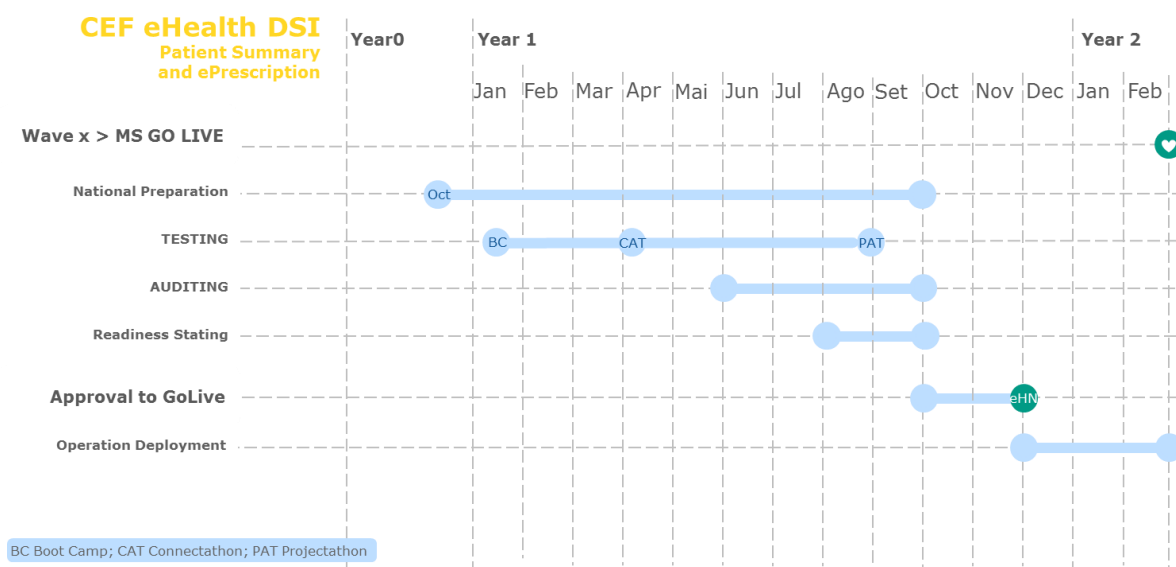


Figure 3: eHDSI Generic Services default time plan

The steps as indicated in figure 3 are further described below:

² eHOMB will support eHMSEG in this process via their secretariat.

4.1 Testing

MS's activities for testing the deployed services. Testing events are organized every year during the CBeHIS implementation under CEF eHDSI and follow the eHDSI SP Test Framework.

Three major testing events (or more if needed) are planned and result in a report to eHMSEG:

- **Boot Camp(s)** (January): preparatory event to coach and guide the MS regarding the adoption of specifications, reference implementation and testing mechanisms, organized by MS or the European Commission;
- **Connect-a-thon** (April): conformance-testing event organised by IHE;
- **Project-a-thon** (September): conformance-testing event organised by the eHDSI SP.

After the testing, the test report is produced and sent to eHMSEG.

Source: See Annex 8

4.2 Auditing

The auditing activity performed by the Auditing Body objectively evaluates the adherence of NCPeH to legal, organizational, semantic and technical criteria as defined by the eHDSI SP Audit Framework. A MS can apply for the auditing procedure whenever it wishes within the foreseen timeframe based on Figure 3. After the auditing, the Auditing Body submits the Member States Audit Report to eHMSEG.

Source: See Annex 3

4.3 Readiness Stating

Each individual MS activity to summarise all evidence in a common format (i.e. MS Overall Readiness Statement) which is provided to eHMSEG for review. Readiness Stating is best done after successfully going through the Testing and Auditing procedures. Upon a successful Readiness Stating and after reviewing the Audit and Test reports (i.e. combined), eHMSEG³ prepares a report (i.e. Recommendation Report to Go Live) for the eHN in order to support the application of the MS for the Go Live decision.

Source: See Annex 6 & 7

4.3 Approval to Go Live

The eHN's decision to permit an MS to move into the Operation stage of CBeHIS implementation, i.e. to Go Live which is based on the Recommendation Report to Go Live produced by eHMSEG⁴ after reviewing the reports from Auditing, Testing and Readiness Stating. After this approval is made, a MS is permitted to share cross-border information with other MS that are in Operation stage.

Source: eHN Meeting documentation

³ eHOMB will support eHMSEG in this process via thier secretariat

⁴ Id.

5. Recommendations

The eHN members are asked to agree with the recommendations listed below:

RECOMMENDATION 1

The eHN agrees to use the **Policy Papers and Technical documents (i.e. Technical Annexes)** for the intended purpose of guiding the Member States through the **Preparation and Deployment stages of CBeHIS implementation including Assessment and Decision phase**, as described in Chapter 3 of this document.

**NOTE: FUTURE RELEASES OF THESE TECHNICAL DOCUMENTS
NEED TO BE ADOPTED BY eHMSEG IN A TRANSPARENT MEMBER
STATE REVIEW PROCESS**

RECOMMENDATION 2

The eHN agrees with the policy processes, as described in Chapter 4 of this document.

6. Annex

Overview table of Technical Annexes

Annex Number	Document Name	Source	Drafted by	Official Review Process by MS
1	MS Requirements and Recommendations	LINK	eHDSI Owner	No
2	MS Service Deployment Plan and MS Preparation Progress	 Depl-Plan_Template_to-be-filled-in_v8.xl	eHMSEG	eHMSEG MS (18.04.2017)
3	Audit Framework	LINK	eHDSI Solution Provider	eHMSEG MS (04.04.2017)
4	Readiness Criteria Checklist	 eHealth-Readiness Criteria Checklist_v1	eHDSI Solution Provider	eHMSEG MS (04.04.2017)
5	Audit Report Template	LINK	eHDSI Solution Provider	eHMSEG MS (04.04.2017)
6	MS Overall Readiness Statement	(not available yet)	eHDSI Owner	No
7	Go Live Recommendation	JAsEHN D5.6.3, Annex	JAsEHN, T5.6	JAsEHN sPSC MS (11.04.2017)
8	Test Framework	LINK	eHDSI Solution Provider	No