eHealth Network

POLICY PAPER

on

assessment and decision procedures under CEF funding

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, Brussels, 21 November 2016

-Keep this page free-

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1. Executive summary

The purpose of this document is to describe the approval process for a Member State's (MS) decision to "go live" with its Cross-Border eHealth Information Services (CBeHIS), specifically the infrastructure and the operations used to exchange real patient related data, in particular health data, between its members. It also includes a description of the responsibilities, procedures and methodology used to create a report upon which the decision making process will be based.

This proposal is to be approved by the eHealth Network (eHN) at its 10th meeting on 21st November 2016.

2. Introduction

There are three stages that have to be completed by a Member State aiming to participate in the eHDSI as foreseen in the Guideline on an Organisational Framework of National Contact Points for eHealth (OFW-NCPeH): Preparation, Deployment and Operation, and several instruments to support the CBeHIS stages are foreseen. For every stage JAseHN provides or has already provided supporting documents as described in Figure 1.
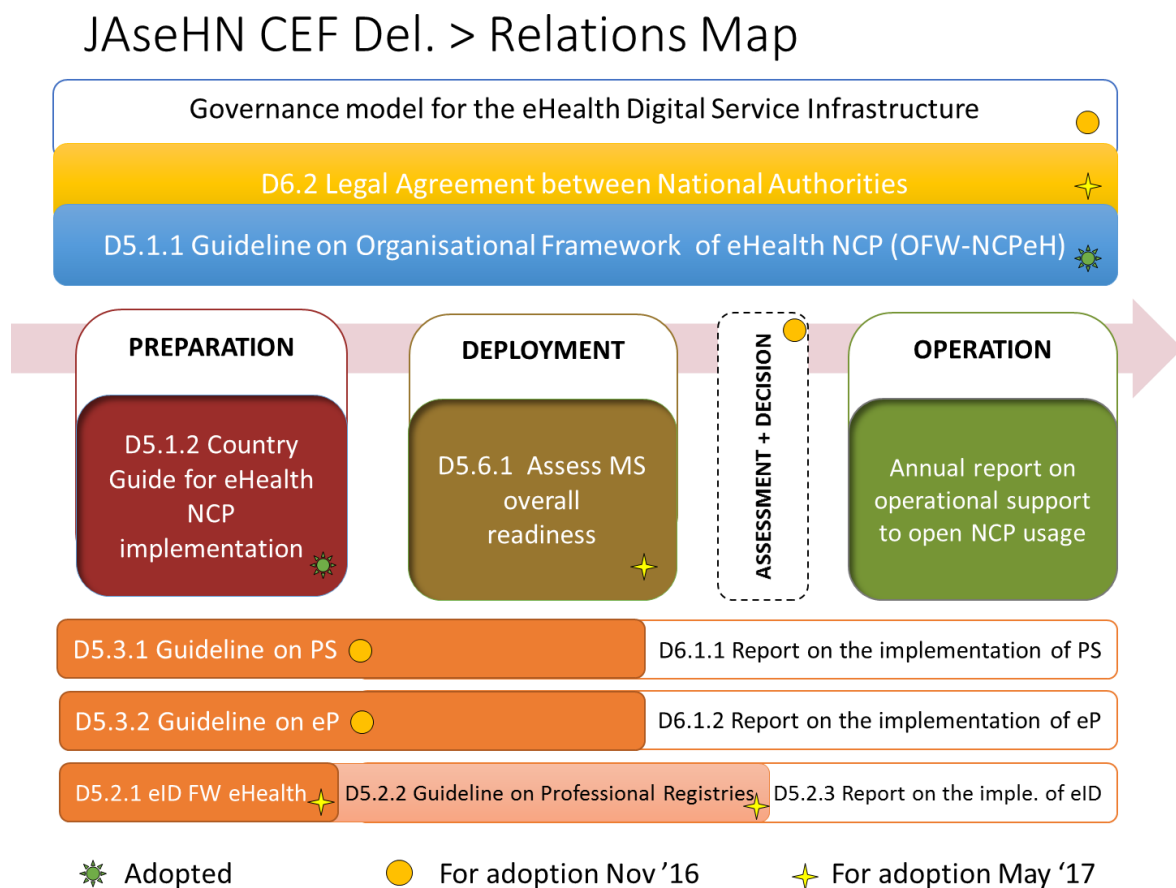
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Governance model for the eHealth Digital Service Infrastructure

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🌸 Adopted   🟠 For adoption Nov '16   ✦ For adoption May '17

Figure 1: Alignment of CBeHIS instruments and work in progress

D5.1.2 Country Guide for NCPeH implementation was adopted by eHN at its 9th meeting. The recommendations given in this Country Guide touch upon several aspects of the preparation stage for the NCPeH, but their focus is mostly on the semantic and technical aspects. With regard to the legal requirements for CBeHIS, the process will be based on the *Legal Agreement between National Authorities responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross-Border eHealth Information Services* (LA), whereas the OFW-NCPeH will provide the basis for the organisational aspects.

D5.6.1 Assess Member States' overall readiness is a document which describes a process that responsible parties need to implement in order to establish trust between the Member States and Service Providers. It provides explanations about which steps must be taken by MS while stating their readiness and the approval process for taking their CBeHIS online. The document will be submitted to eHN for adoption in May 2017.

3. Status of previous deliverables

 D5.1.2 and D5.6.1 both summarise the need for Member States to fulfil the Preparation and Deployment phases and describe the implementation strategy for CBeHIS provision. D5.1.2 was adopted by eHN on a generic level but is still missing the technical annexes (i.e. Member State Requirements and Recommendations checklist) that are needed by the Member States' technical experts when they prepare for CBeHIS implementation. D5.6.1 was not presented to eHN but is available as a draft without the completed technical annexes, such as checklists, the report template for the Initial Audit and the Readiness Statement (draft available as Annex I of this document).

Due to the significant level of technical complexity involved, it has turned out that JAseHN is not in a position to finalise the above-mentioned technical annexes for both documents. It is therefore proposed that the finalisation of the technical annexes listed above be handed over to the eHDSI Solution Provider in close liaison with JAseHN-WP5. Both annexes have to be approved by eHMSEG; D5.1.2 will be sent as an update for information only and D5.6.1 for adoption at the 11th eHN meeting in May 2017.

4. Objective

The objective of this document is to focus on the elaboration of the processes, roles and responsibilities for each stage of CBeHIS development under CEF with a strong focus on the stage between Deployment and Operation. The reason for this is that the final decision to "go live" will be taken by eHN between these two stages of CBeHIS development.

The other stages have been described elsewhere (see 3. Status of previous deliverables) and will not be covered in greater detail in this document. All stages of CBeHIS development under CEF will be mentioned to some extent. The final decision to permit a MS to "go live" is based upon the processes in the Preparation and Deployment stages.

As such, this document aims to provide eHN members with a summary report (Recommendation Policy Report Template) of all the necessary preconditions presented to each MS and their fulfilment status. This report will provide decision-making support to eHN when it makes the decision to permit a MS to go into the Operation stage, i.e. "go live" with its CBeHIS.

5. Proposed processes and responsibilities

The following chapter focuses on the processes that describe the stages of CBeHIS development. As previously stated, the purpose of this document is not to focus on all the stages of CBeHIS development but to provide information regarding the **Assessment and Decision** process performed by eHN. This intermediate stage of CBeHIS takes place between the Deployment and Operation stages and its purpose is to collect and validate evidence that a MS is able to go live and produce a summary of all the results collected in previous stages in order to support the claim of the MS to be permitted to go into the Operation stage.

Figure 2 further outlines the main responsibility in each individual stage and the related technical documents that need to be delivered when the three stages are completed:
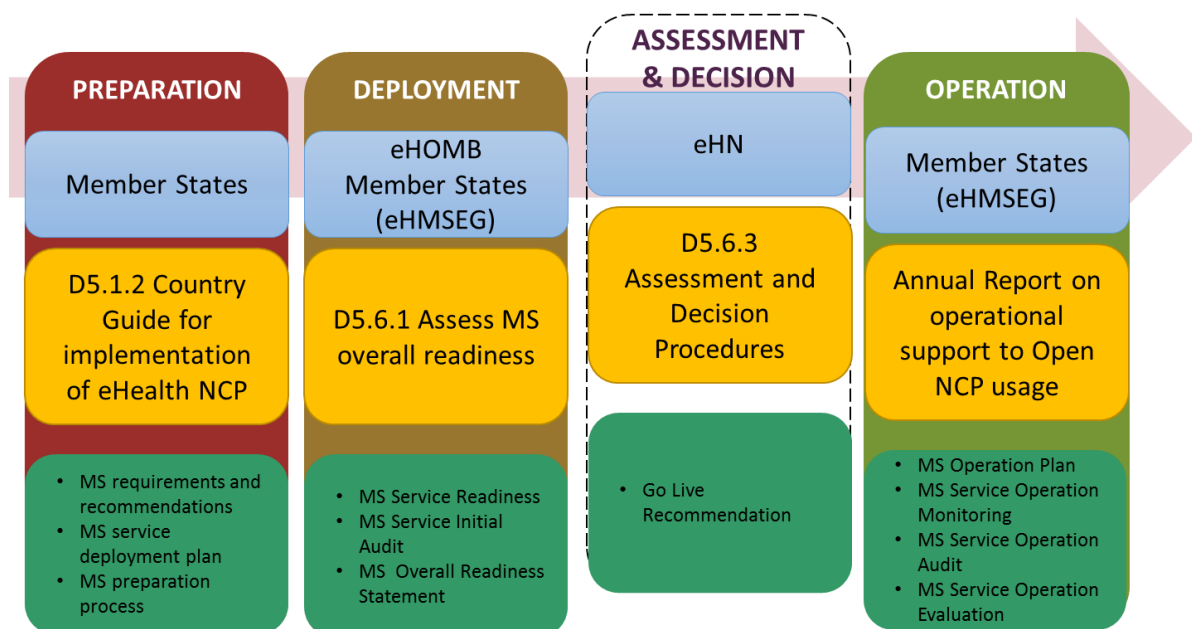
JAseHN CEF Del. > Responsibility and Delivery Map

Figure 2: Responsibility and Delivery Map

The whole process of CBeHIS development under CEF begins with the Preparation stage. During the Preparation stage, a MS relies on the Country Guide for implementation of eHealth NCP to produce the first CBeHIS deliverables and build up its national infrastructure for CBeHIS. As a formal result of this stage, a MS is required to submit a series of reports described in further detail in the OFW-NCPeH (namely: Member State Service Plan, Member State Requirements and Recommendations, and Member State Preparation Progress). When it has reached an expected level of readiness, a MS enters the Deployment stage where it performs specific testing activities.

The Deployment stage marks the second phase of CBeHIS development. During this stage, the MS gathers evidence on its readiness level, namely by performing the activities identified in the eHDSI Testing and Audit Frameworks.

The evidence collected throughout this stage is then compiled in the Readiness Statement (for draft, see Annex I) prepared by the MS, validated by the third party auditing body (hereinafter referred to as the Auditing Body) and sent to eHMSEG for assessment. Their

recommendation, i.e. the recommendation report to go live, will finally be submitted to eHN for decision.[1]

Due to the need for a consolidated approach to decision-making with regard to CBeHIS, the final decision is made by eHN in accordance with its Rules of Procedure. In order to support this decision-making process, eHMSEG submits to eHN a filled-in Go Live Recommendation report that summarises the MS's overall readiness statement in conjunction with the evidence produced in the Preparation and Deployment stages that uphold the claim of a MS to "go live" with its CBeHIS.[1]

The flow and progress along the different stages proposed will follow a default timescale agreed for the eHDSI, reinforcing the orchestrated and coordinated approach to decision-making. The following figure and table describe the default timescale for the full process to occur.
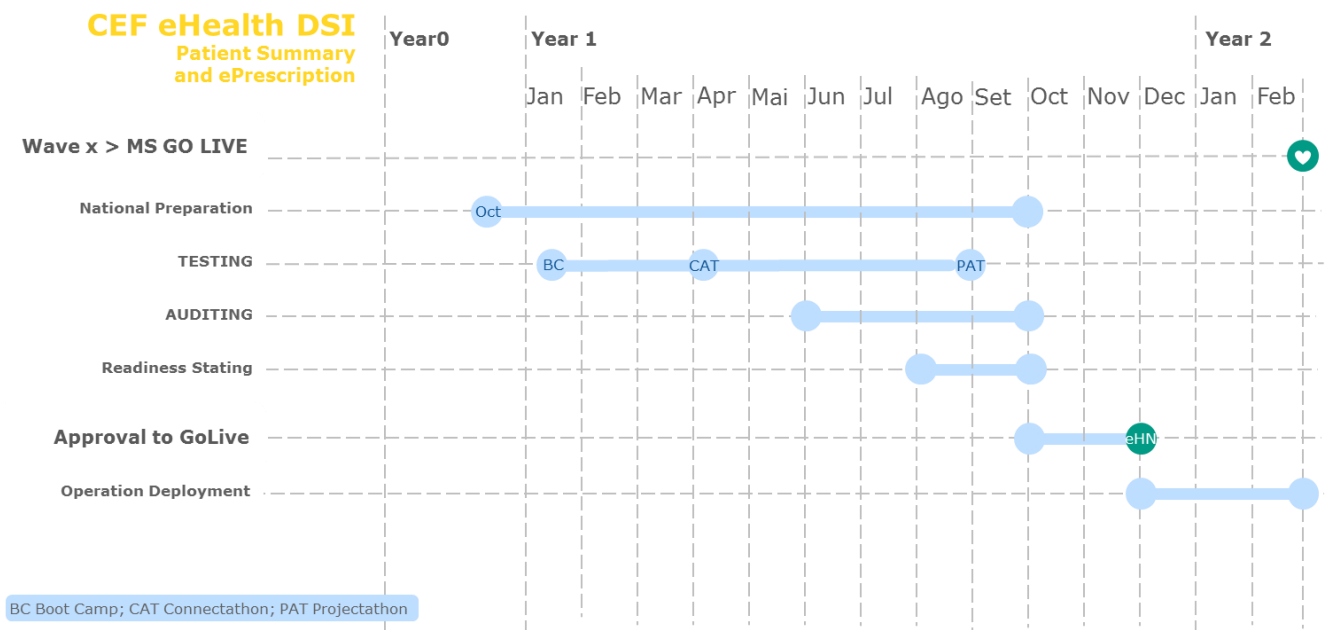

Figure 3: Default timescale for a MS under the CBeHIS development cycle

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[1] eHOMB will support eHMSEG in this process via their Secretariat.

The description of the steps foreseen for the default timescale for going live:

STEP	DESCRIPTION
Wave X – Go Live	The commonly agreed date for a MS to go live (services available for public use) with CBeHIS, depending on the wave chosen: • Wave 1 – February 2018 • Wave 2 – February 2019 • Wave 3 – February 2020
National Preparation	MS's specific activities towards reaching the CBeHIS readiness levels needed to go live. A 12 month period is recommended to prepare the NCPeH.
TESTING[2]	MS's activities for testing the services provided by the NCPeH. Three events are foreseen: • Boot Camp (January): ramp up event to coach and guide the MS regarding the adoption of specifications, reference implementation and testing mechanisms; • Connect-a-thon (April): conformance testing event organised by a third party; • Project-a-thon (September/October): conformance testing event organised by the EC. These events should, if possible, occur every year during the CEF eHealth DSI.
AUDITING	Audit performed by the Auditing Body of each MS's NCPeH, ending with the finalisation and validation of the Readiness Statement produced by the MS
Readiness Stating	MS's activity to summarise all the gathered evidence in a common format, which will then be verified by the Auditing Body and submitted to eHMSEG for assessment
Elaborate Go Live Recommendation	eHMSEG activity[3] to prepare Go Live Recommendation, including any specific instructions to the MS to improve the NCP implementation
Approval to Go Live	eHN decision regarding the "Recommendation Report to Go Live" received
Operation Deployment	MS's activities, once eHN's decision has been made, towards the operational environment in which services will be made publicly available

Table 1: Description of the steps for every wave

All the stages that the MS goes through before the Operation stage (i.e. final approval for CBeHIS to "go live" by eHN) are set out in detail below.

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[2] Information according to the eHDSI Testing Framework. This document is not yet available but the information was obtained through close collaboration with the eHDSI Solution Provider responsible for its preparation.
[3] eHOMB will support eHMSEG in this process via their Secretariat.
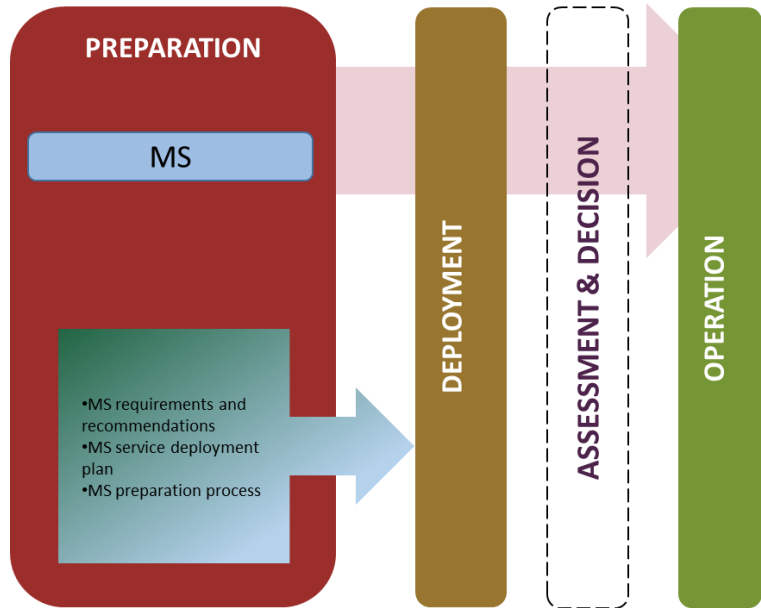
5.1 Stage I: Preparation

Figure 4: From the Preparation to the Deployment stage

Tools and mechanisms (as defined by OFW-NCPeH) - Figure 3:

The documents included in the OFW-NCPeH (Chapter 4.2 Process) that guide Member States and provide evidence of successful CBeHIS implementation during the Preparation stage are:

- Member State Service Plan (PLAN)
- Member State Requirements and Recommendations (CHECKLIST)
- Member State Preparation Progress (REPORT)

Rationale:

According to the OFW-NCPeH (Chapter 4.2 Process), Member States design the national deployment plan and perform national preparatory activities towards the provision of cross-border eHealth activities. The purpose of these three documents is to describe the Preparation stage completed by the MS that will lead into the Deployment stage.

Process:

The Member State Preparation Progress Report, which includes the Member State Service Plan and the Member State Requirements and Recommendations, ensures that a country is permitted to enter the Deployment stage, during which further evidence is gathered in order for the Member State to "go live".[4]

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[4] Member State Service Plan and Member State Preparation Progress are to be provided in the JAseHN D5.1.2. Checklist of Requirements and Recommendations, which will be finalised jointly by the eHDSI solution provider and JAseHN WP5.

5.2 Stage II: Deployment
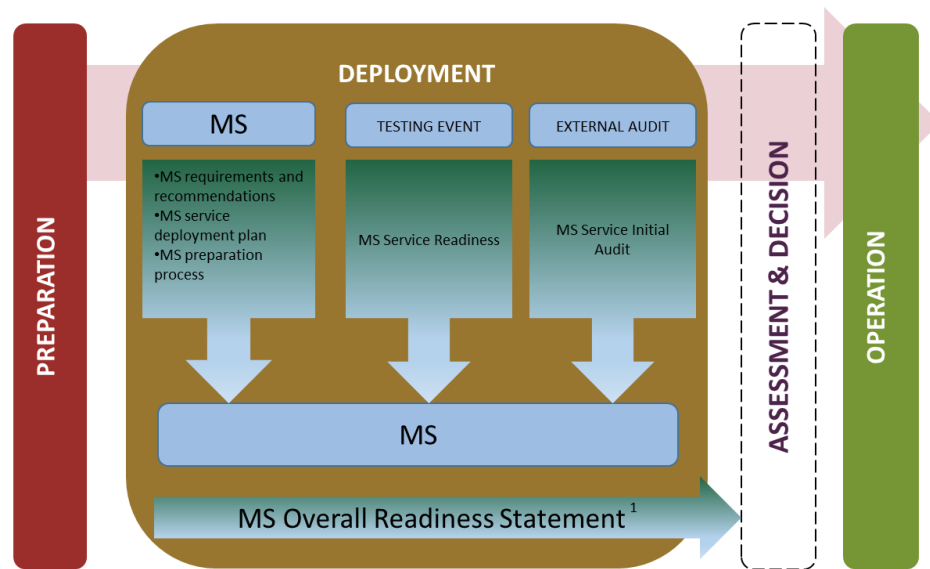
MS Overall Readiness Statement will be validated by the Auditing body

Figure 5: From Deployment to the Assessment and Decision stage

Tools and mechanisms (as defined by the OFW-NCPeH) - Figure 4:

The documents included in the OFW-NCPeH (Chapter 4.2 Process) that guide Member States and provide evidence of successful CBeHIS implementation during the Deployment stage are:

- Member State Service Readiness (CHECKLIST)
- Member State Services Initial Audit (REPORTS)
- MS Overall Readiness Statement (CHECKLIST)

Rationale:

The purpose of these three documents is to support the Member States in setting up and adopting the measures required for operational establishment of the NCPeH. The Member State Service Readiness Checklist, Member State Services Initial Audit Reports and MS Overall Readiness Statement (validated by the Auditing Body) provide evidence that supports the claim of each Member State to move from the Deployment stage and "go live".

Process:

During the Deployment stage, an individual Member State tests its CBeHIS in a formal testing event. The purpose of this is to test the services in a scrutinised and independently operated context. The resulting report serves as evidence of technical readiness for CBeHIS implementation.

The Auditing Body performs this test and submits the MS Services Audit Report to the MS.

After these two steps have been performed and documents produced, the third step is for the MS to produce the Overall Readiness Statement (for draft, see Annex I). This statement should be validated by the Auditing Body and then provided to eHMSEG, where it should be assessed before the Member State can proceed towards eHN with a Go Live Recommendation Report.
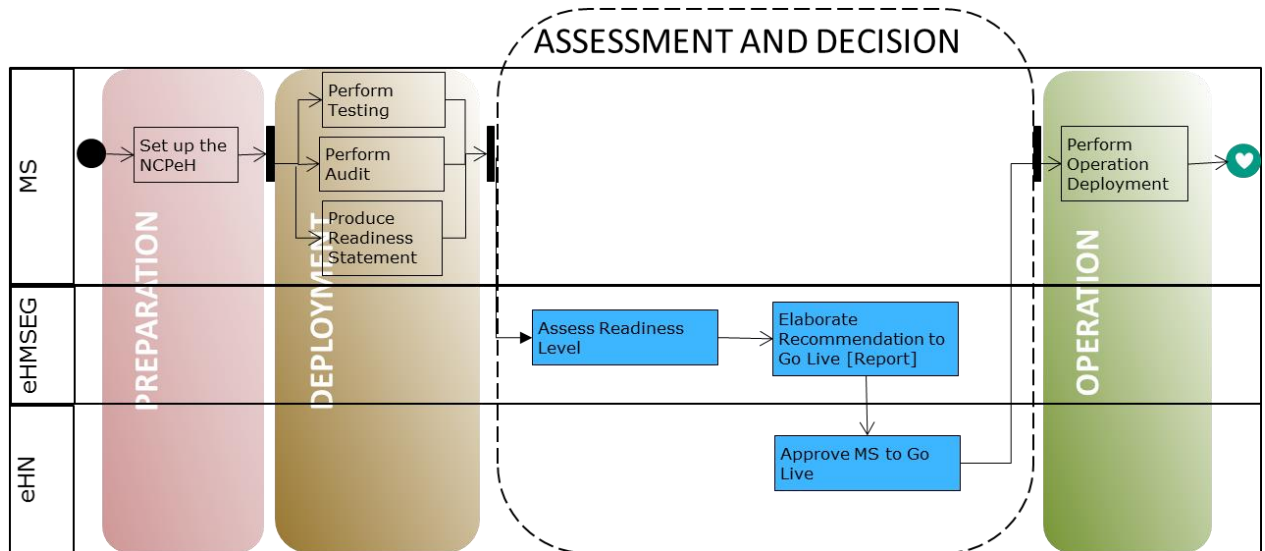
5.3 Assessment and Decision procedure

Figure 6: Assessment and Decision procedure

Tools and mechanisms – Figure 5:

The document that eHN will need for the approval and decision that a Member State is ready to "go live" is the:

- Recommendation to Go Live (REPORT)

Rationale:

Between the Deployment and Operation stages, there needs to be an assessment and decision phase during which a Member State's readiness will be evaluated by eHN. All available tools and mechanisms produced during previous stages will provide the basis for eHMSEG[5] to deliver the Recommendation Report to Go Live, which will be submitted to eHN in order for the Member State's request to "go live" to be approved.

This report will be based on the MS Overall Readiness Statement, which provides a measurable set of criteria and a ranking methodology as a decision-making tool.

Process:

The documents from earlier stages (Preparation and Deployment) provide the basis for a MS to produce the Overall Readiness Statement, which summarises the conclusions of all the aforementioned documents and expresses the final readiness to "go live". Following its validation by the Auditing Body, the Member State submits the Overall Readiness Statement together with other documents to eHMSEG. eHMSEG then assesses the submitted documents and produces the Recommendation Report to Go Live[8]. This report will be submitted to eHN for final approval, upon which a Member State is allowed to "go live" and move into the Operation stage

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[5] eHOMB will support eHMSEG in this process via their Secretariat.

of CBeHIS development. The MS Overall Readiness Statement is attached as a draft document in Annex I of this document for information. The final version of this statement will become part of the JAseHN deliverable 5.6.1 Assess Member States' overall readiness, which is to be submitted for adoption at the 11th eHN meeting in May 2017.

The approval to "go live" is given by eHN in accordance with its Rules of Procedure, as is the case with any other eHN decision. eHN bases its decision upon the Recommendation Report to Go Live, which contains the results elaborated in the submitted MS Overall Readiness Statement. The statement contains the summary results describing the achieved level of performance of deployed generic services and the overall readiness of each MS to "go live".

STEP	STAGE	DESCRIPTION
Set up the NCPeH	Preparation	MS's specific activities towards reaching the CBeHIS readiness levels necessary to go live
Perform Testing	Deployment	MS's activities for testing the services provided by the NCPeH
Elaborate Readiness Statement [Readiness Criteria]	Deployment	MS's activity to summarise all the gathered readiness evidence, in a common format, and state its readiness to go live. This will be validated by the Auditing Body.
Perform Audit	Deployment	MS NCPeH audit performed by a third party
Elaborate Go Live Recommendation (eHN template)	Assessment & Decision	eHMSEG[6] activity to prepare Go Live Recommendations according to the Readiness Statement provided by the Member State and validated by the Auditing Body
MS Go Live Approval	Assessment & Decision	eHN's approval of the Go Live Recommendations
Operation Deployment	Operation	MS deploy the NCPeH in the operational environment in which services will be made publicly available

Table 2: Description of the steps foreseen in the Go Live assessment decision

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[6] eHOMB will support eHMSEG in this process via their Secretariat.

6. Recommendations

eHN members are asked to:

- Agree with the recommendations listed below:

Recommendation 1

eHN agrees with the sequence of interlinkage of the documents as illustrated in Figure 1 and Figure 2 of this document.

Clarification:

> Because several other documents already exist, particularly the Legal Agreement that contains cross-references to all the documents listed in Figure 1 and Figure 2, a decision by eHN is needed in order to reach a final basis for future reference.

Recommendation 2

eHN agrees with the proposed processes, including the responsibilities as described in Table 2

Clarification:

> It turns out that there is a lack of clarification relating to the needed and necessary procedures, processes, methodology, functions and responsibilities. This document provides the process for obtaining the correct information and the information that needs to be provided to eHN in order to be able to make a decision about a Member State going live.

Recommendation 3

Future reports linked to the Operation stage that refer to the "Annual report on operational support to Open NCP usage" will be elaborated by eHMSEG (and not by JAseHN, as initially planned).

Clarification:

> JAseHN has already produced one report that generally refers to the preparatory work done so far in this context. The future alignment work between the Member States concerning the coordination of the technical and organisational implementation of the NCPeH will be done within eHMSEG. Therefore, it is reasonable to appoint eHMSEG as the responsible body for reporting on operational support to Open NCP usage at Member State level.

Recommendation 4

- **The Member States agree to commit themselves to process, at their 11th meeting, the technical annexes to**
    - D5.1.2 Country Guide for NCPeH implementation for information;
    - D5.6.1 Assess Member States' overall readiness for adoption;
    - The technical annexes will be finalised and completed by the eHDSI solution provider in close liaison with JAseHN-WP5 by the end of February 2017, after which they will be reviewed by eHMSEG.

- **The OFW-NCPeH, which has already been adopted, needs some fine-tuning in terms of consistency, which will be done by JAseHN, before its adoption by eHN at its 11th meeting in May 2017.**

Clarification:

The OFW-NCPeH, which serves as one of the main basic documents, provides clear references to D5.1.2 Country Guide for NCPeH implementation, including the technical annexes. These aim to support the Member States in setting up and adopting the measures required for optimal establishment of the NCPeH and are needed by the Member States to enable them to understand the requirements and recommendations for compliance with other Member States' NCPeH.

Annex I:

Member State Overall Readiness Statement (Template)

Country name:	
Service:	○ ePrescription A ○ ePrescription B ○ Patient Summary A ○ Patient Summary B
Range of coverage of the service:	○ Local ○ Regional ○ National

Contact person details:	
Name:	
Organisation:	
Official address:	
Email:	
Telephone number:	+'country code' 'area code' 'number'
Fax number:	+'country code' 'area code' 'number'

List of annexes:	
Name of document:	Abbreviation:
Member State Service Plan	ISO Alpha-2 Country Code-SP[7]
Member State Requirements and Recommendations	ISO Alpha-2 Country Code-RR
Member State Preparation Progress	ISO Alpha-2 Country Code-PP
Member State Service Readiness	ISO Alpha-2 Country Code-SR
Member State Services Initial Audit	ISO Alpha-2 Country Code-SIA
(…)[8]	

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[7] The ISO alpha-2 country codes are part of ISO 3166, which is the International Standard for country codes and codes for their subdivisions. The country codes represented as a two-letter code are called ISO alpha-2 country codes, e.g. AT, BE, HR, DE, FR, etc. (http://www.iso.org/iso/home/standards/country_codes.htm)
The second part of the abbreviations are the abbreviations of the document referred to (SP = Member State Service Plan, RR = Member State Requirements and Recommendations)
[8] Additional documents may be added if necessary but it would be useful for the same abbreviations as above to be used.

Services in operation stage[9]		
Service	YES	NO
Patient Summary - Country A		
Patient Summary - Country B		
ePrescription - Country A		
ePrescription - Country B		

This statement about a member state's overall readiness to provide CBeHIS is envisioned to be the baseline for producing the Recommendation Report to Go Live. Information is about a Member State's (MS) readiness to go live and move into the Operations stage of cross-border eHealth services (CBeHIS) development. It is divided into legal, organisational, technical and semantic preparedness in accordance with the European Interoperability Framework.

The rankings used in this template are:

- **Critically deficient** — suggests a serious inability to comply with the Approval Criteria.

- **Weak** — unable to comply entirely with Approval Criteria.

- **Satisfactory** — Approval Criteria are complied with in a satisfactory manner, but there is some room for improvement as only some criteria have been met.

- **Good** — Approval Criteria are complied with and most criteria have been met.

Final considerations:

The purpose of this template is to allow the Member State to make a final statement that it is able to provide the relevant service. This statement is submitted to eHMSEG, which may recommend to eHN that the MS be allowed to go live and provides eHN with the final document upon which it can give its approval. As such, the statement should be based on other documents that support the claim of each MS for CBeHIS operational readiness.

The template is filled in by the Member State and provides a summary of the results described in documents created in the Member State during the preparation phase and the Initial Audit and conformance testing event. The filled-in template is then validated by the Auditing Body, after which it will become the basis for the Recommendation Report produced by eHMSEG[10] for eHN to make a final decision on the MS's readiness to "go live". The template itself is not a substitute for a deeper involvement and insight into the MS' CBeHIS operational preparedness but serves as an aid in creating a decision-making recommendation report in order to reduce the risk of permitting a MS to enter CBeHIS operations.

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[9] This refers to the services already provided in previous waves. Mark with an x where applicable.
[10] Same as no. [1]

1. LEGAL Interoperability Readiness Criteria

NO.	CRITERION	READINESS LEVEL STATEMENT	REFERENCE TO THE DOCUMENT (abbreviation, section and/or page)	REMARKS
1.1	MS has made all necessary legal provisions including those required under Directive 2011/24/EU for CBeHIS operation, guaranteeing this through the signature of the Legal Agreement by its competent National Authority responsible for NCPeH	1-Yes 2-No		

2. ORGANISATIONAL Interoperability Readiness Criteria

NO.	CRITERION	READINESS LEVEL STATEMENT	REFERENCE TO THE DOCUMENT (abbreviation, section and/or page)	REMARKS
2.1	*A single NCPeH* communication gateway is responsible for interaction.	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
2.2	The *monitoring procedures* are established.	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
2.3	*National training materials and activities* are provided to support CBeHIS operation.	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
2.4	*Support* system is designed and set up.	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
2.5	*Health professionals* are engaged in order to sustain the service operation.	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
2.6	Citizens are informed about CBeHIS provision.	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
2.7	The responsible data controller and data processor in accordance with the provisions of Directive 95/46 EC	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		

	are identified.			
2.8	Member State is able to provide figures on the usage of the cross-border Patient Summary by its own patients (acting as Country A) and/or foreign patients (acting as Country B).	1-Yes 2-No 3-N/A[11]		
2.9	Member State is able to provide figures on dispensed cross-border ePrescriptions to its own patients (acting as Country A) and/or foreign patients (acting as Country B).	1-Yes 2-No 3-N/A[12]		
2.10	Member State is able to design, set up and implement an evaluation strategy to measure national *usage* and *impact* of cross-border eHealth service(s) provision.	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
2.11	An *incident management* solution to support health professionals, healthcare providers and citizens is established and maintained.	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
2.12	An appropriate *audit trail* system is established (allowing authorised official bodies to duly inspect the data collected, processed, translated and transmitted).	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		

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[11] Member State applies for ePrescription only.
[12] Member State applies for Patient Summary only.

3. TECHNICAL Interoperability Readiness Criteria

NO.	CRITERION	READINESS LEVEL STATEMENT	REFERENCE TO THE DOCUMENT (abbreviation, section and/or page)	REMARKS
3.1	Member State is able to *connect the NCPeH technical gateway to the national infrastructure.*	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
3.2	Appropriate *security and data protection* systems to conform to CBeHIS requirements are established.	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
3.3	Results of Connect-a-thon testing event are available and MS is able to perform scrutiny and peer-to-peer tests, supervised by *external entity.*	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		

4. SEMANTIC Interoperability Readiness Criteria

NO.	CRITERION	READINESS LEVEL STATEMENT	REFERENCE TO THE DOCUMENT (abbreviation, section and/or page)	REMARKS
4.1	Member State has the current versions of the *Master Translation Catalogue* (MTC) and the national part of the *Master ValueSet Catalogue* (MVC), and keeps them updated and maintained to the latest version.	1-Yes 2-No		
4.2	There is a *designated national competent entity* that is responsible for the accuracy and integrity of the semantic transformation (e.g. translation and mapping).	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
4.3	National versions used in the semantic transformation of the controlled vocabularies are maintained.	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		

5. OVERALL Interoperability Readiness Criteria

NO.	CRITERION	READINESS LEVEL STATEMENT	REFERENCE TO THE DOCUMENT (abbreviation, section and/or page)	REMARKS
5.1	Member State adheres to and cooperates in accordance with the"*Governance model for the eHealth Digital Service Infrastructure during the CEF funding*", and will continue to do so.	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
5.2	MS's competent national authority responsible for NCPeH has *signed the Legal Agreement (LA).*	1-Yes 2-No		
5.3	Member State has complied with the "Organisational Framework of eHealth NCP (*OFW-NCPeH*)".	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		
5.4	MS has produced a service compliant with eHN's "*Restructured Guidelines for cross-border exchange of patient summaries and ePrescriptions*".	1-Critically deficient 2-Weak 3-Satisfactory 4-Good		

General remarks (further improvement plans, overall picture, etc.)

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