



# **CBeHIS**

# **Security Requirements and Impact**

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# What is CBeHIS?

**Cross-Border eHealth Information Services** are processed via NCPeH for the purpose of cross-border healthcare, as they were agreed by the eHN (Patient Summary for unscheduled care; ePrescriptions and eDispensations) and as they will be agreed by the eHN in the future.

**Infrastructure** = eHDSI

**Operations** = 2 use cases

- Patient Summary
- ePrescription and eDispensation
- ...EHR?...???



# eHDSI Governance Model

**eHealth Digital Service Infrastructure** enables the provision of CBeHIS via NCPeH as Generic Services under the responsibility of the Contracting Parties and Core Services.

- **eHealth Policy Owner – eHealth Network**
- **eHDSI owner and co-owner:** EC - DG SANTE (Directorate B), CNECT (Directorate H)
- **Operational Management Board (eHOMB):** European Commission - DG SANTE (B3, A4), CNECT (H3), DIGIT, Chair and co-chairs of eHMSEG
- **eHealth Member State Expert Group (eHMSEG)-** Managers responsible for implementing the eHealth National Contact Point, nominated by the participating Member States (MS)
- **eHDSI Solution Provider:** EC - SANTE (A4), DIGIT (A3, B4)

# eHDSI Services System

CONFIGURATION

CENTRAL SERVICES

Configuration services

Terminology services

RUN-TIME

DISTRIBUTED SERVICES

NCPeH  
Country x

NCPeH  
Country y

NCPeH  
Country z

NCPeH  
Country ...

## Central Services

- 1 EU wide instance
- Configuration

## NCPeH – National contact Point for eHealth

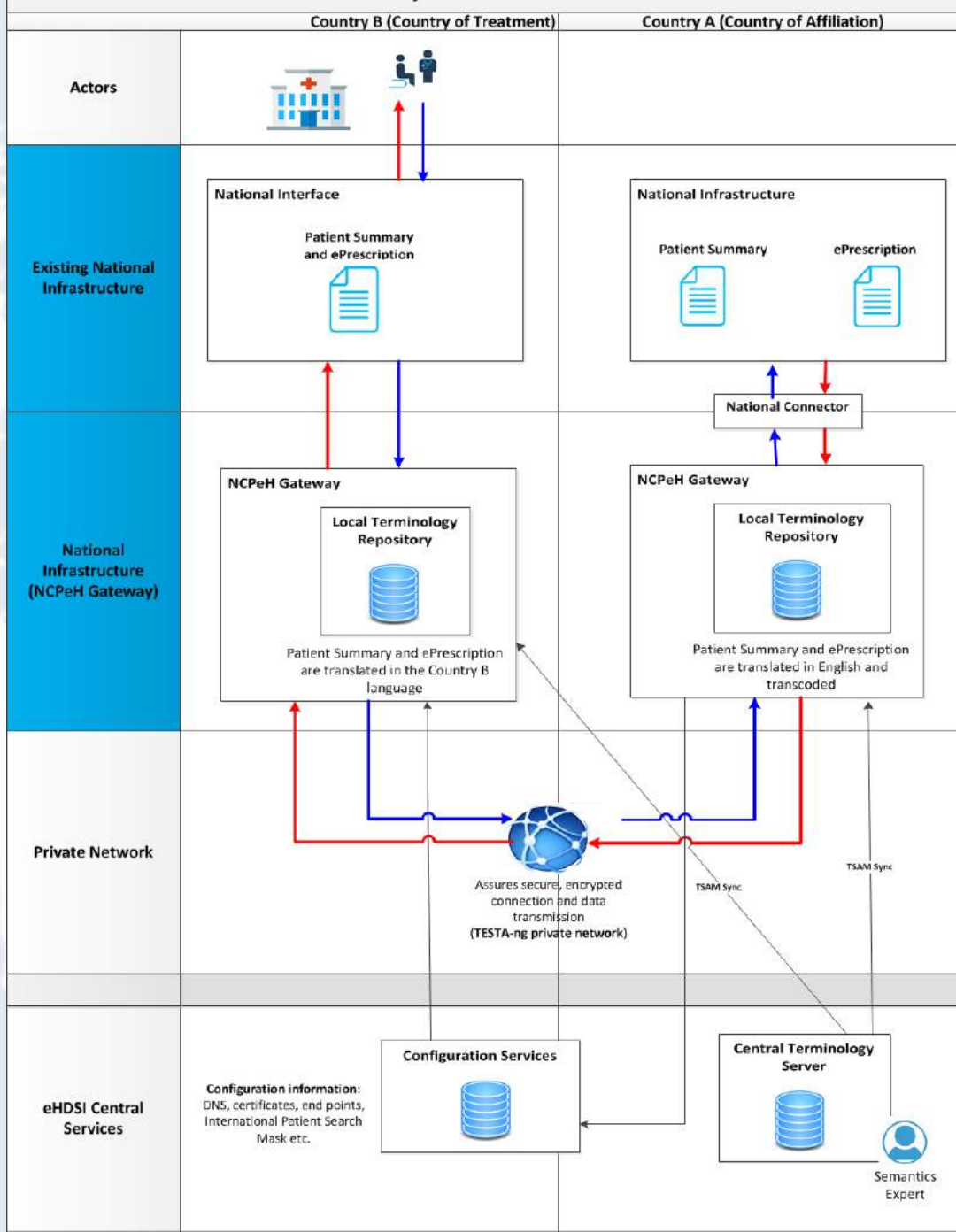
- 1 per Country
- Run-time



eHDSI Waves		2018 - Wave 1				2019 - Wave 2				2020 - Wave 3				2021 - Wave 4			
eHDSI Services		PS A	PS B	eP A	eP B	PS A	PS B	eP A	eP B	PS A	PS B	eP A	eP B	PS A	PS B	eP A	eP B
1	Finland			X					X								
2	Estonia				X			X		X	X						
3	Czech Republic	X	X									X	X				
4	Luxembourg		X			X						X					
5	Portugal	X	X	X	X												
6	Croatia		X	X	X	X											
7	Malta	X	X														
8	Cyprus					X	X	X	X								
9	Greece						X	X	X	X							
10	Belgium						X			X							
11	Sweden											X	X				
12	Austria									X	X	X	X				
13	Italy									X	X	X	X				
14	Hungary									X	X	X	X				
15	Ireland									X		X					
16	Poland											X	X				
17	Germany									X	X						
18	France									X	X						
19	Spain									X	X					X	X
20	Slovenia													X	X	X	X
21	Lithuania															X	X
22	Netherlands														X		
Wave SUMMARY		3	5	3	3	3	3	3	2	10	7	8	6	1	2	3	4
eHDSI ACCUMULATED		3	5	3	3	6	8	6	5	16	15	13	12	17	17	16	16



# eHDSI – Systems and Data Flow





# eHDSI



# Security aspects of CBeHIS

*What needs to be taken care of to enable health data secure flow across borders?*

- Protection of personal (sensitive) data
- Secure identification/authentication of patients/healthcare professionals
- Technical security of the infrastructure
- Circle of trust between MS
- European legislation - GDPR
- Central services – MVC, MTC, SMP



# **ALL NCPs MUST ENSURE THE SECURITY**

- **Confidentiality**
- **Integrity**
- **Availability**
- **Non-repudiation**
- **Authenticity**
- **Auditability**

**OF ALL DATA PROCESSED ON THEIR  
TERRITORY!!!**



# Tools for ensuring security in CBeHIS

- Test Framework
- Audit Framework.
- Agreement between NCPeH's – circle of trust
- TESTA-NG and TESTA Access Points in MS
- Informed Patient Consent
- Patient Information Notice



# TEST FRAMEWORK

## PURPOSE:

Define the common methodology and procedures to test and assess the generic services infrastructure (NCPeH Technical Gateway) conformance with eHDSI Specifications.

Testing conformity to the eHDSI interoperability specifications for:

- a) The NCPeH technical gateway (e.g. peer to peer workflow tests);
- b) The clinical documents exchange (e.g. documents scrutiny tests);
- c) The Functional use cases (e.g. functional testing, semantic and document validation as well as formal compliance testing of audit trails and security provision)

Testing tools – TESTA connectivity, IHE Gazelle, ...

Testing reports (conformance and functional) need to be presented, when a MS requests to „go live“.

# TESTA NG AND TESTA ACCESS POINTS (TAP)

- Technical change made in 2017 to the eHDSI – moving the exchange processes to TESTA-ng
- **The TESTA-ng network is a proven, operational and secure infrastructure with guaranteed service and performance levels. The infrastructure and security provisions can ensure**
- **Currently it supports EU institutions, agencies and their bodies, through secured connectivity exchange of data and interoperability for more than 100 applications, many of which require a high level of security for high sensitive and critical data.**
- **NCPeHs connect to the infrastructure via their „TAP“ – TESTA access points**

# TESTA NG AND TESTA ACCESS POINTS (TAP)

- Technical change made in 2017 to the eHDSI – moving the exchange processes from IPsec VPN over internet to **TESTA-ng**
- **TESTA-ng – under the responsibility of DG-DIGIT**
- The TESTA-ng network is a **proven, operational and secure infrastructure with guaranteed service and performance levels.**
- NCPeHs connect to the infrastructure via their „**TAP**“ – **TESTA access points.**
- MS use TESTA-ng for two purposes:
  - To retrieve from the eHDSI Central Service (point 1f. below) the necessary configuration files for the proper operations of the NCPeH Gateway and Terminology services.
  - As a channel to transfer the ePrescription and Patient Summary in a secure way between the Member States.



# AUDIT FRAMEWORK

## PURPOSE:

**Objective and independent evidence that each NCPeH implemented and operates in compliance with agreed Administrative & Technical & Physical {requirements}**

## AUDIT CRITERIA:

**Set of the applicable requirements that have been defined and mutually agreed through a number of arrangements throughout the evolution of eHealth:**

- **Legislative and regulatory requirements including mutual agreements (MoU's)**
- **Organisational and management requirements**
- **Information Systems Security and Service Continuity requirements**
- **Operational requirements including Service Level Agreements**
- **Requirements on Semantics incl. security and privacy of data**





# **AGREEMENT BETWEEN NCPeH's**

**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**

- **Describes the criteria for the processing of personal data concerning health for the purpose of cross-border healthcare according to Directive 2011/24/EU by means of the CBeHIS**
- **Is voluntary**
- **Materializes the commitment of the Contracting Parties to fulfil all the criteria required for the participation in CBeHIS**
- **Helps to build the „circle of trust“ between the involved entities**
- **Handles Patient Consent principles and requirements**



# PATIENT INFORMATION NOTICE

## „PIN“

- MS have to find ways of providing the PIN to citizens/patients – informing them about what will happen with their data in eHDSI
- Informing EU citizens about their data protection rights in different European countries
- Country „A“ PIN vs. Country „B“ PIN
- Fulfilling legal obligations stemming from GDPR
- Art. 13 (Information to be provided where personal data are collected from the data subject) and art. 14 (Information to be provided where personal data have not been obtained from the data subject) of the GDPR
- The use of the PIN has been highly recommended by the Art29 WP on DP.
- eHDSI – our goal is to provide common information concerning the patient’s data protection that can be used and shared among the participating MS – communication and collaboration tools



NCP - Liferay   Patient Summary   +

localhost:8080/web/guest/ncp   Search

My Sites 0   Petr Pavlinec













# NIX-ZD Liferay

Welcome   **NCP**

NCP

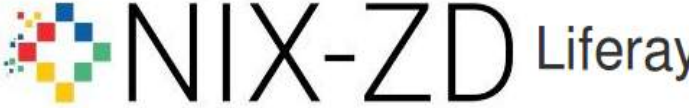
portalb

## Select the country of the patient

<b>Austria</b> 	<b>Switzerland</b> 	<b>Czech Republic</b> 	<b>Germany</b> 	<b>Denmark</b> 	<b>Estonia</b> 
<b>Spain</b> 	<b>France</b> 	<b>Italy</b> 	<b>Netherlands</b> 	<b>Sweden</b> 	<b>Slovakia</b> 

NCP - Liferay Patient Summary



localhost:8080/web/guest/ncp?p\_auth=5NtXFBf1&p\_p\_id=portalb\_WAR\_epsosportal&p\_p\_lifecycle=1&p\_p\_st



Welcome NCP

NCP

portalb

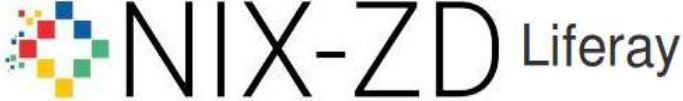


**You can find the patient using the follow**

Unique Identifier:\*

NCP - Liferay Patient Summary



localhost:8080/web/guest/ncp?p\_auth=5NtXFBf1&p\_p\_id=portalb\_WAR\_epsosportal&p\_p\_lifecycle=1&p\_p



Welcome NCP

NCP

portalb



**You can find the patient using the following criteria**

Unique Identifier:\*

[Download the eID Middleware](#)

Given Name: Pierre  
Surname: Bouchez  
Date of Birth: July 13, 1980  
Street:  
Zip/Postal Code: 1040  
City: Bruxelles  
Country: BE

[View Patient Summary](#)  
[View ePrescriptions](#)  
[Consent Handling](#)  
[Submit a HealthCare Encounter Report](#)

NCP - Liferay Patient Summary



localhost:8080/web/guest/ncp?p\_auth=5NtXfBf1&p\_p\_id=portalb\_WAR\_epsosportal&p\_p\_lifecycle=1

Welcome NCP

NCP

portalb

You have to declare why do you want to have access to the patient data

**Patient Summary**

Given Name: Pierre  
 Surname: Bouchez  
 Street:  
 Zip/Postal Code: 1040  
 City: Bruxelles  
 Country: BE

**You must enter the Patient Confirmation for your C**

Purpose of use

Emergency Department (EMERGENCY)  
 Healthcare Facility (TREATMENT)



NCP - Liferay Patient Summary

localhost:8080/web/guest/ncp?p\_auth=5NtXfBf1&p\_p\_id=portalb\_WAR\_epsosportal&p\_p\_lifecycle=1&p\_p\_state=nc

NCP

My Sites 0 Petr Pavlinec




portalb

**You will now have access to the patient summary documents of the patient below**

**Patient Summary**

Given Name: Pierre  
 Surname: Bouchez  
 Street:  
 Zip/Postal Code: 1040  
 City: Bruxelles  
 Country: BE

Creation Date/Time:	Description:	Author:	
February 14, 2017	The Patient Summary document (CDA L3 / Structured body) for patient 1		 
February 14, 2017	The Patient Summary document (CDA L1 / PDF body) for patient 1		

# eHEALTH DSI Operations

<https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/>

***Thank you for your attention!***

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