



**HEALTHeID**  
eIDAS – OpenNCP  
Connector for eHealth

## **eHN update on technical implementation and Member States participation in the HEALTHeID Transfer-a-thon**

**Information Note**  
**eHN meeting**  
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## Acronyms

Acronym	Description
AAL	Authentication Assurance Level.
CEF	Connecting Europe Facility
CBeHIS	Cross Border eHealth Information Services
DG	European Commission Directorate General
DG CONNECT	Directorate General for Communications, Networks and Technology
DG DIGIT	Directorate General for Informatics
DG SANTÉ	Directorate General for Health & Food Safety - European Commission
DSI	Digital Service Infrastructure
EC	European Commission
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHealth Member State Expert Group
eP	ePrescription
e-SENS	Electronic Simple European Networked Services
EU	European Union
MS	Member States
LSP	Large Scale Pilot
NCP	National Contact Point
NCPeH	National Contact Point for eHealth
PS	Patient Summary
SPID	Sistema Pubblico di Identità Digitale (Digital Identity Public Service – Italy)
WS	Workshop

## 1 Preamble

HEALTHeID has been a CEF supported project, which brought together the NCPeH and the eIDAS nodes from 4 core MS, joining efforts to conceptualize, design, implement and test a legally robust technical solution that would have the potential to replace the currently manual - and to a great extent insufficiently secure – patient identification and authentication procedures in the current Cross Border eHealth Information Services (CBeHIS). Establishing a secure connection to the national eIDAS is clearly a responsibility of the on-line service providers. In the present eHDSI use cases, there are no on-line services provided directly to the patient e.g. in the form of accessing data, providing consent or managing access to their data. HEALTHeID has explored how the concept of eIDAS based electronic identification may be transferred to the current cross border context of Patient Summary and ePrescription services and has concluded that, in this case the NCPeH in the country of treatment would become an on-line service provider for the patient. However, it was envisaged and was reconfirmed in practice that the implementation of the HEALTHeID or similar Connector would be needed at national level.

Against this background, the four core countries developed and tested a common solution of a HEALTHeID Connector, reported and exchanged regularly with the eHMSEG and developed documentation in the form of a Briefing Paper and an Implementation Guide, with the aim to facilitating transferability to other MS wishing to adopt the solution and/or build national flavours based on it. The resulting eID solution components are made available as Open Source Software to the eHDSI Owner and the National Contact Points for eHealth.

The Information Note provides essential information on the legal and technical requirements and formulates a number of Recommendations on the further steps needed in order to support the transition to eIDAS based patient identification and authentication, leveraging on the analysis, design and implementation of this HEALTHeID initiative.

## 2 Why eIDAS based electronic identification and authentication for cross border eHealth?

**The eIDAS Regulation** enables the use of electronic identification means and trust services (i.e. electronic signatures, electronic seals, time stamping, registered electronic delivery and website authentication) by citizens, businesses and public administrations to access on-line services or manage electronic transactions. It relies on a robust trust framework, which supports common definitions of key aspects such as Authentication Assurance Levels (AALs) and requirements for national eID schemes that may be notified. Importantly, it ensures that qualified means and services have the same legal value as paper based documents and wet signatures in cross border transactions and makes mutual recognition of notified electronic identification schemes mandatory as of autumn-2018. The Regulation is furthermore a self-contained legal framework in its own, in other words it contains all elements that are necessary to create the needed legal certainty for citizens and digital service providers in cross border encounters.

Cross border eHealth is subject to this Regulation to the extent that on-line services are provided cross border directly to European citizens – health professionals or patients. In this cases, compliance will therefore a legal requirement, if they become a online service, but also a unique enabler of building trust in national eID frameworks. It furthermore promotes - and the eIDAS based solutions support - a paradigm where the citizens/patients may identify and authenticate themselves using their national

eID credentials via a trust network of national eIDAS nodes; once robustly identified and authenticated, the citizen may access cross border on-line services and manage and control access to own personal documents and data, including health data. These are important pre-requisites for the implementation of the EC “**Communication on enabling the digital transformation of health and care in the Digital Single Market**; empowering citizens and building a healthier society” in all of its three pillars:

- **Priority 1** - Citizens’ secure access to electronic health records and the possibility to share their records across borders, and the use of e-prescriptions.
- **Priority 2** - Supporting data infrastructure, to advance research, disease prevention and personalised health and care in key areas included rare, infectious and complex diseases.
- **Priority 3** - Facilitating feedback and interaction between patients and healthcare providers, to support prevention and citizen empowerment as well as quality and patient-centred care, focussing on chronic diseases and on a better understanding of the outcomes of healthcare systems.

The Multi Annual Work Programme 2018-2021 of the eHealth Network is also focused on topics relevant to the above DTHC DSM priorities, including patient access, use of data and digital health literacy of patients, mHealth apps, telehealth and patient-generated data; innovating use of health data; enhancing the continuity of care (e.g. stimulating and supporting the adoption of eHDSI services) and overcoming implementation challenges (e.g. interoperability & standards, skills, trust, security and privacy).

In the e-SENS’ WP4 Implication of eIDAS Regulation for eHealth<sup>1</sup> is recommended that: “The eHealth Network should consider, in the relevant guidelines, appropriate authentication assurance levels (eIDAS AAL) for electronic identification and authentication for the purposes of cross border eHealth services supported by the eHealth DSI balancing the risks associated to individual or groups of health services and existing national laws and infrastructure capabilities”

### 3 Reframing Patient identification in the eIDAS legal framework

The exploration on the topic of electronic identification and authentication is not new. It was first addressed in the epSOS Large Scale Pilot (LSP), with a view to providing a practical solution to running the LSP. The co-operation with STORK, at that time through the STEPS initiative, did not come to fruition of a realistic approach, mainly because the scenarios explored by STORK did not resonate with the on-site presence of the patient and the cross border transmission of patient identifiers submitted by the health care professional, on behalf of the patient. As a result, epSOS did not address the issue of electronic patient Identification and Authentication. This topic was explored in e-SENS, as part of its eHealth pilot and the relevant contributions were invaluable in understanding the implications of eIDAS for cross border eHealth; HEALTHeID has built further on that work.

The definitions provided in the eIDAS Regulation differ in their articulation from those of the eHDSI Identity Management Specification, however they are not in effect misaligned. It is important, however, to clarify that patient identifiers serve primarily to locate the person in the national eHealth system, while electronic identification of the person aims at identifying and authenticating an

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<sup>1</sup> One view on the Implications of the eIDAS Regulation for eHealth is laid down in the eponymous document from the legal expertise center of e-SENS, which was presented and discussed in the e-SENS JAsEHN Joint Workshop which took place on the 30<sup>th</sup> January 2017 in Berlin. Both parts of the eIDAS Regulation were equally addressed in the e-SENS document.

individual. Both aspects are necessary for realizing patient enabled on-line cross border eHealth use cases; it should be however noted that such use cases need not necessarily be realized on the current DSI. In all cases, the Service Provider should first expose the on-line service to the patient, which in HEALTHeID is realized through the Health professional triggering the creation of a health encounter by creating a session and sharing that reference with the patient.

Where a notified, nationally issued eID scheme with unique identifier that is used as the patient ID number for eHealth use cases will be employed by country A, citizen and patient identification may collapse into one single step. The same applies in the currently few situations where a notified, nationally issued sector specific eHealth eID scheme with sector specific patient ID number for eHealth use cases will be employed.

In all other cases, patient identification and authentication in cross border eHealth may be generally described as a two-step process: in the first step, the citizen involved in a cross border eHealth encounter must be authenticated under eIDAS; subsequently the citizen must be further identified *as a patient*, by means of his/her patient identifier which links the person uniquely to his/her electronic health documents and entitlements in the national health care system. For example, Where a MS is in the position to technically and legally map the person identifiers to the patient identifiers, this mapping will become a national level action, Where such mapping is not possible or the preferred approach, the authenticated citizen may be prompted to submit his/her own patient identifier, electronically on-line, replacing the respective action performed by the health professional.

For example, in the Italian case, the presently suitable attribute to identify the patients is the Fiscal Code, which is available among the minimum data set of SPID<sup>2</sup> eID. However, the Italian eIDAS notified minimum data set did not include the Fiscal Code, Italy was able to request to, the SPID Identity Providers to retrieve the Fiscal Code from the SPID assertion and inject it as an optional data into the eIDAS token, to allow the patient identification and clinical document retrievals. The Italian Digital Agency has gained awareness of the need to have the Fiscal Code (PatientID) available in the authentication message released by their eIDAS node thanks to the project HEALTHeID: very recently has become available for individuals the “TaxIdentifier” (i.e the Fiscal Code) as additional attribute over the minimum data set notified by Italy.

## 4 Patient - oriented on-line services in the context of eIDAS

eIDAS assumes interaction between three parties: a **Citizen** wishing to access a cross border service and therefore interacting with a **Service Provider** operating in a country other than his/her country of affiliation, the latter being a *relying party* for identifying and authenticating this citizen through its respective **national eIDAS node**.

In the eIDAS realm, it is therefore essential to recognize and map three roles: **the patient from country A**, is seeking to receive an **(on-line) service** i.e., enable access of PS or ePrescription by a HP in country B from **NCPeH in country B**, which is then **“the relying party”** i.e. relies upon the **national eIDAS node** of country B for identifying and authenticating the individual.

In the absence of currently implemented eHDSI on-line services provided directly to the patient e.g. in the form of accessing data, providing consent or managing access to own data, HEALTHeID has

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<sup>2</sup> The Italian network SPID provides a common service to authenticate Italian citizens among hundreds of domestic on-line Service Providers

explored how the concept of eIDAS based electronic identification may be transferred to the current cross border context of Patient Summary and ePrescription services and has reached the following preliminary conclusions.

1. Irrespective of chosen legal basis for access to patient data in a MS, the patient must be informed on the identity of the data controller, purpose of the processing and the time period for which the data will be kept (as detailed in Articles 5 and 13, of the GDPR) through a Patient/Privacy Information Notice (PIN). Providing an **on-line PIN service** is therefore a potential on-line service relevant to all MS;
2. Identification attributes provided by Country of Affiliation (Country A) may or may not include a patient identifier. In the latter case the patient identifier must be uniquely associated to the person identified and authenticated. Providing a functionality for patient entering their **patient identifier on-line** (a function today performed by the Health Professional) could be a second on-line service that would be relevant to certain MS

A third service “**Patient providing on-line consent** in country B” has in addition been analysed, however its technical development is not within the scope of HEALTHeID.

## 5 Design and Implementation of the HEALTHeID Connector – Re-usable Assets

HEALTHeID developed functional specifications, design component, as well as a reference implementation of the HEALTHeID Connector. More specifically, the following technical assets are of relevance to MS implementing the HEALTHeID Connector and the eHDSI Solution Provider:

1. **Functional Requirements** which included:
  - a. Definition of the high-level requirements for HEALTHeID implementation, taking into account authoritative sources (e.g. eIDAS specification v1.1) in order to ensure technical and regulatory compliance of the HEALTHeID Connector implementation.
  - b. Data gathering and description of the different eIDAS dataset and NCPeH nodes, with the purpose to catch the peculiarities of different countries scenarios.
2. **Design of the reference implementation** of the HEALTHeID Connector, situated in country B (Country of Treatment) as a generic software component allowing the mandatory eIDAS functionalities into an eHealth DSI’s eHealth NCP architecture, as well as into stationary and mobile end-user eID-enabling services.
3. The set-up of the **specific test-beds** for HEALTHeID network, meaning the country-specific eIDAS node and NCPeH node, as well as the set-up and testing to interact among different components.
4. The implementation of components with the **reference of the HEALTHeID architecture** (source code and documentation) which also included:
  - a. Development of specific components, not strictly in the HEALTHeID Connector, to allow the establishment of a full working testing environment (e.g. the Italian National adaptor)
  - b. **Documentation:** the Integration Guide, to properly document installation and configuration of components

## 6 Transferability of the Solution

Optimizing transferability to other MS was pursued by means of regular updates during the eHMSEG meetings ensuring timely information and receiving of feedback and also by facilitating the participation of MS not participating in HEALTHeID in the Transfer-a-thon, organized at the end of the project. More specifically:

### 1. Communication

Since October 2018, reporting of project activities was provided at each eHMSEG meeting (October 2018, December 2018, March 2019, May 2019, October 2019). Updates were provided by means of brief Cover Notes provided to the eHMSEG members before the meeting, as well as PPTs presented during the meeting, followed by a discussion/questions.

HEALTHeID Vision, Usability Requirements, and Functional Specifications were provided to MS and to eHDSI Owner and Solution Provider by e-mail and also via the project-dedicated website <https://www.spms.min-saude.pt/healtheid/>.

Information about the Transfer-a-thon as well as about the workflow and the implementation tool kit and other project information was provided to MS during the bi-weekly “Cross-border Implementation TCons”, which is regularly attended by eHMSEG members and members of the MS NCPeH teams.

### 2. Transfer-a-thon

The Transfer-a-thon was organized as a Demonstration activity aiming at demonstrating on site the practical use and implementation of the HEALTHeID Connector, to which all MS and the European Commission were invited to participate. The Transfer-a-thon was preceded by workshops/presentations to DG SANTE (Solution Provider), DG Connect, DG DIGIT, and eHMSEG Chairs (representing the Solution Owner). The workshops have also helped co-design the Transfer-a-thon event.

Representatives of the following countries have attended the event: Croatia, Czech Republic, Sweden, Greece, Italy, Lithuania, Netherlands, Portugal and Romania. The event was also actively attended by representatives of DG SANTE and DG DIGIT.

The Transfer-a-thon ran in two streams and included a practical demonstration of NCPeH – eIDAS integration.

- ✧ The **Business Workstream** focused on a productive exchange following presentation of HEALTHeID Vision and legal aspects, Usability Requirements, Use Cases and technical approach which was attended by MS representatives and the EC participants and resulting in the formulation of a set of Recommendations on the next steps presented in the next section.
- ✧ The **Technical Workstream** was attended by MS and EC technical experts, who followed the implementation of the Integration Guide under the direction of the HEALTHeID Core development team. This activity involved practical guidance of the NCPeH-eIDAS installation manual with HEALTHeID piloting countries and with other participating MS. Practical demonstration finally took place between PT and IT.



## 7 Conclusions and Recommendations

The rich discussion focused primarily considered the usability, security and patient empowerment. Aspects as well as on the actions needed to migrate the HEALTHeID Connector in to the Cross Border eHealth Interoperability Services. The Conclusions may be summarized as follows:

### 1. From a legal and organizational perspective:

- a. eIDAS eID appears as the only way to enable widespread adoption of patient strong authentication, as it allows to leverage the relevant EU policy and legal basis, the existing technical eIDAS infrastructure and the common specification of Levels of Authentication as a way to compare and make interoperable different authentication schemas at broad European level.
- b. It is generally agreed that patient active participation in his identification process has a significant impact on the security of the cross border workflows
- c. The proposed solution supports the implementation of the DTHC Communication and as such it is expected to find a major field of application in future use cases fostered by the Communication.
- d. An eventual transition to CBeHIS that would include eIDAS based patient authentication would further require that the current model PIN “Patient Information Notice Guide”, is updated, taking into account the HEALTHeID contribution and allowing a smooth extension with minimal impacts for Member States and users.

### 2. From an Organisational and Operational Perspective:

- a. The adoption of the HEALTHeID Solution requires that the eID attribute schema and the patient identifier may be uniquely correlated. To allow such interoperability, a Member State should:
  - i. either notify an eID scheme that is specific to the health sector, or allow the patient insert own patient identifier
  - ii. have the appropriate structure to manage and reconcile the attribute retrieved through eIDAS with the patient identifier required for the provision cross border eHealth services.
- b. Adoption of the HEALTHeID Connector will further require co-ordination action with the national eIDAS nodes.

### 3. From a Usability Perspective:

- a. Despite some concerns as to the impact on the usability of the current CBeHIS, it is agreed that the HEALTHeID Connector architecture is a novel solution aiming to empower the patient in the usual NCPeH flow with a new authentication opportunity. The new service requires different steps in the overall service provision and hence some changes from the usability perspective of the different actors. The workflow of patient enabled electronic identification and authentication may vary depending on the practices adopted by the patient Country of origin.
- b. It is generally agreed that introduction of patient enabled identification and authentication changes the HP workflow and influences usability, in a way that is yet to be determined in practice.

#### 4. From a technical perspective:

- a. the Transfer-a-thon event achieved a more profound understanding of different member state scenarios of the HEALTHeID proposed scenarios with respect to patient authentication and the national eIDAS eID readiness.
- b. the "minimum-disruption" principle as a design guideline has resulted in insignificant modification to the implementation of the NCPeH gateway infrastructure, allowing both the present and the "HEALTHeID Connector" workflows to co-exist at the technical level.

Based on the above Conclusions, the HEALTHeID group of national NCPeH and eIDAS nodes have formulated the following set of Recommendations:

1. The eHealth Network are invited to consider
  - a. An eIDAS based approach as the way to ensure transparent and consistent interpretation of eIDAS AAL (Authentication Assurance Levels) across MS, leaving no doubt as to the level of trust that is being guaranteed;
  - b. the eIDAS legal framework, integrated in the eHDSI legal framework, as an important enabler and the governing instrument for establishing cross border eHealth electronic identification and authentication Regulation;
  - c. that the functionality for electronic patient identification and authentication in the eHDSI should now be examined in the light of eIDAS, leveraging on national notified eID schemes and cross border eIDAS infrastructure; this option should run in parallel with the current non electronic procedures until all MS have notified an eID scheme and, possibly, are able to persons and patients identification.
2. HEALTHeID has demonstrated a working technical solution which was reproducible among the core MS and transferable to MS participating the Transferathon. In order to support uptake of this solution, it will be necessary that over the next months. The eHN and **eHMSEG** are invited to consider,
  - a. Agree upon and establish the requirement for online services for Patients
  - b. Agree on the Authentication Assurance Level required for cross border services.
  - c. Ways to engage MS over the next months, to explore the potential to adopt and adapt the HEALTHeID Connector
  - d. Support a process for transferring assets and knowledge from the core MS
  - e. Orchestrate the addition of the capability for eIDAS based electronic patient authentication to the current manual procedures.
3. The **HEALTHeID core MS** should be prepared to support MS wishing to implement the HEALTHeID Connector
  - a. Once there is evidence on acceptability by a critical mass of MS, and the eHN has reached its decisions on the Recommendation 1,
  - b. Submit a change proposal to the **Solution Provider** for modifications/additions to the current eHDSI business and functional requirements.



## 8 Reference information from HEALTHeID:

- D1.1 HEALTHeID Vision<sup>3</sup>
- D1.2 Usability Requirements<sup>4</sup>
- D2.1 HEALTHeID Functional Specification<sup>5</sup>
- HEALTHeID Integration Guide
- HEALTHeID Briefing From Business to Use Case

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<sup>3</sup> [https://spms.min-saude.pt/wp-content/uploads/2019/08/D1.1.-HealtheID-Vision\\_Final\\_v1.pdf](https://spms.min-saude.pt/wp-content/uploads/2019/08/D1.1.-HealtheID-Vision_Final_v1.pdf)

<sup>4</sup> <https://spms.min-saude.pt/wp-content/uploads/2019/08/T1.2-Usability-Requirements-Final.pdf>

<sup>5</sup> [https://spms.min-saude.pt/wp-content/uploads/2019/08/D2.1\\_HealtheID\\_functionalSpecs\\_20190523\\_rev.pdf](https://spms.min-saude.pt/wp-content/uploads/2019/08/D2.1_HealtheID_functionalSpecs_20190523_rev.pdf)