TTP eHealth

Batch_Codage

User Manual version 1.1 dated 23/07/2018/04/2018

Researchers or policymakers oft request medical data to make scientific studies. In order to protect the privacy and medical confidentiality, it is especially necessary to ensure that medical information is coded or anonymized before being transferred.

As part of its missions, the eHealth platform can intervene as Trusted Third Party for this "codage" or anonymization, under the surveillance of a Sectorial Committee.

In this role, the eHealth platform has developed a free service, hereinafter called "Batch_Codage", that allows a given medical data owner (institution, healthcare professional, etc.) to code and to transfer medical data to an identified receiver.

The present document is destined to medical data requesters and owners.

All the prerequisites to fulfill before being able to use the "Batch_Codage" service are summarized in the first section of the document. Information concerning the service use is detailed in the second section. This section covers:

- contact information concerning the service,
- some recommendation concerning data encryption,
- the steps to follow in order to build a correct input file,
- the procedure to submit this input file to the service,
- the procedure to access the output file and ask for "decodage".

1. Prerequisites:

Three elements are pre-required to use the eHealth "Batch_Codage" service.

1.1. Agreement from a Sectorial Committee

> Any request for the use of the "Batch_Codage" service requires an agreement from a Sectorial Committee.

The list of the different Sectorial Committees and information concerning the introduction of an authorization request are available at:

FR: *http://www.privacycommission.be/fr/comites-sectoriels*

NL: *http://www.privacycommission.be/nl/sectorale-comites*

Extra information demands can be submitted to *TTP@ehealth.fgov.be*

1.2. Electronic signature of a global document

Once an agreement has been delivered by a Sectorial Committee, a "TTP_GlobalDoc" will be written by the TTP eHealth service (contact: *TTP@ehealth.fgov.be*). This document summarizes the procedure (people involved, transmission details, etc.) of medical data exchange, in accordance with the deliberation of the Sectorial Committee.

The "TTP_GlobalDoc" must be electronically signed by all parts namely in contact with the eHealth platform during the procedure.

A template of this document is available in annex.

Based on the treatment of the global document, the TTP eHealth service will mail back the data owner(s) inviting him (them) to send data. This mail will provide the minimal information needed to call the "Batch_Codage" service" (definitive project name, address of the service, etc.).

1.3. Access to eHealthBox

The use of the eHealth "Batch_Codage" service implies the use of an eHealthBox (secure email box provided by eHealth).

An eHealth certificate must be requested for both sender (as healthcare professional) and receiver to access an eHealthBox.

Detailed information concerning the request of an eHealth certificate is available at these addresses:

FR : *https://www.ehealth.fgov.be/ehealthplatform/fr/certificats-ehealth*
NL : *https://www.ehealth.fgov.be/ehealthplatform/nl/ehealth-certificaten*

- eHealth certificates for acceptation can be requested via the "ETEE Requestor":
  FR : *http://wwwacc.ehealth.fgov.be/JWS/ETEE/etee-requestor_fr.jnlp*
  NL : *http://wwwacc.ehealth.fgov.be/JWS/ETEE/etee-requestor_nl.jnlp*
- eHealth certificates for production can be requested via the "ETEE Requestor":
  FR : *http://www.ehealth.fgov.be/JWS/ETEE/etee-requestor_fr.jnlp*
 NL : *http://www.ehealth.fgov.be/JWS/ETEE/etee-requestor_nl.jnlp*

To require a certificate in the "eHealth Platform Certificate Manager":

- Localize the "Nouvelle Demande/Nieuwe Aanvraag" section (see figure below),
- Select "Demandez un nouveau certificat/Vraag een nieuw certificaat aan",
- Follow the steps

- When asked, choose to "define an application ID"
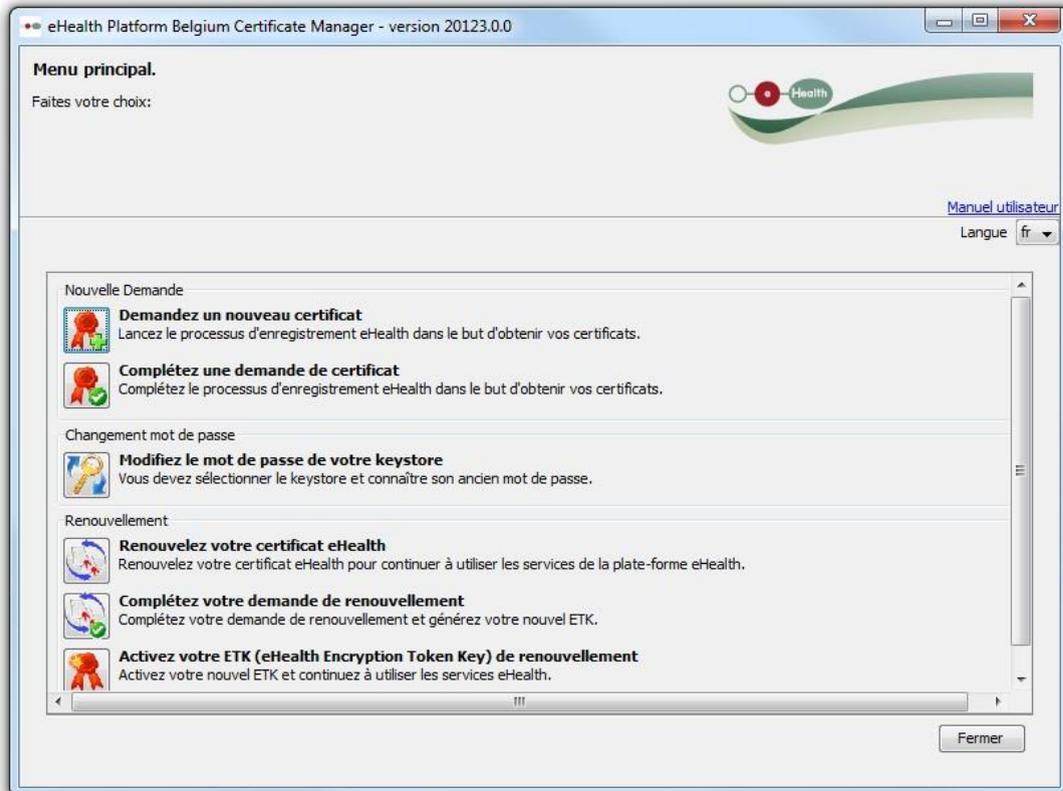
- Enter "TTP" as Application ID (see figure below)
- Submit your request.
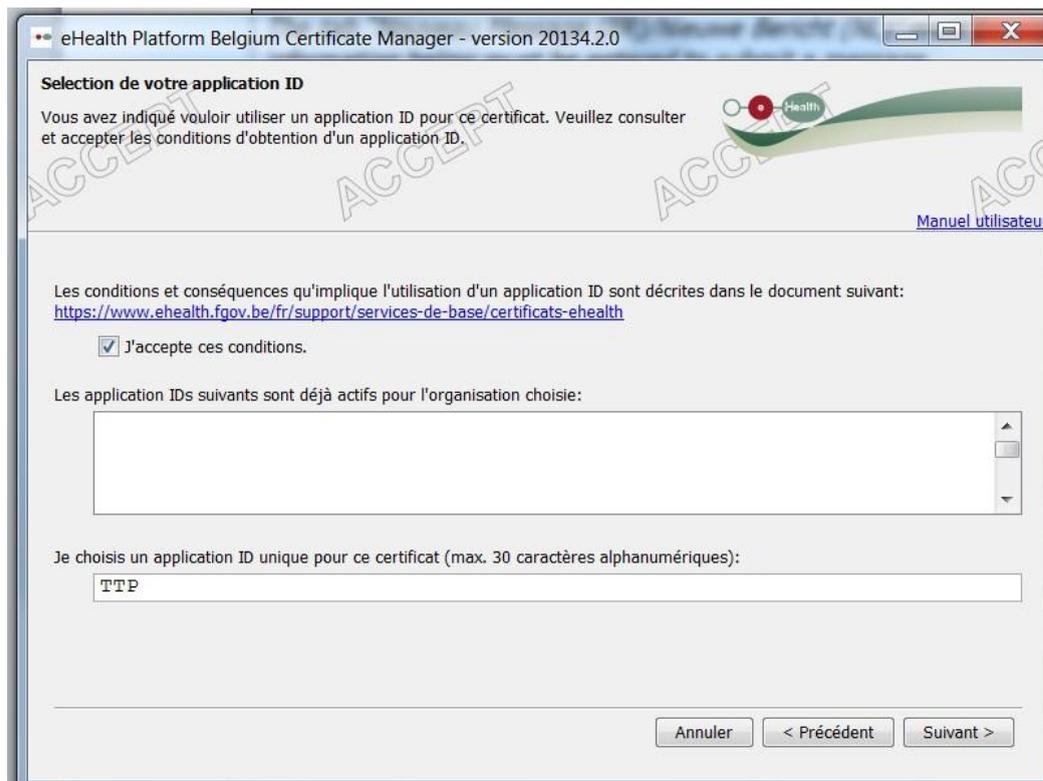
Once eHealth has delivered the new certificate, open the "ETEE Requestor" and

- Select "Compléter une demande de certificat/Vervolledig de aanvraag voor het eHealth-certificaat en ETK".
- Follow the steps

Once all the prerequisites have been fulfilled, the procedure involving the use of the "Batch_Codage" service can be initiated.

2. Using the "Batch_Codage" service:

This section details systematically the complete procedure from the making of a medical data file to its transfer to the receiver.

2.1. Medical Data Encryption:

> This step can only be skipped if the deliberation of the Sectorial Committee specifically authorizes an unencrypted input.

Typically, the medical data of an individual can be split in two different parts: identifiers (like INSS) which need to be coded to prevent any identification of this individual, and all other medical variables.

To prevent any access to this second part, an encryption algorithm can be applied on the data. By this way, the medical data owner is assured only the receiver will be able to see the data.

> The eHealth platform has developed encryption frameworks that can perform end-to-end encryption.

All information concerning the use of these services is available on eHealth portal:
FR *: https://www.ehealth.fgov.be/ehealthplatform/fr/cryptage-end-to-end*
NL *: https://www.ehealth.fgov.be/ehealthplatform/nl/end-to-end-vercijfering*

Encryption with eHealth services is not mandatory but strongly recommended. Other encryption algorithms (not developed by the eHealth platform) may be used but this is not recommended.

Whatever the choice, the use of an encryption algorithm to code medical data fields must be performed in accordance with the receiver. In other words, the encryption must be done with the key of the receiver (aimed for the receiver) or he won't be able to decrypt and access the data.

2.2. Build Input Message:

The sender must prepare an input file that must be structured as below.

The size of the input must not exceed 10MB. Several input files must be built if this limit is reached.

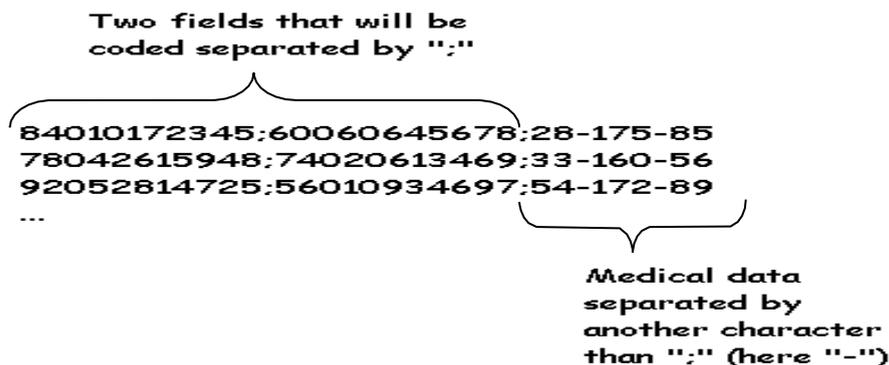The file must be built without headers and must not contain any empty line.

The organization of the variables fields must follow the order described in the "TTP_GlobalDoc" to avoid variables identification problems.

$a_{1,1}$	$a_{1,2}$	$a_{1,...}$	$a_{1,(n-1)}$	$a_{1,n}$
$a_{2,1}$	$a_{1,2}$	$a_{2,...}$	$a_{1,(n-1)}$	$a_{2,n}$
$a_{...,1}$	$a_{...,2}$	$a_{...,...}$	$a_{...,(n-1)}$	$a_{...,n}$
$a_{(p-1),1}$	$a_{(p-1),2}$	$a_{(p-1),...}$	$a_{(p-1),(n-1)}$	$a_{(p-1),n}$
$a_{p,1}$	$a_{p,2}$	$a_{p,...}$	$a_{p,(n-1)}$	$a_{p,n}$

Each row represents a set of data whose columns are separated by the character ";".

All the white shaded columns will be coded one by one via the "Batch_Codage" service. In practice, it will identify each ";" on a row and will code all fields ahead of the last ";".

The grey shaded zone represent data behind the last ";" (medical data, which were encrypted with an algorithm, see previous point). This part of the file will not be modified. The sender must absolutely assure not using any ";" in this zone or the file structure will collapse.

> The easiest way to build such a structure in a file is using spreadsheets. With this method, the organization of the file by line/column is very simple. Once the file has been correctly organized, it must be saved via: File ⮕ Save As ⮕ Save as Type "CSV" (comma delimited).
> Spreadsheets usually use by default the character ";" as separator in a CSV file (verification after saving is strongly recommended).

Example of input file:

```
Two fields that will be
coded separated by ";"

84010172345;60060645678;28-175-85
78042615948;74020613469;33-160-56
92052814725;56010934697;54-172-89
...

Medical data
separated by
another character
than ";" (here "-")
```

2.3. Send message with the input file to the Batch_Codage eHealthBox:

The sender will use his eHealthBox to send a message containing his input file to the eHealthBox defined for the eHealth "Batch_Codage".

The sender must correctly log on the eHealth platform portal via "My eHealth".
FR (ACC):
https://wwwacc.ehealth.fgov.be/fr/myehealth/login?destination=myehealth/page
FR (PRD):
https://www.ehealth.fgov.be/fr/myehealth/login?destination=myehealth/page

NL (ACC):
https://wwwacc.ehealth.fgov.be/nl/myehealth/login?destination=myehealth/page
NL (PRD):
https://www.ehealth.fgov.be/nl/myehealth/login?destination=myehealth/page

As mentioned in the prerequisites, the data sender must have an eHealth certificate. He will be redirected to his eHealthBox.

The tab "Nouveau Message (FR)/Nieuwe Bericht (NL)" must be selected and the information below must be entered to submit a message.

The entries in red are invariables: they cannot be changed and the brackets are mandatory. The other entries will vary from one project to another.

« Nouveau message/Nieuwe Bericht » Tab :
Destinataire: 0809394427-Entreprise (ID of the eHealthBox "Batch_Codage") Sujet:
[Batch_Codage_Encode]
Message: ⦿ Texte + ☑ 📧 Encrypter
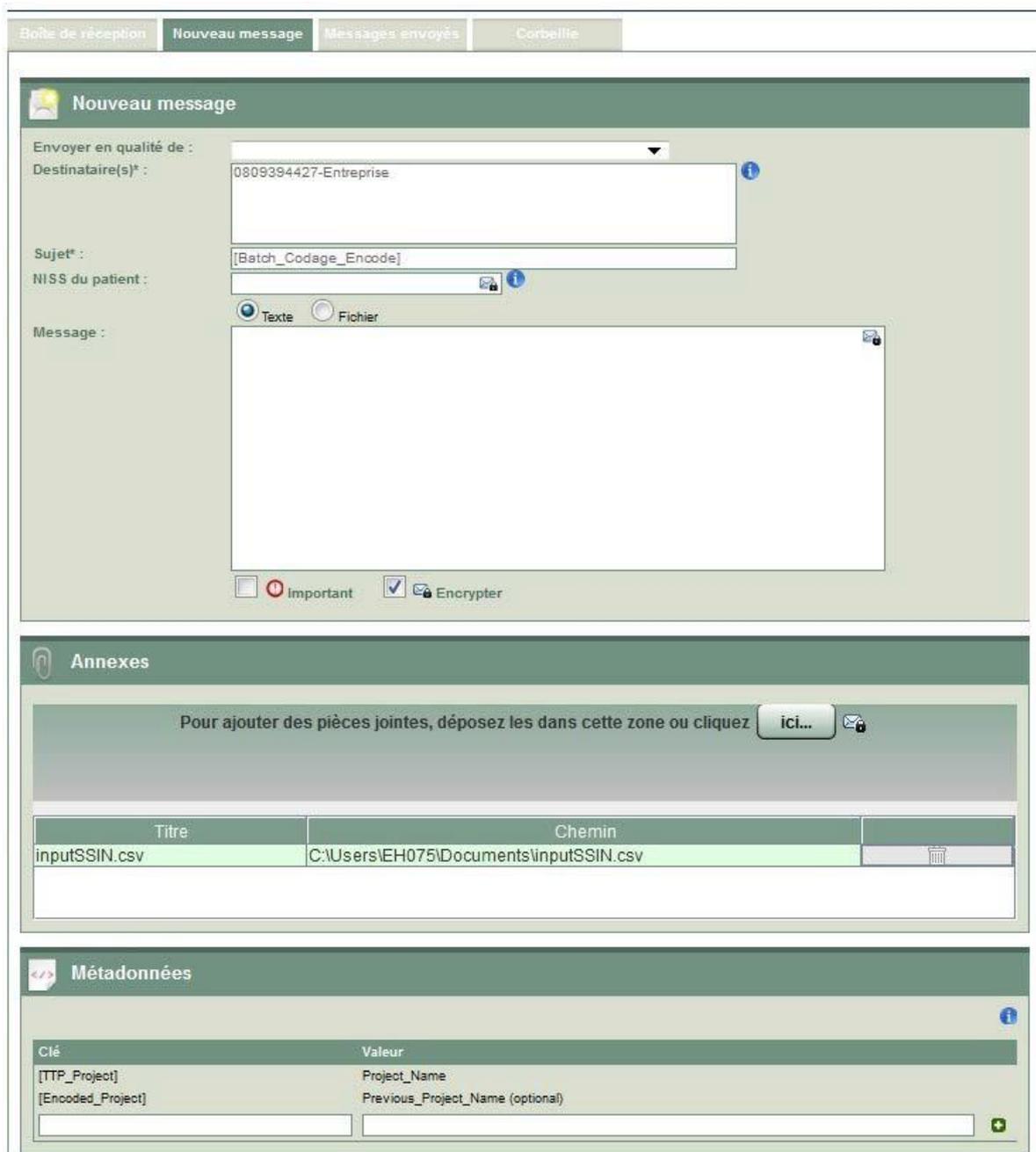
« Annexe/Bijlagen » Tab :
Add TXT/CSV input file containing medical data

« Metadonnées/Metadata » Tab :

Clé/Sleutel :		Value/Waarde :	
	[TTP_Project]		Project_Name
	[Encoded_Project]		Previous_Project_Name
	(optional)		

The figures below illustrate all information that needs to be entered.

Once the message has been written and titled, a simple click on"Envoyer/Versturen" will submit it to the "Batch Codage" service.

All extra information concerning the use of eHealthBox can be found:
FR : *https://www.ehealth.fgov.be/ehealthplatform/fr/eHealthBox*
NL : *https://www.ehealth.fgov.be/ehealthplatform/nl/eHealthBox*

2.4. Download / Open output message:

The receipt, through his private key, will be able to decrypt the output message and then to download and open the processed file.

The sender must correctly log on the eHealth platform portal via "My eHealth".

FR (ACC):
https://wwwacc.ehealth.fgov.be/fr/myehealth/login?destination=myehealth/page
FR (PRD
https://www.ehealth.fgov.be/fr/myehealth/login?destination=myehealth/page
NL (ACC):
https://wwwacc.ehealth.fgov.be/fr/myehealth/login?destination=myehealth/page
NL (PRD):
https://www.ehealth.fgov.be/fr/myehealth/login?destination=myehealth/page

Once in the eHealthBox environment, the output generated by the Batch_Codage process will appear as a message in the receiver eHealthBox.

The message in your inbox will have the following subject:
[Reply_Batch_Codage_Encode]

	!	✉	🔒	📎	📇	Expéditeur	Description	Date de création	Date d'expiration	Taille (Ko)
☐		✉	🔒	📎	📇	EHEALTH-PLATFORM	[Reply_Batch_Codage_Encode]	05/08/2014	05/11/2014	7

The metadata of the output message will appear like in the figure below: in lowercase format.

Description				
Intitulé	**Valeur**		**Métadonnées utilisateur**	
Date de publication			[file_name]	coded_file_name
Date d'expiration			[ttp_project]	project_name
Nom de l'émetteur	EHEALTH-PLATFORM			
Qualité de l'émetteur	Entreprise			

2.5. Decodage:

If the deliberation of the Sectorial Committee authorizes decodage, the receiver will be allowed to send back coded data through eHealthBox in order to question the data.

The sender must correctly log on the eHealth platform portal via "My eHealth".
FR (ACC):
https://wwwacc.ehealth.fgov.be/fr/myehealth/login?destination=myehealth/page
FR (PRD
https://www.ehealth.fgov.be/fr/myehealth/login?destination=myehealth/page
NL (ACC):
https://wwwacc.ehealth.fgov.be/fr/myehealth/login?destination=myehealth/page
NL (PRD):
https://www.ehealth.fgov.be/fr/myehealth/login?destination=myehealth/page

The tab "Nouveau Message (FR)/Nieuwe Bericht (NL)" must be selected and the information below must be entered to submit a message.
The entries in red are invariables: they cannot be changed and the brackets are mandatory.
The other entries will vary from one project to another.

« Nouveau message/Nieuwe Bericht » Tab :
Destinataire: 0809394427-Entreprise (ID of the eHealthBox "Batch_Codage") Sujet:
[Batch_Codage_Decode]
Message: ⦿ Texte + ☑ ✉🔒 Encrypter

« Annexe/Bijlagen » Tab :
Add TXT/CSV coded output file containing medical data.

« Metadonnées/Metadata » Tab :
Clé/Sleutel :   [TTP_Project]   Value/Waarde :   Project_Name
                     [File_name]   Output_File_Name

The Output_File_Name is mandatory and must be the same as the file name received through
"Batch_Codage" service.
If the coded file received via [Batch_Codage_Encode] is "outputSSIN.csv", the annexed file
name and the metadata [File_name] for [Batch_Codage_Decode]
must also be "outputSSIN.csv".
The file itself must only contain the records to contest.

3. Appendix: TTP Global Document

<div style="border:1px solid;display:inline-block;text-align:center">

TTP eHealth GlobalDoc
Project: Project_Name

</div>

1. Deliberation:

N°XX/XXX (Sectorial Committee XXX)

« DELIBERATION_TITLE ».

The deliberation of the Sectorial Committee provides the legal framework of the project. Any changes will necessitate a new application to the same sectorial committee.
Although the text of this document may differ slightly from the official text, all elements of the procedure in this document are derived directly from the deliberation.

2. Purpose :

Short description of the study.

3. Workflow:

Schema of the workflow and description of data exchange steps.

4. Actors:

Step 1:
Actor 1:

Contact:
XXX (mail address)

Data to code:
XXX

Medical data Package:
Variable 1, variable 2,...

Transmission protocol: XXX ▯ XXX (eHealth)
                                              via EXCHANGE METHOD.

Step 2:
Actor 2:

…

5.   Validation:

From a legal point of view regarding the conformity with the decision of the sectorial committee and the mode of transmission implemented between the parties.
From the security aspects related to the modalities and means of transmission of personal data in the course of the procedure.

eHealth Legal Service	eHealth Security service

eHealth Responsible physician