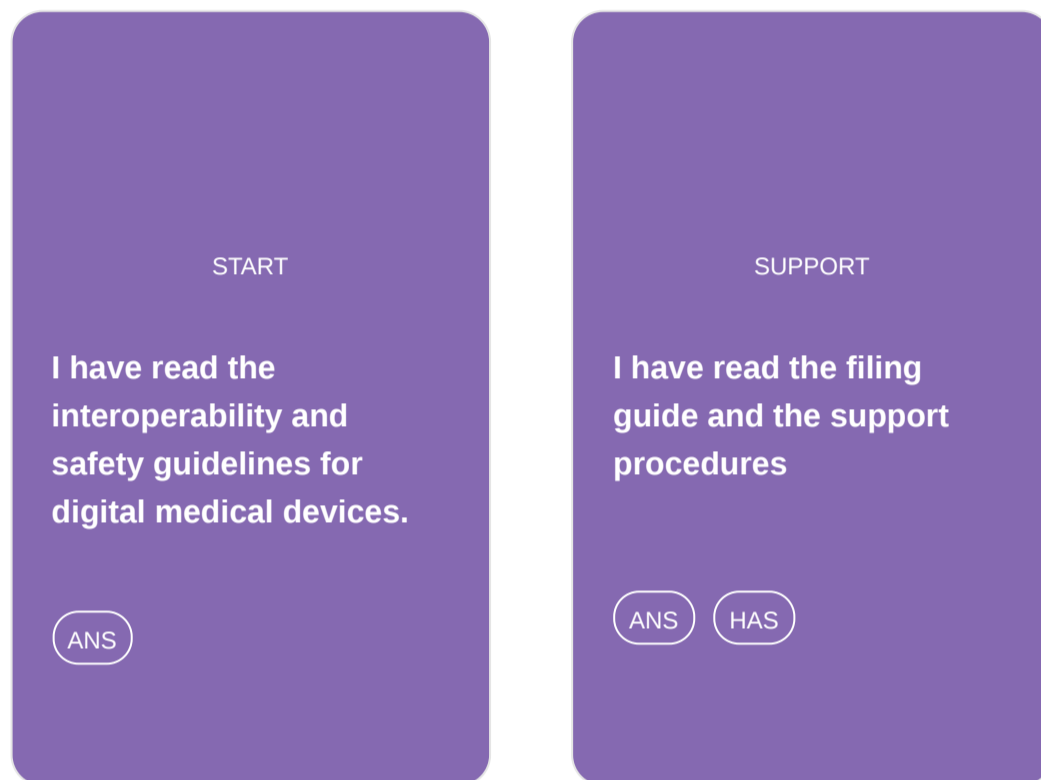


# How to obtain advance payment

Find out what to do, who to contact, advice and tips on how to best prepare for the process, as well as all the documentation and useful resources.

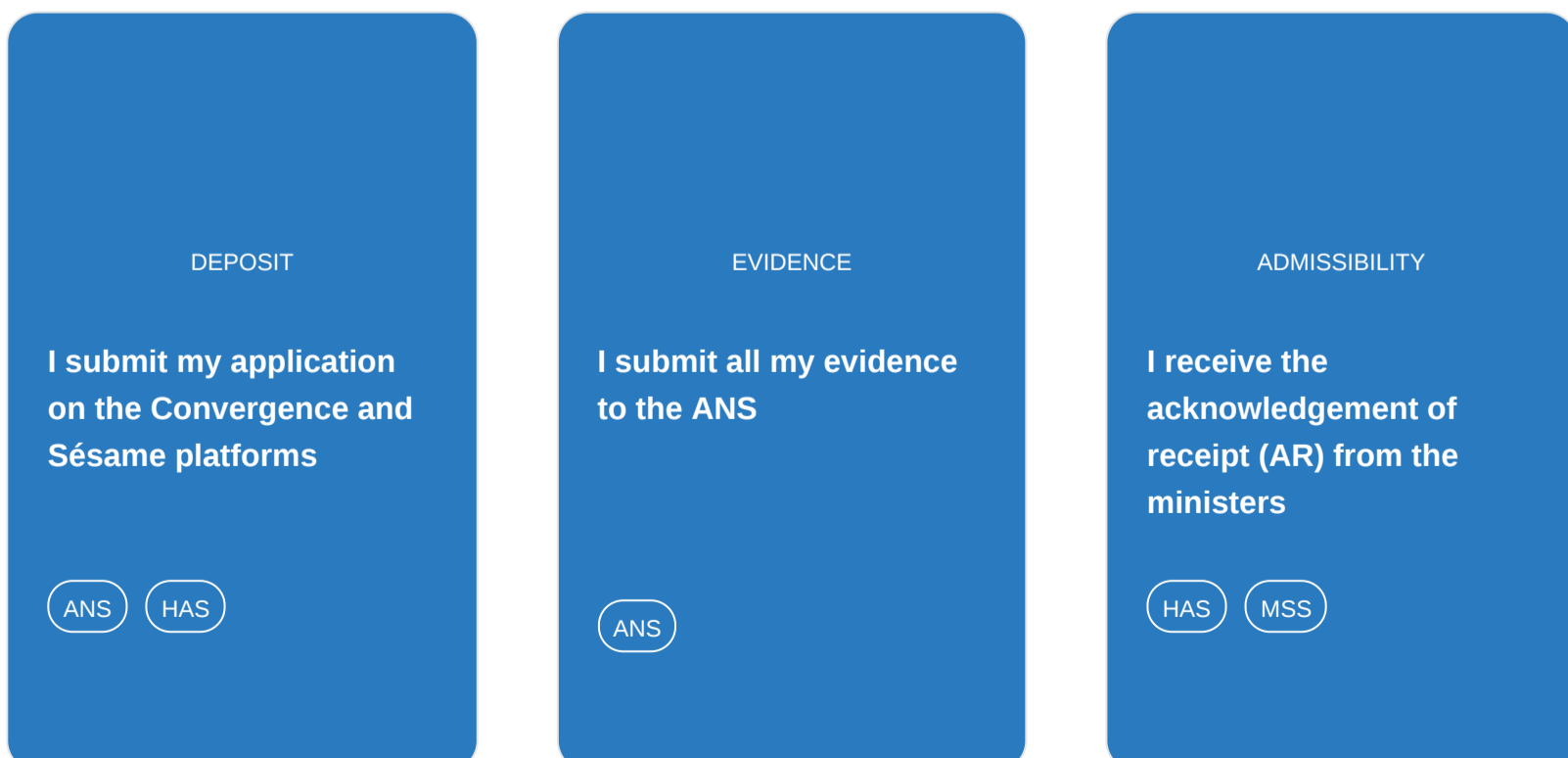
## Getting to know you

I assess my compliance with the requirements of the interoperability and security guidelines. If I have any questions, I read the HAS submission guide and the support services offered before I submit my application.



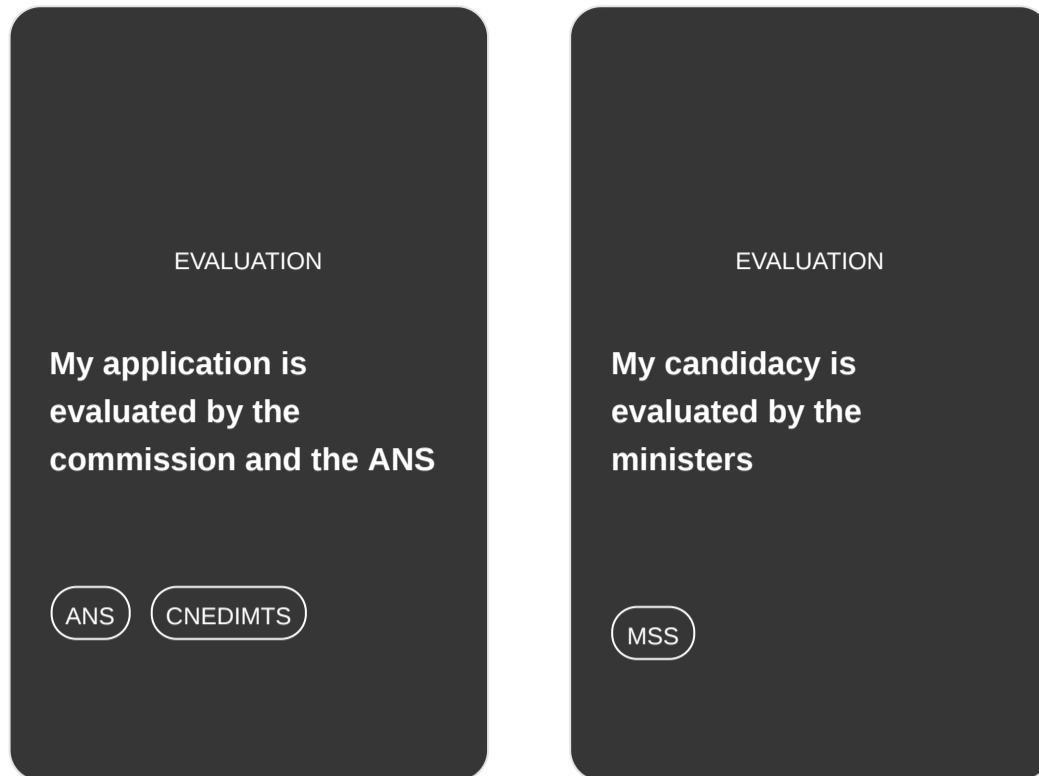
## Submitting my application

To ensure that my application is processed more quickly, I am filing my two applications in parallel with the CNEDiMTS (HAS) and the ANS.



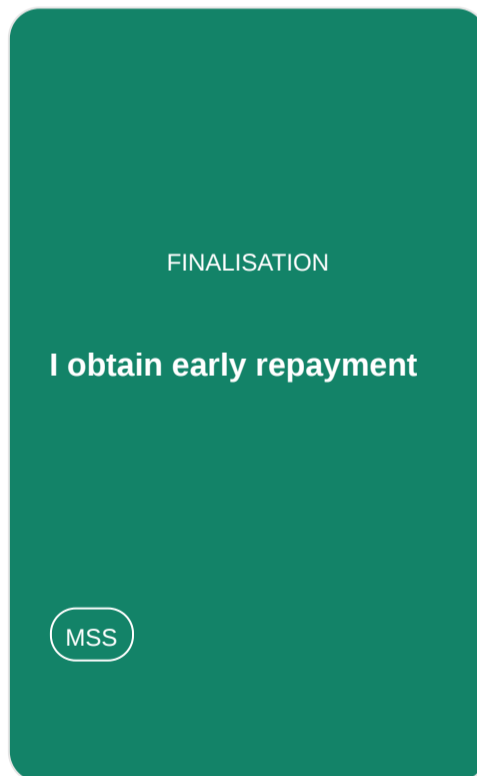
## Evaluation of my application

During the assessment I may be asked to complete the evidence.



## Obtaining early repayment

In the event of a favorable decision by the ministers, I obtain the PECAN.



# I have read the interoperability and safety guidelines for digital medical devices.

## Prerequisites

The solution must be CE marked.

## 01. I identify the base documentation that concerns me

START **ANS**

**I have read the interoperability and safety guidelines and all associated documentation.**

Consult the documentation on the [site](#) of ANS.

## 02. I'm upgrading my solution

START **ANS**

**I'm bringing my solution into line with the standards**

**Point of attention:** Updating your digital device may have an impact on your CE marking.

### Help wanted

In case of difficulties, you can contact the team in charge via the Convergence platform's internal messaging system.

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## I have read the filing guide and the support procedures

### 03. I would like to consult the terms and conditions of support

START **ANS** **HAS**

#### I would like to know more about the support services offered by the HAS:

- Some [early meetings](#) to discuss a study protocol;
- Des [pre-filing appointments](#) to discuss any questions you may have when building your file.

**Please note:** These meetings are free and confidential. They are not binding, but if you need them, you can call on us.

#### I would like to know more about the support services offered by ANS:

- The [FAQ](#) from manufacturers;
- The [webinars](#) on the theme of telemedicine;
- The [form](#) for contacting the ANS by selecting "Certification of medical devices with digital functions" in the "Subject" field.

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# I submit my application on the Convergence and Sésame platforms

## Prerequisites

The solution must be CE marked.

### 04.a I log in to my account on the Convergence platform

ADMINISTRATIVE **ANS**

#### I do not yet have an account on the Convergence platform

**Delay** 3 days to open an account

- I create my account on the [iSC Identity Provider](#) subsequently allowing me access to the Convergence platform.
- Supporting documents to be provided: Kbis of the company and verification of the identity of the corporate officer on the basis of a valid ID.

**Please note:** To enroll in a scheme, the representative of your structure must be registered on the Identity Provider as its representative.

#### I already have an account on the Convergence platform

**Login**

### 04.b I log in to my account on the Sésame platform

ADMINISTRATIVE **HAS**

#### I do not yet have an account on the Sésame platform

**Point of attention:** To submit a file on Sésame, I must have an access account to the platform. I can request, from HAS, the creation of my account through the [corresponding form](#).

I find all the access modalities in the dedicated [FAQ](#).

### I already have an account on the Sésame platform

Login

DEPOSIT **ANS**

### I submit my administrative file on the Convergence platform

A certain number of administrative documents will have to be submitted on the Convergence platform.

In particular, don't forget to bring the following documents with you:

- Functional documentation;
- Personal data protection certificate;
- CE marking declaration;
- HDS certificate;

Consult [le guide de dépôt](#) on Convergence for all the documents you need to provide.

**For information:** I'm kept informed by e-mail on the progress of each stage of my application.

### Need help?

The ANS examines the admissibility of my application. In case of difficulty, you can contact the team in charge via the internal messaging system of the Convergence platform.

## 05.a I submit my file to Convergence

## 05.b I submit my file to the Sésame platform

DEPOSIT HAS

### I apply via the HAS Sésame platform

I find the [FAQ](#) dedicated from the Sésame platform.

Each time the status of my file changes, I receive an email notification.

### Need help?

At any time, I can check the status of my file on Sésame.

In case of difficulty, a [pre-filing appointment](#) is made available by HAS to discuss any questions you may have during the construction of your dossier.

## 06.a My file is studied

DEPOSIT ANS

### My request will be considered

The ANS examines the admissibility of my application.

### Need help?

In case of difficulty, you can contact the team in charge via the Convergence platform's internal messaging system.

## 06.b My file is studied

DEPOSIT HAS MSS

### My request will be considered



The ministers, in conjunction with the HAS, study the admissibility and completeness of my file.

### Need help?

At any time, I can check the status of my file on Sésame.

## 07. My request is approved

DEPOSIT **ANS**

**I will be informed by e-mail about the admissibility of my application**

## 08. I sign the agreement

DEPOSIT **ANS**

**I receive a signed agreement to return to ANS via the electronic signature tool.**

**Please note:** Without this step, the application cannot be successful and does not allow the submission of proofs to verify compliance.

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# I submit all my evidence to the ANS

## 9. I deposit the evidence

EVIDENCE **ANS**

### I submit ALL proof of compliance via the Convergence platform

I submit evidence of my compliance with the requirements of the Digital Medical Devices (DMN) interoperability and safety guidelines, then respond to requests for additions to my file.

I have the option of **depositing evidence section by section**. If any of the evidence is invalid, I have the option of correcting the evidence or my digital medical device, in order to be compliant.

**Point of attention:** An application submitted more than 6 months ago but which has not evolved may be considered abandoned.

### Need help?

In case of difficulty, you can contact the team in charge via the Convergence platform's internal messaging system.

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## I receive the acknowledgement of receipt (AR) from the ministers

### 10. My request is received by the ministers

EVALUATION MSS

#### I receive an acknowledgement of receipt (AR)

If my file is complete both on the Sésame platform and on Convergence (I have submitted all my proofs of conformity), I receive an acknowledgement of receipt (AR) from the ministers in charge of health and social security. This acknowledgement of receipt initiates the official 60-day examination of the file.

**Please note:** If any information is missing, I receive notification by e-mail.

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# My application is evaluated by the commission and the ANS

## Prerequisites

I have received the acknowledgement of receipt (AR) from the ministries.

## 11.a ANS evaluates my evidence

EVALUATION ANS

### ANS examines my evidence on the Convergence platform

Delay 60 days

- The NSA has a maximum of 60 days from the date of submission of ALL evidence to evaluate the file. **Please note:** this is not a deadline but an analysis time.
- During this phase, the ANS may contact me via the Convergence platform's internal messaging system if it needs to provide clarification on the evidence.

### If the documents supplied are incomplete or do not comply with the requirements

Delay 30 days

- I am being solicited by ANS.
- If I do not transmit the requested elements within the allotted time, my registration request is at least deprioritized and in some cases, is deemed abandoned.

**Please note:**Application processing time will be tracked and time-stamped on the application management tool. Evaluation time on the ANS side is not counted as soon as additional information is pending on the ENS side.

## 11.b The CNEDiMITS examines my application

### My application on the Sésame platform is examined by the CNEDiMITS

**Delay** 60 days from AR

**Please note:** The CNEDiMITS issues its opinion within 60 days, upon acknowledgement of receipt of a complete file.

### If the parts supplied do not contain all the necessary information

**Delay** 30 days to complete your application

- I am notified by the ministers in charge of health and social security, where applicable on the proposal of the CNEDiMITS, of the list of additional elements to be provided.
- If I do not send the requested elements within 30 days of receiving the list of required elements, the application is deemed abandoned.

## 12.a I receive a positive opinion and certification

### I receive a favorable opinion from the ANS and obtain the certificate of conformity.

I receive my conformity certification documents by e-mail as well as information for the rest of the conformity certification procedure for digital medical devices.

## 12.b I receive the notice from CNEDiMITS

### I receive a notice from the commission

**Delay** 60 days

- The commission's opinion is sent to me within 60 days.
- I receive the CNEDiMITS opinion, favorable or unfavorable, via the Sésame platform.

- It is published on the HAS website and also sent to the relevant national professional councils (CNP) if it concerns remote medical monitoring.

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## My candidacy is evaluated by the ministers

### 13. My application is evaluated

EVALUATION **MSS**

#### My candidacy is evaluated by the ministers

**Delay** 30 days from receipt of both notices

On receipt of the last of the two favourable opinions, my application is considered by the ministers responsible for health and social security.

#### If the parts supplied do not contain all the necessary information

**Delay** 10 days

- I am notified by e-mail. I must provide the additional information within **10 days**.
- If I do not provide the requested information within the allotted time, my registration request is deemed abandoned.

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## I obtain early repayment

### Prerequisites

I have obtained the favorable opinion of the ministers.

### 14. I'm eligible for a refund

FINALISATION **MSS**

#### I'm eligible for early repayment and I'm reimbursed one year before I come under ordinary law.

The decision to reimburse in advance an MND intended for therapeutic purposes or used as part of a remote medical monitoring activity is established by joint order of the ministers in charge of health and social security.

#### Please note that, following the ministers' decision, I have :

- **6 months** to submit my application for coverage on the **LLPR**.
- **9 months** to submit my application for coverage on the **LATM**.

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### You have completed your course

You are aware of all the steps involved in advance care



