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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

**EVIDENT Database**

**User manual**

Updated version – August 2020

## BRIEF PRESENTATION OF EVIDENT

EVIDENT database was developed in order to enable sharing information on **additional studies** arising from HTA reports – studies requested by HTA agencies for those technologies for which HTA pointed out that there was still some evidence missing.

Agencies provide information on the conclusions of their HTA reports, requirements for additional studies and their follow-up once implemented.

Additional studies registered in EVIDENT are meant to fill-in the evidence gaps identified in a HTA report, and can be asked for all types of technologies (drugs, devices, procedures). They can be part of Coverage with Evidence Development schemes or of simple follow-ups (gathering of long term data). Study information should be entered at the earliest stage possible. Most of the studies in the database are planned or on-going, but information stays in even when a study is finalized.

In addition to information on evidence gaps and study requirements registered by one agency, for technologies of specific interest, other EUnetHTA members can contribute by providing information on assessment and reimbursement of the given technology in their country thanks to a special system of queries put in place (see chapter 5).

EVIDENT database therefore groups information on:

- **Post-launch evidence generation (PLEG)** requested by European HTA Agencies. PLEG stands for any generation of new evidence further to the initial assessment of a technology, including trials, observational studies, data on appropriateness of use, etc. Information in the database includes study **PICO**, **protocol**, **results** etc.
- conclusions of HTA reports regarding **evidence gaps** that could be of interest for on-going assessments
- **assessment and reimbursement of new technologies in Europe.**

### DATABASE GOALS

- facilitate European collaboration in conducting additional primary research
- promote generation of further evidence (critical mass of consistent data) and enable global analysis of consistent results
- stay up to date with areas of research (PLEG) in other countries via data inquiries and consultation
- stay up to date with assessment, coverage and available evidence for new technologies in Europe.

## DATABASE USE

### **- Sharing early information on evidence gaps and PLEG requests:**

HTA agencies can:

- register information about PLEG they have requested following the identification of evidence gaps during HTA
- search for studies being registered by other agencies in order to avoid the duplication of work
- launch a call for collaboration on PLEG
- seek information on evidence gaps and PLEG for ongoing assessments.

In order to promote collaboration, studies should be registered at the earliest stage possible (while still in development).

### **- Sharing information on PLEG progress**

Once a PLEG is registered, its progress can be reported on in the database, until the publication of the results.

## EVIDENT's information sharing process and basic glossary

Agencies that can request PLEG further to the identification of evidence gaps during HTA should enter information about their PLEG by completing the “[full registration form](#)” – please see the chapter 3 “Add a project”.

In addition, for technologies of specific interest, EVIDENT queries could be launched (optional functionality, see chapter 5).

- all EUnetHTA members can respond to EVIDENT queries by completing “[the minimal set of information form](#)”
- an overview<sup>1</sup> of the responses of all users, technology’s “[panoramic view](#)”, is then generated.

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<sup>1</sup> overview of the status of the related technology in Europe: HTA status, coverage/reimbursement status, additional study/ies requested or not

# GENERAL INFORMATION

EVIDENT has been developed and maintained by HAS. The IT hosting has been transferred to DIMDI in Joint action 3.

## **1. Access and access rights**

EVIDENT is accessible through the following link: <https://eunetha.dimdi.de/EVIDENT/pages/home.xhtml> or from EUnetHTA's website ([www.eunetha.eu](http://www.eunetha.eu)), under the TOOLS section.

To log in the EVIDENT database you need to use your [EUnetHTA ID](#) If you do not have a EUnetHTA ID, please contact the EUnetHTA Secretariat by following the procedure explained [here](#)

Access is currently restricted to EUnetHTA Partners and Associates who contribute to the EVIDENT database by providing information on PLEG and/or responding to queries.

The number of users from each agency is not limited.

If you (as EUnetHTA Partner or Associate) want to become an EVIDENT database user and provide input, please contact the [EVIDENT database administrator](#) for further details.

## **2. Confidentiality of information**

The information made available by the EVIDENT database is restricted to EUnetHTA Partners and Associates who contribute to the database.

Information shall not be disseminated to other EUnetHTA partners or associates, nor to third parties without permission from the originating agency.

## **3. Misuse of information**

When informed of a misuse of information provided by EUnetHTA behind a login and password, secretariat/EVIDENT database administrator will block the access to the user and inform user's organisation about infringement and request the organization to take appropriate action.

## **4. Roles**

For the moment there are three possible roles (access rights levels) within the EVIDENT database:

### 1. Reader

- search for projects
- see all published projects (from all agencies) and corresponding panoramic views
- see the news published by the administrator

### 2. Contributor

- same as reader plus
  - add and edit projects (on behalf of contributor's agency)
  - respond to EVIDENT queries (on behalf of contributor's agency)

### 3. Administrator (from HAS)

- same as contributor plus
  - validate and publish projects submitted by all contributors
  - manage EVIDENT queries
  - archive projects further to a specific request from a contributor
  - add, edit and publish the news
  - generate and send notifications
  - generate and send newsletters
  - publish the statistics regarding database's use
  - administration of agencies' and users' access rights and roles

## HOW TO USE EVIDENT DATABASE



Before using EVIDENT database please ensure that you have read the introduction and got familiar with the information sharing process and basic glossary described in the paragraph “Brief presentation of EVIDENT” (page 3).

### 1. LOG-IN

- EVIDENT is accessible through the following link: <https://eunetha.dimdi.de/EVIDENT/pages/home.xhtml> or from EUnetHTA’s website ([www.eunetha.eu](http://www.eunetha.eu)), under the TOOLS section.
- To log in the EVIDENT database you need to use your [EUnetHTA ID](#) If you do not have a EUnetHTA ID, please contact the EUnetHTA Secretariat by following the procedure explained [here](#).



Please note that after 120 minutes of inactivity your session will expire and you will need to log in again.

From the log-in page the user can also access EVIDENT’s public pages:

- About:  
Provides an overview of the objectives and the history of the database.
- FAQ  
Provides responses to frequents inquiries
- Links  
Provides links to EUnetHTA’s, HAS’, POP database’s and EU DG Health and consumers’ websites
- Contact  
Provides e-mails of contact persons for different inquiries.

## 2. NAVIGATE THE HOME PAGE

Once you are logged in the EVIDENT database, from the home page you can:

1. get an overview of recent activities through 3 quick links:
  - a) last ten projects
  - b) last ten drafts
  - c) last ten ongoing queries (minimal sets of information)
2. perform a quick search or access the advanced search form through the search box
3. add a project
4. consult the list of your agencies' published projects (through the link 'My projects') or to your agencies' drafts (through the link 'My drafts')
5. consult the help section
6. read the news published by the administrator
7. access EVIDENT's public pages (About, FAQ, Links and Contact).

The screenshot shows the EVIDENT Home page with several elements annotated with numbers and letters:

- 7**: A yellow navigation bar at the top containing links for Home, About, FAQ, Links, and Contact.
- 2**: A search box on the left with the placeholder text "Name of technology / English study title" and a "SEARCH" button.
- 3**: A "Add Project" button in the left sidebar.
- 4**: "My Projects" and "My Drafts" links in the left sidebar.
- 5**: A "Help" link in the left sidebar.
- 1a)**: "Last ten projects" section, which lists various medical technologies such as Jevtana (cabazitaxel), DUOPLAVIN (clopidogrel, acetylsalicylic acid), GILENYA (fingolimod), MELODY (Transcatheter Pulmonary Valve), SUTENT (sunitinib), STRUCTOFLEX (GLUCOSAMINE SULFATE), Gilerya (fingolimod), LUCENTIS (RANIBIZUMAB) IN DIABETIC MACULAR EDEMA, and ipilimumab.
- 1b)**: "Last ten drafts" section.
- 1c)**: "Last ten ongoing queries (minimal sets of information)" section.
- 6**: A "News" section on the right that currently displays "No News available yet".

Figure 1. EVIDENT Home page

## 2.1. Quick links

### 2.1.a) Last ten projects

This box gives the list of [ten most recent projects](#) entered in EVIDENT (**by all contributors**).

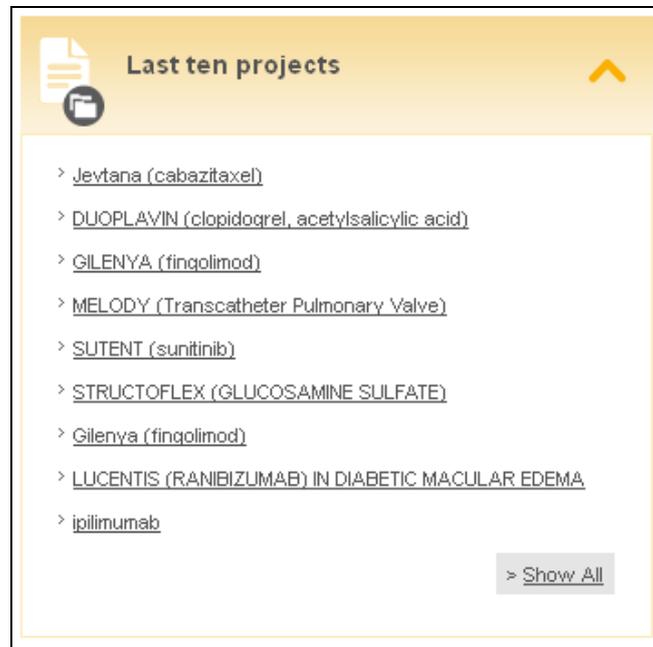


Figure 2. Quick links to last ten published projects

- When [clicking on the name of the technology](#) users will be directed to the project's form, that they could consult or [edit](#) (if the form had been published by their agency) by clicking on the [“edit” button at the bottom of the page](#).

From the project's page, by clicking on the [magnifier icon](#), they can access the [technology's panoramic view](#), established thanks to the EVIDENT query.

Figure 3. Link to the technology's panoramic view from the project's form

- From this box users can also access the *list of all projects* entered in EVIDENT by clicking on **“Show all”** button at the bottom of the box.

> **Projects list**  

Your search criteria : Approved

15 result(s) found 12

Name of technology ▼▲	Study Title ▼▲	Agency ▼▲	Project status ▼▲	Action	Panoramic view
ARIXTRA (fondaparinux sodium)	Standard of care for acute symptomatic spontaneous SVT of lower limbs in adults in non-hospital vascular practice	HAS	★	 	<a href="#">Show</a>
DUOPLAVIN (clopidogrel, acetylsalicylic acid)	DUOPLAVIN	HAS	★	 	<a href="#">Show</a>
FDG-PET/CT FOR CANCER STAGING	None	Agenas	★		<a href="#">Show</a>
Gilenya (fingolimod)	Gilenya Monitoring registry	AIFA	★		<a href="#">Show</a>
GILENYA (fingolimod)	VIRGILE on GILENYA (fingolimod)	HAS	★	 	
Hadrontherapy for cancer treatment	None	Agenas	★		<a href="#">Show</a>
ipilimumab	unknown CA184143	CVZ	★		<a href="#">Show</a>

Figure 4. List of all published projects

From the projects list page users can:

- see how many projects have been published in EVIDENT (number of results found)
- see the name(s) of technologies(s) concerned by the studies, study titles and which agency published the project
- see the details of each project by clicking on the **magnifier icon** in the column “Action”
- edit **their agency’s projects** by clicking on the **pen icon** in the column “Action”
- access the technology’s Panoramic view by clicking on **Show** in the column “Panoramic view”
- print the list of all projects by clicking on the **printer icon** in the right upper angle
- extract the list of all projects under a form of an Excel sheet by clicking on the **table icon** in the right upper angle.

Users can sort the results by alphabetic (▼) or inverse alphabetic order (▲) of the technology’s name, study title or agency’s name by clicking on the corresponding icon in the column’s header.

N.B. The green star in the ‘project status’ column confirms that the project has been published.

## 2.1. b) Last ten drafts

From this box users can access up to the last ten drafts saved **by user's agency**.

When clicking on the name of the technology users will be directed to the project's form, that they could consult, [edit](#) (if possible)<sup>2</sup> or [delete](#) by clicking on the “[edit](#)” or “[delete draft](#)” button [at the bottom of the page](#).

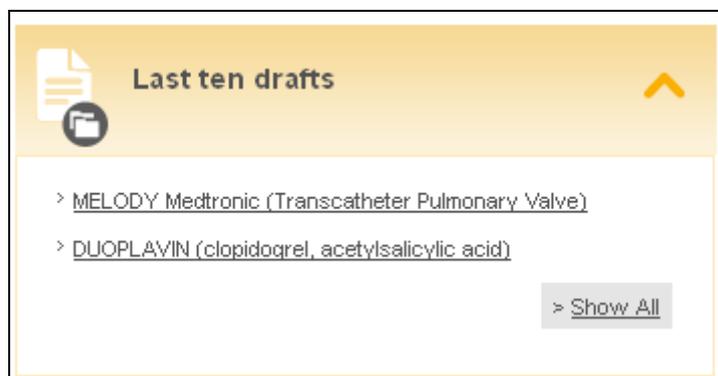


Figure 5. Quick links to agency's last ten drafts

Users can also access the [list of all drafts](#) saved by user's agency by clicking on “[Show all](#)” button at the bottom of the box [gives the same result as the link 'My drafts', please see the section 2.4.b].

## 2.1. c) Last ten ongoing queries (minimal sets of information)

This box gives an overview of the technologies concerned by up to *ten most recent EVIDENT queries* (figure 6). Users can either consult the *details of the initial project* by clicking on “[see details](#)” or directly *provide* their *agency's minimal set of information* by clicking on “[minimal set of information](#)” (see chapter 5).

Users can also access the [list of all ongoing queries](#) by clicking on “[Show all](#)” button at the bottom of the box.

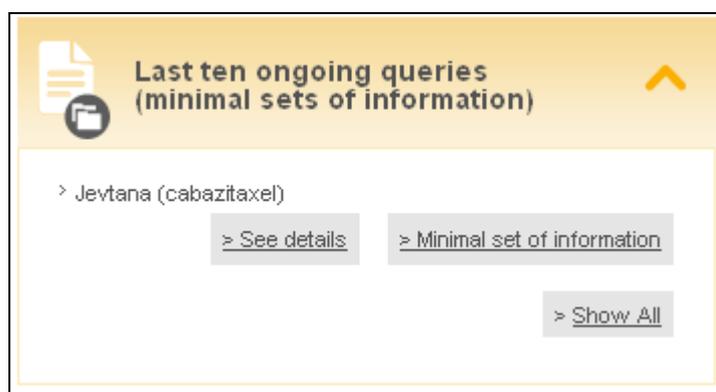


Figure 6. Quick links to up to ten last ongoing queries

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<sup>2</sup> For more details on drafts and possibilities to modify them please refer to the section 2.4.b

## 2.2. Search – please see the chapter “Consultation of the database”

## 2.3. Add a project – please see the chapter “Add a project”

## 2.4. Access your agencies’ projects or drafts

**2.4.a)** The button “*My projects*” will lead you to the list of all projects published by your agency.

The screenshot shows a web interface for viewing projects. At the top, there is a header '> Projects list' and a search criteria box containing 'Approved'. Below this, a yellow banner indicates '8 result(s) found'. The main content is a table with columns: 'Name of technology', 'Study Title', 'Agency', 'Project status', 'Action', and 'Panoramic view'. The first two rows of data are visible, each with a green star in the 'Project status' column and a 'Show' link in the 'Panoramic view' column. The 'Action' column contains magnifying glass and pen icons. In the top right corner, there are printer and table icons.

Name of technology ▼▲	Study Title ▼▲	Agency ▼▲	Project status ▼▲	Action	Panoramic view
ARIXTRA (fondaparinux sodium)	Standard of care for acute symptomatic spontaneous SVT of lower limbs in adults in non-hospital vascular practice	HAS	★		Show
DUOPLAVIN (clopidogrel, acetylsalicylic acid)	DUOPLAVIN	HAS	★		Show
GILENYA (efinafenece)	VIRGILE on GILENYA	HAS	★		

Figure 7. “My projects” link

Users can:

- see how many projects have been published<sup>3</sup> by their agency (number of results found)
- see the names of technologies concerned by the studies and study titles
- see the details of each project by clicking on the [magnifier icon](#) in the column “Action”
- edit the projects by clicking on the [pen icon](#) in the column “Action”
- access to the technology’s Panoramic view by clicking on [Show](#) in the column “Panoramic view”
- print the list of all projects by clicking on the [printer icon](#) in the right upper angle
- extract the list of all projects under a form of an Excel sheet by clicking on the [table icon](#) in the right upper angle.

Users can sort the results by alphabetic (▼) or inverse alphabetic order (▲) of the technology’s name or study title by clicking on the corresponding icon in the column’s header.

<sup>3</sup> N.B. The green star in the ‘project status’ column confirms that the project has been published.

**2.4.b)** The button “*My drafts*” will lead you to the list of all projects of your agency that are still not published:

a) projects that are still not completed, and saved under a form of a draft (marked with a yellow star)

b) projects that have been completed, and submitted for publication, but have still not been validated by the administrator (marked with a orange star)

c) projects that have been completed, and submitted for publication, but have been returned by the administrator for modification (marked with a red star).

Name of technology ▼▲	Study Title ▼▲	Agency ▼▲	Project status ▼▲	Action	Panoramic view
ARDXTRA (fondaparinux sodium)	Standard of care for acute symptomatic spontaneous SVT of lower limbs in adults in non-hospital vascular practice	HAS	★	🔍 ✎ ✕	
ARTISS - FIBRIN SEALANT (HUMAN)	ARTISS - FIBRIN SEALANT (HUMAN)	HAS	★	🔍 ✎ ✕	
BOTOX (type A botulinum toxin) in Urinary Incontinence	BOTOX in the treatment of detrusor overactivity leading to neurological urinary incontinence not controlled by anticholinergic therapy in spinal cord injury patients & patients with multiple sclerosis patients using catheterization as a voiding mode	HAS	★	🔍	
BRILIQUE (ticagrelor)	BRILIQUE (ticagrelor)	HAS	★	🔍 ✎ ✕	

Figure 8. “My drafts” link

From this list users can:

- see how many of their agency’s projects have still not been published (number of results found)
- see the names of concerned technologies and study titles
- distinguish classic drafts from those awaiting validation or been rejected (project status column)
- see the details of each project by clicking on the [magnifier icon](#) in the column “Action”
- **edit the drafts that are not completed or need to be modified (but not those that are awaiting validation! (orange))** by clicking on the [pen icon](#) in the column “Action”
- **delete the drafts that are not completed or need to be modified (but not those that are awaiting validation! (orange))** by clicking on the [cross icon](#) in the column “Action”

- print the list of all projects by clicking on the [printer icon](#) in the right upper angle
- extract the list of all projects under a form of an Excel sheet by clicking on the [table icon](#) in the right upper angle.

Users can sort the results by alphabetic (▼) or inverse alphabetic order (▲) of the technology's name or study title by clicking on the corresponding icon in the column's header.

### 2.5. Help section

This section contains database's manual and links for different inquiries.

### 2.6. Access to the EVIDENT's public pages (About, FAQ, Links and Contact)

For more details please see the Chapter 1 (Log-in).

### 3. ADD A PROJECT

The registration form (figure 9) is accessible from the Home page, by clicking on 'Add project'.

The form consists of three tabs:

- 1) technology – containing information on the **technology** concerned by the PLEG, *results of its assessment*, details on *identified evidence gaps* and information on its *reimbursement*.
- 2) study description and protocol - containing information on the **PLEG** (title, PICO elements etc)
- 3) study progress and results - containing information on the **progress of PLEG** (progress, results, reassessment of the technology etc).

The form contains information belonging to different life cycles of a technology (first assessment, PLEG, reassessment). The form can be updated as new information becomes available.

#### 1° How to fill-in the items



**Only the fields followed by an asterix are mandatory  
(please see Annex 1)**

Explanations are displayed when mouse is passed over the most important items.  
For the full list of items and related explanations please consult the Annex 2.

Specific tips for registering a project:

- if you have to enter several types of data in one field separate them with a comma
- when one study is intended to cover two or more technologies:
  - a) if the technologies have different characteristics (for example coverage status) then several projects should be created, one for each technology, citing the same study afterwards
  - b) if all characteristics are the same, one single project should be created, but all the technologies should be cited in the field 'Name of technology'

Specific fields (in red in figure 9)

Some fields of the registration form are not presented in the Annex 2:

- the tab "History" contains all the history of the project – first data entry, modifications, validation etc
- the field "Approved by" is filled-in automatically when an administrator validates a project
- the button "Manage matching projects" will be currently used only by the administrator. **The database is actually able to recognise if there are "matching" projects** (concerning same technology) and the administrator checks whether the projects are really matching and put that information in the field "Matching projects".

> Add Project

**Technology** | Study description & protocol | Study progress & results | **History**

Ref. n°

Agency: HAS  
Country: France  
Contact: Irena Guzina  
To be approved by: [ ]

**TECHNOLOGY DETAILS**

Name(s) of technology \* [ ]  
Type(s) of technology \*  
 Medical device  Drug  
 Therapeutic procedure  Diagnostic procedure  
 Screening procedure  Other  
ATC code [ ]

Medical condition (MeSH term) \*

[ ] MeSH term browser  
[ ] MeSH term browser  
[ ] MeSH term browser  
[ ] MeSH term browser [Add a MeSH term](#) +

**HT ASSESSMENT**

Health Technology Assessment status \* Finalised  
HTA report completing date MM YYYY  
Title of HTA report [ ]  
URL of HTA report [ ] +

Identified evidence gaps (Rationale for AEG) concerning: \*

<input type="checkbox"/> Safety	<input type="checkbox"/> Clinical effectiveness
<input type="checkbox"/> Cost effectiveness	<input type="checkbox"/> Costs (units/indirect costs)
<input type="checkbox"/> Budget impact	<input type="checkbox"/> Conditions of use
<input type="checkbox"/> Investment (materials and premise)	<input type="checkbox"/> Personnel recruitment and training

Please precise (free text) \*

[ ]

**REIMBURSEMENTS STATUS OF HT**

Coverage - reimbursement status of HT (after 1st HTA) \* Covered

**ADDITIONAL STUDY REQUESTED**

Additional study requested Yes

Comments [ ]

**MATCHING PROJECTS**

[MANAGE MATCHING PROJECTS](#)

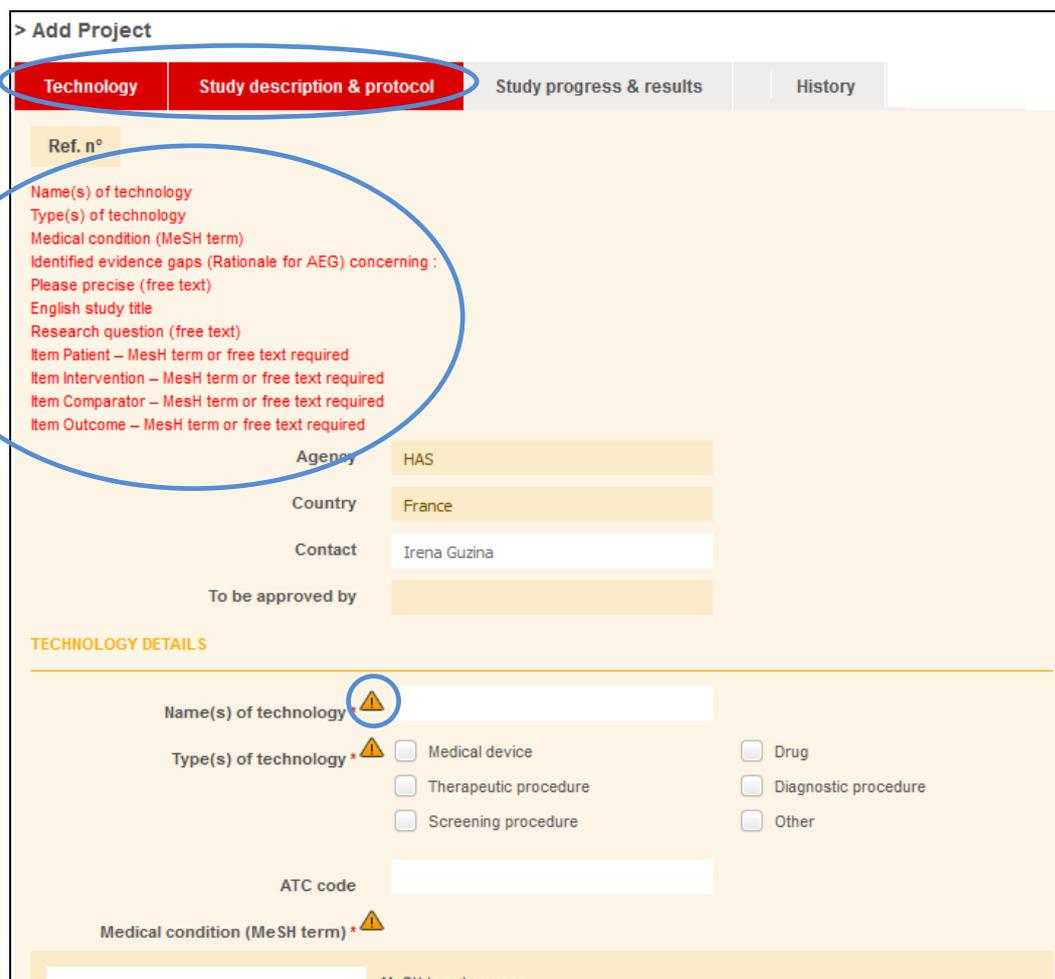
Fields with \* are mandatory

[SAVE DRAFT](#) [SUBMIT FOR VALIDATION](#)

Figure 9. First tab of the registration form

## 2° How to save or publish a project

- The form does not have to be completed in one session. You can save the entered information as a draft (button “[Save draft](#)”) and complete/edit the form later. A message ‘Your action has been successfully completed’ will appear in the left upper angle.
- Once saved, you can access and edit or delete your draft either from the ‘Last ten drafts’ box or through the link ‘My drafts’, both available on the Home page (please see chapters 2.1.b) and 2.4.b)).
- Once you wish to publish your project click on the “[Submit for validation](#)” button. A message ‘Your action has been successfully completed’ will appear in the left upper angle and the database’s administrator will receive a notification about your request.
- If you have not completed all mandatory fields (marked with an asterisk), you won’t be able to submit your form. The list of missing fields will appear at the top of the form, the tabs with missing fields will be coloured red and each field will be marked also with an exclamation mark .
- The project that has been sent for validation will be stored in the ‘drafts’ section, and marked with an orange star, until its publication. The user will be able to consult the form but **no editing** will be possible while the project is awaiting validation.



> Add Project

Technology Study description & protocol Study progress & results History

Ref. n°

Name(s) of technology  
Type(s) of technology  
Medical condition (MeSH term)  
Identified evidence gaps (Rationale for AEG) concerning :  
Please precise (free text)  
English study title  
Research question (free text)  
Item Patient – MesH term or free text required  
Item Intervention – MesH term or free text required  
Item Comparator – MesH term or free text required  
Item Outcome – MesH term or free text required

Agency	HAS
Country	France
Contact	Irena Guzina
To be approved by	

TECHNOLOGY DETAILS

Name(s) of technology \* 

Type(s) of technology \*   
 Medical device  Drug  
 Therapeutic procedure  Diagnostic procedure  
 Screening procedure  Other

ATC code

Medical condition (MeSH term) \* 

MeSH term browser

Figure 10. Missing fields

### **3° a) Your project has been validated**

Once the project is validated by the administrator, it will be published in the 'projects' section and the author, as well as the other users, will be notified by e-mail.

### **3° b) Your project has not been validated**

If the administrator has some questions or comments related to your project, he/she will return the draft. You will be notified about it by e-mail, and you could access your draft either directly from the e-mail, either from the 'drafts' section.

The draft in question will be marked with a red star.

The administrator's comments will be presented in the bottom of the form, in the field 'Admins Comments'.

The administrator will also indicate which fields need to be corrected or completed in the tick boxes next to each field. The corresponding tab will be coloured orange.

> Show Project

Technology Study description & protocol **Study progress & results** History

Study status \*  Planned  Ongoing  Finalised  Unknown  Cancelled

Expected or effective starting date MM YYYY

Anticipated or effective date of results MM YYYY

Shared coordination/monitoring funding with another EVIDENT partner  yes  no

Main study results Not available

>> Attach summary No file selected **UPLOAD**

Reassessment status > Not envisaged

URL reassessment report

Results taken into account for reassessment  yes  no

Comments

Admins Comments

Figure 11. Returned form

Once the form is completed or modified, you may re-submit it for validation.

## 4. CONSULTATION OF THE DATABASE (SEARCH FUNCTION)

The search engine is accessible from the Home page.

### a) Basic search:

Users can search for a technology or related study/ies by typing the key words (of the study title, or of the name of the technology) in the field and clicking on the “Search” button.

Please note that you have to enter at least 3 characters in order to launch a search!

In order to launch a new search, click on “Reset” button.

### b) Advanced search:

By clicking on the “Advanced search” button you can access the advanced research engine that enables the search by multiple criteria:

- the key words (of the study title, or of the name of the technology)
- the type of the technology (select in the drop-down menu)
- ATC code for drugs (enter the code)
- medical condition (select the corresponding MeSH term in the enclosed browser)
- agency (select in the drop-down menu)
- country (select in the drop-down menu)
- status of the study (tick box)
- whether the results of the study are available or not (select in the drop-down menu)
- whether the ‘project’ has been approved, sent for validation or still in the drafts (select in the drop-down menu).

In order to close the advanced form the user should click on the ‘Less items’ button.

### c) Search results

The search results would appear in form of a list of database records that match the given criteria.

Figure 12. Search box and the advanced search form

> **Projects list**  

Your search criteria : valve

1 result(s) found

Name of technology ▼▲	Study Title ▼▲	Agency ▼▲	Project status ▼▲	Action	Panoramic view
MELODY (Transcatheter Pulmonary Valve)	FRENCH REGISTRY ON MELODY (PULMONARY VALVE IMPLANT)	HAS		 	<a href="#">Show</a>

Figure 13. Search results

On the results' page users can:

- see how many projects match the given criteria (number of results found)
- see the names of technologies, study titles and which agency registered the projects
- see whether the project has been published (project status column)
- see the details of each project by clicking on the [magnifier icon](#) in the column "Action"
- edit the projects published by user's agency by clicking on the [pen icon](#) in the column "Action"
- access to the technology's Panoramic view by clicking on [Show](#) in the column "Panoramic view"
- print the list of search results by clicking on the [printer icon](#) in the right upper angle
- extract the list of search results under a form of an Excel sheet by clicking on the [table icon](#) in the right upper angle.

Users can sort the results by alphabetic (▼) or inverse alphabetic order (▲) of the technology's name, study title or agency's name by clicking on the corresponding icon in the column's header.

## 5. EVIDENT QUERIES – THE MINIMAL SET OF INFORMATION FORM

For technologies of specific interest, EVIDENT users can be asked to participate to a [query](#) and input the minimum information on the related technology (HTA status, coverage status), and eventually on similar studies if requested or planned. This functionality is activated by the database administrator, in agreement with partners.

The “Minimal set of information” form is accessible either by following the link from the EVIDENT e-mail announcing the query (figure 14), or from the 3rd Quick link box<sup>4</sup> on the Home page, by clicking on “[minimal set of information](#)”.

The information about the initial project that launched the Query is to be found at the head of the form. Users can see the details of that project by clicking on “[See details](#)” or access to the project’s Panoramic view by clicking on “[Panoramic view](#)” (figure 15).

**Forms should be submitted no later than three weeks upon the launch of the query.**

### **1° How to fill-in the items**

The list of items with explanations is presented in the Annex 3.

### **2° How to submit the minimal set of information form**

The form can be submitted by simply clicking the “[Submit your minimal set of information](#)” button.

Once the form sent, it is integrated in the overview of the technology’s status in Europe – [the Panoramic view](#).

### **3° How to modify information in the form**

You may modify or update information present in the form at any moment, from the Panoramic view page (see n°4), by clicking on “Provide or edit your agency’s minimal set of information” (figure 16).

### **4° Panoramic view**

The overview of the technology’s status in Europe (Panoramic view) goes with the project’s form and is accessible either from the project’s page either from the column ‘Panoramic view’ from the Search results table.

From the panoramic view page (figure 16) users can:

- see the results of the EVIDENT [query](#) under a form of a table (on the page) or under a form of map, by clicking on “[Switch to map view](#)”
- see the basic information on the [initial project](#) (name of the agency that published it, related technology and study title) and access its details by clicking on the “[See details](#)” link
- provide or edit the minimal set of information for their agency
- print the table by clicking on the [printer icon](#) in the right upper angle

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<sup>4</sup> Please see section 2.1.c) and figure 6.

- extract the table under a form of an Excel sheet by clicking on the [table icon](#) in the right upper angle.

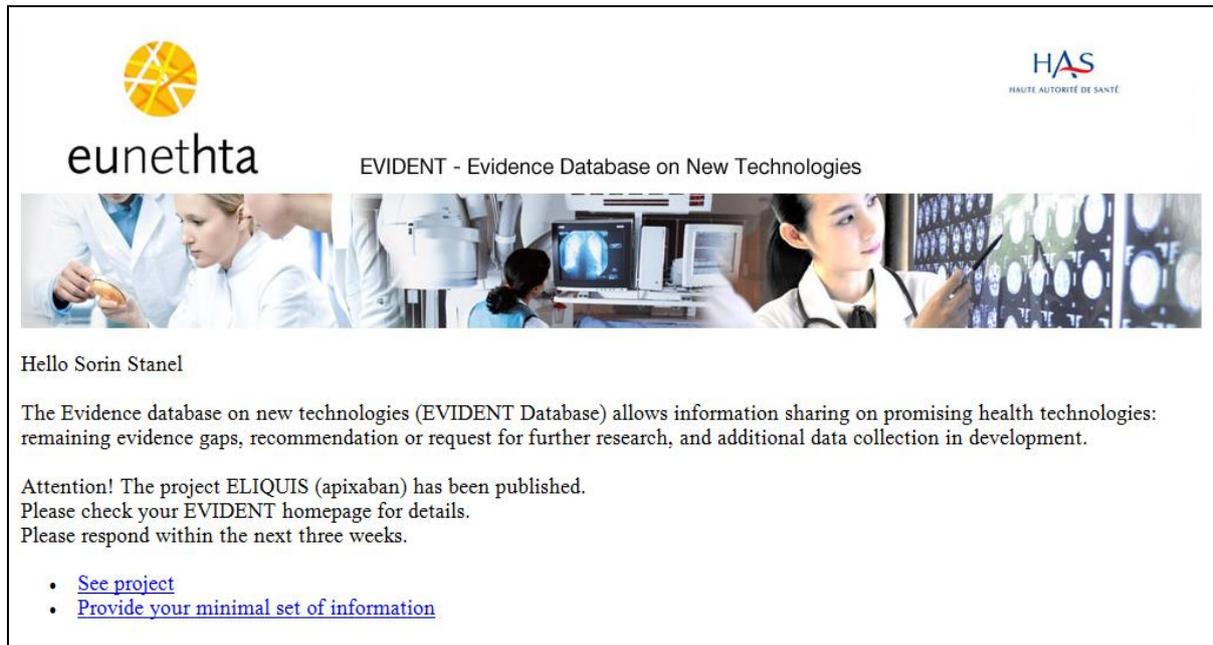


Figure 14. EVIDENT query e-mail with the link to the MSI form (“Provide your minimal set of information”)

**> Provide your minimal set of information**

Ref. n° : 3193-34 | Agency : HAS | Country : France  
 ELIQUIS (apixaban) ( Drug ) - ELIQUIS (apixaban) in Venous Thromboembolism > [See details](#)

Please provide your agency's minimal set of information on the technology concerned by this study. Your answer is needed to create an overview of the technology's status in Europe and generate potential interest for collaboration. > [Panoramic view](#)

**MINIMAL SET OF INFORMATION**

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Agency : KCE Country : Belgium Contact : Patrice Chalon

HT assessment status

Identified evidence gaps

<input type="checkbox"/> Safety	<input type="checkbox"/> Clinical effectiveness
<input type="checkbox"/> Cost effectiveness	<input type="checkbox"/> Costs (units/indirect costs)
<input type="checkbox"/> Budget impact	<input type="checkbox"/> Conditions of use
<input type="checkbox"/> Investment (materials and premise)	<input type="checkbox"/> Personnel recruitment and training

Coverage - reimbursement status of HT

Additional study requested  [If yes, you will be directed to the full registration form in order to provide details on your study. Thank you.]

**SUBMIT YOUR MINIMAL SET OF INFORMATION**

Figure 15. Minimal set of information form

> Project Panoramic view > [Switch To Map View](#)

Ref. n° : 3241-67 | Agency : AVALIA-t | Country : Spain

CANALOPLASTY FOR OPEN ANGLE GLAUCOMA ( Therapeutic procedure ) - Canaloplasty for open angle glaucoma > [See details](#)

> Provide or Edit your agency's minimal set of information

Agency	Contact	Updated on	HT assessment status	Identified evidence gaps	Coverage - reimbursement status of HT	Additional study requested
AVALIA-t	Beatriz Casal					
A. Gemelli	Marco Marchetti					
AHTAPol	Marta Polkowska					
AIFA	Agnese Cangini					
ASSR	Luciana Ballini					
Agenas	Antonio Migliore					
CEM	Juergen Hohmann					
CMCC	Yves Bouch...					

**Legend :**

**HT assessment status**

- Finalised
- Ongoing
- Planned
- Not assessed (not yet planned)
- Not applicable / out of scope

**Identified evidence gaps**

- Safety
- Clinical effectiveness
- Cost effectiveness
- Costs (units/indirect costs)
- Budget impact
- Conditions of use
- Investment (materials and premise)
- Personnel recruitment and training

**Coverage - reimbursement status of HT**

- Covered
- Not covered
- Covered when associated with another technology
- Conditionally covered
- Restricted/ limited coverage
- Pending decision
- Unknown/ not applicable

**Additional study requested**

- Yes
- No
- Not applicable
- Not officially requested, only recommended
- No but interested in participating
- No but interested in receiving information

No response

Figure 16. Panoramic view and its legend

## ANNEX 1 : MANDATORY ITEMS

Tab 1: Technology	
Ref. n° (Country code_id)	Automatically generated
Agency	Automatically generated when you sign-in with your EUnetHTA ID
Country	
Contact	
Name(s) of technology	
Type(s) of technology  <i>drug</i> <i>medical device</i> <i>diagnostic procedure</i> <i>screening procedure</i> <i>therapeutic procedure</i> <i>other</i>	<ul style="list-style-type: none"> <li>- <span style="color: red;">proprietary name should be put first, with generic name into brackets</span> for example: transcatheter heart valve (Edwards SAPIEN)</li> <li>- if one study concerns more than one technology, names of all technologies should be entered, separated by commas</li> </ul> <ul style="list-style-type: none"> <li>- multiple answers possible if needed <span style="background-color: yellow;">(tick boxes)</span></li> </ul>
Medical condition (MeSH term)	<p><b>Search for</b> or <b>directly select</b> the MeSH term describing the medical condition <b>in the enclosed browser</b>. You can enter up to 4 MeSH terms in the form, if you need to create an additional field click on 'Add a MeSH term'.</p>
Health Technology Assessment status  <i>finalised</i> <i>ongoing</i> <i>not yet envisaged</i> <i>planned</i> <i>not applicable-out of scope</i>	Refers to the assessment of the technology concerned by PLEG <span style="background-color: yellow;">(tick boxes)</span>
Identified evidence gaps (Rationale for PLEG) concerning:  <i>safety</i> <i>clinical effectiveness</i> <i>cost effectiveness</i> <i>costs (units/indirect costs)</i> <i>budget impact</i> <i>conditions of use</i> <i>investment (materials and premise)</i> <i>personnel recruitment and training</i>	Please indicate in the drop down menu the domain(s) in which evidence gaps have been/are likely to be identified during HTA (multiple answers possible if needed) <span style="background-color: yellow;">(tick boxes)</span>
> <i>Please precise (free text)</i>	Please provide more detailed description of identified evidence gaps in free text (the rationale for asking for an additional study) <span style="background-color: green; color: green;">Free text</span>
Coverage - reimbursement status of HT (after 1st HTA)  <i>covered</i> <i>not covered</i> <i>covered when associated with another technology</i> <i>conditionally covered</i> <i>restricted/ limited coverage</i> <i>pending decision</i> <i>unknown / not applicable</i>	Refers to the coverage-reimbursement status after the first HTA has been performed but before the study (potentially modifying the decision) has been carried out. <span style="background-color: yellow;">(tick boxes)</span>

Tab 2 : Study description & protocol	
English Study Title <sup>5</sup>	Please enter the title of the study in English, if possible in the PICO format.
Research question (free text)	Please specify <b>study</b> 's research question in free text
Patient (MeSH term) OR (free text)	Please indicate study's population by selecting a MeSH term (in the enclosed browser) <b>and/or</b> in free text
Intervention (MeSH term) OR (free text)	Please indicate the intervention by selecting a MeSH term (in the enclosed browser) <b>and/or</b> in free text
Control Intervention - comparator (MeSH term) OR (free text)	Please indicate the control intervention by selecting a MeSH term (in the enclosed browser) <b>and/or</b> in free text. In case of a non-comparative study you can put 'Not applicable'.
Key Outcomes of interest (MeSH term) OR (free text)	Please indicate the key outcomes by selecting a MeSH term (in the enclosed browser) <b>and/or</b> in free text
Tab3: Study progress & results	
Study status	(tick boxes)
<i>planned</i>	
<i>ongoing</i>	
<i>finalised</i>	
<i>unknown</i>	
<i>cancelled</i>	

<sup>5</sup> the fields in the tab 2 should indicate the basic requirements for the study that could answer the identified evidence gaps. For all fields that however can not be defined you may put 'not defined'.

**ANNEX 2 : ALL EVIDENT ITEMS (mandatory fields followed by an asterix)**

Tab 1: Technology	
Ref. n° (Country code_id)	Automatically generated
Agency	Automatically generated when you sign-in with your EUnetHTA ID
Country	
Contact	
Name(s) of technology *	<ul style="list-style-type: none"> <li>- <b>proprietary name should be put first, with generic name into brackets</b></li> <li>for example: transcatheter heart valve (Edwards SAPIEN)</li> <li>- if one study concerns more than one technology, names of all technologies should be entered, separated by commas</li> </ul>
Type(s) of technology *	<ul style="list-style-type: none"> <li>- multiple answers possible if needed (tick boxes)</li> </ul>
<i>drug</i> <i>medical device</i> <i>diagnostic procedure</i> <i>screening procedure</i> <i>therapeutic procedure</i> <i>other</i>	
ATC Code	For drugs only.
Medical condition (MeSH term) *	<p><b>Search for or directly select</b> the MeSH term describing the medical condition <b>in the enclosed browser</b>. You can enter up to 4 MeSH terms in the form, if you need to create an additional field click on 'Add a MeSH term'.</p>
Health Technology Assessment status *	<p>Refers to the assessment of the technology concerned by PLEG</p> <p>If there are several HTA reports you may add Title and URL fields by clicking on the Plus icon.</p>
<i>finalised</i> <i>ongoing</i> <i>not yet envisaged</i> <i>planned</i> <i>not applicable-out of scope</i>	
HTA report completing date (MM/YYYY)	
Title of HTA report	
URL of HTA report	
Identified evidence gaps (Rationale for PLEG) concerning: *	<p>Please indicate the domain(s) in which evidence gaps have been/are likely to be identified during HTA (multiple answers possible if needed - tick boxes)</p>
<i>safety</i> <i>clinical effectiveness</i> <i>cost effectiveness</i> <i>costs (units/indirect costs)</i> <i>budget impact</i> <i>conditions of use</i> <i>investment (materials and premise)</i> <i>personnel recruitment and training</i>	
> <b>Please precise (free text)*</b>	Please provide more detailed description of identified evidence gaps in free text (the rationale for asking for an additional study)
Coverage - reimbursement status of HT (after 1st HTA) *	Refers to the coverage-reimbursement status after the first HTA has been performed but before the study (potentially modifying the decision) has been carried out.
<i>covered</i> <i>not covered</i> <i>covered when associated with another technology</i>	

	<i>conditionally covered</i> <i>restricted/ limited coverage</i> <i>pending decision</i> <i>unknown / not applicable</i>
<b>Additional study requested</b>  Yes No <i>Not applicable</i> <i>Not officially requested, only recommended</i> <i>No but interested in participating</i> <i>No but interested in receiving information</i>	In this field you can indicate whether your agency has formally asked for the PLEG or if it is a simple recommendation to gather additional evidence.
<b>Comments</b>	This field is to be used if you need to further explain information entered in any of the above fields or if you want to put any additional information
<b>Tab 2 : Study description &amp; protocol</b>	
<b>English Study Title *<sup>6</sup></b>	Please enter the title of the study in English, if possible in the PICO format.
<b>Sponsor / Funder type</b>  <i>public</i> <i>private</i> <i>public/private partnership</i> <i>other</i>	
<b>Sponsor / Funder name</b>	
<b>Domain question</b> <i>health problem and current use of the technology</i> <i>description and technical characteristics of technology</i> <i>safety</i> <i>effectiveness</i> <i>cost and economic evaluation</i> <i>ethical analysis</i> <i>organisational aspects</i> <i>social aspects</i> <i>legal aspects</i>	Please indicate the domain of the Core model which the <b>research question (study's objective)</b> refers to (multiple answers possible if needed - tick boxes).  Please note that the 'research question' refers to the question/objective the <u>additional study</u> should answer in order to fill-in the evidence gaps identified during the initial assessment of a technology. <i>It should not be confused with research question of the HTA Core Model.</i>
<b>Research question (free text) *</b>	Please precise <b>study's</b> research question in free text
<b>Patient (MeSH term) *</b>	Please indicate study's population by selecting a MeSH term (in the enclosed browser) <b>and/or</b> in free text
<b>Patient (additional description in free text )</b>	
<b>Intervention (MeSH term) *</b>	Please indicate the intervention by selecting a MeSH term (in the enclosed browser) <b>and/or</b> in free text
<b>Intervention (additional description in free text )</b>	
<b>Control Intervention - comparator (MeSH term) *</b>	Please indicate the control intervention by selecting a MeSH term (in the enclosed browser) <b>and/or</b> in free text.  In case of registries you can put 'Not applicable'.
<b>Control Intervention - comparator (additional description in free text )</b>	
<b>Key Outcomes of interest (MeSH term) *</b>	Please indicate the key outcomes by selecting a MeSH term (in the enclosed browser) <b>and/or</b> in free text
<b>Key Outcomes of interest (additional description in free text )</b>	
<b>Design of study</b>  <i>RCT</i> <i>pragmatic trials</i> <i>cohort (exposed/unexposed)</i>	Multiple answers possible if needed - tick boxes

<sup>6</sup> mandatory fields in the tab 2 should be filled-in in a way to indicate the basic requirements for the study that could answer the identified evidence gaps. For all fields that however can not be defined you may put 'not defined'.

	<i>longitudinal follow-up</i> <i>registry (exhaustive)</i> <i>case-control</i> <i>retrospective Cohort</i> <i>cross sectional</i> <i>case-series</i> <i>models (clinical, economical)</i> <i>other</i>	
<b>Patient Sample size</b>		
<b>Duration of Follow-up (in months)</b>		Follow-up of the patient once he has been included to the study
<b>Protocol finalised</b>	yes no	
<b>&gt; If Yes attach Synopsis</b>		You can attach the protocol once it is publicly available. Please insure that the attachment does not exceed 10 MB.
<b>Comments</b>		This field is to be used if you need to further explain information entered in any of the above fields or if you want to put any additional information
<b>Tab3: Study progress &amp; results</b>		
<b>Study status *</b>	<i>planned</i> <i>ongoing</i> <i>finalised</i> <i>unknown</i> <i>cancelled</i>	
<b>&gt; Reasons for cancellation</b>	<i>financial issues</i> <i>legal issues</i> <i>organizational issues</i> <i>recruitment issues</i> <i>technology diffusion issues</i>	To be completed only if the status of the study is 'cancelled'
<b>Expected or effective starting date (MM/YYYY)</b>		of the study
<b>Anticipated or effective date of results (MM/YYYY)</b>		of the study
<b>Shared coordination/monitoring/funding with another EVIDENT partener</b>	Yes No	To be completed only if joint coordination/monitoring/funding of the study with an EVIDENT partner took place (further to an EVIDENT query for example)
<b>&gt; if Yes which one</b>		Scroll-menu containing names of agencies involved with EUnetHTA. Multiple choices possible (by holding Ctrl)
<b>Main Study results</b>	<i>not available</i> <i>published</i> <i>intermediary results available</i>	
<b>&gt; if Available attach Summary</b>		Please insure that the attachment does not exceed 10 MB
<b>Reassessment status</b>	<i>planned</i> <i>ongoing</i> <i>finalised</i> <i>not envisaged</i>	Refers to the additional assessment that could be performed once the missing evidence (identified in the initial HTA) had been gathered.

<b>URL reassessment report</b>	
<b>Results taken into account for reassessment</b>	<i>yes</i> <i>no</i>
<b>Comments</b>	This field is to be used if you need to further explain information entered in any of the above fields or if you want to put any additional information

## ANNEX 3 ITEMS OF THE MINIMAL SET OF INFORMATION FORM

<b>Agency</b>	Automatically generated when you sign-in with your EUnetHTA ID
<b>Country</b>	
<b>Contact</b>	
<b>HT assessment status</b>  <i>finalised</i> <i>ongoing</i> <i>planned</i>  <i>not assessed ( not yet planned)*</i> <i>not applicable-out of scope**</i>	Refers to the assessment of the technology concerned by the initial project  <i>* Not assessed ( not yet planned) = could be assessed but not planned for the moment</i> <i>** not applicable – out of scope = cannot be assessed at all (because the agency does not assess that type of technology)</i>
<b>Identified evidence gaps</b>  <i>safety</i> <i>clinical effectiveness</i> <i>cost effectiveness</i> <i>costs (units/indirect costs)</i> <i>budget impact</i> <i>conditions of use</i> <i>investment (materials and premise)</i>  <i>personnel recruitment and training</i>	Please indicate the domain(s) in which evidence gaps have been identified during technology's first assessment (multiple answers possible if needed - tick boxes)
<b>Coverage - reimbursement status of HT</b>  <i>covered</i> <i>not covered</i> <i>covered when associated with another technology</i> <i>conditionally covered</i> <i>restricted/ limited coverage</i> <i>pending decision</i> <i>unknown</i>	Refers to the coverage-reimbursement status after the first HTA has been performed but before the study (potentially modifying the decision) has been carried out.
<b>Additional study requested</b>  <i>Yes*</i> <i>No</i> <i>Not applicable</i> <i>Not officially requested, only recommended</i> <i>no but interested in participating</i> <i>no but interested in receiving information</i>	Further to the first assessment of the technology concerned by the initial project

\* ATTENTION: if you have requested an additional study, upon submission of your MSI form, you will be directed to the full registration form in order to provide details on your study. For details on how to fill-in that form please see the chapter 3 "Add a project".