

SANTE Data Collection Platform Online Help



ERN Applicant User Manual

Health and Food Safety

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WHAT IS THE SANTE ERN HCPA PLATFORM?

There are two system used in the ERN application process:

1. The SANTE Data Collection Platform

The SANTE Data Collection Platform holds the actual ERN application form – any required revisions to the actual application form should be made in this system. If you are requested to update and re-submit your application you will receive emails with links to direct you back to your application.

2. The SANTE ERN HCP Applications Status

The <u>SANTE ERN HCP Applications Status platform</u> is the platform from where you can monitor the status of your application, after its submission.

Here you will also be able to review any feedback from the Commission or the various bodies during the review. If required, you will also be able to provide additional feedback on your application on this system.

Please carefully read all notification emails that will be send during the assessment phase as it contains instructions you shall follow.

To have access to it, go to the main page of the <u>SANTE Data Collection Platform</u> and click on "ERN Application Status":

Home Forms About	Нер	user name
Useful documentation		
This webpage provides detai on the link to monitor your a	ils of the status of ERN applications – please click ERN Application Stat	us
Privacy statement:	specific-privacy-statement.pdf	
	To request deletion of your personal data in relation to this data collection controller listed in this Specific Privacy Statement.	n only, please contact the data
Contact Helpdesk:	SANTE-ERNSD-ITSUPPORT@ec.europa.eu	
Warning:	ONLY ENTER DATA INTO THE FORM USING ONE	COMPUTER/BROWSER
	AT A TIME. If more than one user enters and saves even if using the same login, data may be lost. If mo	data at the same time, ving to another computer.
	save your data and close the browser window with th	he form.
European Reference Net	works	
European Reference Net	works	

You will be redirected to the "SANTE ERN HCP Applications platform":



The home page provides you with an overview of the submitted application, with details related to its status, the decisions already taken and the number of days left.

Use the navigation menu on the left to browse between the different pages:



Home	Go back to the main page of the ERN HCPA Platform
HCPA Histories Overview	Click on "ERN Reviewed Application" to go to the applications that have already been reviewed by the ERN or click on "All HCP Applications" to display all the applications that are in the review process.
Recent HCPA Histories	Go to your most recent applications
Sante Data Collection Platform	Go back to the Sante Data Collection Platform

HOW TO MONITOR THE APPLICATION PROCESS

After submitting your application, you can monitor its status during each review stage, from the **SANTE ERN HCP Applications platform**.

1								
Hone HOR Hobris overlev Roart HCR-Hobris Austri HCR-Hobris Jurients-HDR-Hobris SAVITE Data Collection Pattom	ERN HCP Applicati Europe Referer Networ	ions nce rks each applications received from Healthcare Pr each application and includes the decisi	roviders applying to join a ons, court-down times a	Co-financed Connecting El s members of European Reference Network d comments provided during each review st	by the European urope Facility sin accordance with Directive 2011/24EU.	Union		
	D 2019112542055556A 201911254010458W 20191125-010F4Rey See more here » Browser Advisory fo	ERN ERN-BOND ERN-LUNG ERN-BOND Ir HCPA - Process Engir	Stage Eligibility (Eligibility (Eligibility)	hedvERN review complete hedvERN review complete hedvERN review complete	Decision EPN (svorable EPN (svorable (fmed out) (fmed out)	j: Days left 365 365 365	Received 2019/11/26 2019/11/26 2019/11/25	Status Open Open Open

If you have submitted more than one application – the applications will display (by ID) in the list as shown above and you can track the progress of each application

To keep track of your applications, click directly on its *ID*, at the beginning of the row:

D	ERN	Stage	Decision	J≞ Days left	Received	Status
20191127- AYK6CQUX	BOND	Eligibility check/ERN review complete	ERN favourable (timed out)	365	2019/11/27	Open

Commission SANTE ERN	HCP Applications			💄 applicant user name
/ hcpahistory / 20191004-9WYWEF3P				
♠ Home	HCP Application:	20191004-9WYWEF3P		
L HCPA Histories overview	HCP Application ERM	Review details		
Recent HCPA Histories 20191004-9WYWEF3P	ICF Application ERI	N Review details	0191004-9W/WEE3P	
SANTE Data Collection Platform	ERN.		RNBOND	
	Stage:		ligibility check/ERN review complete	
	Received:	2019/10/04 14:53	Progressed:	2018/10/04 15:48
	Days remaining:	365	User:	n602pu2q
	Applicant email:	testi@test.com	Decision:	ERN favourable (timed out)
	Provider:	Centre Hospitalier de Luxembourg	Country:	LU
	City:	luxemburg		
	0			
	Submitted Fligibility Check	ERN Review EC Consultation IAE Draft Assessment IAE I	inal Associament BoMS Approval Final Decision	
	Withdraw application			
	History:			
	Stage: HCP-Application (submitted)			
	Date: 2019/10/04 14.53 Message:			
	Catherine Colelli			
	 20191004-9WYWEF3P-subm 	itted pdf		
	 agreement-oeo.pdf hcp-representative.pdf 			
	 letter-of-national-endorsement 	txtsx		
	Download all attachments in this sta	6e		
	Stage: EC - Eligibility Check (1st) (e	ligibility-check)		
	Decision: eligible			
	Message: This is a acceptable application			
	Reason 1 Demons 2			
	•			
	Collapse			
	Stage: ERN draft opinion pending	(review)		
	Date: 2019/10/04 15:48 Decision: ERN tayourable			
	Message:			
	rins application has timed out in the	process acure em-review stage while in ERN feview state.		
	Download all attachments for this ap	oplication (you will only receive files that you have rights to vie	W).	
	Current stage: ERN review comple	te, final opinion issued.		
	To view your application, follow this	ink: https://webgate.acceptance.ec.europa.eu/sante-xm/gate	#!roms/em-application/v1/20191004-9WYWEFSP Open	3

All the information related to the selected application will be displayed in a new page:

At the beginning of the page you can find all relevant details concerning the application:

/ hcpahistory / 20191004-9WYWE	F3P			
 Home Li CDA Listorios autoniauti 	HCP Application	on: 20191004-9WY	WEF3P	
 Recent HCPA Histories 	HCP Application E	RN Review details		
> 20191004-9WYWEF3P	ID:		20191004-9WYWEF3P	
SANTE Data Collection Platform	ERN:		ERN-BOND	
	Stage:		Eligibility check/ERN review complete	
	Received:	2019/10/04 14:53	Progressed:	2019/10/04 15:48
	Days remaining:	365	User:	n002pu2q
	Applicant email: Update email address	test@test.com	Decision:	ERN favourable (timed out)
	Provider:	Centre Hospitalier de Luxembourg	Country:	LU
	City:	luxemburg		
	Submitted Eligibility Check	ERN Review EC Consultation U	AB Draft Assessment IAB Final Assessment BoMS Approval	Final Decision

The Status Tracker Bar

What it is noteworthy in this section is the **status tracker bar** that helps you follow the progress of your application during the whole review process.

The legend below shows the main icons that are used in the tracker bar:

ICON	MEANING
	application submitted and/or stage successfully completed
0	application pending review
0	application returned to applicant for editing
	application rejected
	stages to come

After submitting an application, the tracker bar will show a green tick confirming that the submission was successful and that the review process has begun.

Note: the current status of your application is always the last circle before the transparent ones:

Submitted	Eligibility Check	ERN Review	EC Consultation	IAB Draft Assessment	IAB Final Assessment	BoMS Approval	Final Decision

When the circle is in white, it means that your application is pending and waiting for review.

In case the application is returned to you for a review the tracker bar will show this activity with an orange circle:

Submitted	Eligibility Check	ERN Review	EC Consultation	IAB Draft Assessment	IAB Final Assessment	BoMS Approval	Final Decisio

If the review is positive, the progress of your application will be shown on the tracker bar with a green tick:



In this way, if your application is fully approved and passed all the stages, the tracker bar will show the green tick for all the stages:



On the contrary, if your application is rejected, your application will not go further in the process review and the track bar will mark the rejection with a red circle:

Submitted	Eligibility Check	ERN Review	EC Consultation	IAB Draft Assessment	IAB Final Assessment	BoMS Approval	Final Decision

Note: If the application is marked ineligible, please check the message area at the bottom of the page to review the feedback from the Commission



Viewing the application progress history

Scrolling down the page, you find "History": a detailed summary of the application review process, from its submission until the current stage



From the submission to the current stage, you have information about the date, the decisions taken, the feedback provided on the application and the attachments uploaded at every stage of the process.

In this section you can:

Download the *pdf* uploaded with the application and all other attachments included in it.
 To do it, click on each individual attachment or on "download all attachments for this application" to bulk download them all

Stage: Returned to applicant for editing (eligibility-revision) Date: 2019/10/03 15:23 Message: Catherine Coletti submission bis Attachments: • 20191003-CDWGAKKW-eligibility-revision.pdf • agreement-ceo.pdf

- hcp-representative.pdf
- letter-of-national-endorsement.xlsx

Download all attachments in this stage

Use the link at the bottom of the page to go back to the application form and go through its sections, in view-only mode.

Current stage: ERN review complete, final opinion issued.

To view your application at any time, follow this link: https://webgate.acceptance.ec.europa.eu/sante-xmlgate/#I/forms/em-application/v1/20191127-AYK6CQUX Open

HOW TO RESPOND TO FEEDBACK REQUESTS AT EC ELIGIBILITY CHECK OR ERN REVIEW STAGES

After the submission, your application will have to pass different evaluation phases in the <u>application process</u>. The first two stages are the **EC Eligibility Check** and the **ERN review**.

In case your application receives an unfavourable opinion at either stage and you are asked to provide more information or update your application, the system will send a message to the contact email provided in your application form. Below is an example of an email from the Board of Network:

ear Applicant,	De
our application has received an unfavourable decision of the Board of the Network.	Yo
ease click the link below to follow the status of your application. There, you will be able to see the comments provided by the ERN Board, open, update and resubmit your application. Upon esubmission there will be a pop-up box for you to provide simple feedback or any other comment to the ERN. You will be able to provide more detailed feedback, including the possibility of ploading feedback documents, at the next stage of the process.	Ple re uț
ttps://webgate.acceptance.ec.europa.eu/sante-xmlgate/ern-hcpa/#/hcpahistory/20191128-QQBZC64Y	ht
you are not the intended recipient, or if this message has been sent to you mistakenly, please inform the administrator at SANTE-ERNSD-ITSUPPORT@ec.europa.eu and we will try to rectify the tuation for you as quickly as possible.	lf i sit
nis is an automated email notification.	Th
his message is from the ACCEPTANCE environment. The dossier and actions in this message do not involve Production data. If you are not the intended recipient, or if this message has been sent to ou mistakenly, please inform the administrator at <u>SANTE-ERNSD-ITSUPPORT@ec.europa.eu</u> and we will try to rectify the situation for you as quickly as possible.	Th yc

To start revising your application click on the link in the email to go to <u>SANTE ERN HCP</u> <u>Applications Platform</u>. You will notice that your application has changed its status *to in revision* on the main page:

I.							
Home Home HCPA Historius ovorview Recent HCPA Historius SANTE Data Collection Platform	ERN HCP Applic	ations		Co-financed by the Europ	oean Union		
	Netw	orks	****	Connecting Europe Facility			
	This platform provides detail The platform tracks the statu	s of applications received from He	althcare Providers applying to the decisions, count-down th	join as members of European Reference Networks in accordance with Directiv nes and comments provided during each review stage.	≘ 2011/24/EU		
	Your applications. These are	the applications that you currently ERN	have in the system. Stage	Decision	j≞ Days left	Received	Status
	20191125-070F4RAY See more here »	ERN-BOND	Application re	vision ERN unfavourable	4	2019/11/25	Open

The application will appear under **"Your HCP Application for revision"** in the *HCPA Histories Overview*:

/ hcpahistories							
 Home HCPA Histories overview Recent HCPA Histories SANTE Data Collection Platform 	HCP Application Please note that submissions and Auto-refresh Your submitted HCF	INS resubmissions made by applica PApplications	ants can take up to an hour to appear here. These	lists are refreshed automatically.			
	Submitted Eligibility Check	ERN Review EC Consultat	ion M8 Draft Assessment M8 Final Assessment I made an application on SANTE Data Collection	bMS Approval Final Decision Platform, it may take up to an hour for it to appear here.			
•	These are your draft application	ERN Stor revision ERN Review EC Consultat hat have been given an unfavo	Stage	Decision MS Approval Field Decision sitted.	j≞ Days lett	Received	Status
	D 20191125-070F4RAY Your finally approve Optimized Eligibility Check	ERN ERN-BOND d HCP Application ERN Review EC Consultat	Stage Application revision S MB Draft Assessment MB Final Assessment I	Decision ERN unfavourable	j≞ Days left 3	Received 2019/11/25	Status Open

By clicking on the application *ID*, you can consult the application details and read the feedback provided about your application:

/hcpshistory/20191125-070F4RAY				
A Home		HCP Application: 20191125-070F4RA	Y	
HCPA Histories overview		HCP Application ERN Review details		
 20191125 070F4R/Y 			20191125-O7OE4RAY	
SANTE Data Collection Platform		ERN:	ERN-BOND	
You have 1 month		Stage:	Application revision	
to revise the application		Received: 2019/11/25 11:00	Progressed:	2019/11/25 12:00
The number of days left	Γ,	Days remaining: (10)	User: Decision:	ERN unfavourable
will count down 30 days		Update email address		
		Provider: City: Brussele	Country:	8F
The track bar				
shows the stage of the	e 🛁	0-0-0-0		
review process		Submitted Eligibility Check ERN Review EC Consultation IAB Draft Assess	iment 14B Final Assessment BoMS Approval. Final Decision	
		Withdraw application		
		History:		
		Stage: HCP-Application (submitted)		
		Date: 2019/11/25 11:00		
		ok Affaelmente		
		20191125-070F4RAY-submitted.pdf		
		agreement-cec.pdf hcp-representative.pdf		
		letter-of-national-endorsement.docx		
		Download an attactments in this plage		
		Stage: EC - Eligibility Check (1st) (eligibility-check)		
		Date: 2019/11/26 11:03		
		Expand		
		Stage: ERN - draft opinion pending (review)		
ERN's opinion		Decision: FRN unfavourable		
and feedback	\rightarrow	Message: attachment not readable, information incomplete, more details needed		
		Connecto:		
		Stage: Application revision (revision)		
Click on the link to		Date: 2019/11/25 12:00 Dear applicant, please see the feedback above. You can reopen your application for e	diling/updating by clicking the following link or pressing the 'Open' bullon.	
open your application	↦	https://webgale.acceptance.ec.europa.eu/sante-xmlgale/W/forms/em-application/v1/2	0191125-O7OF4RAY Open If you have recently resubmitted your applica	alion, please be
and re-edit it		patient as it may take up to an neur for this to update while the system processes you	rupdated submission.	
		Download all attachments for this application (you will only receive files that you have	rights to view).	
		Dear applicant, please see the feedback above. You can reopen your application for e	difinglupdating by clicking the following link or pressing the 'Open' button: I	https://webgate.acceptance.ec.europa.eu/sante.xmlgate/ii/Morms/em-
		application/v1/20191125-O7OF4RAY Open		

There are two steps of the revision of your application:

Step 1: Go to the application form, back on the **SANTE Data Collection Platform**, using either the **"Open"** button or on the link at the bottom of the page:



Here, you can revise your application form:

Auto	Save - When checked, your work will automatically save every 5 minutes	
Enter th stage of	e email address associated with the EU Login used to access this form. This email will receive the automated notifications the application process has completed.	when each
maddal	ena.iandimarino@gmail.com	
Appl	ication form Self-assessment checklist	
1:	Information on the healthcare provider	•
2:	Area of expertise of the healthcare provider	Þ
3:	Services covered by the healthcare provider	Þ
4:	Number of patients seen by the healthcare provider	۱.
5:	Healthcare professionals in the multidisciplinary team	۱.
6:	Specialised equipment, infrastructure and information technology used by the healthcare provider to support diagnosis, care and treatment Θ	•
7a:	Description of healthcare provider activities or strategies	•
7b:	Contributions of the healthcare provider – research activities	•
7c:	Contributions of the healthcare provider – clinical practice guidelines	•

After you have revised your application, you have to submit it again by clicking on the button **"Finish and Submit"** at the bottom of the application form:

ID: 20191125-070F	4RAY Show form information	n	
Submit and close form	Download PDF of dossier	Clear form	Finish and exit form
Set dossier to 'hold'	Archive this dossier		

A message will pop up asking you to confirm your action. Here you also have the possibility to add a comment by writing in the blank field:

Submission to workflow

You are submitting this dossier to the HCPA workflow where it will be reviewed. If you are resubmitting, you must take further actions to continue your submission in the HCPA workflow. Are you sure you wish to continue? Comment (optional):

You will receive progress notifications at the email address entered in this form, and you can follow the progress of your submission at https://webgate.acceptance.ec.europa.eu/santexmlgate/ern-hcpa/ - it may take up to an hour for your submission to appear there.

		Submit	Cancel	
	L			
V	Note: C	omments are not manda	atory	

If you wish to proceed with the resubmission, click on "Submit".

Another message will pop up confirming that the application has been submitted:



The form data has been submitted to workflow with a dossier ID of 20191125-O7OF4RAY, and is now awaiting approval. It is no longer available for editing.



Immediately after the new submission you will receive an email confirming that your application form has been updated:

Note: your resubmission has not been finalised yet!

Your resubmission is not finalised until you complete the following steps on the SANTE ERN HCP Application Platform

Step 2: Go to the *SANTE ERN HCP Application Platform* to finalize your new submission using the link mentioned in the email.

Note: the system may take up to an hour to update with your re-submitted application and allow you to add feedback

The link will redirect you back to the application dossier:

/ hcpahistory / 20191126-UZO65PEA						
A Home	HCP Application:	20191126-UZO65PEA				
HCPA Histories overview Decent HCPA Histories	HCP Application ERN	HCP Application FRN Review details				
SANTE Data Collection Platform						
	IU:		20191120-02000PEA			
	ERN:		ERN-BOND			
	Stage:		Application revision			
	Received:	2019/11/26 13:23	Progressed:	2019/11/26 13:40		
	Days remaining:	18	User:	Maddalena landimarino		
	Applicant email:	maddalena.iandimarino@ext.ec.europa.eu	Decision:	ERN unfavourable		
	Update email address					
	Provider:	UZ Gent	Country:	BE		
	city.					
	Application revision					
	Withdraw application					
	History:					
	Stage: HCP-Application (submitted)					
	Date: 2019/11/26 13:23					
	Message:					
	Attachments: 20191126-UZ065PEA-submitte	ed.pdf				
	 agreement-ceo.pdf 					
	 hcp-representative.pdf 					

letter-of-national-endorsement.docx

Download all attachments in this stage

 Image: Propriet of the property of the propert

Scrolling down the page, under "History", you will find that a new stage has been added:

If you want, you can enter a feedback about your resubmission.

Note: Feedback is not mandatory

You have also the opportunity to add additional attachments here, but to do that you have to **save** your edit first by clicking on **"Save Edits"** at the bottom of the page.

To upload your attachments, click on the grey rectangle below the free text field or simply drag and drop in there your files.

Length of field: 0 / 3,750 characters.
To add file attachments, click on the region below or drag and drop one file at a time to the region below. These can be removed while the stage is still open for editing, but not afterwards.
Save edits Resubmit application
Download all attachments for this application (you will only receive files that you have rights to view).
To view your application at any time, follow this link: https://webgate.acceptance.ec.europa.eu/sante-xmlgate/#//forms/ern-application/v1/20191127-AYK6CQUX Open

To complete your resubmission, click on "Resubmit application".

Your updated application will then be reviewed.

During the whole review process, you will receive <u>email notifications</u> about the progress of your submission:

A message from ERN HCP Applications Processor (https://webgate.acceptance.ec.europa.eu/sante-xmlgate/ern-hcpa/)
A message from SANTE Data Collection Platform (https://webgate.acceptance.ec.europa.eu/sante-xmlgate/)
Dear Applicant,
The status of your application to become a member of a European Reference Network has changed. Please log-in here to view the update:
https://webgate.acceptance.ec.europa.eu/sante-xmlgate/ern-hcpa/#/hcpahistory/20191125-070F4RAY
If you are not the intended recipient, or if this message has been sent to you mistakenly, please inform the administrator at SANTE-ERNSD-ITSUPPORT@ec.europa.eu and we will try to rectify the situation for you as quickly as possible.
This is an automated email notification.
This message is from the ACCEPTANCE environment. The dossier and actions in this message do not involve Production data. If you are not the intended recipient, or if this message has been sent to you mistakenly, please inform the administrator at SANTE-ERNSD-ITSUPPORT@ec.europa.eu and we will try to rectify the situation for you as quickly as possible.

At the same time, you can always keep track of your submissions on the <u>SANTE ERN HCP</u> <u>APPLICATIONS Platform</u>, as explained in <u>"How to monitor the application process"</u>.

HOW TO CHANGE CONTACT ADDRESS

If you wish to update your contact email address, you can do it from the <u>SANTE ERN HCP</u> <u>APPLICATIONS Platform</u>.

Go to the platform and click on the *ID* of your application to open its dossier.

Under the *HCP Application ERN Review Details,* you will find the "applicant email" and the button "Update email address":

HCP Application	ERN Review details			
ID:	20191	127-AYK6CQUX		
ERN:	BONE)		
Stage:	Eligibi	ility check/ERN review compl	ete	
Received:	2019/11/27 22:30	Progressed:	2019/11/27 23:51	
Days remaining:	365	User:	Maddalena landimarino	
Applicant email: Update email address	maddalena.iandimarino@gmail.com	Decision:	ERN favourable (timed out)	
Provider:	Institut Jules Bordet	Country:	BE	
City:				
Submitted Eligibility Ct	neck ERN Review EC Consultation IAB Draft Ass	essment IAB Final Assessment BoMS App	roval Final Decision	

Click on it and insert your new email address in the window that will pop up:



Update contact email address

Enter your updated email address(es) here. You can enter more than one address by separating them with commas (,):



Then click on "Update".

HOW TO WITHDRAW AN APPLICATION

On the <u>SANTE ERN HCP APPLICATIONS Platform</u> you have also the possibility to withdraw your application, if you wish to do so. An application can be withdrawn at any stage during the process.

Similarly as before, go to the platform and click on the *ID* of your application, to open its dossier.

Under the track bar you find the button "Withdraw application".

Click on it to proceed with the withdrawal.

	.ion. 20131121-ATROOQ	0X		
HCP Application	I ERN Review details			
ID:	20191	127-AYK6CQUX		
ERN:		I Contraction of the second		
Stage:	Eligibil	ity check/ERN review comple	ete	
Received:	2019/11/27 22:30	Progressed:	2019/11/27 23:51	
Days remaining:	365	User:	Maddalena landimarino	
Applicant email:	maddalena.iandimarino@gmail.com	Decision:	ERN favourable (timed out)	
Provider:	Institut Jules Bordet	Country:	BE	
City:				
Submitted Eligibility C	theck ERN Review EC Consultation IAB Draft Ass	essment IAB Final Assessment BoMS Appro	val Final Decision	
Withdraw application	-			
History:				

Confirm your action in the window that will pop-up by clicking on "Withdraw application"



Another window confirming the withdrawal of your application will be displayed and you will also receive an email notifying that your application has been withdrawn.



Application withdrawn by Applicant

The application '20191126-W1YA6XBW' has been withdrawn by the applicant and it has been archived.



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