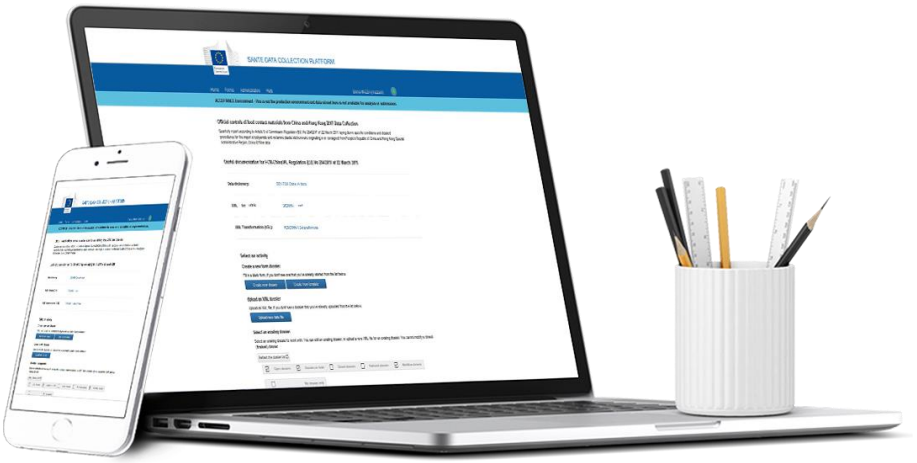
European Commission

SANTE Data Collection Platform



ERN Applicant User Manual

Health and Food Safety

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SANTE Data Collection Platform User Guide

Prerequisites

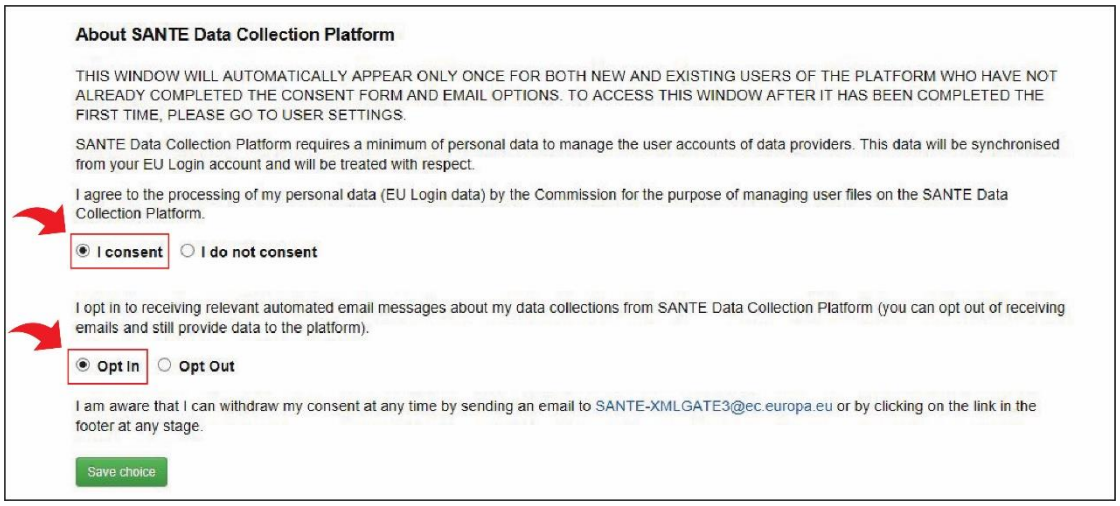
Prerequisites to access the SANTE Data Collection Platform:

- An EU Login (ECAS) account;
- A SAAS Authorisation;

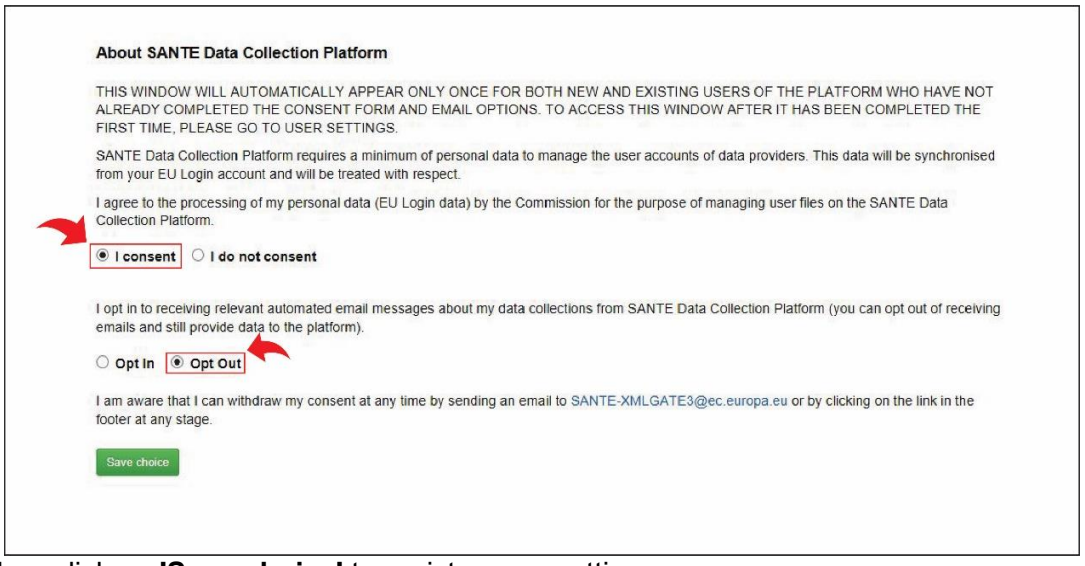
Further information on how to create an EU Login is available here https://webgate.ec.europa.eu/cpnp/public/ecas-create.cfm.

User Data Consent

After the first login (see 'How to access an application form' section), you will be redirected to the User Data Consent page. In order to be able to access Sante Data Collection Platform, you have to agree to the processing of your personal data by clicking on 'I consent'.

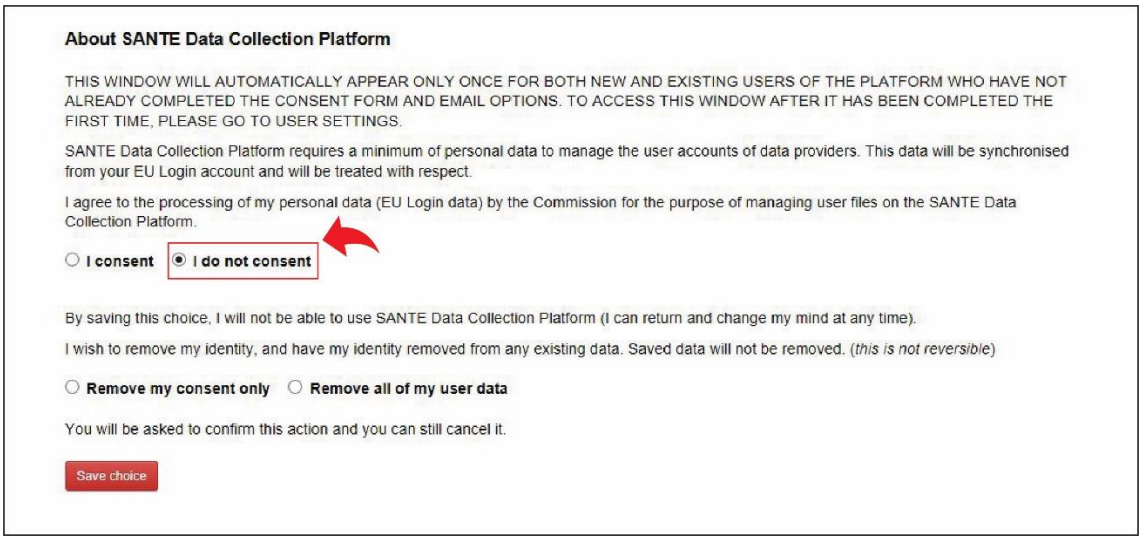


The second option is not binding; you can opt out of receiving emails about your data collections and still provide data to the platform



Then click on **'Save choice'** to register your settings.

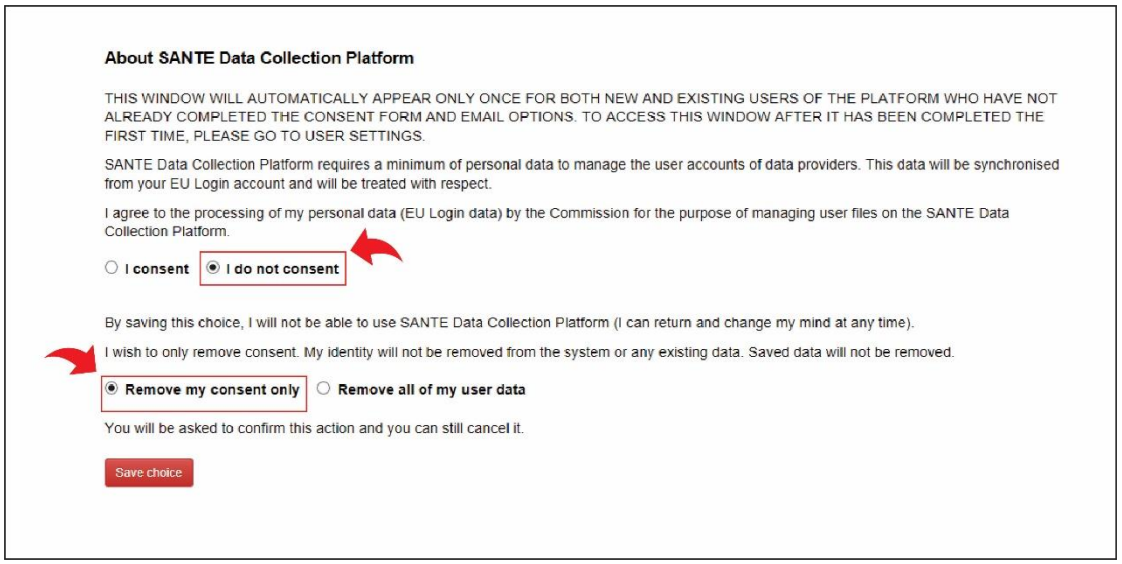
Alternatively, you can refuse to give your consent by clicking on **'I do not consent'**



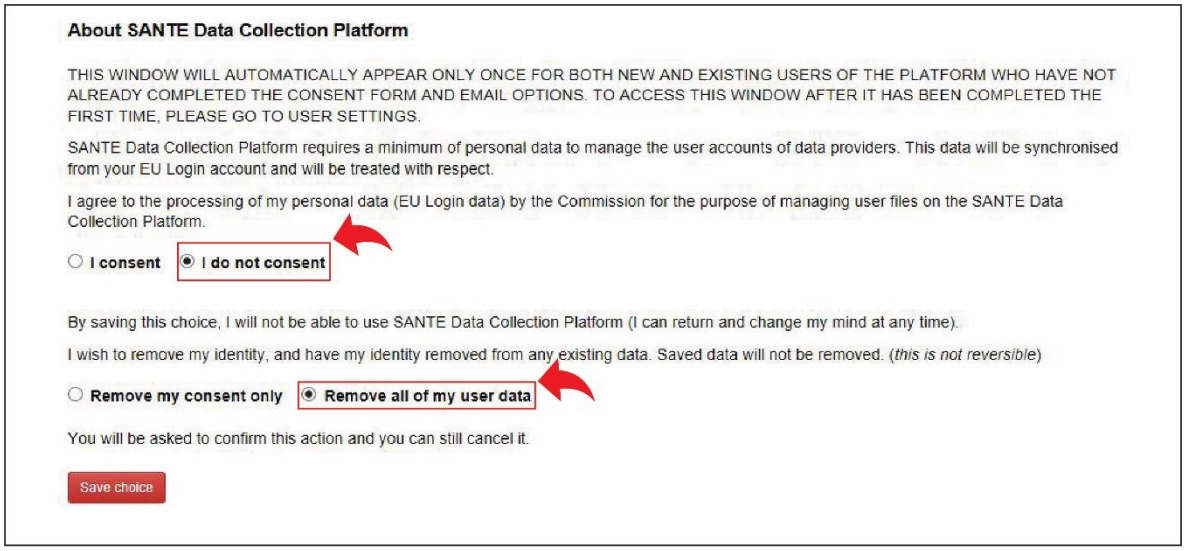
Note: Without giving your consent to the processing of your personal data, you will not be able to use the Sante Data Collection Platform.

If you wish to go further with this choice, you have two options:

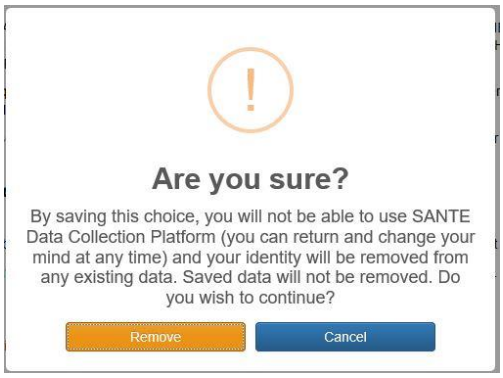
1) by clicking on **'Remove my consent only'**, you decide to remove your consent only, keeping your identity or any existing data in the system.



2) by clicking on **'Remove all my user data'**, you choose to have your identity completely removed from Sante Data Collection Platform

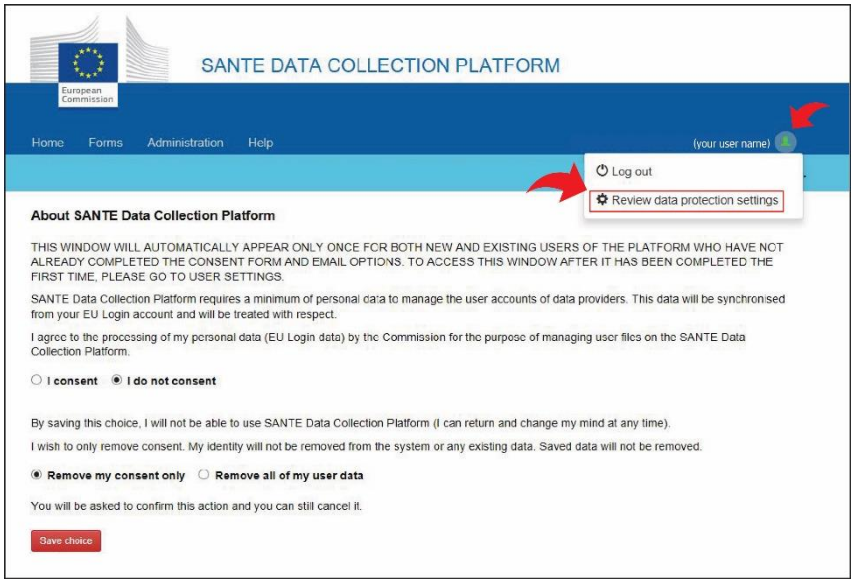


Once you have made your decision, click on **'Save choice'** and you will be asked to confirm this action



Select the button **'Remove'** in order to complete the action.

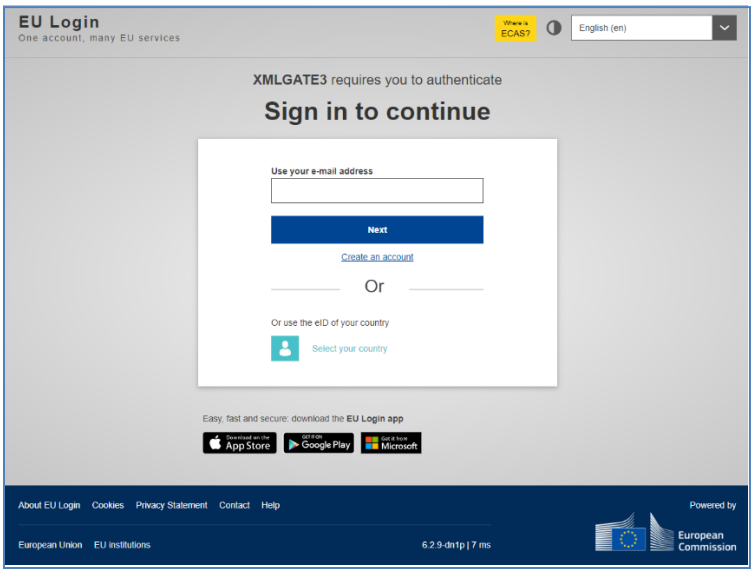
Note: In any case, saved data will not be removed and you can return and change your choices at any time by clicking on your profile icon, on the top right corner of the page, and selecting '**Review data protection settings**'



How to access an application form

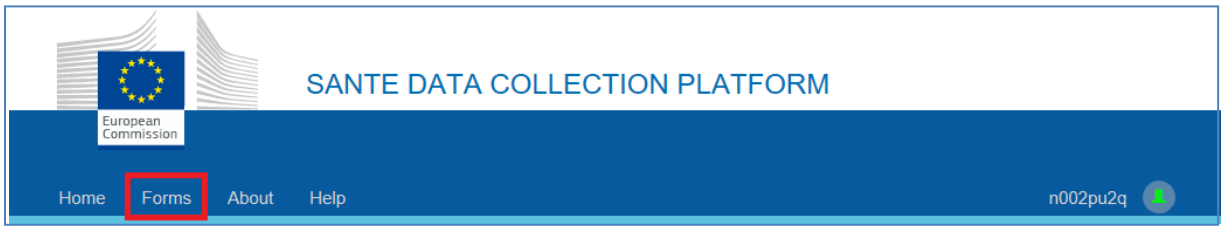
To access a form, go to https://webgate.ec.europa.eu/sante-xmlgate/#!/forms/ern-application

If you have not authenticated with EU Login (ECAS) beforehand, the system will ask you to insert your EU Login details:

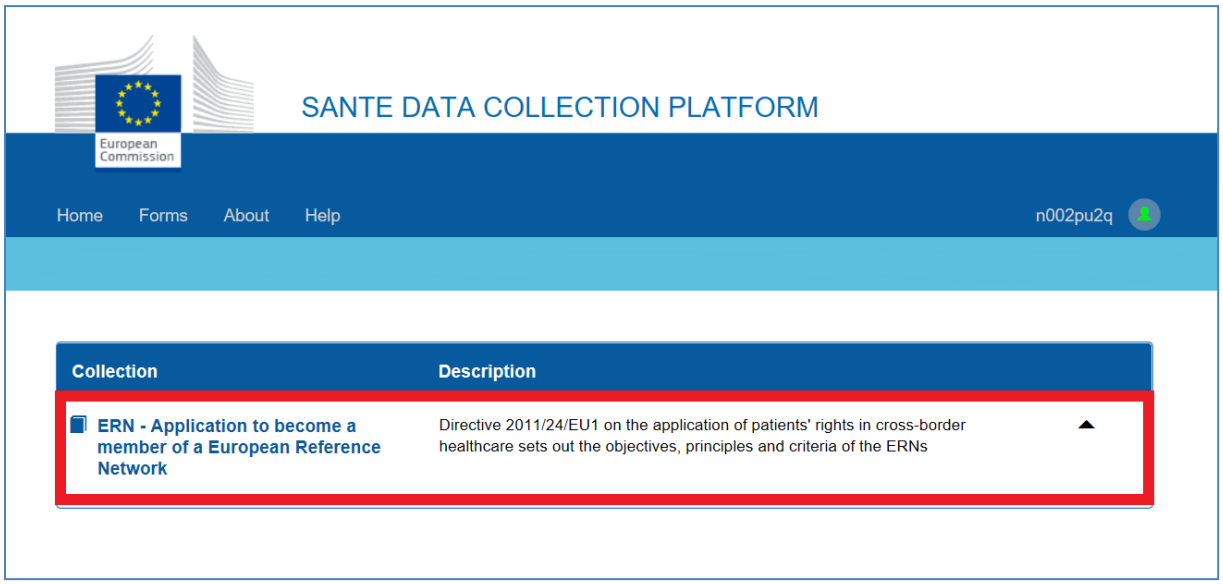


Follow the procedure, inserting your email address and password and, if you are successful, you will be redirected to the **SANTE Data Collection Platform**.

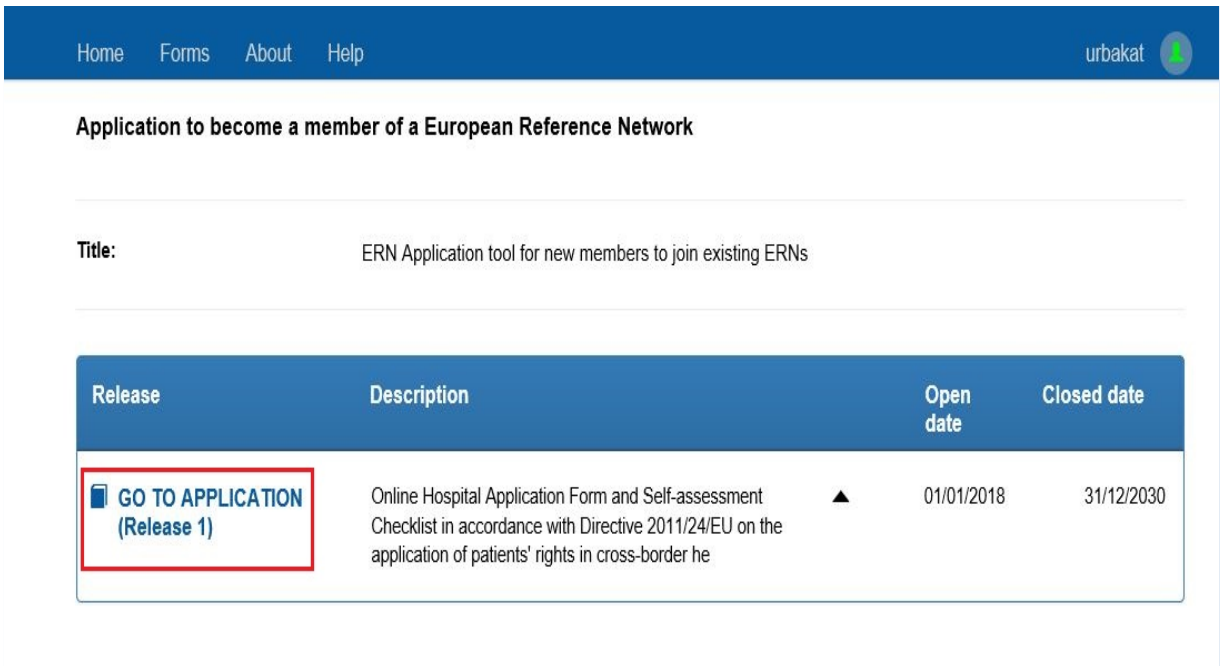
To access the application form, click on "**Forms**" in the top navigation menu:



Select the relevant form for "**ERN – Application to become a member of a European Reference Network".**

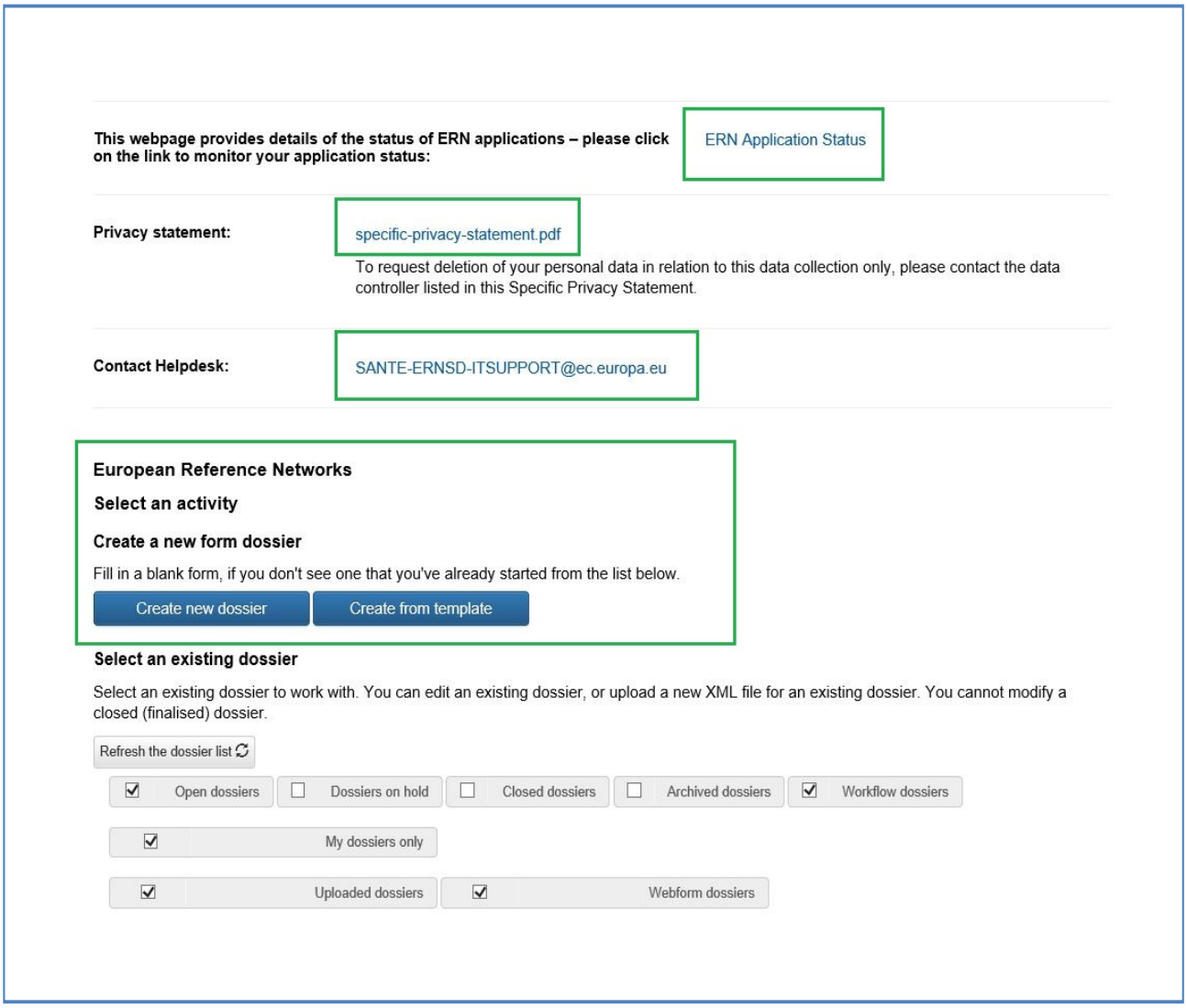


Select the **GO TO APPLICATION** to create your application:



From the new page that will be displayed, you will be able to create a new dossier.

After opening of the **Release 1** "**ERN – Application to become a member of a European Reference Network", the main page is visible**



There are several important fields:

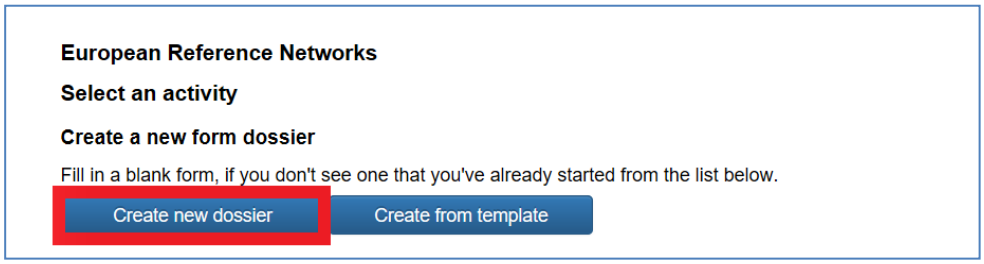
1. ERN Application Status - here you can follow your Application status
2. Specific privacy statement - here you can read all information related to protection of personal data provided in the context of processing of personal data within the ERN HCP Application Tool
3. Helpdesk contact: For technical assistance, please contact the helpdesk
4. Activity buttons for creating new dossiers - explained below

How to create a new application

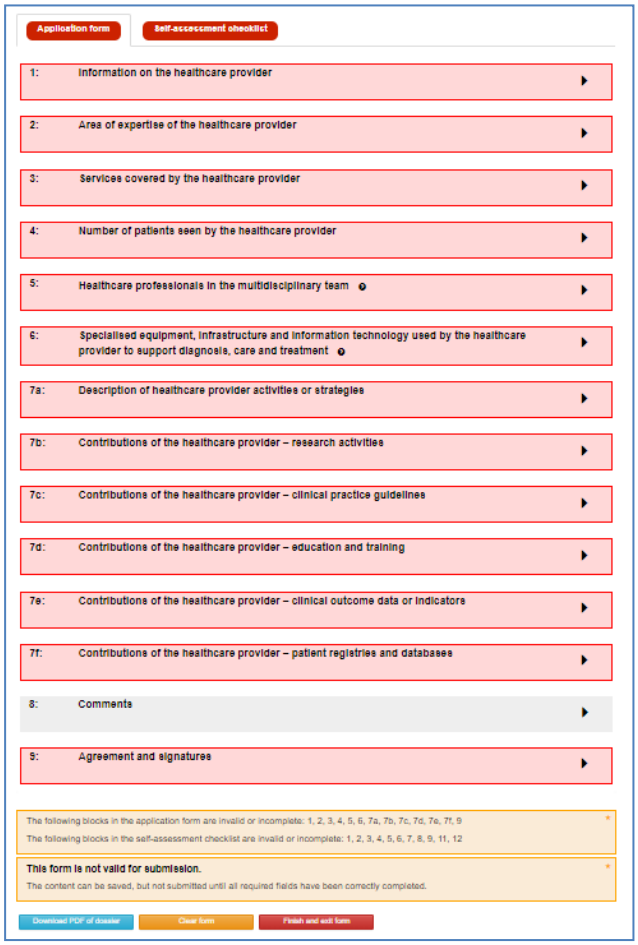
There are three different ways to create a new application: *from scratch*, *from a template* or *duplicating an existing application*.

Create an application "from scratch"

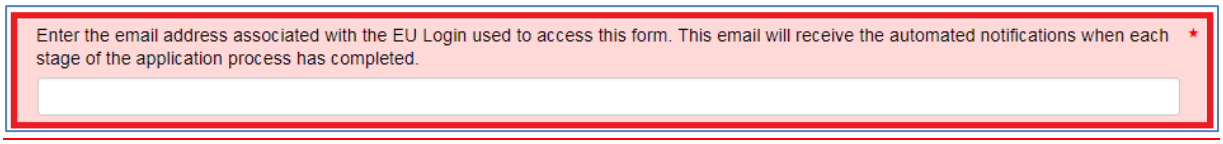
You can create a new dossier entirely *from scratch* by simply clicking on "**create new dossier**"



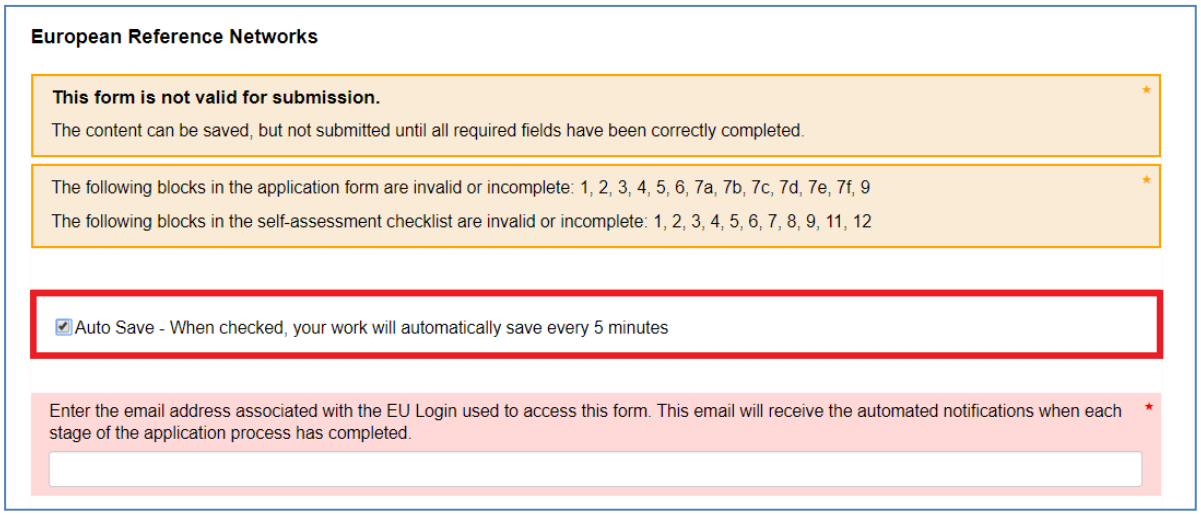
The form will be displayed below:



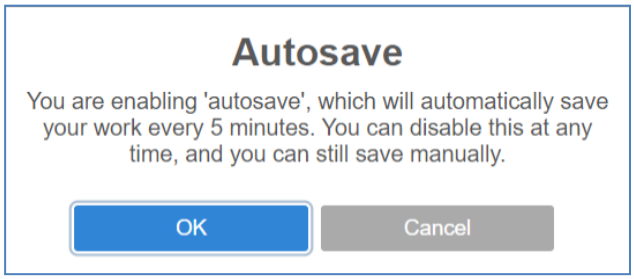
Before you start, insert the email address associated with the EU Login that you have used to access the form. In this way you will receive automated notifications when each stage of the application process has completed:



You can also enable the "**Autosave**" functionality which will automatically save your work every 5 minutes. To do so, just tick the box as shown in the print screen below:



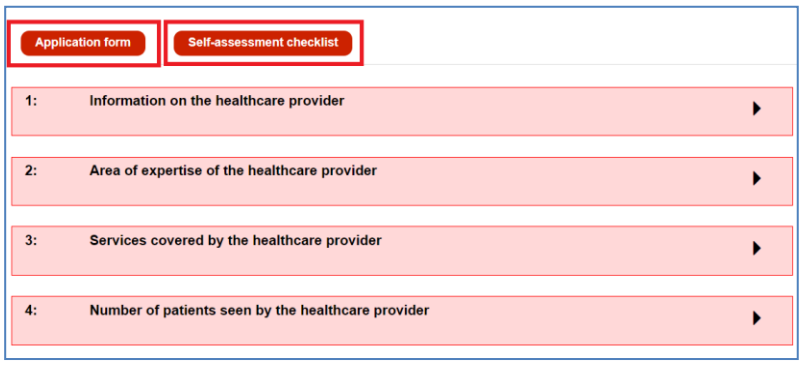
You will have to confirm your action:



You can disable this at any time, and you can still save the form manually.

Back to the application form:

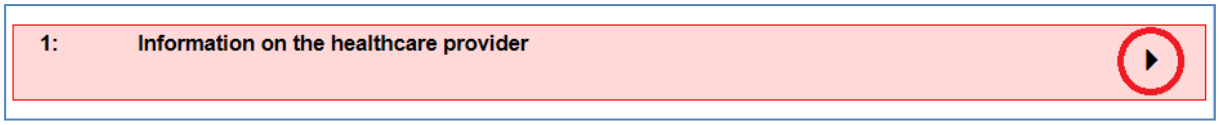
Note: the form is composed of two tabs: “Application form” and “Self-assessment checklist”:



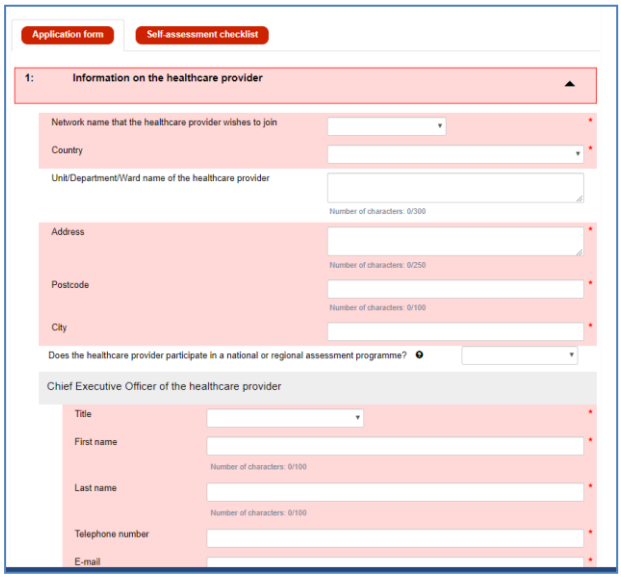
Start filling in the 9 sections below the first tab "Application form".

It is recommended to fill in the sections following their numerical order, because some sections are linked and depend on the previous ones.

To open each section, just click on the small arrow at the end of the row:



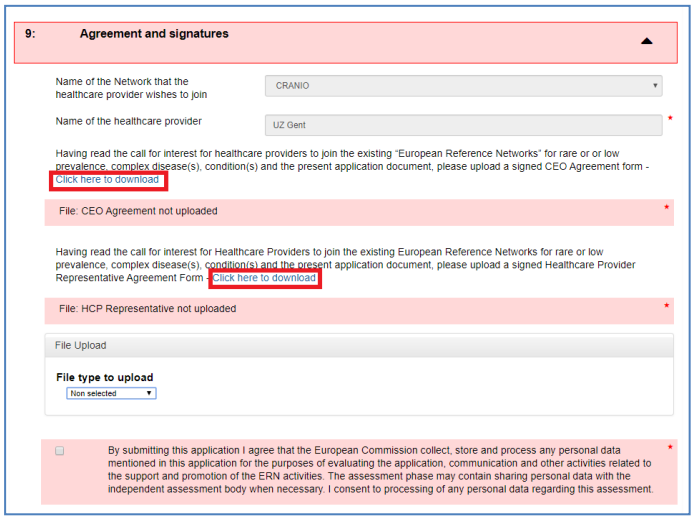
The related section will be displayed below:



Note: all the fields marked with the red asterisk * are mandatory.

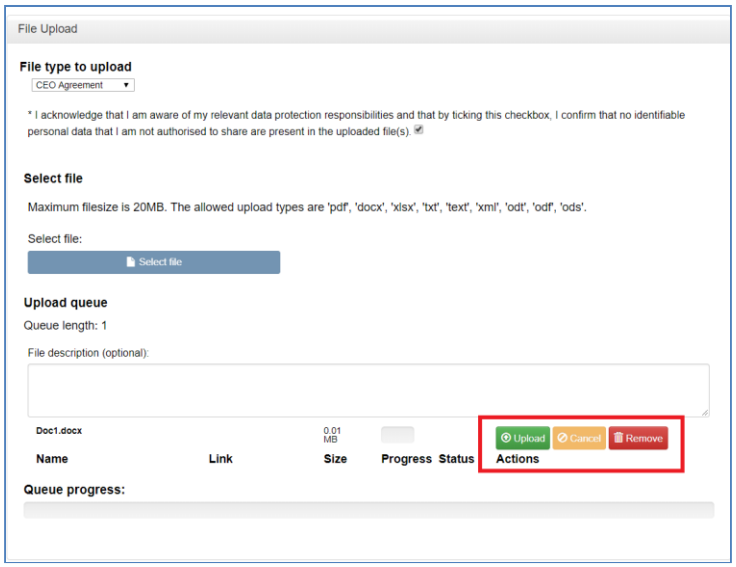
As soon as a section is complete, its colour will change to green and you can move to the next one:

In section 9 of the "**Application Form**", you are requested to upload a signed *CEO Agreement form* and a signed *Healthcare Provider Representative Agreement F*orm. Both forms are mandatory and can be downloaded from links in the same section:



Note: in order to be able to upload attachments you **must** select the file from the drop-down menu under "**File type to Upload**"

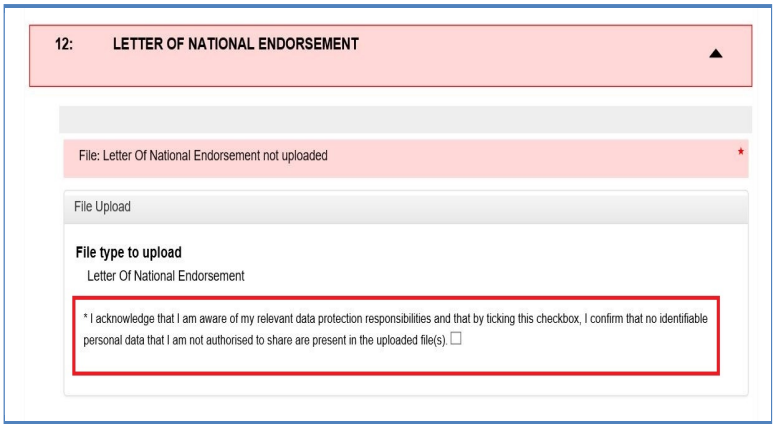
Only after ticking the checkbox acknowledging the Data Protection Regulation, the option "**Select file**" will appear below:



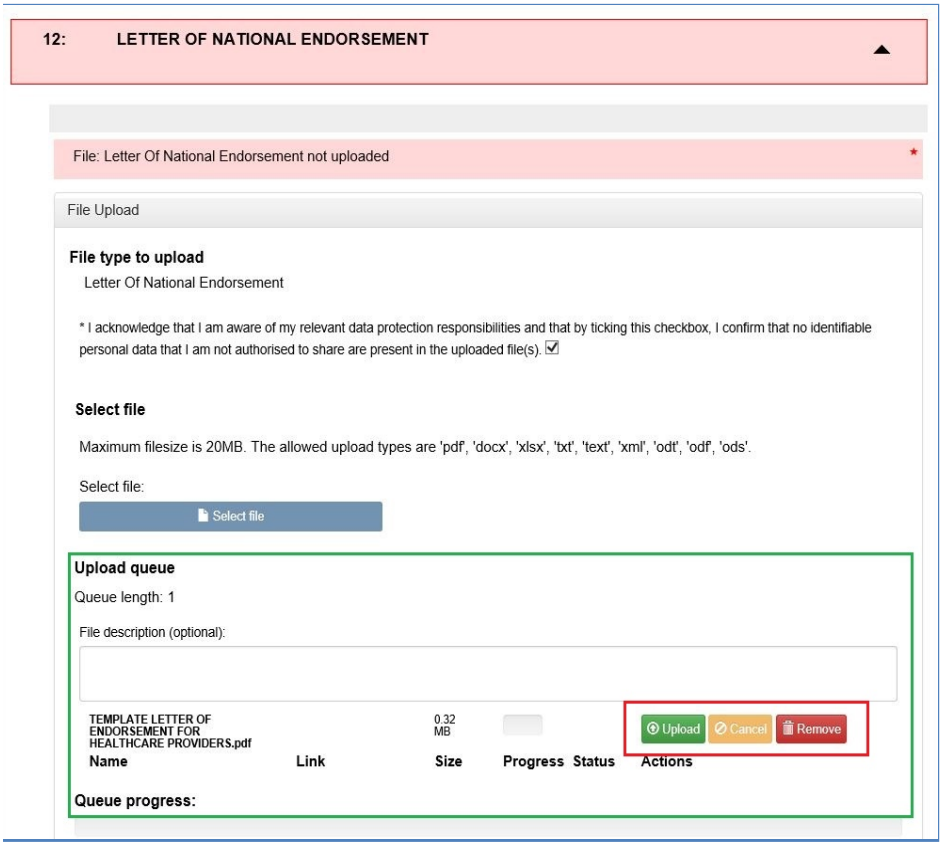
You will have to repeat this operation for both documents.

To upload the file you should click on the 'upload' button.

Before uploading the **Letter of National Endorsement** you should tick the check-box



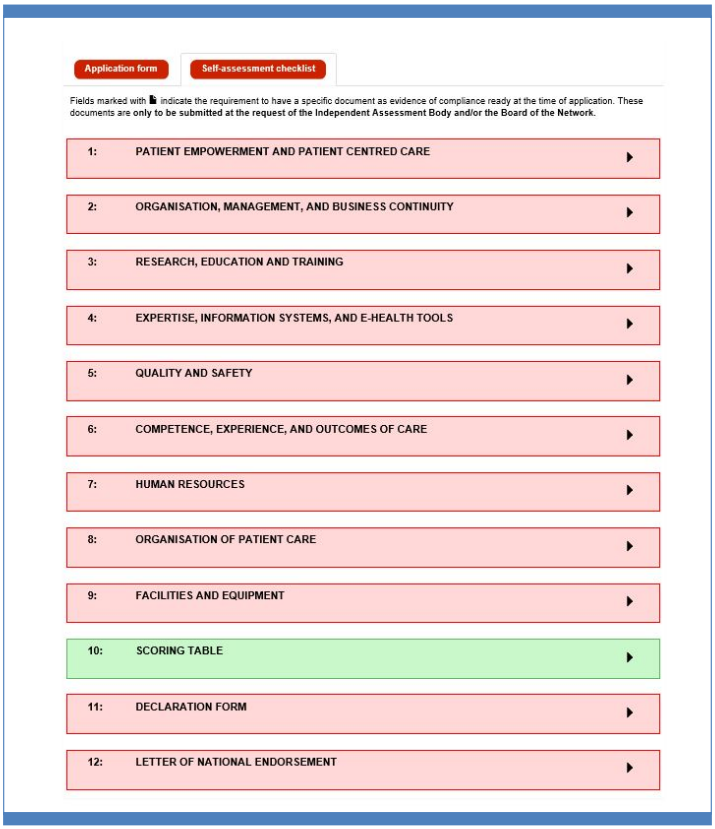
Note: Only after ticking the checkbox acknowledging the Data Protection Regulation, the option "**Select file**" will appear below:



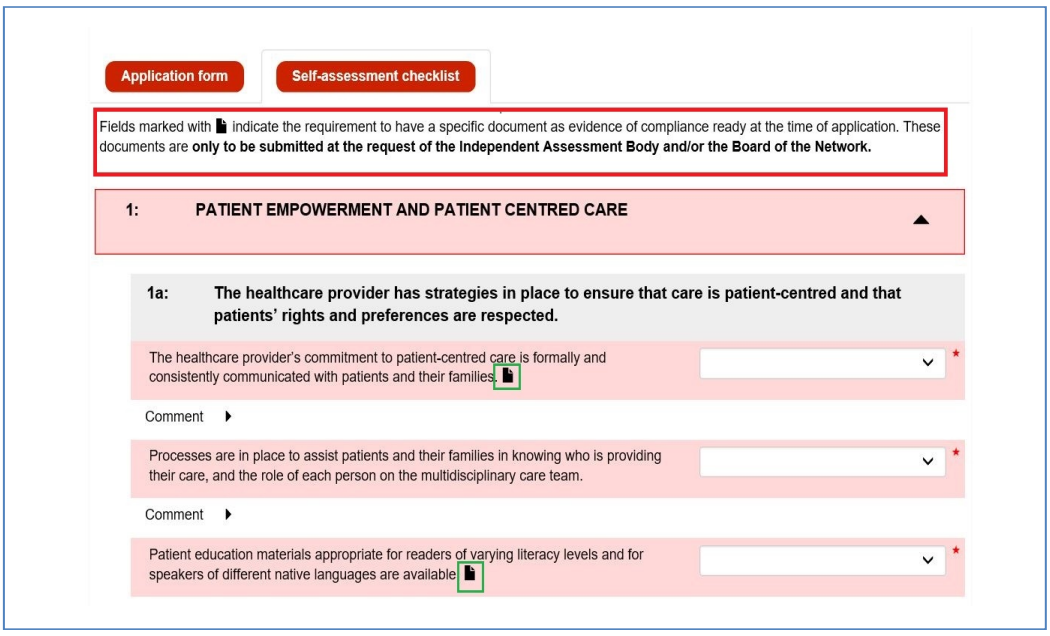
Clink on the 'upload' button to upload the selected file.

To fill-in the '**Self-assessement**' you should click on the tab '**Self-assessment checklist**'

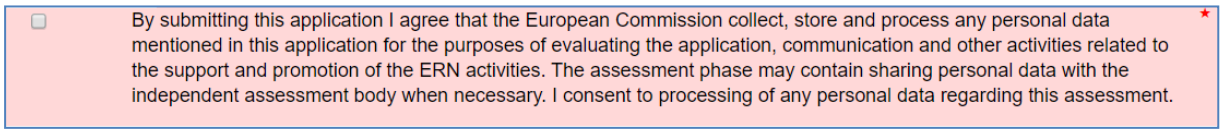
The form will be displayed below:



You **are not requested** to submit the specific documentation at the time of submission of the application. These documents must be provided to the Independent Assessment Body and/or the Board of the Network **at their request.**



Before moving forward with the application you must tick the checkbox to give your consent to the processing of any personal data mentioned in the form.

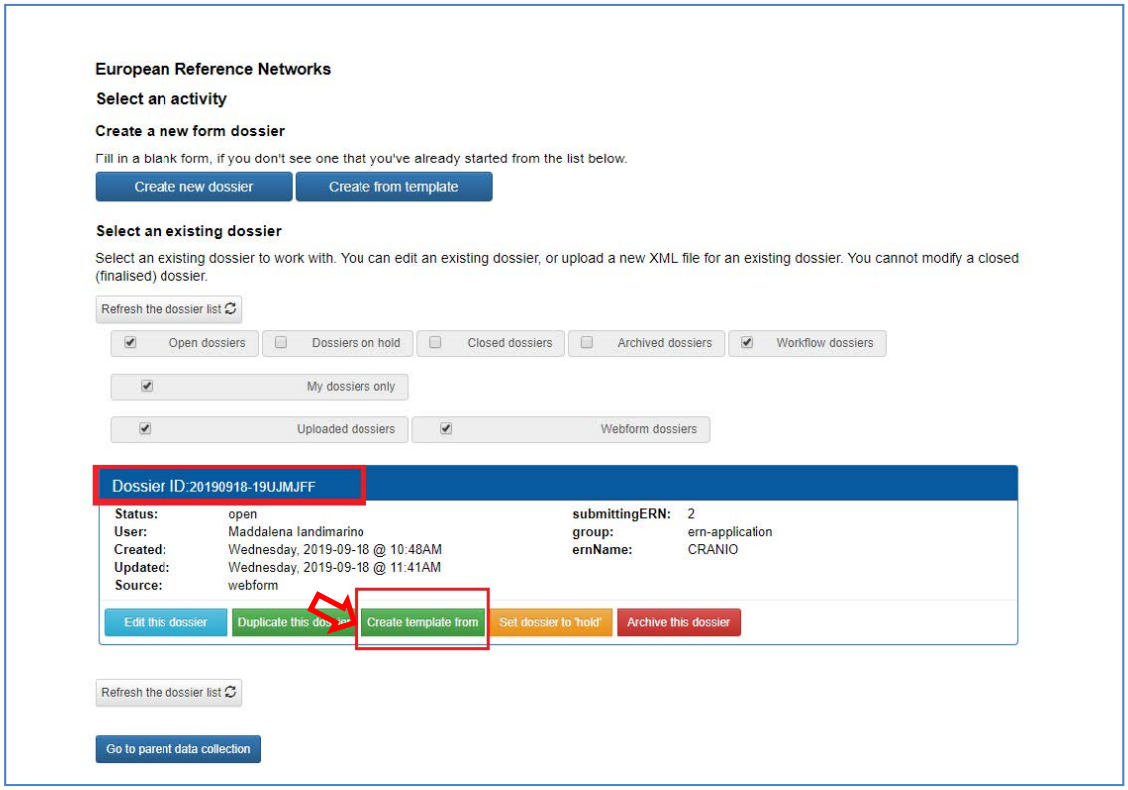


Once you have completed the first tab, click on the second tab "**Self-assessment checklist**" to finalize the application. You will need to upload a Letter of National Endorsement in Section 12 of this checklist.

At the bottom of the form you find the following buttons:

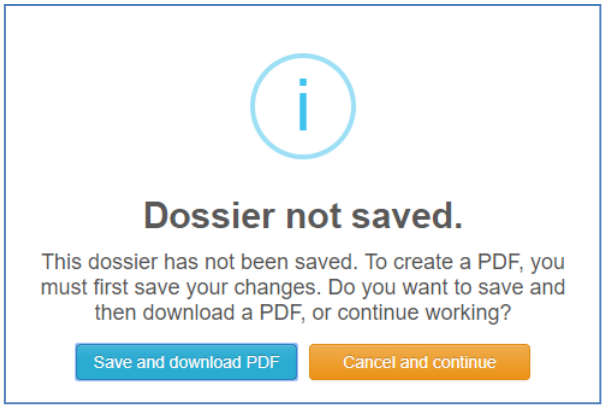
- By clicking on "**Save Form**", you can save your form even if it is not complete yet. After saving it, your dossier will be given an **ID number** and you will receive an automated email confirming the creation of a new dossier.
  The new dossier will appear on the main page of the **ERN Application Form**, from where you will be able to retrieve it and complete it later. To do that, simply click on the button "**Edit this dossier**".

Note: You also have the option to create a template from this dossier (see section 'Create an application from a template')



- By clicking on "**Download PDF of dossier**", you can download the PDF of your dossier before submitting it but you must save it first.

  If you try to download the pdf before saving your form, an information message will pop up:

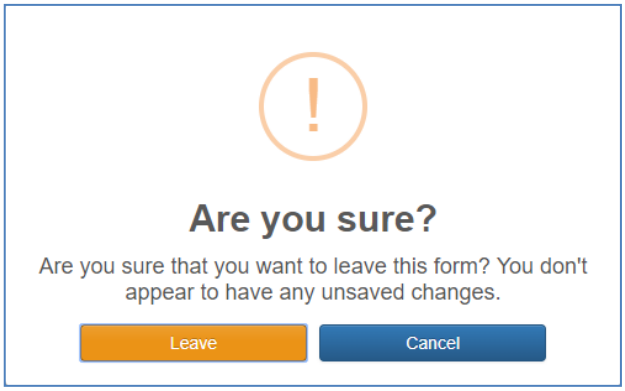


  You can either save the dossier and download the PDF or you can just cancel your action and continue completing the form.

- By clicking on "**Clear form**", all content entered until that moment will be erased.

- The button "**Finish and exit form**" allows you to leave the form.

  In case you haven't saved the form before a message will pop up asking you to confirm your action:



- "**Set dossier to hold**" means that it cannot be edited or submitted until it is released by a senior user or administrator (a person in the European Commission).
  Note: you should avoid using this option.

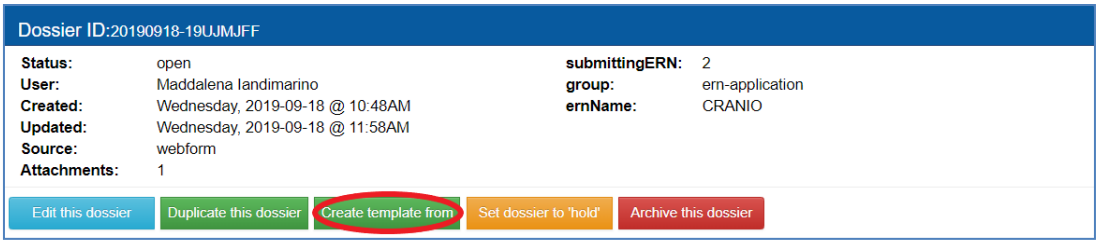
- If you "**Archive the dossier**" you will remove it from use. An administrator will be able to recover it. If the data has already been submitted, this will not affect the submission and the attachments will not be deleted.

Create an application from a "template"

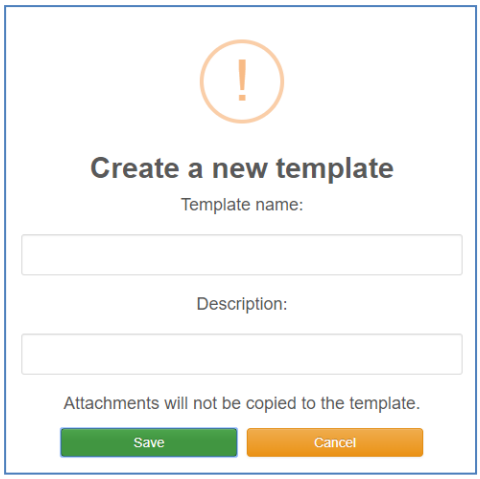
You can also create a new dossier from a template, but in order to do that, **you have to create a template first.**

To create a template, go to the list of your saved **(but not yet submitted)** dossiers, on the main page of the **ERN Application Form.**

Choose the dossier that you wish to use as template and click on the related button "**Create template from**"

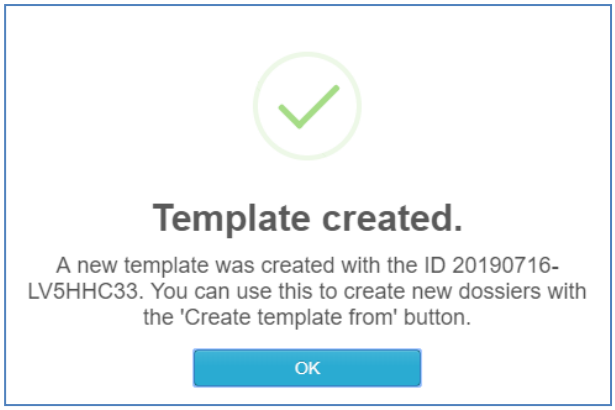


A message will pop up and to proceed forward you are suggested to give a name to the template and add a short description, for ease of reference:



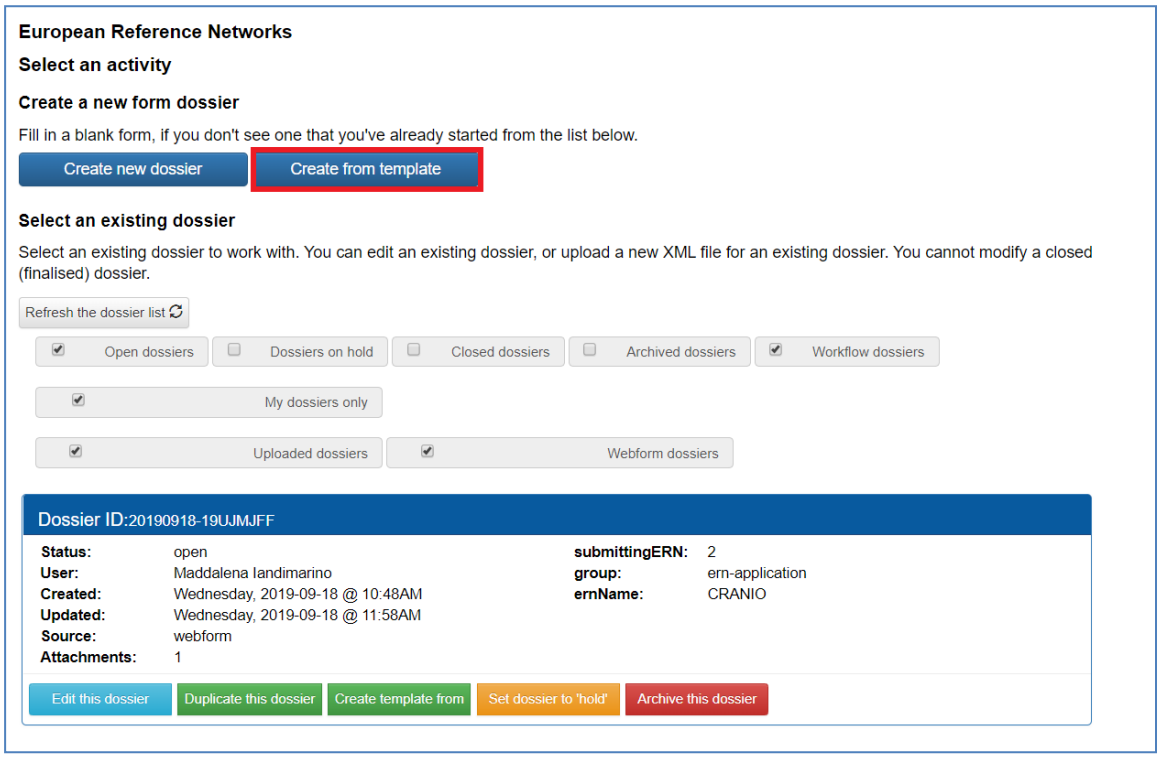
Click on "**Save**" to complete your action.

A message will confirm the creation of your template and will assign a new ID number to it:



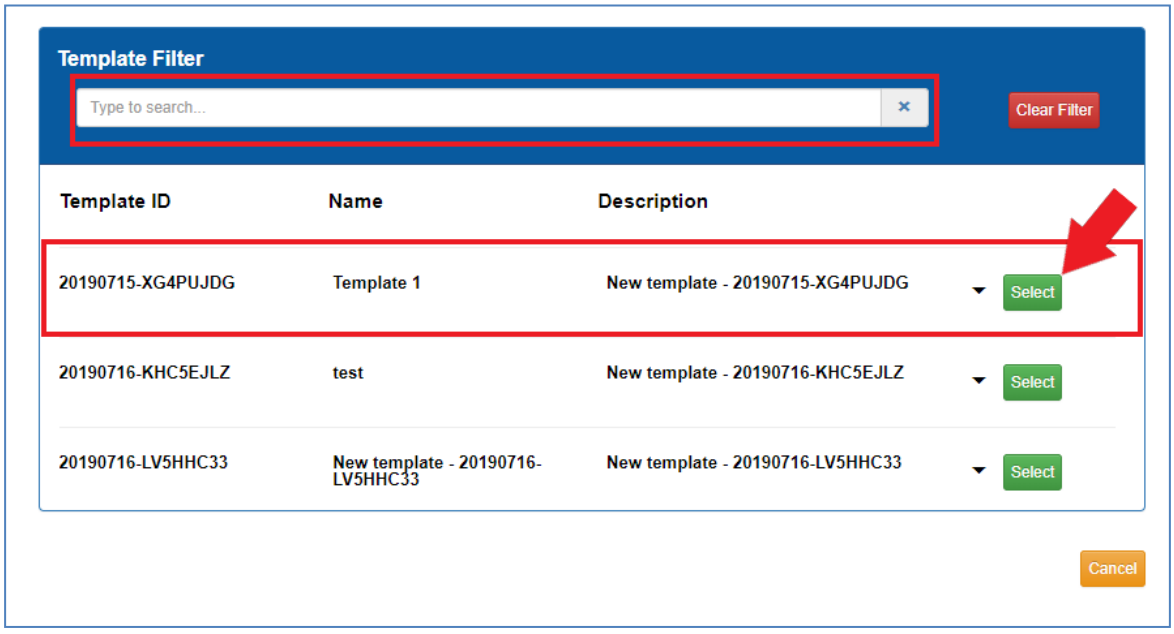
Note: the attachments uploaded in the original dossier will not be copied in the template.

At this point, to create a new dossier from a template, simply click on "**Create from template**" on the main page of the ERN Application Form:



A list of all the templates that you have created will pop up.

Search for the template that you wish to use applying the *Template ID* or the *Name* as filter and then click on "**Select**":



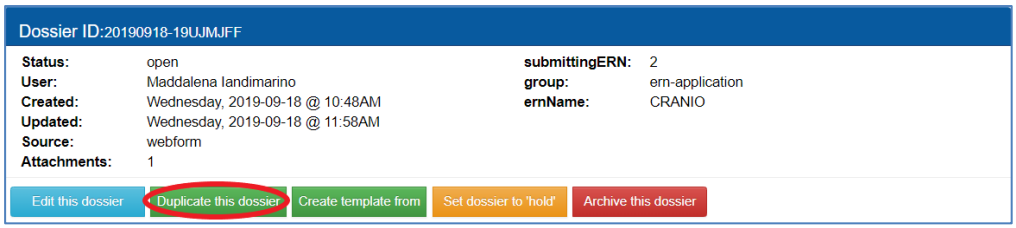
A new dossier, with a *new ID number*, will be immediately created and ready to be edited.

You will receive an automated email confirming the creation of the new dossier and it will appear in your list of dossiers on the main page of the ERN Application Form.

Create a new application from a "duplicate"

A third way to create a new dossier re-using an existing dossier is to duplicate it.

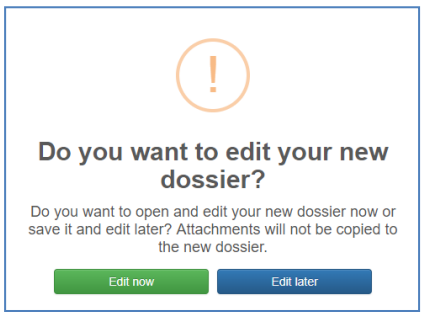
For every dossier that you have created you have the option: "**Duplicate this dossier":**



By clicking on this button, you will create directly another dossier, based on the one you chose to duplicate but with a new ID.

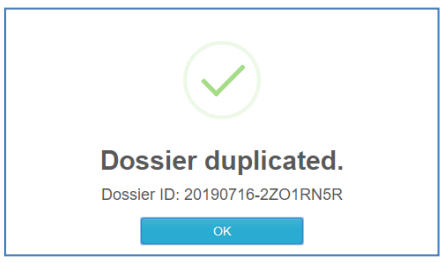
Note: also in this case, the attachments uploaded in the original dossier will not be copied in its duplicate.

A message confirming your action will pop up:



By clicking on "**Edit now**", you will open the new dossier in order to edit it.

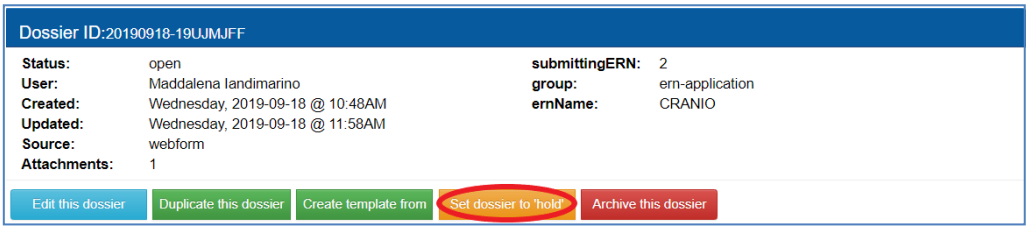
Instead, if you click on "**Edit later**", the new dossier will be saved in your list of dossiers on the main page of the **ERN Application Form** and a message will appear confirming your action and showing the ID number of the new dossier.



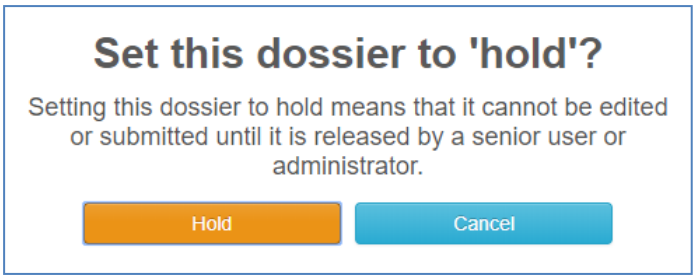
"Hold or archive a dossier"

For every dossier you have also the options of *setting the dossier to "hold"* and *archiving the dossier (you should use these options only in exceptional circumstances)*

- "**Set the dossier to hold**" means that it will not be possible to edit or submit your dossier until it is released by a senior user or administrator (a responsible person from the European Commission).



If you click on this button, you will need to confirm your action in order to proceed:

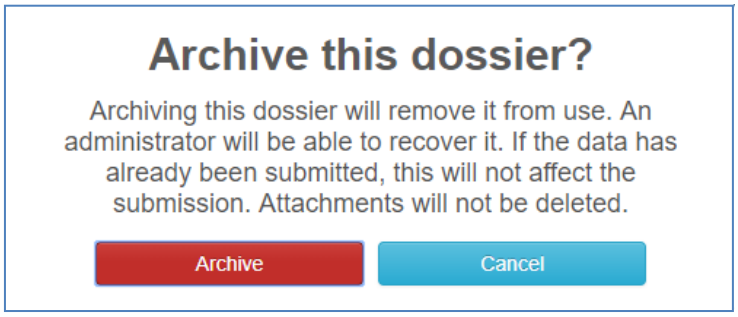


- With "**Archive your dossier**" you will remove the selected dossier from the list of your dossier.

  Note: only an administrator will be able to recover it.

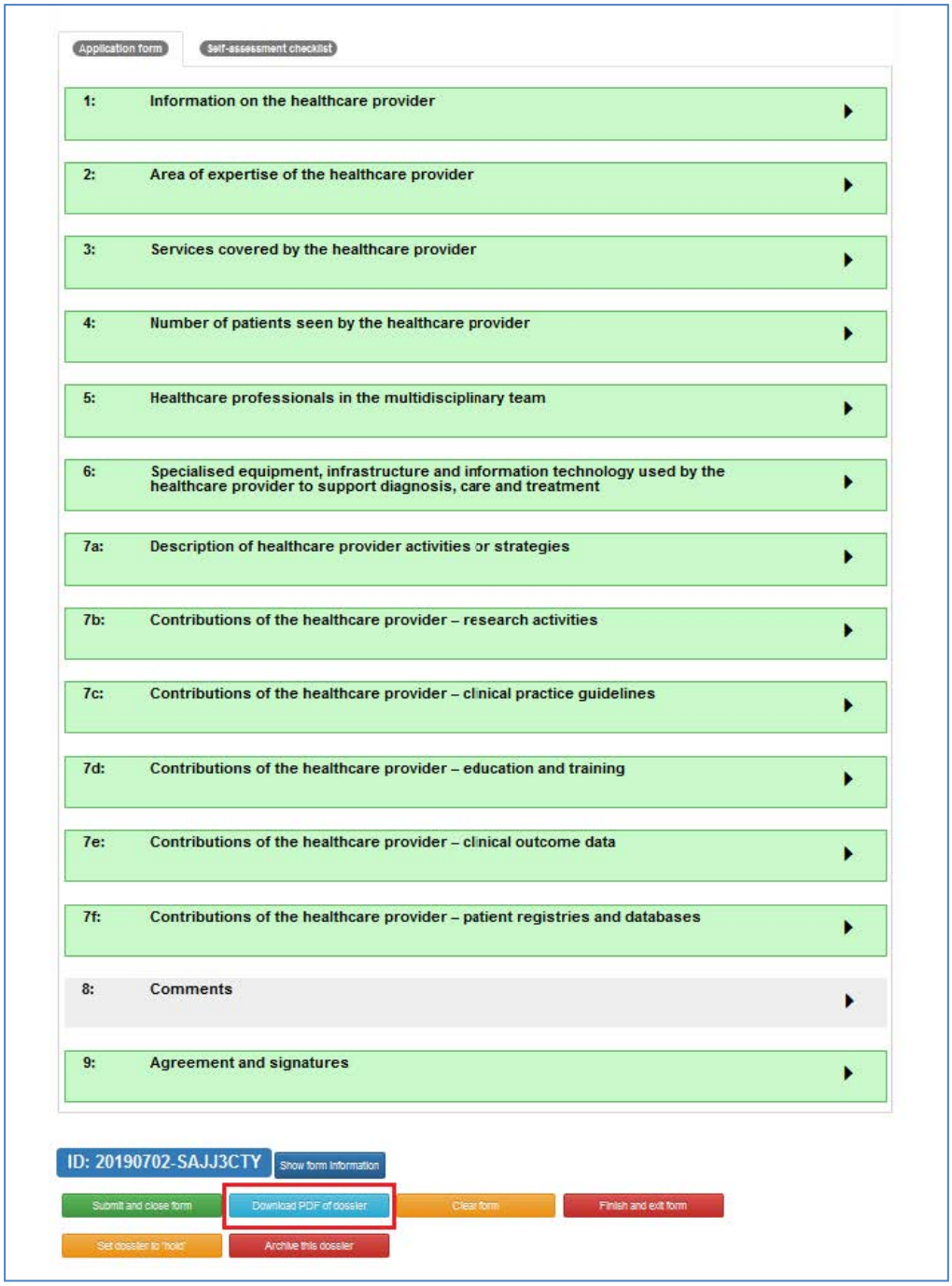
  In any case, if you already submitted the dossier that you want to archive, this will not affect the submission and the attachments will not be deleted.

  Also for this option, you will need to confirm your action in order to proceed:



How to submit an application

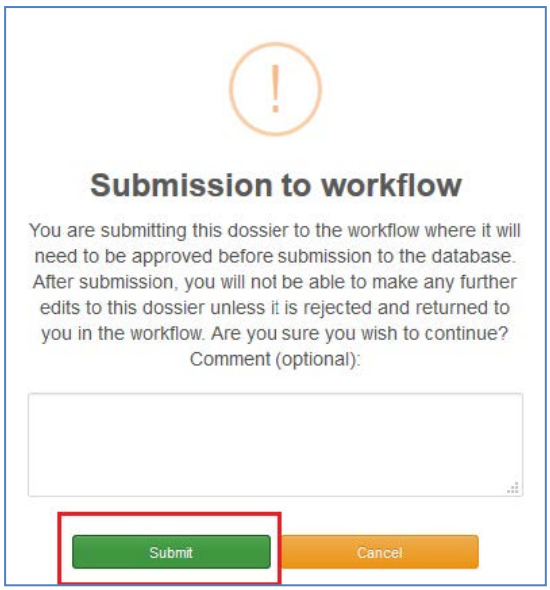
Once you have completed every section of both tabs "**Application form**" and "**Self-assessment checklist**", your form will turn into green and you will be able to submit it.



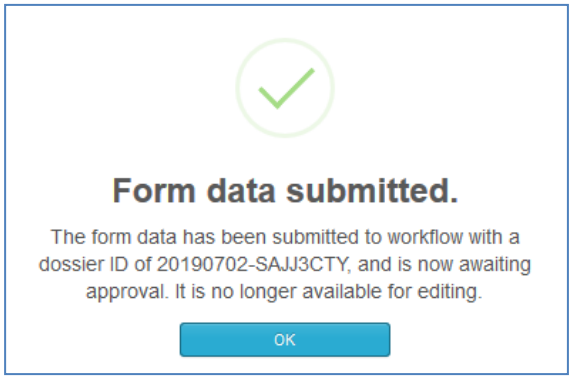
Note: Before submitting the 'Application form' and 'Self-assessment checklist' you can download it as a pdf and send it to your National Authority.

To proceed with the submission, click on the button "**Submit and close form**" at the bottom of the dossier:

In order to proceed with the submission, you must confirm your action. You are also able to add a comment, but this is not mandatory:



If you click on "**Submit"** a message will confirm the successful submission of your dossier:



After the submission, no modification or later editing is possible anymore, unless the dossier is rejected and returned back to you.

However, you still have the option to view and download a PDF of the dossier.

Note: the dossier will be included in the database only if approved. The ERN Coordinator has three months to review your application and decide if it is eligible or not.