AGENZIA ITALIANA DEL FARMACO

USER GUIDE OBSERVATIONAL STUDIES REGISTER – APPLICANT USER PROFILE

User Guide for the "Observational Studies Register" (RSO) System

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1. Introduction – Applicant User

The new "Observational Studies Register" (hereinafter RSO – Registro Studi Osservazionali) system will allow authorized users directly involved in the life cycle of studies (Sponsors, CROs, Ethics Committees, Trial centers) to:

- Register and manage new observational studies falling within their competence
- Search and read information on observational studies of their own competence and/or interest

1.1 Acronyms and definitions

Term	Definition
AIFA	Agenzia Italiana del Farmaco - Italian Medicines Agency
EC	Ethics Committee
CRO	Contract Research Organization
PAES	Post Authorization Efficacy Study– required by EMA
PASS	Post Authorization Safety Study – required by EMA
PAS	Post Authorization Study – required by FDA
RSO	The new Observational Studies Register
ATC	Therapeutic Anatomical Classification
AIC	Authorization for the marketing of a medicine
DB	New Observational Study Register Database
NHS	National Health System (*Sistema Sanitario Nazionale* - SSN)

1.2 Document purpose and solution overview

This document describes the functions of the flows related to the data entry and update of a new observational study by the Applicant.

The process of an *observational study* can be summarized in the following steps:

- The Applicant inserts a new observational study in the Register. The system assigns a unique progressive identifier and guides the user in entering the study detail information.

  At the end of the insertion procedure the user can record the study; the system sends an automatic e-mail/notification to AIFA users and the contacts of the involved Ethics Committees;

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- For *multicentric prospective studies,* the coordinating center's Ethics Committee (EC) must enter the evaluation data and is able to request a review/integration of the study data before the final opinion is entered;
- In this case, the Applicant, after making the required changes, will be able to carry out revisions/integrations to the study;
- When the Applicant submits the updated study data, the coordinating Ethics Committee will be able to enter the final opinion;
- The Ethics Committee of the coordinating centre must enter the data relating to the opinion. For multicentric prospective studies, Ethics Committees of the local centers may accept/reject the favourable opinion of the coordinating EC. In case of an unfavourable opinion, the study cannot be initiated.
- For *NON-prospective studies,* the EC may enter the opinion, if this was expressed during a session, or enter a date of notice and any considerations to share with the Applicant;
- After the study has started, the Applicant will be able to enter the data related to the conclusion and the publications/results.

The phases of an *Observational Study* process can be summarized as follows:

- New study registration
- Ethics Committee evaluation
- Ethics Committee opinion
- Study start-up
- Study conclusion
- Publications and results

The statuses of a study are summarized in the following table:

Study status	User who can operate	Note
New	Applicant (Sponsors/CRO)	*The study is generated and assigned a unique identifier*
Draft	Applicant (Sponsors/CRO) also by delegation	*In this status, you can edit data, attach documents, and delegate a study*
Submitted	Coordinating and local Ethics Committees	/
Under review	Applicant (Sponsors/CRO) also by delegation	*In this status you can receive any requests for revision/integration and you can make the necessary changes*
Updated/Integration Response	Coordinating and local Ethics Committees	*In this state, it is possible to enter the EC opinion*

Notified	Coordinating and local Ethics Committees	*When no revisions/integrations of the study are required and the opinion/acknowledgement can be entered*
Under Evaluation	Coordinating and local Ethics Committees	*In this status, revisions/integrations of the study may be requested*
Unfavourable Opinion	Applicant (Sponsors/CRO) also by delegation	*In this state, the study cannot be started*
Favourable Opinion	Applicant (Sponsors/CRO) also by delegation	*In this state, the study can be started*
To be started	Applicant (Sponsors/CRO) also by delegation	*In this state, the study can be started*
Started/Not started	Applicant (Sponsors/CRO) also by delegation	*If the status is started, you can proceed to the conclusion phase*
In Conclusion	Applicant (Sponsors/CRO) also by delegation	*In this state, it is possible to proceed to the conclusion phase*
Concluded	Applicant (Sponsors/CRO) also by delegation	*It will always be possible to add publications and/or results once the study has ended*

1.3 Copyright (specific properties and usage limit)

2. Access to the System

The RSO system will be accessible only to registered and enabled users of the application, who will be able to log with CNS (National Services Card), SPID (Public Digital Identity System) or a registered user account to the AIFA services portal.

Figure 1 - System Access

3. Menu

The Applicant user, through the *Menu* feature in the upper left, will be able to access following sections: *Observational Studies, Administration* and *Help*.

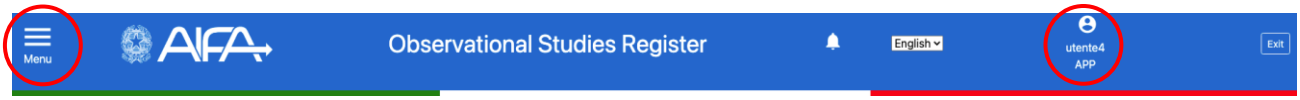

Figure 2 - Header RSO

These sections will provide access to the following features:

a) *Observational Studies*:
- *Studies List*
- *New Study Registration*
- *Study Delegation*
- *Studies Research/Search a study*
- *Delete a Study*

b) *Administration*:
- *Operations History*
- *Notifications Preferences*

c) *Help*:
- *User Guide*
- *FAQs*

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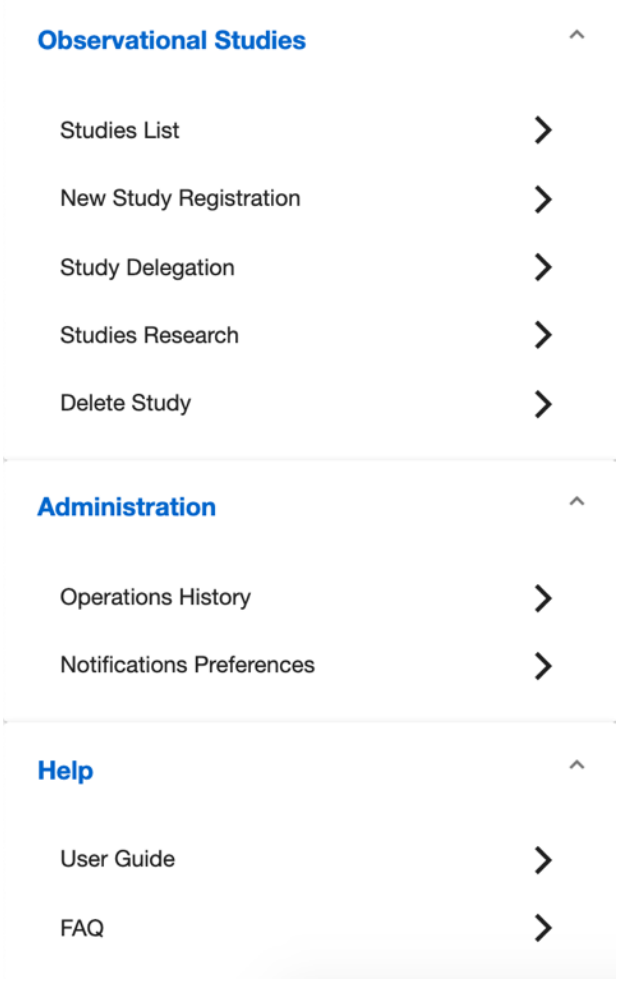

Figure 3 - Applicant Menu

In addition to the Menu, the user's name and profile are shown. The acronym APP refers to the profile of the Applicant user

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4. Studies List

In the *Studies List* section, the Applicant can view a table containing all their studies and, for each study, check the progress made in the individual stages.

The Applicant will be able to filter the list of studies using the filters "*Study status" (↑)* and "*Study typology" (↑)* (see figure 4 – Studies List).

For each study, it is possible to print the summary data in PDF format using the button , while through the button you can print in PDF format the module of the observational study related to Covid-19 vaccines, if applicable.

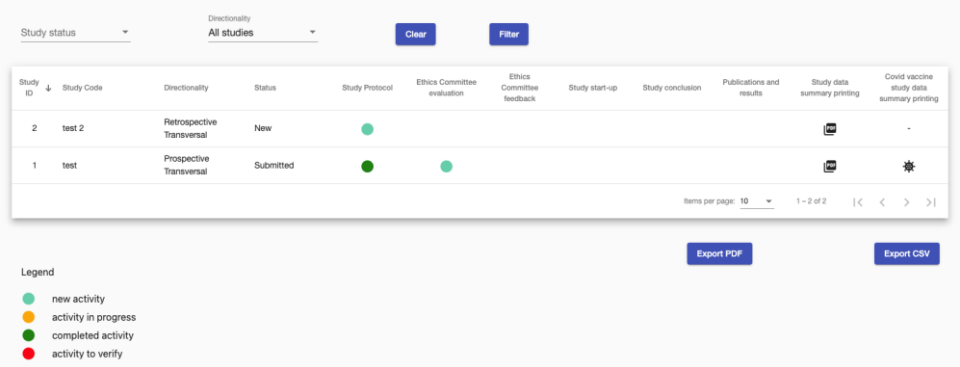

Figure 4 - Studies List

For each individual step, there is a different color icon indicating the activity that is taking place in that stage:

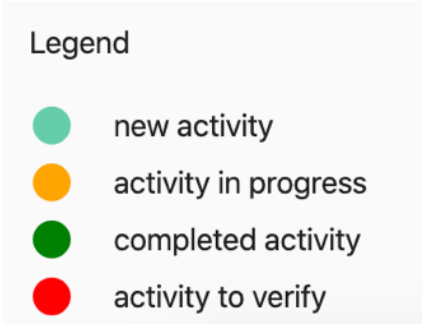

Figure 5 - Legend

Each icon has access links associated with the user's role.

Using the buttons Export PDF and Export CSV you can export the Studies List in PDF and CSV formats.

5. New Study Registration

Only RSO-enabled users with the *Applicant* role (Sponsors, CRO), or any *delegate,* can register a new observational study in the system.

Once the first recording of a new study is made (i.e. by entering the data in the sheet "Registration of a new study – Identification data"), the system will guide the user (or any delegate) in the entry of information in multiple steps. Users can enter the data in the order they prefer. The data will be saved for each step of the process.

Throughout the *Registration* phase, switching from one section to another (using the appropriate *Stepper* buttons, or with *Back* and Save *and proceed*) the save function will occur automatically, even if you have not entered all the required data.

5.1 Entering Identification Data

After selecting in the left menu the entry *New Study Registration,* the applicant, under the Section *Observational Studies*, will be able to enter the identification data of a new study.

In particular, the user will be required to write the *Study Code* and general information regarding the following categories:

- *Study typology*: it is mandatory to select at least one of the three possibilities: prospective, retrospective or transversal; multiple choice (e.g. both prospective and retrospective) is also allowed;
- *Study site*: it is mandatory to indicate at least one place where the study will be conducted among those in the checklist.

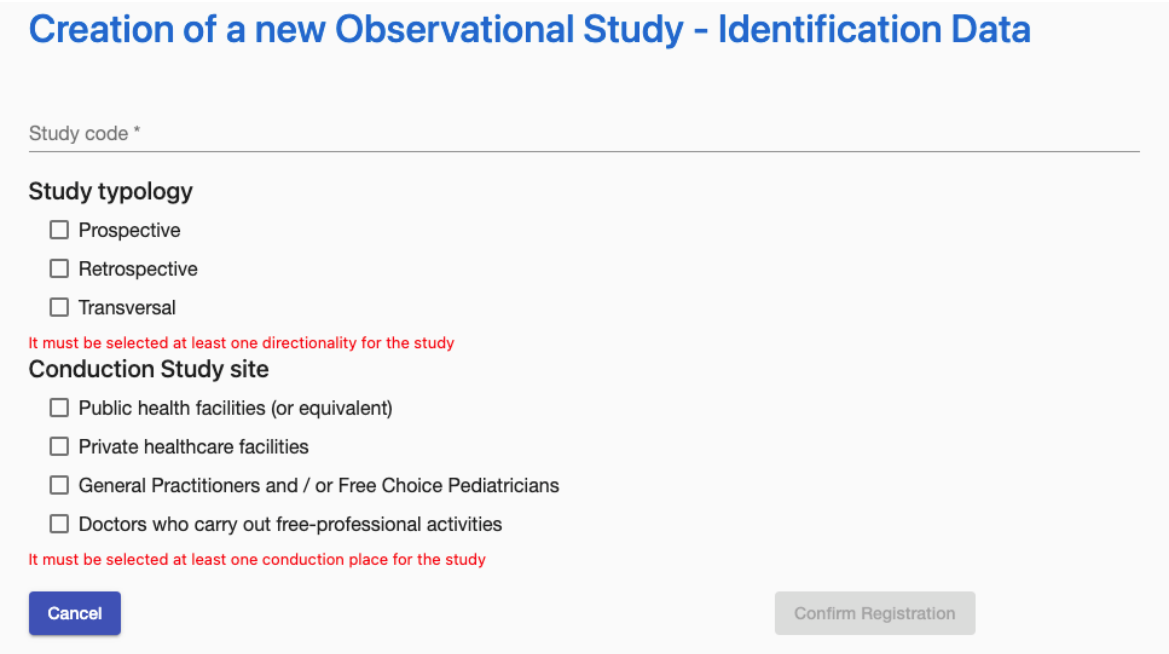

Figure 6 - Identification data

After entering the above-described data it is possible to return to the system Homepage, using the "*Cancel*" button, without saving the entered data. In this case, no study will be entered in the system.

Instead, by selecting the "*Confirm Registration"* button, the system assigns a unique identifier to the study (*Study ID)* and asks the user whether to continue registering the Observational Study ("*Confirm and continue"* button) or delegate it to another user that may also belong to another organization (*"Confirm and delegate"* button*)*.

The delegated user will not be able to delegate another user. Following the delegation, the Applicant who entered the study identification data will only have the next steps in view mode, while the delegated user will be able to complete the initial registration and subsequent steps of start-up, end and publications/results (see paragraph 13. Study Delegation).

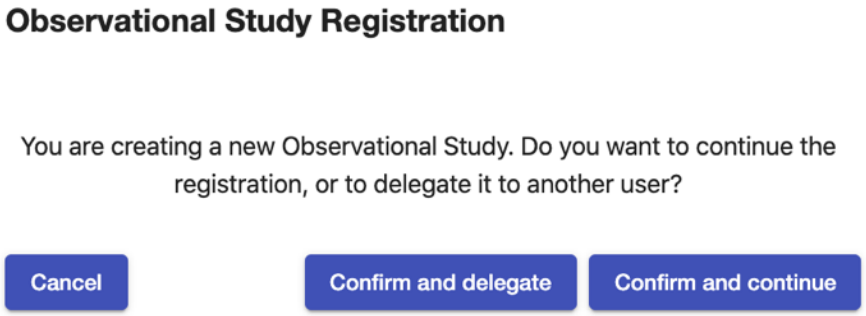

Figure 7 - Delegation

5.2 Sponsors and Applicants

After confirming the registration, the Applicant, or their delegate, will be able to enter the information related to the observational study, moving from one section to another (e.g. from section *1. Sponsors and applicants* to section *4. Description form*).

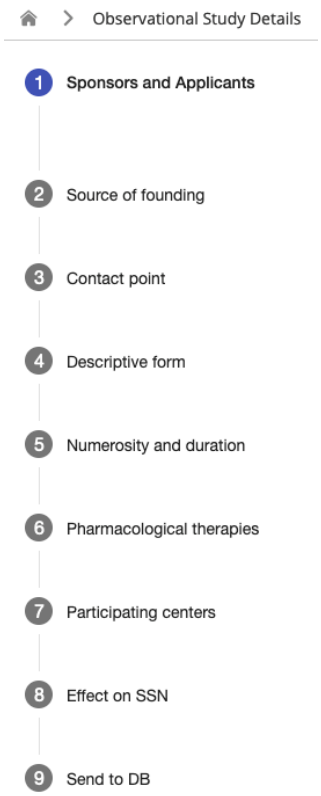

Figure 8 - Stepper

Each section shows the study's identifying data at the top, that cannot be modified.

Figure 9 - Study identification data in non-modifiable mode

In the first section *(1. Sponsors and applicants)*, the user will be able to view the data of the Applicant organization that is automatically populated based on the user's data. Inaccurate data can be changed by pressing the "Edit" button, which will allow the search of the applicant organisation.

Figure 10 - Applicant Data

If the desired Applicant is not found as a result of the search, the system will allow the user, using the button "*You haven't found what you are looking for?*", to view the contact details:

- To write an e-mail to the address helpdesk@aifa.gov.it describing the missing/wrong data and explaining requested modification
- To call number +39 06 6228 9430

This feature is also present in the following sections, specifically, in each search from a specific master data.

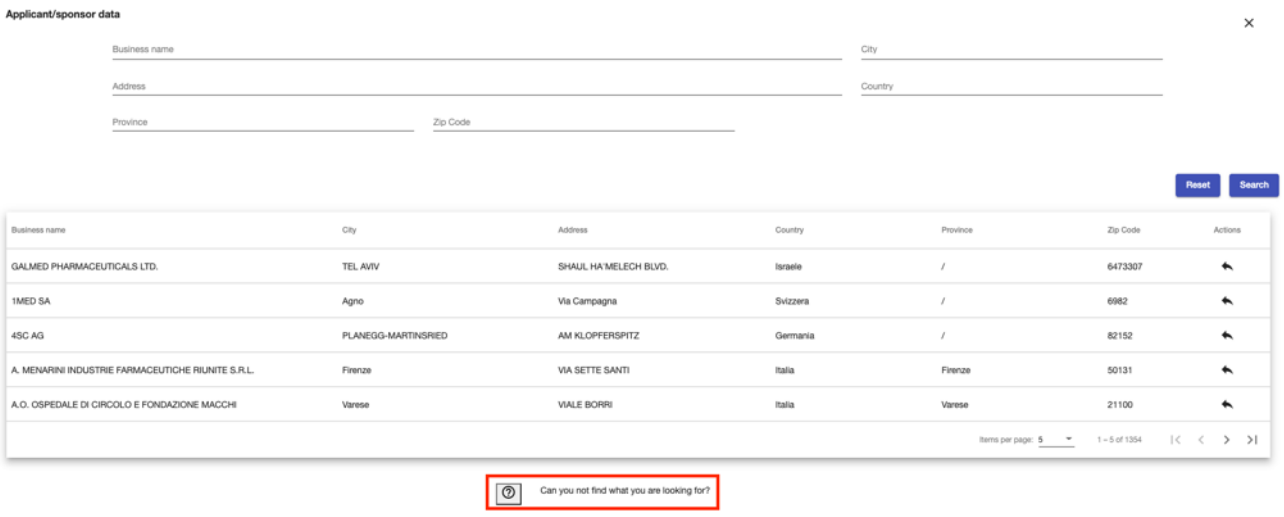

Figure 11 - You haven't found what you are looking for?

The Applicant will have to explain whether the applicant organization is the Sponsor of the observational study: if *NO* (selected by default) the system will show a second panel related to the sponsor data, which will be searched by "*Edit" button*. By selecting *Yes*, the system will not show the panel.

The user will be able to:

- save the entered data by pressing the *Save* button;
- save and go to the next section by pressing the *Save and proceed* button;

- exit the trial recording by pressing the *Cancel* button; this button will notify the user that, if they confirm their exit from the system, any data not saved will be lost.

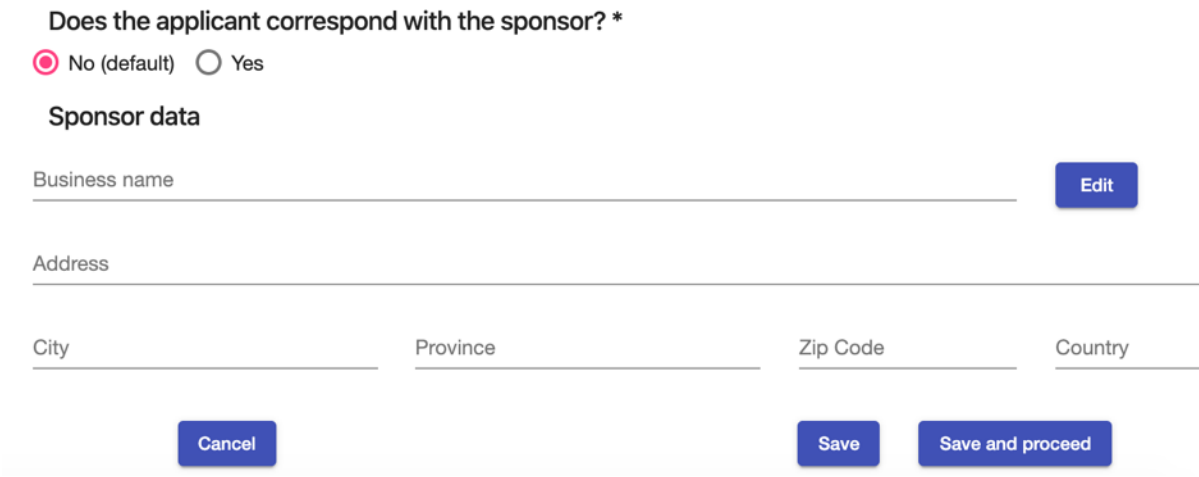

Figure 12 – Sponsor data (if the Applicant does not coincide with the Sponsor)

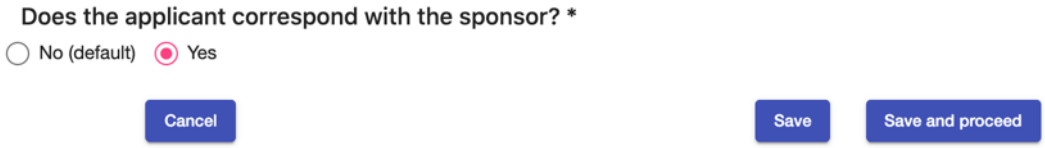

Figure 13 - Sponsor data (if the Applicant coincides with the Sponsor)

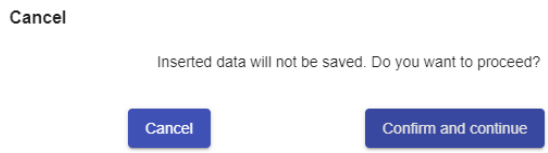

Figure 14 – "Cancel"

Clicking on "Cancel" you go back to the section related to the compilation of the Applicant's data.

By clicking on "Confirm and continue" the system closes the registration session and returns to the homepage.

5.3 Source of funding

In this section, the Applicant must indicate the sources of funding for the study.

The entries *European Commission* and *Other*, if selected, will activate related text fields to enter details that must be filled in by the user.

If *Pharmaceutical company* is selected, it will be mandatory to specify the company. Using the "*Edit*" button, the user will be able to search for the Pharmaceutical Company.

Beside the buttons *"Save", "Save and proceed"* and "*Cancel*" described above, the user can press the "*Back*" button that will save the entered data and will return to the previous section.

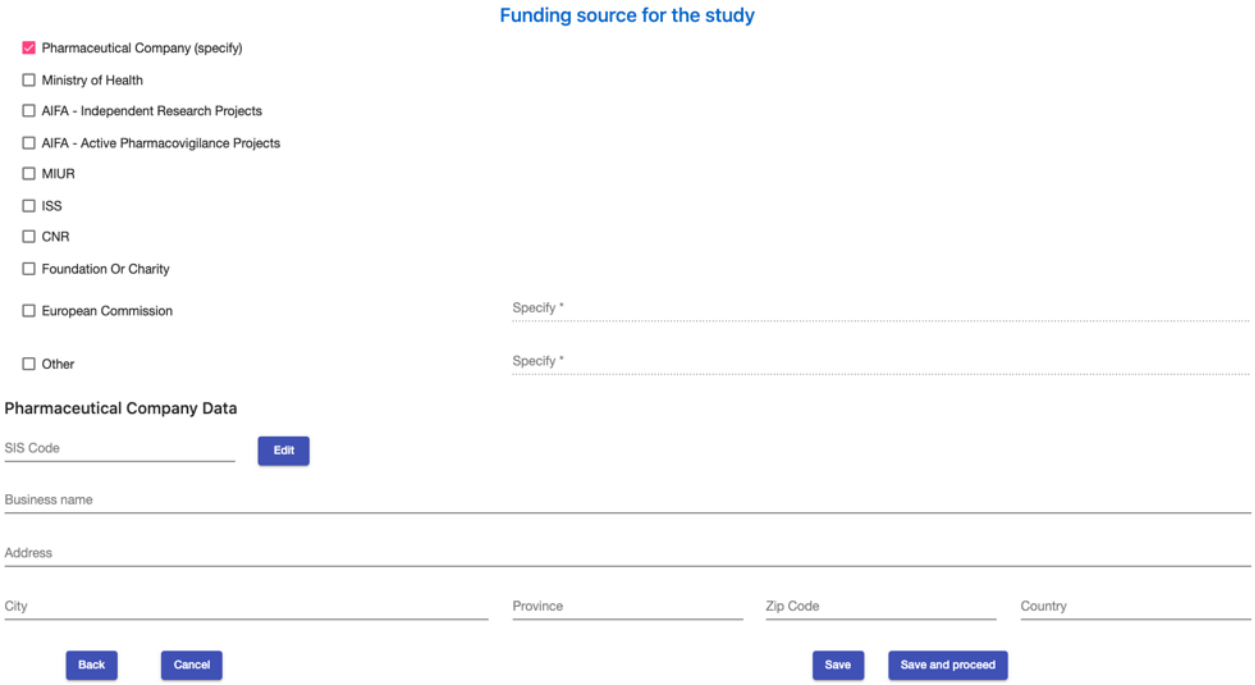

Figure 15 – Funding source

5.4 Contact Point

In this section, the Applicant enters the study's *Contact Points* data, using the button Add. It is mandatory to enter at least one Contact point.

The *Name*, *Surname*, and *Email address* fields are mandatory. After inserting the first Contact Point, the user can edit the contact point or add a new one.

Finally, the user can download the privacy policy related to the processing of personal data, by clicking on the related link.

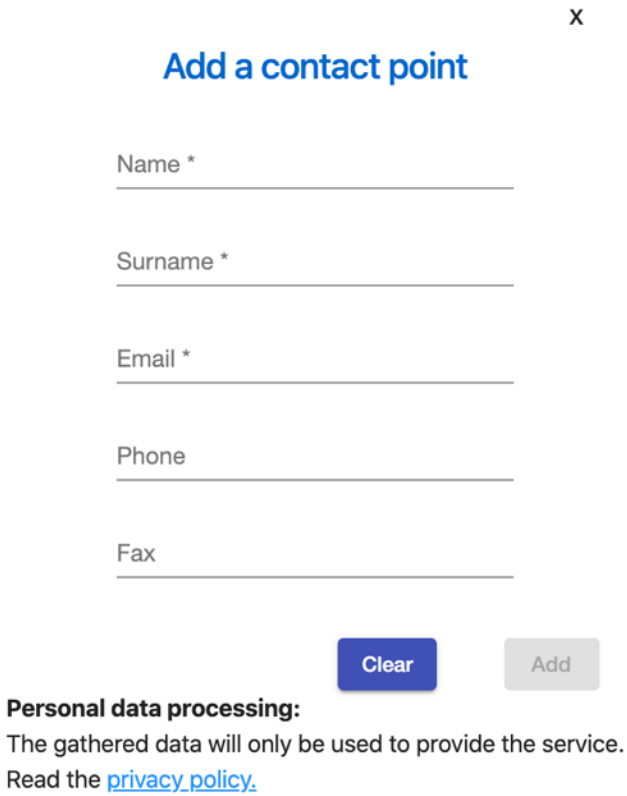

Figure 16 – Contact Point

5.5 Descriptive form

The section is divided into five *tabs,* through which the Applicant can enter the following information:

- *General*: it will be mandatory to enter the *Title of the study* (in English and in Italian) and indicate the *Purpose* and the *Design* of the study. If *Other is selected,* it is required to describe the specifications of *Other Design*. Furthermore, Keywords can be entered (in English and in Italian).

If the Applicant is registering an observational study on Covid-19 vaccines, *the Research Area* fields (Pharmacology, Epidemiology, Immunology, Virology, Other) must be selected.

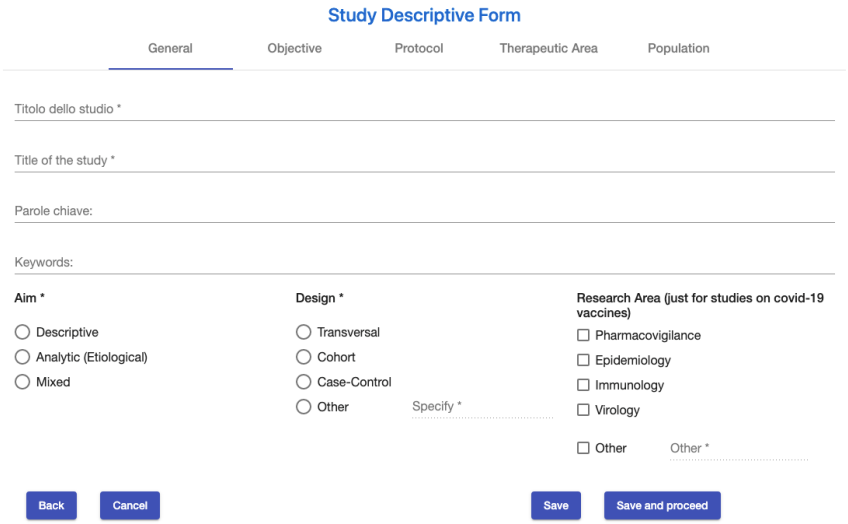

Figure 17 – General

After completing the *'General'* section, the *'Objective'*, *'Protocol'*, *'Treatment Area'* and *'Population'* sections must be completed in order to finalize the registration of the 'Study Description Sheet'. Selecting the *'Save and go on*' button allows you to move on to the next section of stepper 5. Population and duration'.

- *Objective*: the user will have to select at least one *Primary Goal* and enter the description;

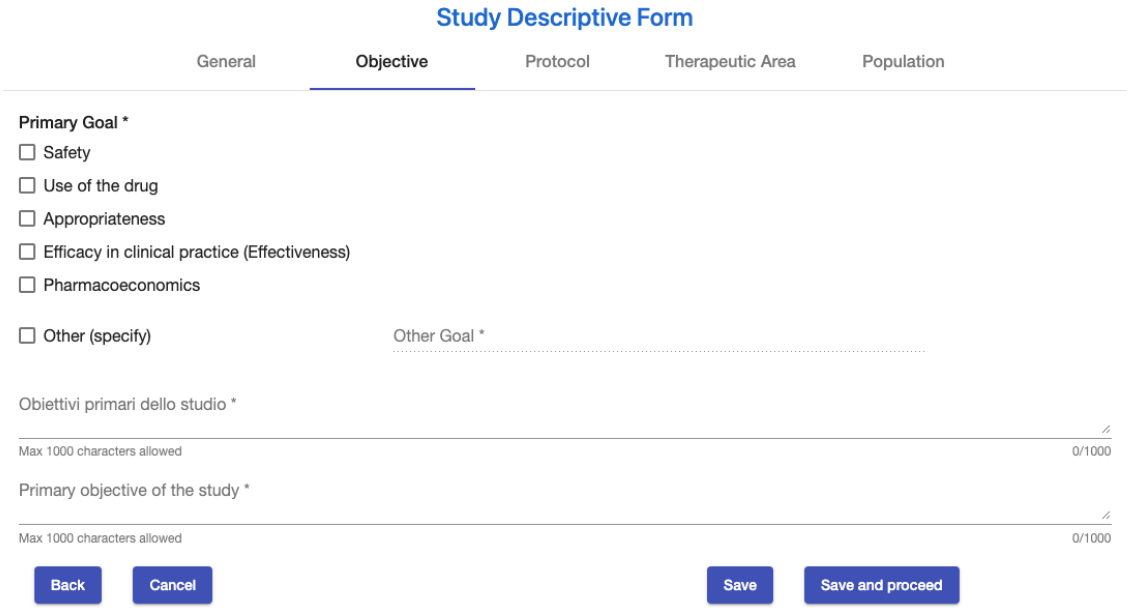

Figure 18 – Objective

- *Protocol*: the user will have to select one *Study scope* and attach at least one Study *Protocol File*.

If the Applicant is recording an observational study on Covid-19 vaccines, the Applicant will be invited to insert the *Principles of analysis of collected material and data*, *Interventions and Procedures, Inclusion criteria*, *Exclusion criteria, Rational study* and *Main outcome measures*.

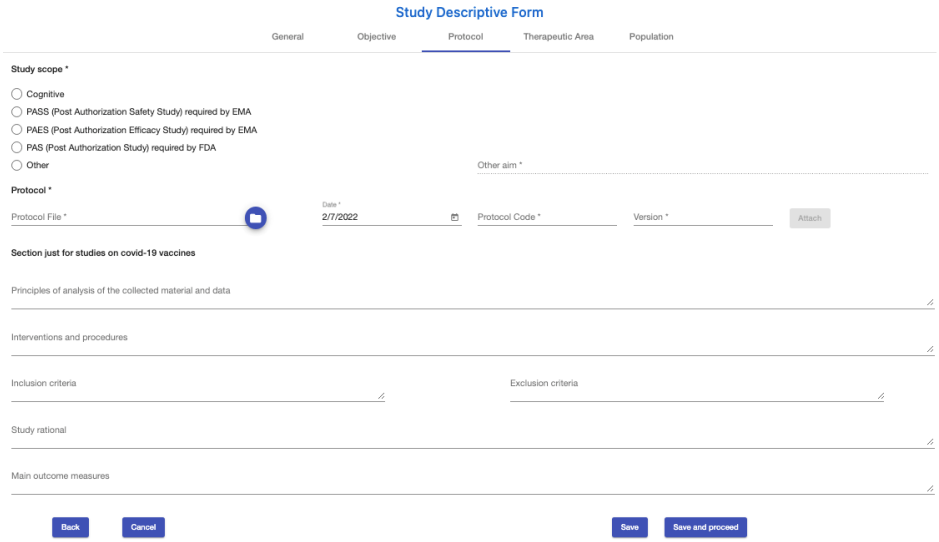

Figure 19 – Protocol

- *Therapeutic Area*: the user will have to enter the *Therapeutic Area* of the observational study using the *MESH* classification, divided into two levels;

- *Clinical Condition:* the user must enter the clinical condition in both Italian and English;

- *MedDRA Classification*: you can enter one or more clinical conditions by selecting them from the MedDRA taxonomy by clicking on the 'Add' button. After inserting them, it will always be possible to remove them. If not applicable, the user will select the appropriate checkbox and enter the mandatory comment.

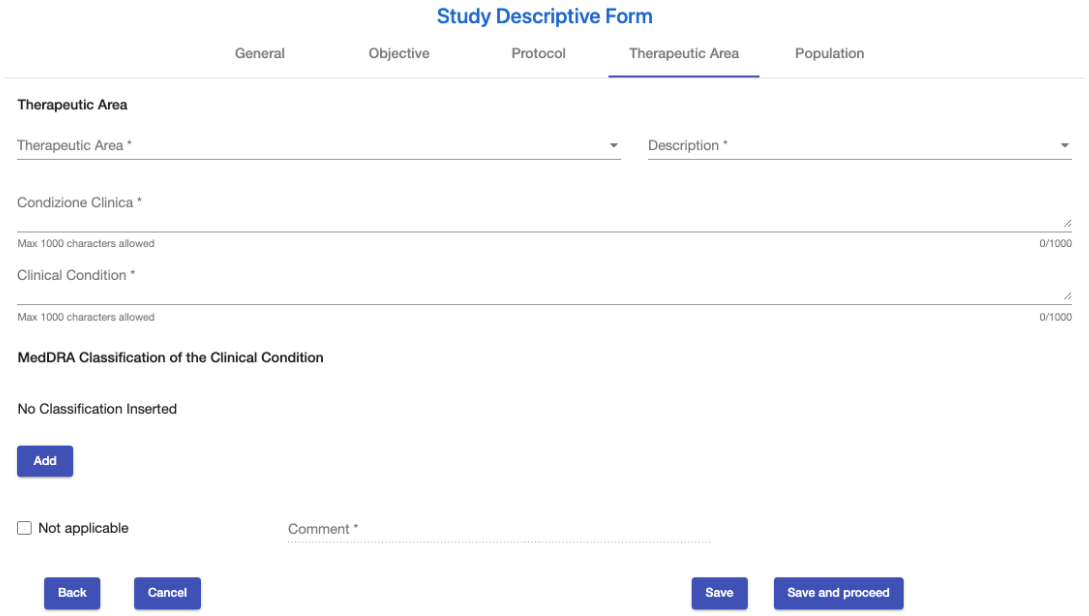

Figure 20 – Therapeutic Area

- *Population*: the user will have to select the *Gender* and *Age Group* of the population included in the study. The user may also indicate some *Special populations* and can select more than one checkbox for each field.

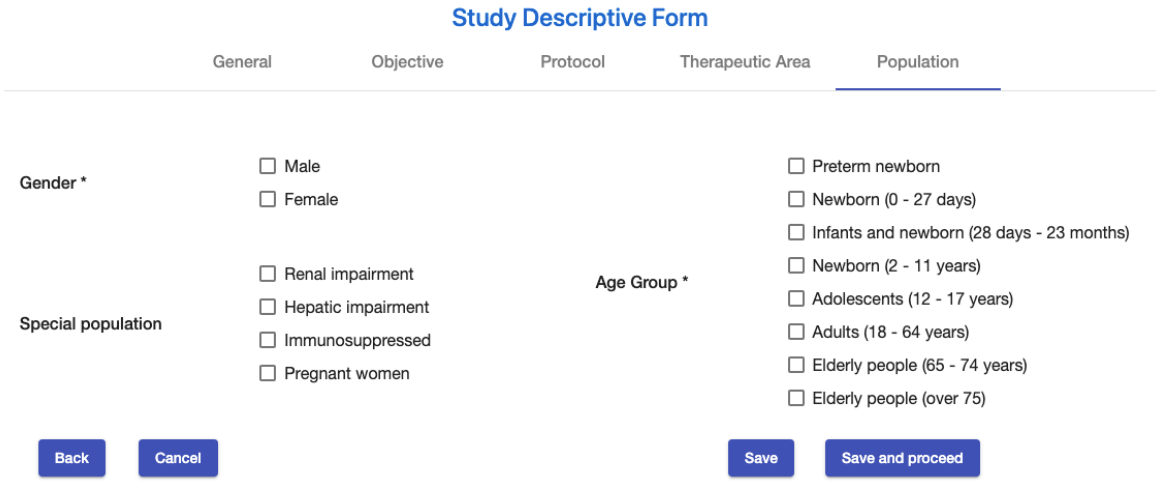

Figure 21 – Population

5.6 Numerosity and duration

The Applicant will have to select the *Expected number of subjects* in the World, the European Union or Italy and the *Number of participating countries*.

Finally, (s)he will have to include the *Expected study duration* (expressed in days/weeks/months/years) and the *Expected end date of the study* (month and year only).

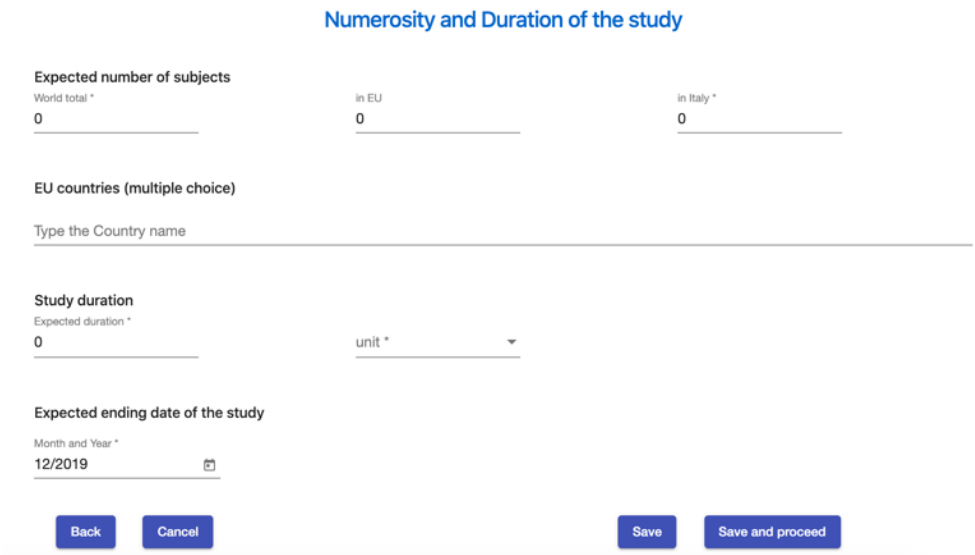

Figure 22 – Numerosity and duration

5.7 Pharmacological therapies

The Applicant will be able to enter the medicines and data related to a *Pharmacological therapy* using two research criteria:

- *Add by ATC*

It will be possible to select a category of medicines related to a pharmacological therapy. It will be mandatory to select at least the first level of the ATC classification to perform the search; using the link Show specialty the user can search for the medicinal specialty related to one category of medicines by using a different search criterion;

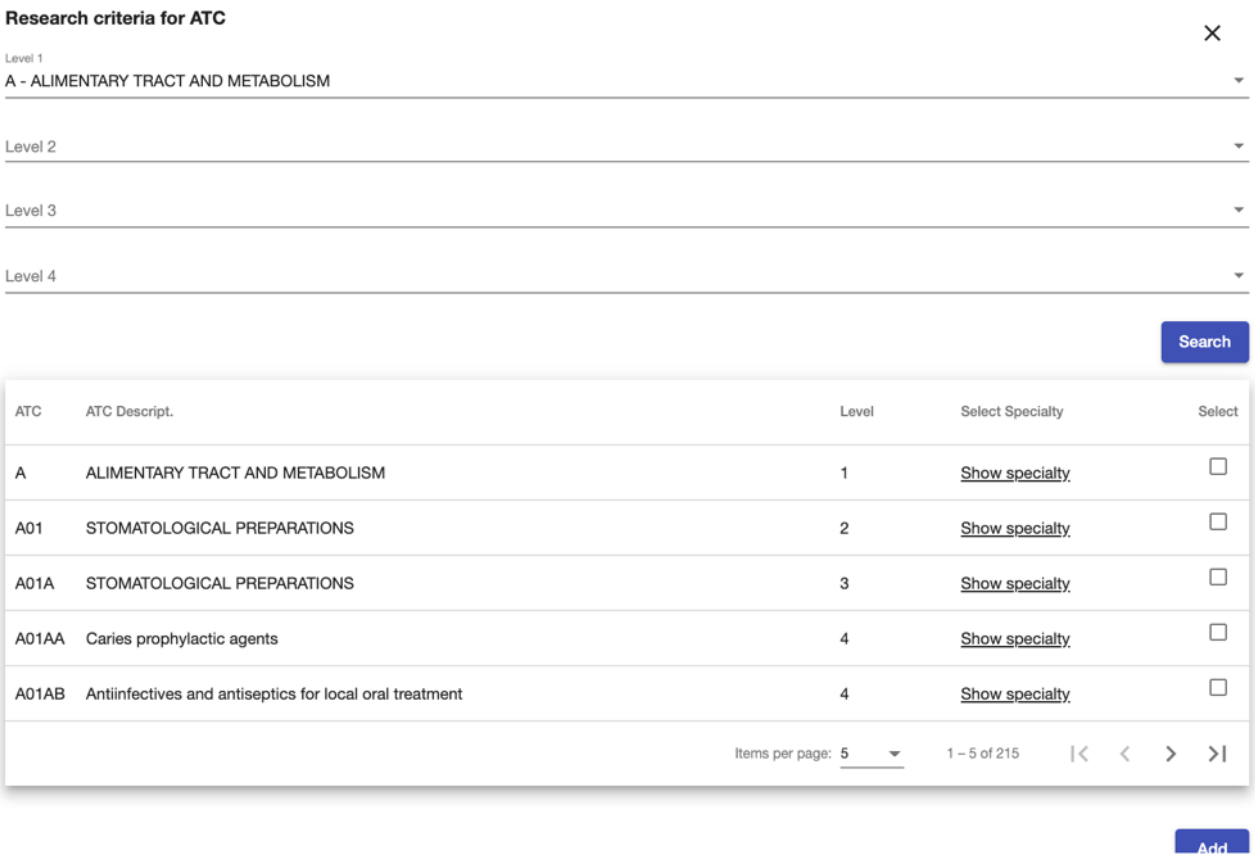

Figure 23 – Search by ATC

- *Add by specialty*

To carry out the search, at least one field must be used, and the minimum string must be of three characters.

After the search, the user will be able to select one or more medicines related to specific therapies. As long as the study is not registered, it will be possible to eliminate them.

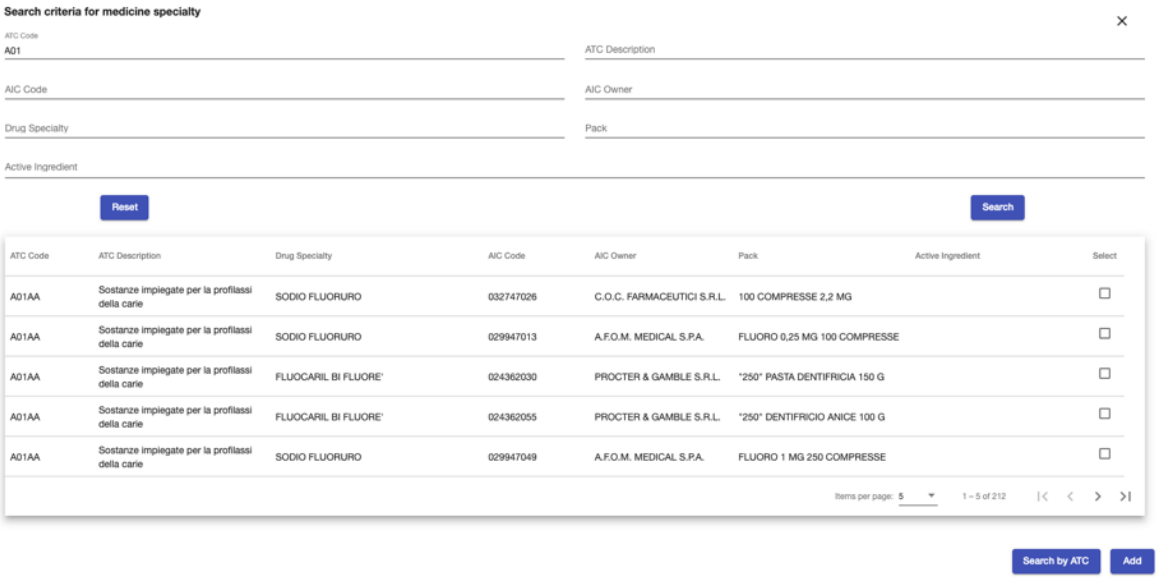

Figure 24 – Search by medicine specialty

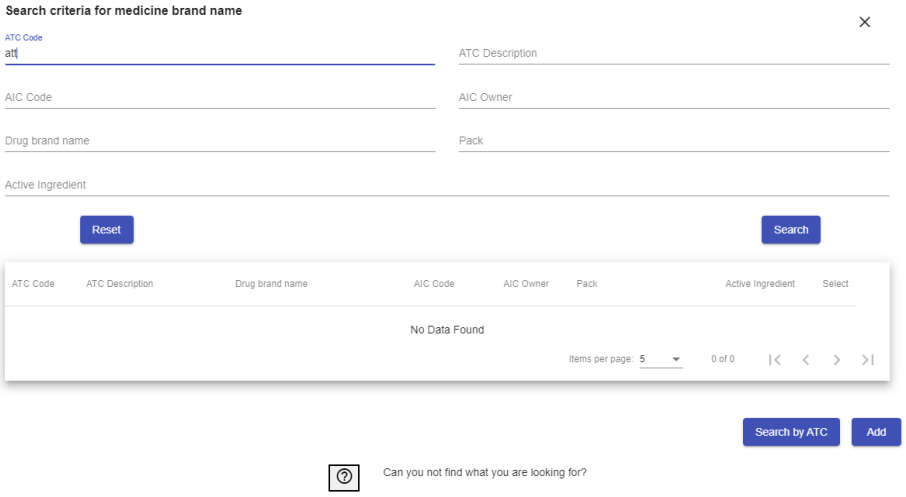

Figure 25 – Search Medicine "Can't find what you are looking for?"

If, after searching by 'Medicinal Speciality', no information is found, the system will allow the user, by means of the button "Can't find what you're looking for?", to view the contact details as described above.

After entering the data for the pharmacological therapy, the Applicant selects the *Declaration* checkbox to view the details of each single therapy and enter information related to the *Declaration of medicine use conditions* and any *Notes*.

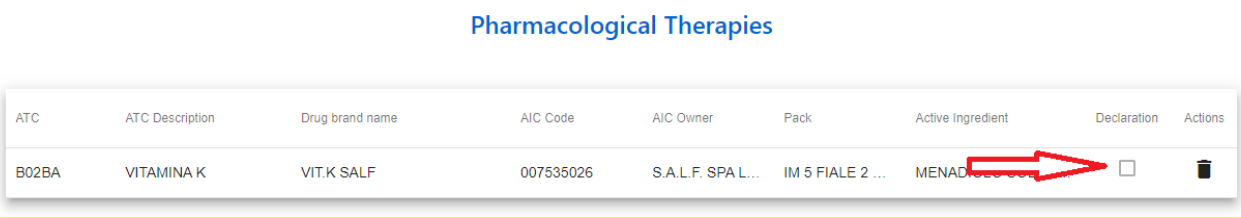

Figure 26 – Declaration

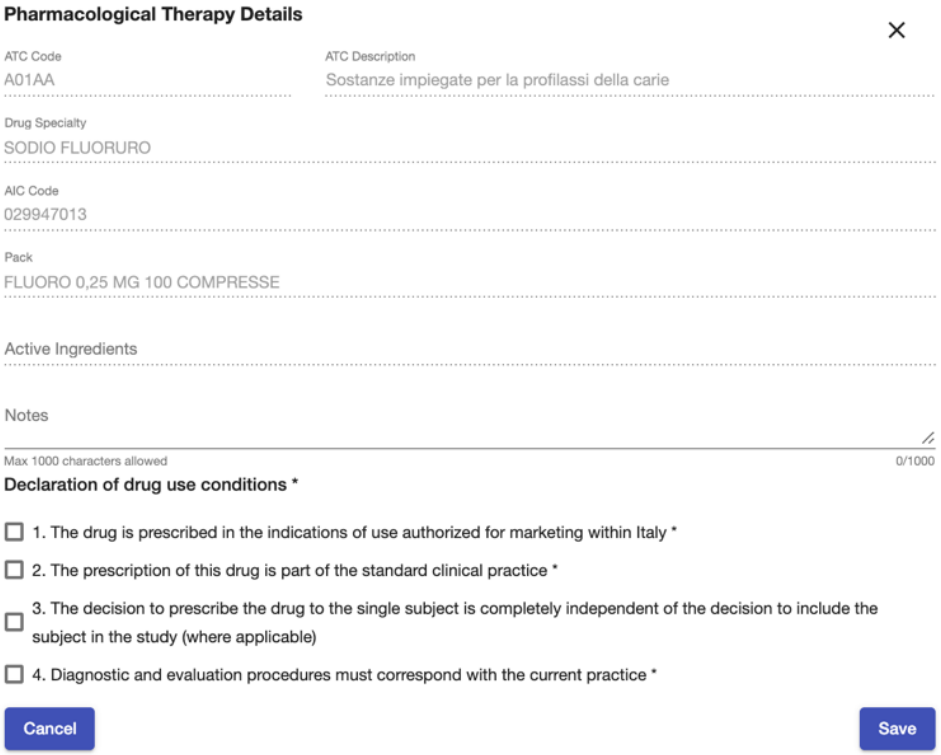

Figure 27 – Therapy Details

If it is not possible to indicate any medicine therapy, the user will be able to select the *"Not Applicable"* checkbox (active only when no therapy is present) and will be required to enter the reasons. In this case, the following messages shown in the figure below will be visible in the system:

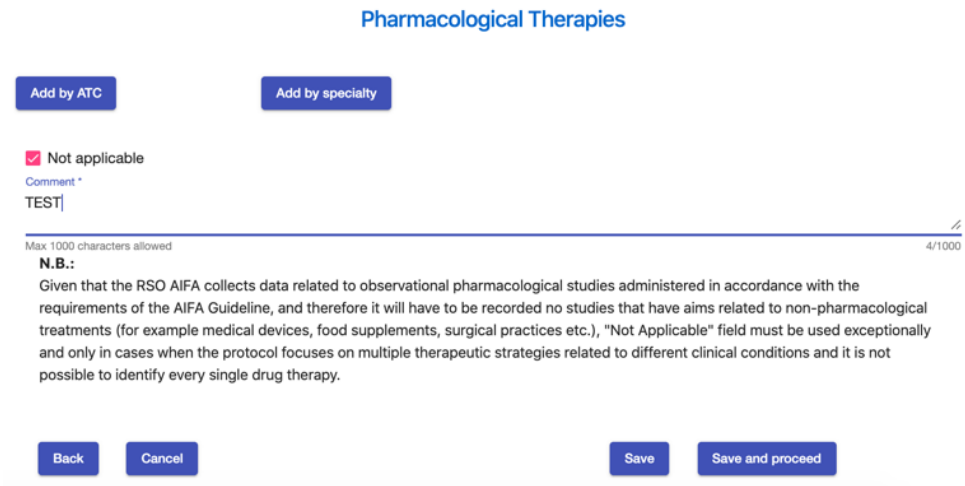

Figure 28 - Not Applicable

5.8 Participant Centers and Ethics Committees

In this section, the Applicant will be able to search for and enter at least one or more *Participant Centers* and *Ethics Committees*.

If the desired trial site is not found, the user, using the "*Indicate Center not in the register"* button, will have the option to add the center not present in the master data, specifying only the name of the center.

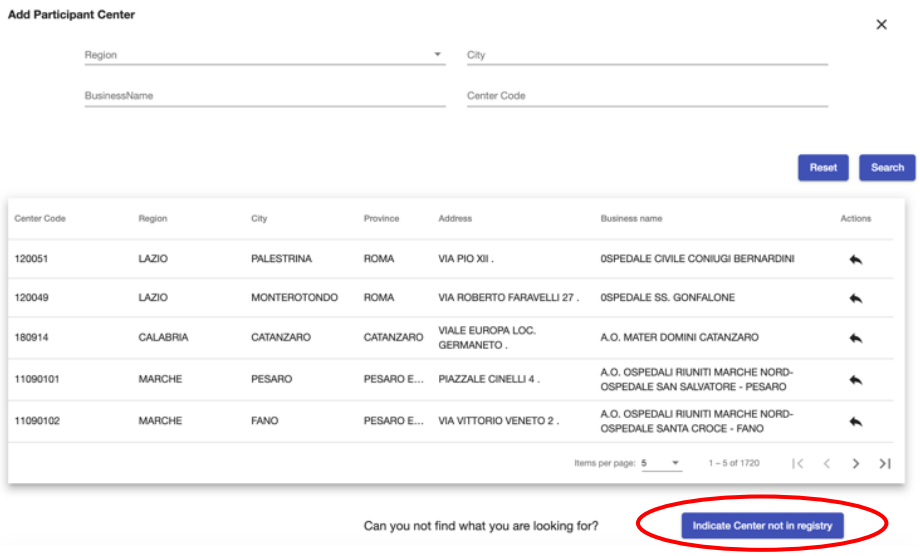

Figure 29 – Search Participant Center

When the participant center is inserted, the user will be directed to view the details of each center, where (s)he will have to:

- declare whether it is a *Coordinating Center*;
- indicate the relevant *Ethics Committee* (automatically selected by the system if the center is present in the master data);
- indicate the *Doctors/pediatricians total number* and attach a document of *the Responsible Doctors/Pediatricians details*;
- enter the details of the *Study Coordinator*.

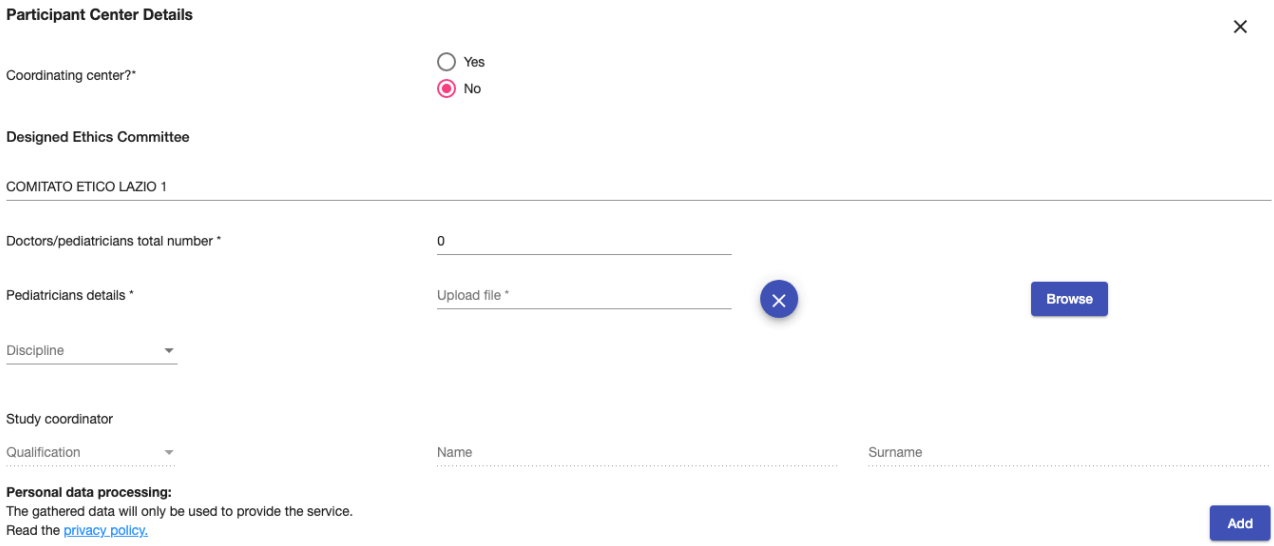

Figure 30 - Participant Center Details

If the structure is an *Azienda Sanitaria Locale* (ASL), the user will be able to enter the details of the local health unit (none is compulsory), indicating the *Number of doctors at public facilities, Number of doctors at private facilities, Number of GPs/pediatricians, Number of self-employed doctors*.

After entering the participating centers, as long as the study is not registered, the user can delete them at any time.

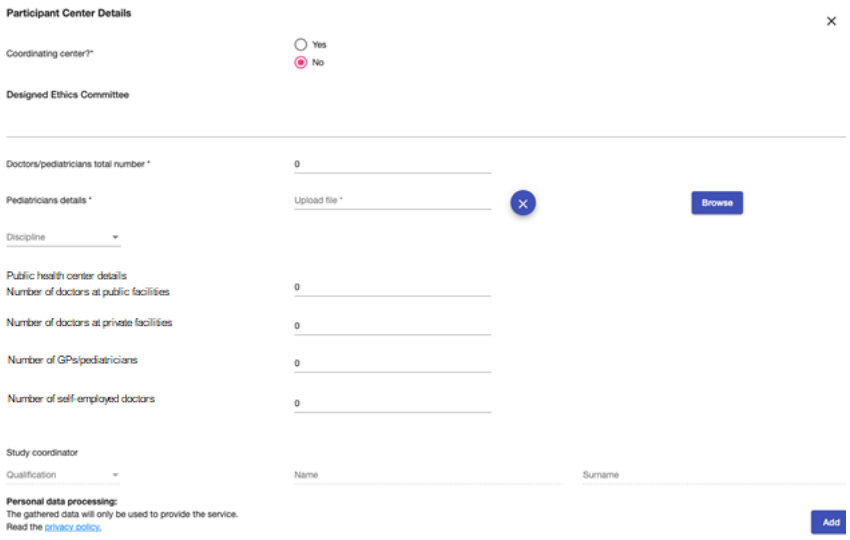

Figure 31 - Details for ASL

5.9 Impact on the National Health System

In this section, if the Applicant is recording an observational study on Covid-19 vaccines, (s)he can insert the Impact on the National Health System (*Sistema Sanitario Nazionale*, SSN) through a specific text field. If the study is not about the Covid-19 vaccines, the user is not required to fill up this step.

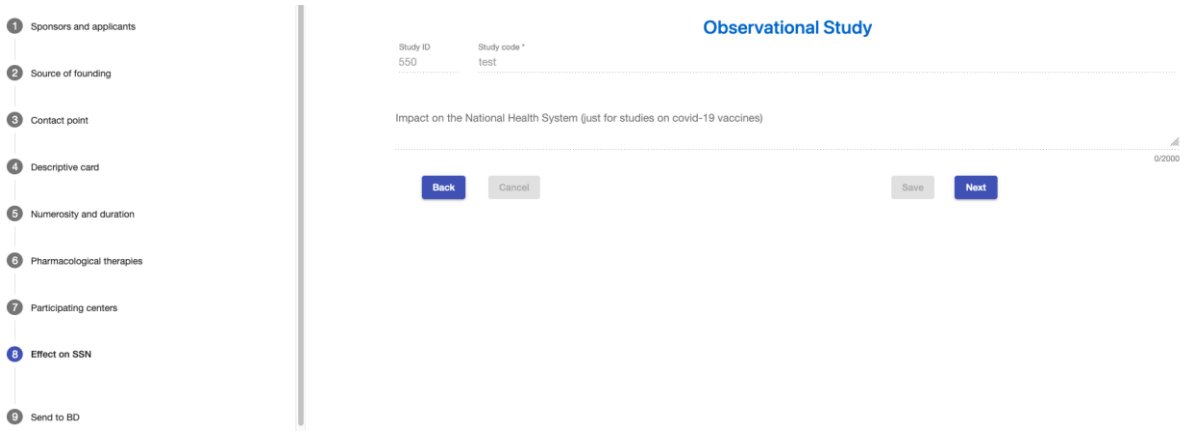

Figure 32 – Impact on NHS

5.10 Send to DB

In this section the user will view a summary overview of the various sections, where any error messages are highlighted arising from sections/tabs that are not filled in or the absence of mandatory data.

If all the data entered in the various sections are correct, the '*Send to DB*' button will be activated. After clicking this button, the user can confirm or not confirm the choice to send the study to DB.

After that, the user will view a page containing a summary table with all the relevant studies.

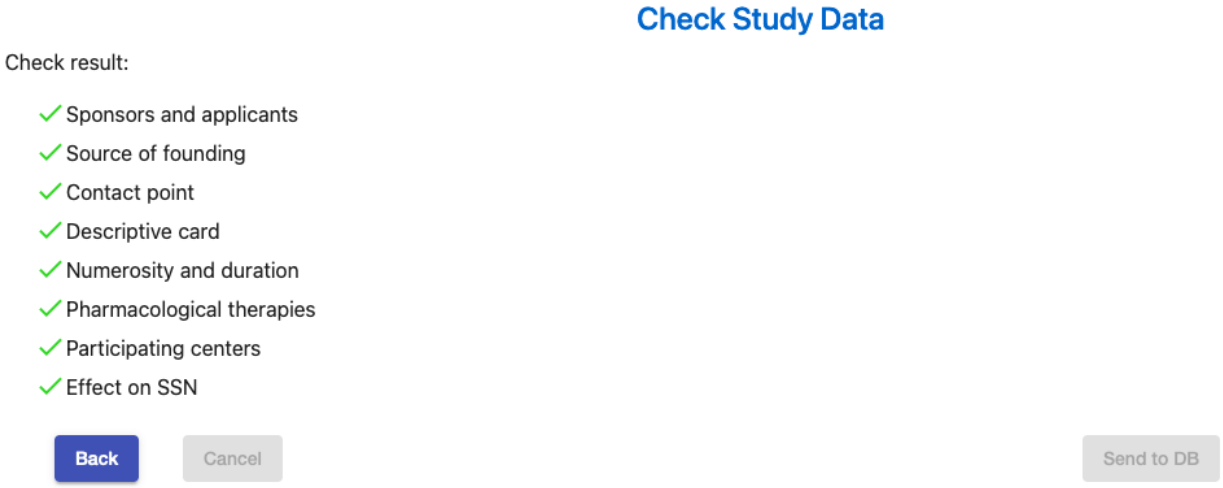

Figure 33 – Check Study Data

6. Revision/integration Study

For prospective directional studies, the *Coordinating Ethics Committee* may request a revision/integration of the study's recording data after viewing it.

In this case, the Applicant will be able to view the requests of the *Coordinating Ethics Committee,* via the appropriate icon (see Figure 34 – Revision Study) present in the *EC Evaluation* column; afterwards, (s)he may modify or integrate the study according to the indications specified in the notes entered by the Ethics Committee.

The user will be able to access the study change via a special icon in the *Study Protocol* column; specifically, there will be an *activity to verify* (red dot).

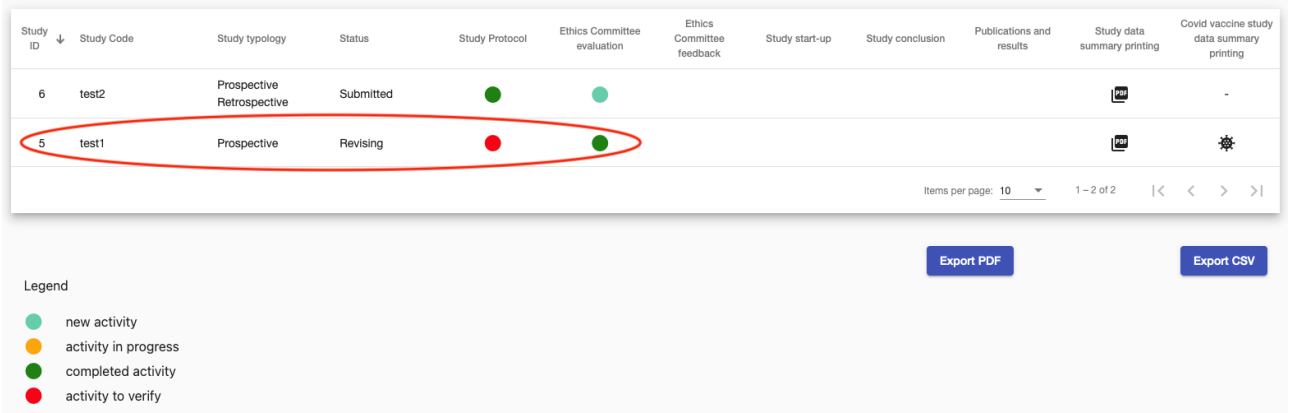

Figure 34 - Revision Study

7. Ethics Committee Opinion

Once a *Coordinating/local Ethics Committee* has expressed its opinion, the Applicant will be able to click on the relevant icon of completed activity (see Figure 35 – EC Opinions) in the *EC Opinions* column and view the details.

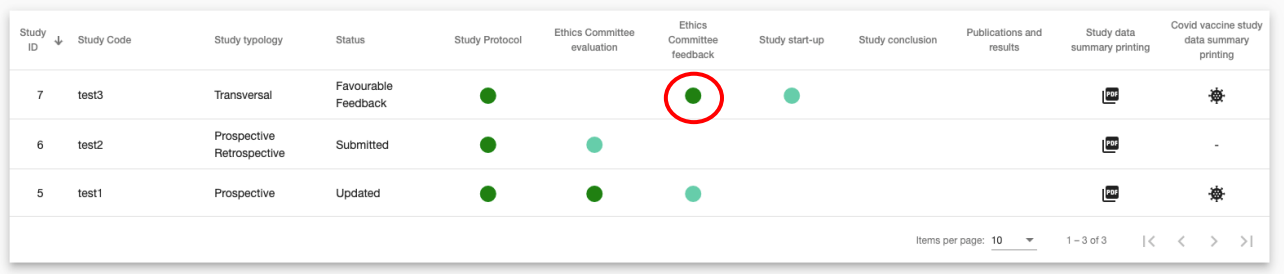

Figure 35 – Ethics Committee opinion

In this section, the summary data of the opinions expressed by the *Ethics Committees* involved in the study will be collected via a table.

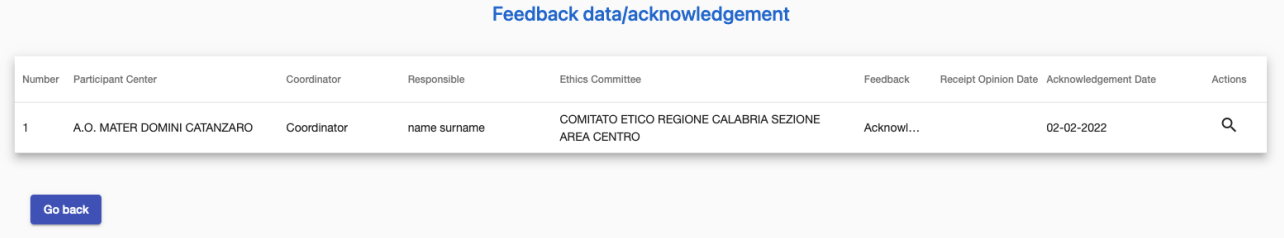

Figure 36 – Opinion data

By clicking on 🔍, the user can access the opinion detail sheet, through which (s)he will be able to view the details of the opinion expressed by the *Ethics Committee*.

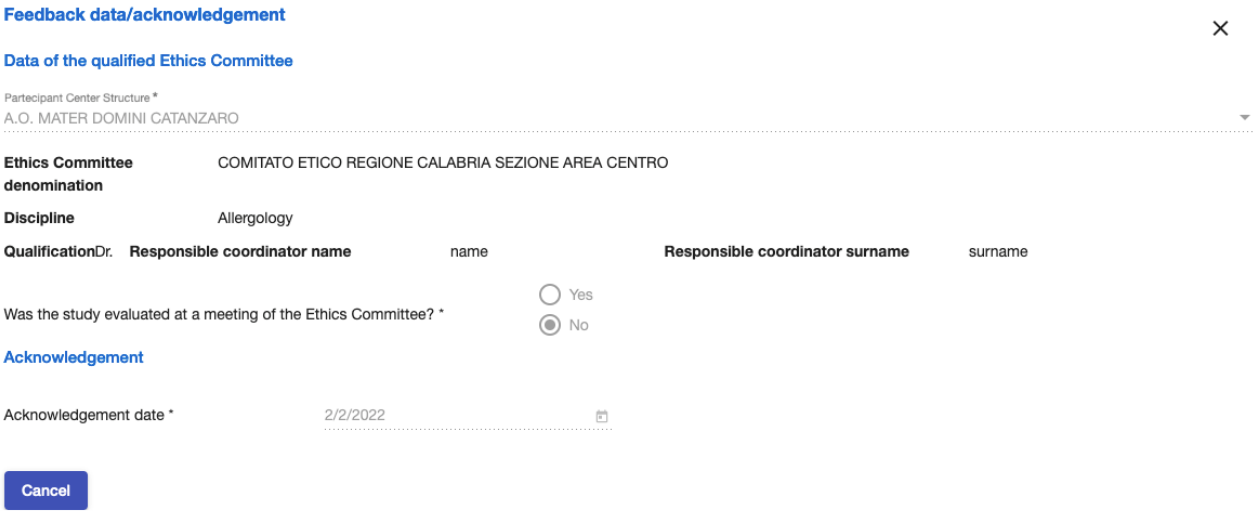

Figure 37 – Details on the opinion

8. Study start-up

By clicking the *new activity* icon (see Figure 33 - *Study start-up*) under the column *Study start-up*, the Applicant can enter the data on the study started.

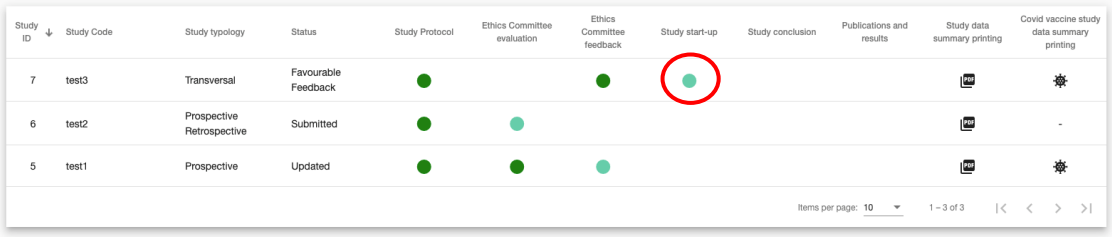

Figure 38 – Study start-up

In particular, it should be specified whether *The Study has been started* or not: if it has been started, the *Study starting date* must be selected*;* otherwise, a text area will open to specify the reasons for the failure to start.

A study can only be started after it has been submitted, i.e. sent to DB, and under the following conditions:

- *Prospective Observational Studies*: when they received a favourable opinion from at least one Ethics Committee (for multicenter studies, the favourable opinion of the Coordinating Ethics Committee);
- *Non-Prospective Observational Studies*: when the acknowledgement or the opinion, if any, has been recorded at least by an Ethics Committee;
- In the absence of the EC's opinion/acknowledgement, AIFA has enabled the entry of startup data. In this case, the Applicant will be notified via notification / ordinary email of the action carried out by AIFA.

The user can save the Study start data at any time using the "*Save"* button and cancel the entered data using the "*Cancel"* button.

Finally, (s)he can confirm the data through the "*Confirm starting data"* button.

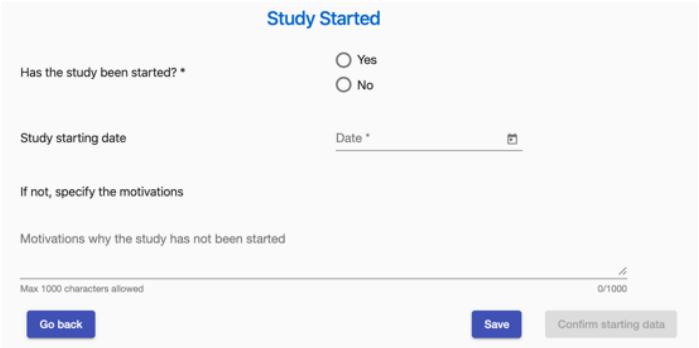

Figure 39 – Study start-up data

9. Study conclusion

After the start of the study, there will be the *New activity* icon (see Figure 40 - Study Conclusion) under the *Study conclusion* column, by which the Applicant will be able to enter the study conclusion data.

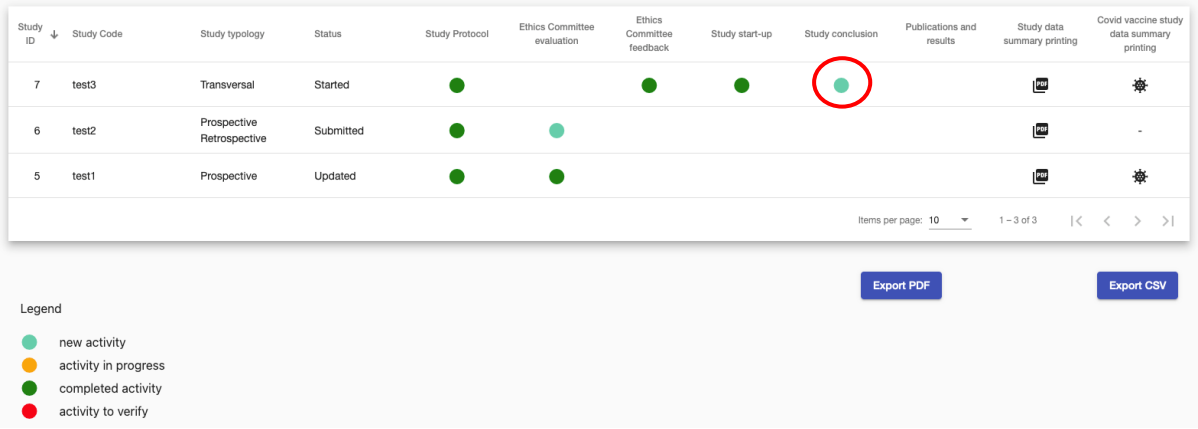

Figure 40 – Study conclusion

In particular, the Applicant will have to enter the *Date of conclusion of the study* and the *Number of subjects included in the study.* In addition, (s)he will have to indicate whether *the study has ended in advance,* and in this latter case report the reasons for the early conclusion.

At any time, the user can save the entered data, with the "*Save*" button, cancel them with "*Cancel*", or confirm the entry of the data with *Confirm Conclusion Data* and move on to the next phase of *Publication*.

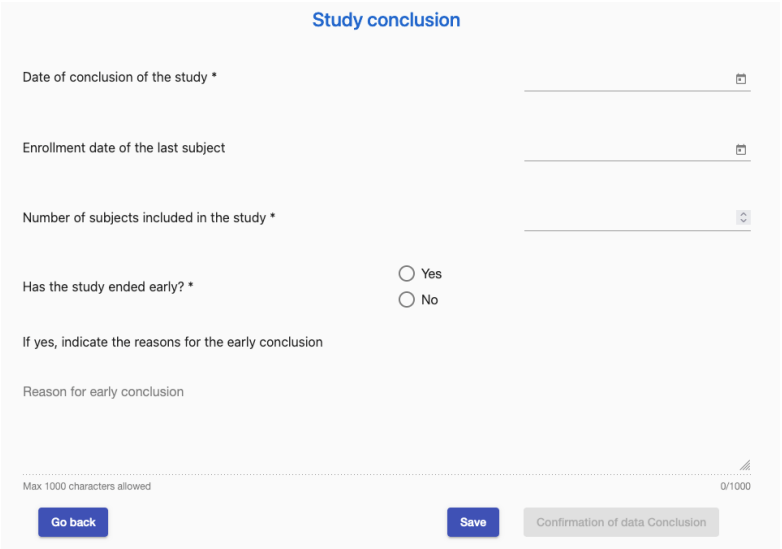

Figure 41 – Study conclusion data

10. Publications and results

After the conclusion of the study, the Applicant will be able to add one or more documents in the *Publication and Results* phase, via the appropriate icon (see Figure 42 - Publication and results).

This phase of the study remains open always (*activity in progress*). It will always be possible to add publications and results even years after the conclusion of the study.

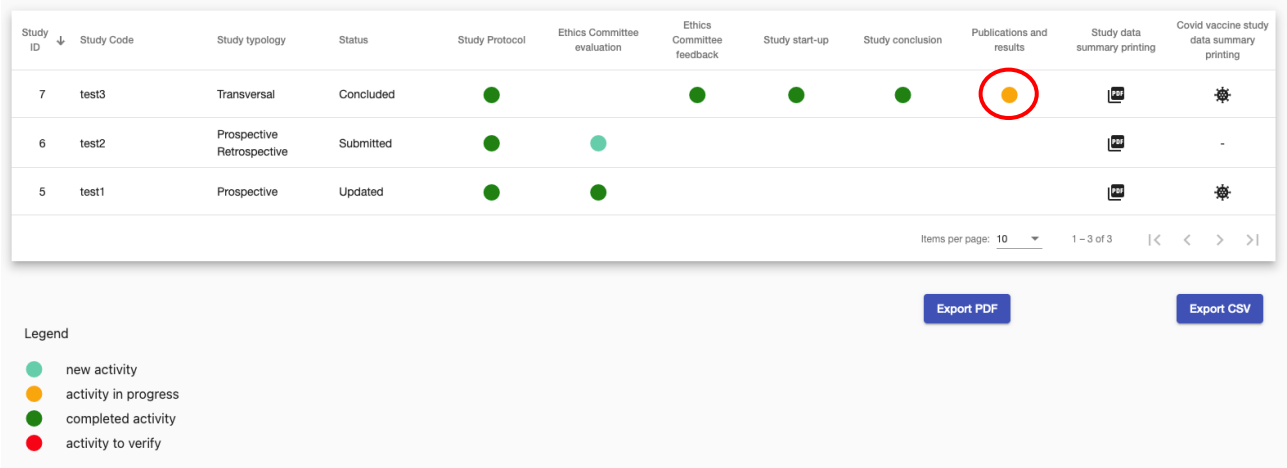

Figure 42 – Publication and results

To add a new document, click on the Add button, located in the *Draft* section (see Figure 43 - Publication and results data).

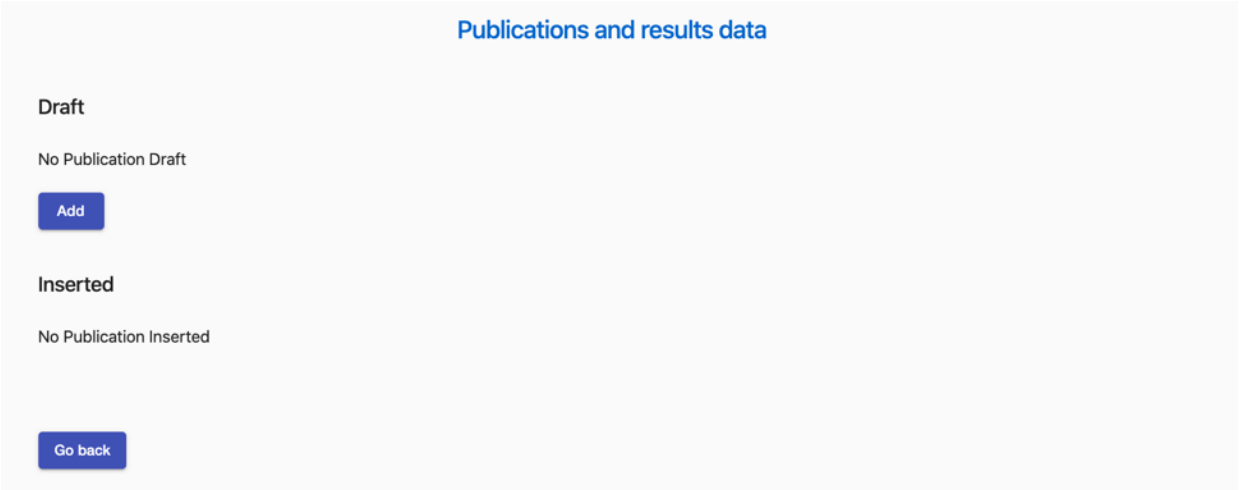

Figure 43 - Publications and results data

In particular, the Applicant will have to indicate the *Document/Publication Title, Document Date* and *Document Type* (*Publication* or *Result*). In addition, (s)he can attach files and insert *Authors* and *References to journals, websites or other*.

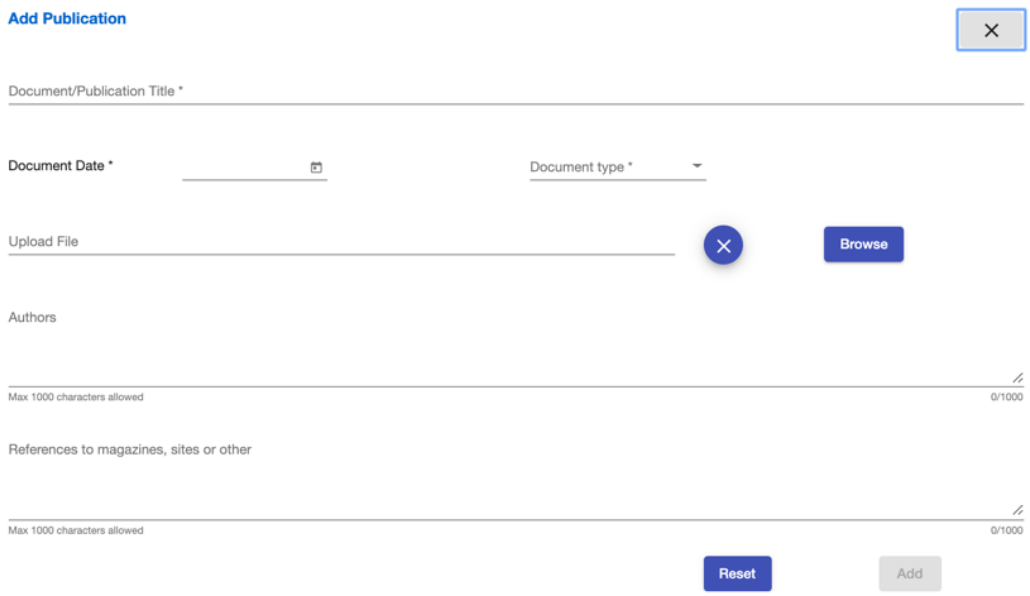

Figure 44 – Add Publication

After adding a document, this will be *In Draft,* and can be edited it with the button and deleted it with . Using the button , the document will be visible to all internal and external users, and it will no longer be possible to edit or delete it.

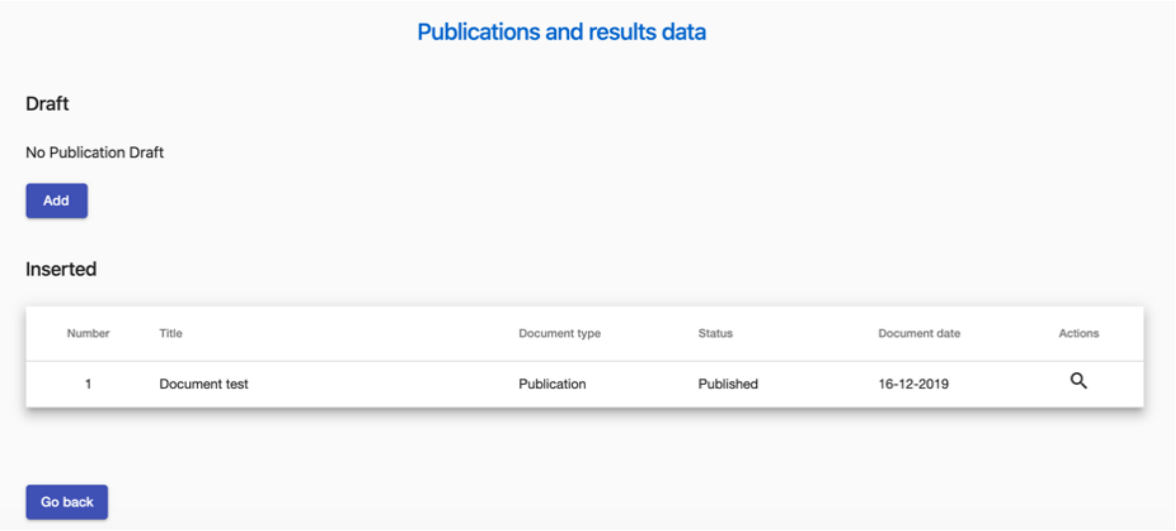

Figure 45 – Inserted publications

11. Studies Search

In this section, the system will allow Applicants to search for the observational studies for which they are Applicant/Sponsor, using different filters grouped as follows:

- *Identification data and general information:*
  - *Study Code*
  - *Study status*
  - *Study objective*
  - *Study submission date*
  - *Study typology*
  - *Keywords*
  - *Research area*
- *Population:*
  - *Gender*
  - *Age group*
  - *Special populations*
- *Pharmacological therapy and therapeutic area:*
  - *ATC Code*
  - *ATC Description*
  - *Medicine specialty*
  - *Pack*
  - *Therapeutic Area - MeSH*
  - *Description - MeSH*
- *Involved organizations:*
  - *Applicant organization*
  - *Sponsor*
  - *Pharmaceutical Company (funding source)*
  - *Partecipant Center*
  - *Ethics Committee*
- *Research Areas:*

- *Pharmacovigilance*
- *Epidemiology*
- *Immunology*
- *Virology*
- *Other*

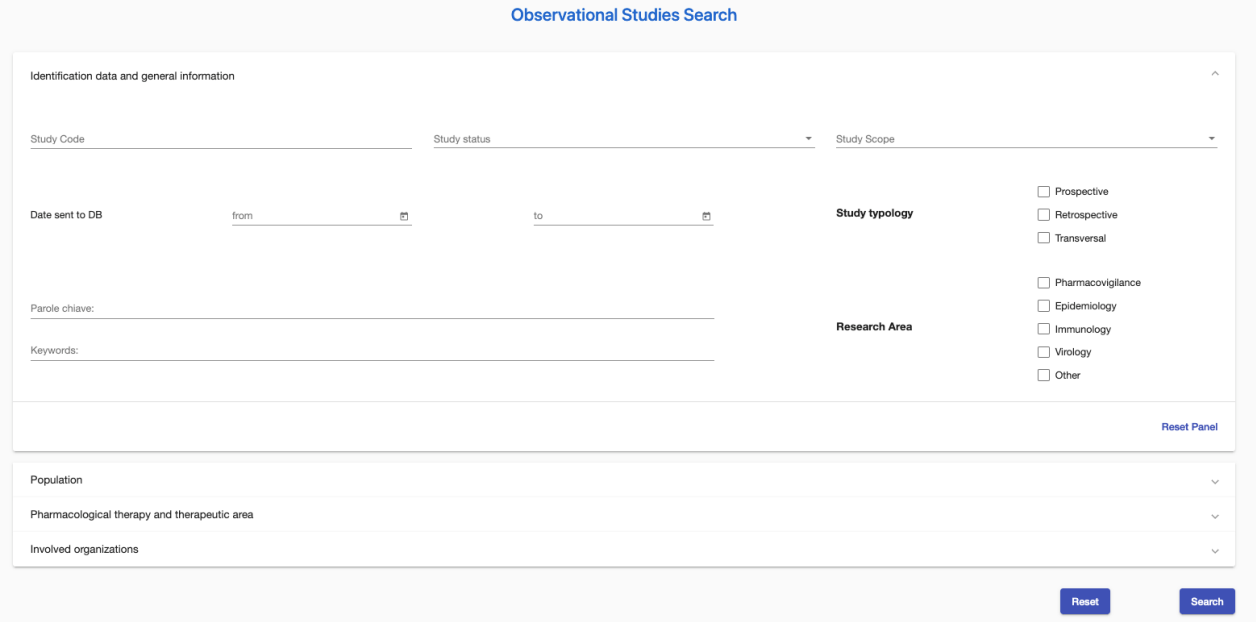

Figure 46 – Applicant Observational Studies Search

The system will allow to export the list containing the search results in PDF and CSV formats.

12. Delete Study

In this section, the Applicant will be able to delete only observational studies previously inserted by the same Applicant via the button 🗑. Therefore, it won't be able to delete studies entered by other users.

In general, it will only be able to delete studies that have not yet been submitted, or sent to DB, that are in the *New* or *Draft* state.

A study registered and rejected by the *Ethics Committee* with a request for review cannot be eliminated.

Finally, if the recording of a study has been delegated by the Sponsor to an Applicant, the Delegate Applicant can delete an assigned study, while the Sponsor can delete it only after the revocation of the delegation.

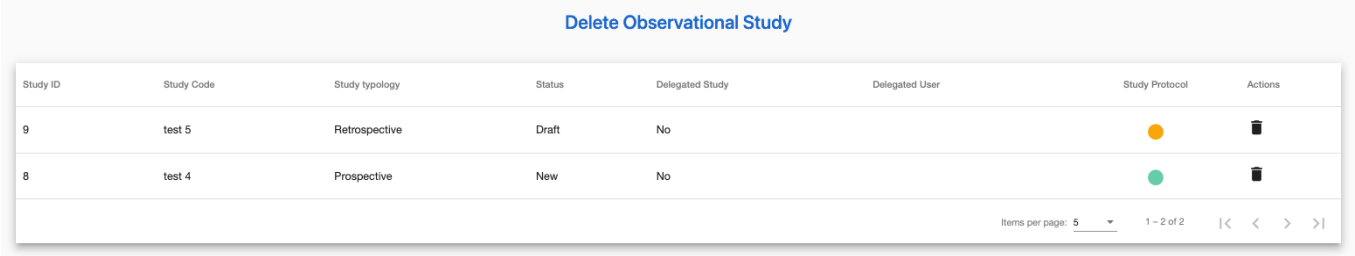

Figure 47 – Delete Study

13. Study Delegation

The Sponsor is allowed to delegate a study. This allows it to delegate an *Observational Study*, for example, to a user of a CRO or a national branch.

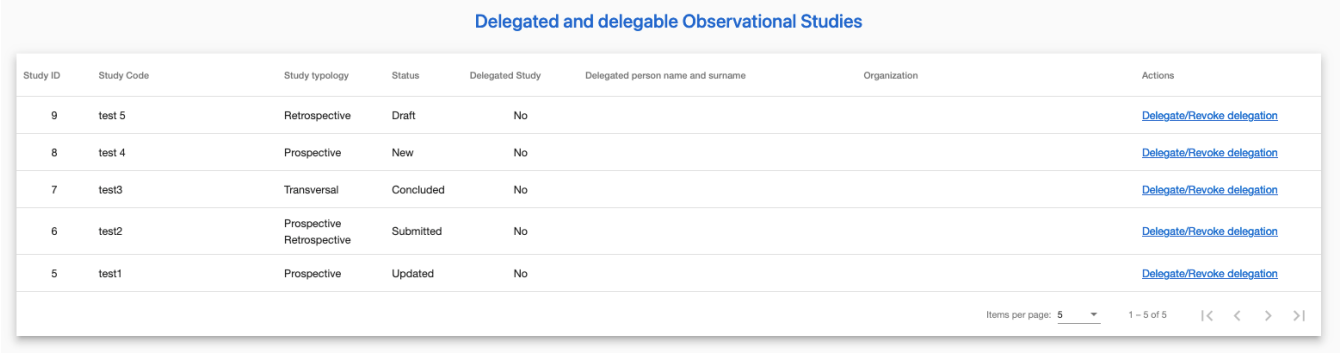

Figure 48 – Study Delegation

Selecting the *Delegate/Revoke delegation* action the system will allow to search for the *delegate,* if the study can be delegated (*delegable)*, or to revoke delegation if the study has been delegated.

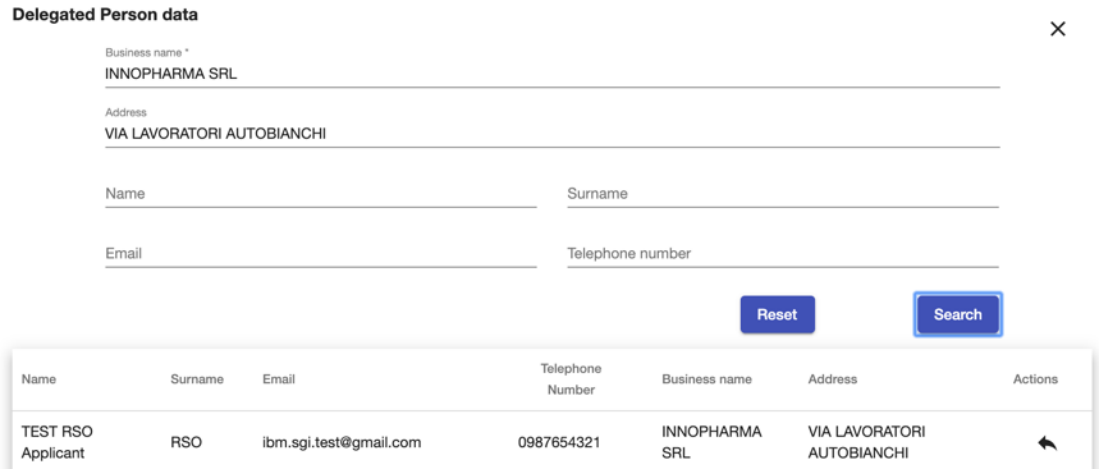

Figure 49 – Delegated Person data

Once the delegation is made, the Applicant will always be able to revoke it and will always have access to the study data as read-only.

Finally, the delegate can delete an assigned study (only under preparation), while the sponsor can delete it only after the delegation is revoked.

14. Operations History

In the *Operations History* section, under *Administration,* the system will allow the Applicant to have a historical view of all operations carried out on the studies.

Only studies within their competence will be visible.

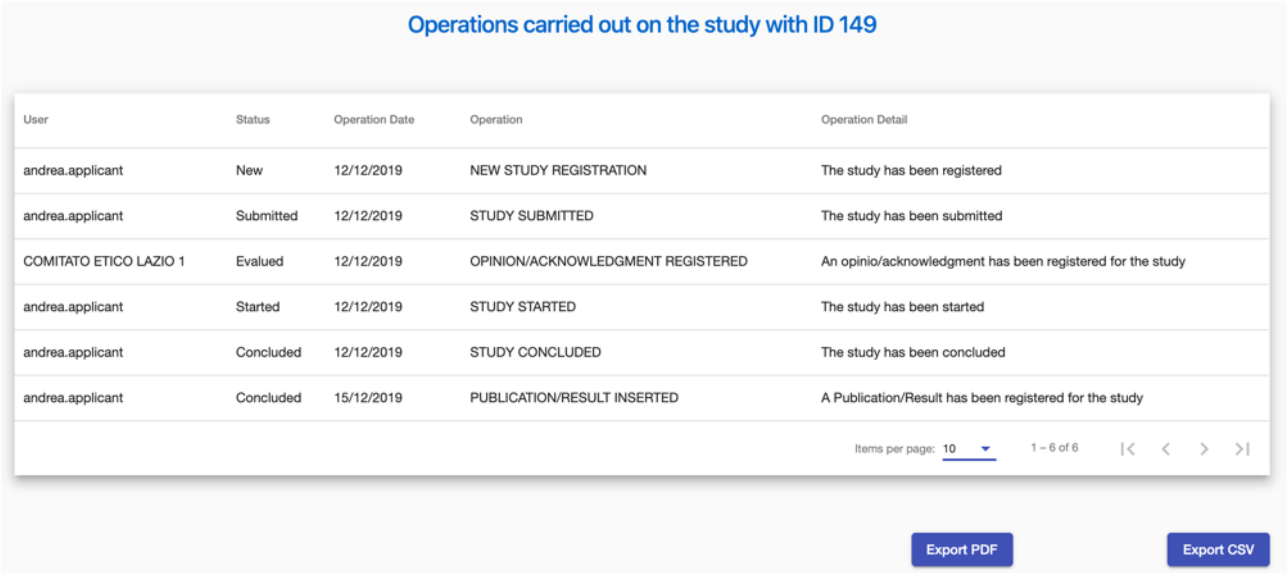

Figure 50 – Operations history

For each operation, the following information is shown:

- Operation date and time
- Study status
- Activity carried out
- Operation detail
- User who did that operation

In particular, the actions that are historicized are as follows:

a) New study registration
b) Sent to DB
c) Integration required
d) Opinion registered
e) Opinion accepted-rejected
f) Opinion/acknowledgment registered
g) Study start/failure to start
h) Enable study start
i) Study conclusion
j) Publications/results

15. Notifications

In the RSO system there will be a section where the user can view the relevant notifications; in particular, it will be possible to access an *inbox* where all notifications associated with the applicant are reported.

Actions that result in a notification (or email) being sent are as follows:

- *EC modification request*
- *EC opinion insertion*
- *Local EC acceptance/refusal of Opinion*
- *Study delegation*
- *Study elimination by the Delegate*
- *Study start enabled*

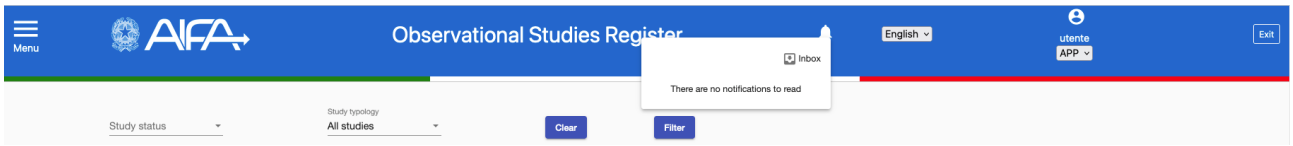

Figure 51 – Applicant Inbox Notifications

16. Notifications and emails preferences

The RSO system will make available to all enabled Applicant a section, under *Administration,* in which they can express their preferences in terms of notifications and emails.

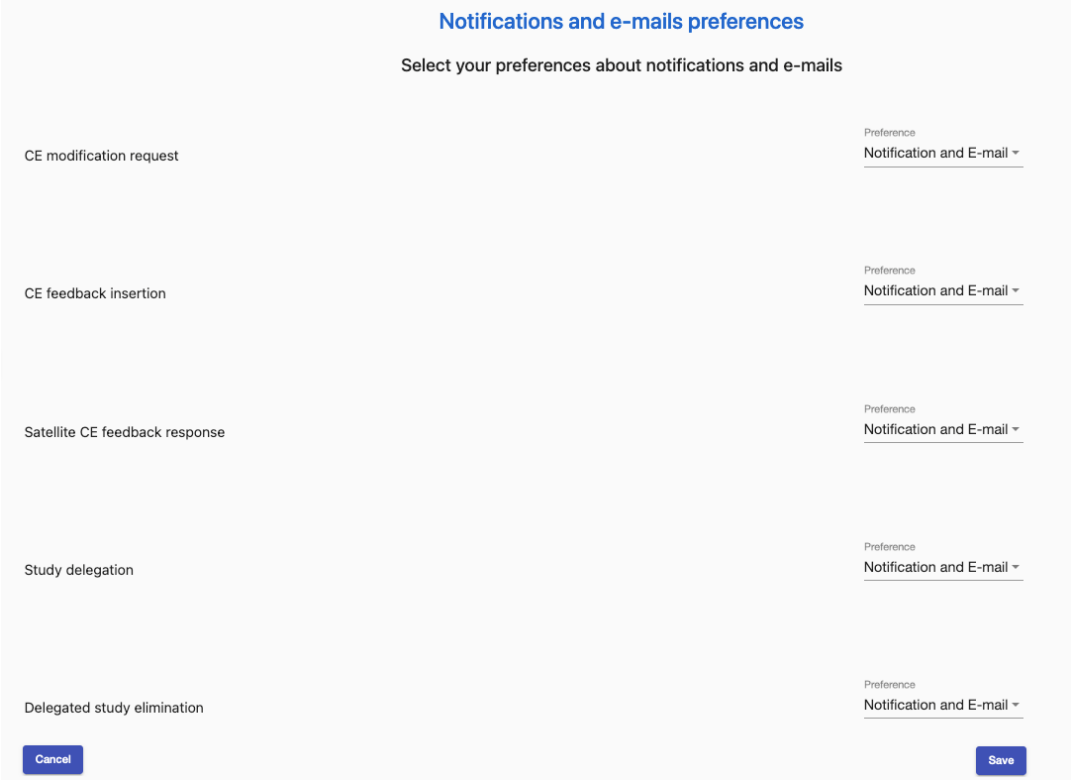

Figure 52 - Notifications/emails preferences