



# 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 ( <i>Sistema Sanitario Nazionale</i> - 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;

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

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

### 1.3 Copyright (specific properties and usage limit)

The following material is property of AIFA, the Italian Medicines Agency.

It can only be used for educational purposes as part of the Observational Studies Register project.

This documentation cannot be copied and/or modified without explicit permission.

## 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*.

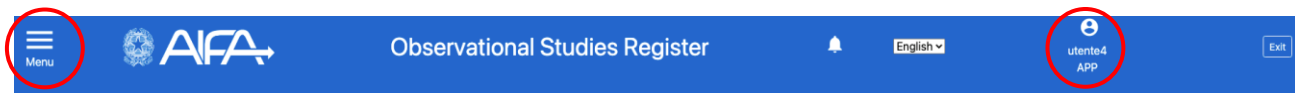


Figure 2 - Header RSO

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*

<b>Observational Studies</b>	^
Studies List	>
New Study Registration	>
Study Delegation	>
Studies Research	>
Delete Study	>
<hr/>	
<b>Administration</b>	^
Operations History	>
Notifications Preferences	>
<hr/>	
<b>Help</b>	^
User Guide	>
FAQ	>



**Figure 3 - Applicant Menu**

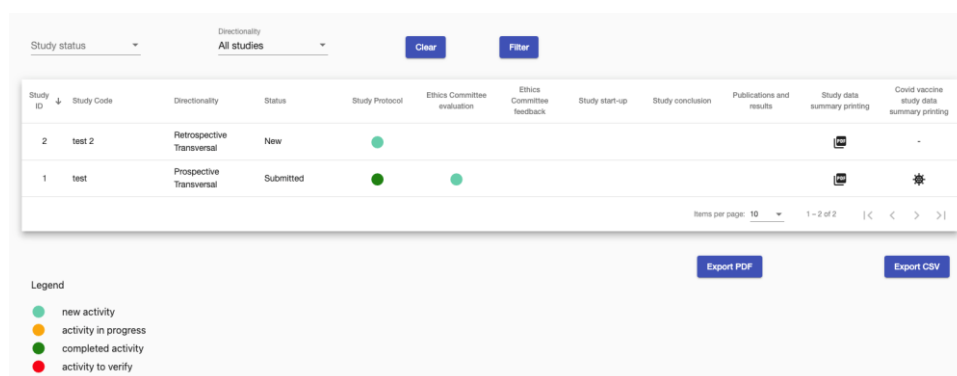
In addition to the Menu, the user’s name and profile are shown. The acronym APP refers to the profile of the Applicant user







## 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.



Study ID	Study Code	Directionality	Status	Study Protocol	Ethics Committee evaluation	Ethics Committee feedback	Study start-up	Study conclusion	Publications and results	Study data summary printing	Covid vaccine study data summary printing
2	test 2	Retrospective Transversal	New								-
1	test	Prospective Transversal	Submitted								

Legend





-  new activity
-  activity in progress
-  completed activity
-  activity to verify

Figure 4 - Studies List

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

Legend







	new activity
	activity in progress
	completed activity
	activity to verify

Figure 5 - Legend

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

Using the buttons  and  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.

#### Creation of a new Observational Study - Identification Data

Study code \*

##### Study typology

- Prospective
- Retrospective
- Transversal

It must be selected at least one directionality for the study

##### Conduction Study site

- Public health facilities (or equivalent)
- Private healthcare facilities
- General Practitioners and / or Free Choice Pediatricians
- Doctors who carry out free-professional activities

It must be selected at least one conduction place for the study

Cancel

Confirm Registration

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).

## Observational Study Registration

You are creating a new Observational Study. Do you want to continue the registration, or to delegate it to another user?

Cancel

Confirm and delegate

Confirm and continue

*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*).

🏠 > Observational Study Details

- 1 Sponsors and Applicants
- 2 Source of founding
- 3 Contact point
- 4 Descriptive form
- 5 Numerosity and duration
- 6 Pharmacological therapies
- 7 Participating centers
- 8 Effect on SSN
- 9 Send to DB

**Figure 8 - Stepper**

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

## Observational Study

Study ID	Study code *
150	test

**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.

**Applicant data \***

Business name **Edit**

---

Address

---

City Province Zip Code Country

**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.

Applicant/sponsor data ×

Business name City


Address Country

Province Zip Code

**Reset** **Search**

Business name	City	Address	Country	Province	Zip Code	Actions
GALMED PHARMACEUTICALS LTD.	TEL AVIV	SHAUL HA'MELECH BLVD.	Israele	/	6473307	↶
1MED SA	Agno	Via Campagna	Swizzera	/	6982	↶
4SC AG	PLANEGG-MARTINSRIED	AM KLOFFERSPITZ	Germania	/	82152	↶
A. MENARINI INDUSTRIE FARMACEUTICHE RIUNITE S.R.L.	Firenze	VIA SETTE SANTI	Italia	Firenze	50131	↶
A.O. OSPEDALE DI CIRCOLO E FONDAZIONE MACCHI	Varese	VIALE BORRI	Italia	Varese	21100	↶

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 Can you not find what you are looking for?

**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.

Does the applicant correspond with the sponsor? \*

No (default)  Yes

Sponsor data

Business name

Edit

Address

City

Province

Zip Code

Country

Cancel

Save

Save and proceed

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

Does the applicant correspond with the sponsor? \*

No (default)  Yes

Cancel

Save

Save and proceed

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

Cancel

Inserted data will not be saved. Do you want to proceed?

Cancel

Confirm and continue

**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.

**Funding source for the study**

Pharmaceutical Company (specify)

Ministry of Health

AIFA - Independent Research Projects

AIFA - Active Pharmacovigilance Projects

MIUR

ISS

CNR

Foundation Or Charity

European Commission

Other

Specify \*

Specify \*

**Pharmaceutical Company Data**

SIS Code

Business name

Address

City  Province  Zip Code  Country

**Figure 15 – Funding source**

## 5.4 Contact Point

In this section, the Applicant enters the study's *Contact Points* data, using the button . 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.

x

### Add a contact point

Name \*

Surname \*

Email \*

Phone

Fax

Clear

Add

**Personal data processing:**

The gathered data will only be used to provide the service.

Read the [privacy policy](#).

**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.

**Study Descriptive Form**

General   Objective   Protocol   Therapeutic Area   Population

---

Titolo dello studio \*

Title of the study \*

Parole chiave:

Keywords:

<p><b>Aim *</b></p> <p><input type="radio"/> Descriptive</p> <p><input type="radio"/> Analytic (Etiological)</p> <p><input type="radio"/> Mixed</p>	<p><b>Design *</b></p> <p><input type="radio"/> Transversal</p> <p><input type="radio"/> Cohort</p> <p><input type="radio"/> Case-Control</p> <p><input type="radio"/> Other   Specify * .....</p>	<p><b>Research Area (just for studies on covid-19 vaccines)</b></p> <p><input type="checkbox"/> Pharmacovigilance</p> <p><input type="checkbox"/> Epidemiology</p> <p><input type="checkbox"/> Immunology</p> <p><input type="checkbox"/> Virology</p> <p><input type="checkbox"/> Other   Other * .....</p>
---	--	--

**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;

**Study Descriptive Form**

General   **Objective**   Protocol   Therapeutic Area   Population

---

**Primary Goal \***

Safety

Use of the drug

Appropriateness

Efficacy in clinical practice (Effectiveness)

Pharmacoeconomics

Other (specify)   Other Goal \* .....

Obiettivi primari dello studio \*

Max 1000 characters allowed 0/1000

Primary objective of the study \*

Max 1000 characters allowed 0/1000

**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.*

**Study Descriptive Form**

General   Objective   **Protocol**   Therapeutic Area   Population



---

**Study scope \***

Cognitive  
 PAS (Post Authorization Safety Study) required by EMA  
 PAES (Post Authorization Efficacy Study) required by EMA  
 PAS (Post Authorization Study) required by FDA  
 Other

Other aim \* \_\_\_\_\_

**Protocol \***

Protocol File \*    
 Date \* 2/7/2022   
 Protocol Code \* \_\_\_\_\_   
 Version \* \_\_\_\_\_   
 Attach 

**Section just for studies on covid-19 vaccines**

Principles of analysis of the collected material and data \_\_\_\_\_ ↗

Interventions and procedures \_\_\_\_\_ ↗

Inclusion criteria \_\_\_\_\_ ↗   Exclusion criteria \_\_\_\_\_ ↗

Study rational \_\_\_\_\_ ↗

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.

### Study Descriptive Form

General   Objective   Protocol   Therapeutic Area   Population

---

**Therapeutic Area**

Therapeutic Area \* Description \*

---

Condizione Clinica \*

Max 1000 characters allowed 0/1000

---

Clinical Condition \*

Max 1000 characters allowed 0/1000

---

**MedDRA Classification of the Clinical Condition**

No Classification Inserted

Not applicable 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.

### Study Descriptive Form

General   Objective   Protocol   Therapeutic Area   Population

---

**Gender \***

Male    Female

**Special population**

Renal impairment    Hepatic impairment    Immunosuppressed    Pregnant women

**Age Group \***

Preterm newborn  
 Newborn (0 - 27 days)  
 Infants and newborn (28 days - 23 months)  
 Newborn (2 - 11 years)  
 Adolescents (12 - 17 years)  
 Adults (18 - 64 years)  
 Elderly people (65 - 74 years)  
 Elderly people (over 75)

---

**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).

**Numerosity and Duration of the study**

**Expected number of subjects**  
World total \*  in EU  in Italy \*

**EU countries (multiple choice)**  
Type the Country name

**Study duration**  
Expected duration \*  unit \*

**Expected ending date of the study**  
Month and Year \*

**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;

**Research criteria for ATC**



Level 1

A - ALIMENTARY TRACT AND METABOLISM

Level 2

Level 3

Level 4

Search

ATC	ATC Descript.	Level	Select Specialty	Select
A	ALIMENTARY TRACT AND METABOLISM	1	<a href="#">Show specialty.</a>	<input type="checkbox"/>
A01	STOMATOLOGICAL PREPARATIONS	2	<a href="#">Show specialty.</a>	<input type="checkbox"/>
A01A	STOMATOLOGICAL PREPARATIONS	3	<a href="#">Show specialty.</a>	<input type="checkbox"/>
A01AA	Caries prophylactic agents	4	<a href="#">Show specialty.</a>	<input type="checkbox"/>
A01AB	Antiinfectives and antiseptics for local oral treatment	4	<a href="#">Show specialty.</a>	<input type="checkbox"/>

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Add

**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.

**Search criteria for medicine speciality** X

ATC Code: A01      ATC Description: \_\_\_\_\_

AIC Code: \_\_\_\_\_      AIC Owner: \_\_\_\_\_

Drug Speciality: \_\_\_\_\_      Pack: \_\_\_\_\_

Active Ingredient: \_\_\_\_\_

Reset
Search

ATC Code	ATC Description	Drug Speciality	AIC Code	AIC Owner	Pack	Active Ingredient	Select
A01AA	Sostanze impiegate per la profilassi della carie	SODIO FLUORURO	032747026	C.O.C. FARMACEUTICI S.R.L.	100 COMPRESSE 2,2 MG		<input type="checkbox"/>
A01AA	Sostanze impiegate per la profilassi della carie	SODIO FLUORURO	029947013	A.F.O.M. MEDICAL S.P.A.	FLUORO 0,25 MG 100 COMPRESSE		<input type="checkbox"/>
A01AA	Sostanze impiegate per la profilassi della carie	FLUOCARIL BI FLUORE'	024362030	PROCTER & GAMBLE S.R.L.	"250" PASTA DENTIFRICIA 150 G		<input type="checkbox"/>
A01AA	Sostanze impiegate per la profilassi della carie	FLUOCARIL BI FLUORE'	024362055	PROCTER & GAMBLE S.R.L.	"250" DENTIFRICO ANICE 100 G		<input type="checkbox"/>
A01AA	Sostanze impiegate per la profilassi della carie	SODIO FLUORURO	029947049	A.F.O.M. MEDICAL S.P.A.	FLUORO 1 MG 250 COMPRESSE		<input type="checkbox"/>

Items per page: 5      1 - 5 of 212      |< < > >|

Search by ATC
Add

**Figure 24 – Search by medicine speciality**

**Search criteria for medicine brand name** X

ATC Code: atf      ATC Description: \_\_\_\_\_

AIC Code: \_\_\_\_\_      AIC Owner: \_\_\_\_\_

Drug brand name: \_\_\_\_\_      Pack: \_\_\_\_\_


Active Ingredient: \_\_\_\_\_

Reset
Search

ATC Code	ATC Description	Drug brand name	AIC Code	AIC Owner	Pack	Active Ingredient	Select
No Data Found							

Items per page: 5      0 of 0      |< < > >|

Search by ATC
Add

 Can you not find what you are looking for?


**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*.



### Pharmacological Therapies

ATC	ATC Description	Drug brand name	AIC Code	AIC Owner	Pack	Active Ingredient	Declaration	Actions
B02BA	VITAMINA K	VIT.K SALF	007535026	S.A.L.F. SPA L...	IM 5 FIALE 2 ...	MENAD...	<input type="checkbox"/>	

**Figure 26 – Declaration**

**Pharmacological Therapy Details** X

ATC Code: A01AA  
 ATC Description: Sostanze impiegate per la profilassi della carie

Drug Specialty: SODIO FLUORURO

AIC Code: 029947013

Pack: FLUORO 0,25 MG 100 COMPRESSE

Active Ingredients:

Notes: 0/1000

**Declaration of drug use conditions \***

- 1. The drug is prescribed in the indications of use authorized for marketing within Italy \*
- 2. The prescription of this drug is part of the standard clinical practice \*
- 3. The decision to prescribe the drug to the single subject is completely independent of the decision to include the subject in the study (where applicable)
- 4. Diagnostic and evaluation procedures must correspond with the current practice \*

Cancel
Save

**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:

### Pharmacological Therapies

Add by ATC
Add by specialty

Not applicable

Comment \*

TEST|

Max 1000 characters allowed 4/1000

**N.B.:**  
Given that the RSO AIFA collects data related to observational pharmacological studies administered in accordance with the requirements of the AIFA Guideline, and therefore it will have to be recorded no studies that have aims related to non-pharmacological treatments (for example medical devices, food supplements, surgical practices etc.), "Not Applicable" field must be used exceptionally and only in cases when the protocol focuses on multiple therapeutic strategies related to different clinical conditions and it is not possible to identify every single drug therapy.

Back
Cancel
Save
Save and proceed

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.

**Add Participant Center** ✕

Region ▼

City

BusinessName

Center Code

Reset Search

Center Code	Region	City	Province	Address	Business name	Actions
120051	LAZIO	PALESTRINA	ROMA	VIA PIO XII .	OSPEDALE CIVILE CONIUGI BERNARDINI	🔍
120049	LAZIO	MONTEROTONDO	ROMA	VIA ROBERTO FARAVELLI 27 .	OSPEDALE SS. GONFALONE	🔍
180914	CALABRIA	CATANZARO	CATANZARO	VIALE EUROPA LOC. GERMANETO .	A.O. MATER DOMINI CATANZARO	🔍
11090101	MARCHE	PESARO	PESARO E...	PIAZZALE CINELLI 4 .	A.O. OSPEDALI RIUNITI MARCHE NORD-OSPEDALE SAN SALVATORE - PESARO	🔍
11090102	MARCHE	FANO	PESARO E...	VIA VITTORIO VENETO 2 .	A.O. OSPEDALI RIUNITI MARCHE NORD-OSPEDALE SANTA CROCE - FANO	🔍

Items per page: 5 | 1 - 5 of 1720 | < > >>

Can you not find what you are looking for? Indicate Center not in registry

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*.

**Participant Center Details** ×

Coordinating center? \*  Yes  No

Designed Ethics Committee

COMITATO ETICO LAZIO 1

---

Doctors/pediatricians total number \*

Pediatricians details \*

Discipline

Study coordinator

Qualification  Name  Surname

**Personal data processing:**  
The gathered data will only be used to provide the service.  
Read the [privacy policy](#).

**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.

**Participant Center Details** x

Coordinating center?  Yes  No

Designed Ethics Committee

---

Doctors/pediatricians total number \* 0

Pediatricians details \* Upload file \*

Discipline

Public health center details

Number of doctors at public facilities 0

Number of doctors at private facilities 0

Number of GPs/pediatricians 0

Number of self-employed doctors 0

Study coordinator

Qualification

Name  Surname

Personal data processing:  
The gathered data will only be used to provide the service.  
[Read the privacy policy.](#)

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.

- 1 Sponsors and applicants
- 2 Source of founding
- 3 Contact point
- 4 Descriptive card
- 5 Numerosity and duration
- 6 Pharmacological therapies
- 7 Participating centers
- 8 Effect on SSN
- 9 Send to DB

**Observational Study**

Study ID 550 Study code \* test

---

Impact on the National Health System (just for studies on covid-19 vaccines)

0/2000

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.

### Check Study Data

Check result:

- ✓ Sponsors and applicants
- ✓ Source of founding
- ✓ Contact point
- ✓ Descriptive card
- ✓ Numerosity and duration
- ✓ Pharmacological therapies
- ✓ Participating centers
- ✓ Effect on SSN

Back

Cancel

Send to DB

**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).

Study ID ↓	Study Code	Study typology	Status	Study Protocol	Ethics Committee evaluation	Ethics Committee feedback	Study start-up	Study conclusion	Publications and results	Study data summary printing	Covid vaccine study data summary printing
6	test2	Prospective Retrospective	Submitted	<span style="color: green;">●</span>	<span style="color: cyan;">●</span>						-
5	test1	Prospective	Revising	<span style="color: red;">●</span>	<span style="color: green;">●</span>						

Items per page: 10 | 1 - 2 of 2 | < > >|

Legend

- new activity
- activity in progress
- completed activity
- activity to verify

[Export PDF](#) [Export CSV](#)

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.

Study ID ↓	Study Code	Study typology	Status	Study Protocol	Ethics Committee evaluation	Ethics Committee feedback	Study start-up	Study conclusion	Publications and results	Study data summary printing	Covid vaccine study data summary printing
7	test3	Transversal	Favourable Feedback								
6	test2	Prospective Retrospective	Submitted								-
5	test1	Prospective	Updated								

Items per page: 10    1 - 3 of 3    |< < > >|

**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.

**Feedback data/acknowledgement**

Number	Participant Center	Coordinator	Responsible	Ethics Committee	Feedback	Receipt Opinion Date	Acknowledgement Date	Actions
1	A.O. MATER DOMINI CATANZARO	Coordinator	name surname	COMITATO ETICO REGIONE CALABRIA SEZIONE AREA CENTRO	Acknowl...		02-02-2022	

[Go back](#)

**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*.

**Feedback data/acknowledgement**



**Data of the qualified Ethics Committee**

Participant Center Structure \*

A.O. MATER DOMINI CATANZARO

**Ethics Committee denomination**      COMITATO ETICO REGIONE CALABRIA SEZIONE AREA CENTRO

**Discipline**      Allergology

<b>QualificationDr.</b>	<b>Responsible coordinator name</b>	name	<b>Responsible coordinator surname</b>	surname
-------------------------	-------------------------------------	------	--	---------

Was the study evaluated at a meeting of the Ethics Committee? \*

Yes  
 No

**Acknowledgement**

Acknowledgement date \*      2/2/2022

Cancel

**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.

Study ID ↓	Study Code	Study typology	Status	Study Protocol	Ethics Committee evaluation	Ethics Committee feedback	Study start-up	Study conclusion	Publications and results	Study data summary printing	Covid vaccine study data summary printing
7	test3	Transversal	Favourable Feedback	●	●	●	●			🖨️	🖨️
6	test2	Prospective Retrospective	Submitted	●	●	●				🖨️	-
5	test1	Prospective	Updated	●	●	●				🖨️	🖨️

Items per page: 10 | 1 - 3 of 3 | < >

**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.

**Study Started**

Has the study been started? \*

Yes  
 No

Study starting date

Date \*

If not, specify the motivations

Motivations why the study has not been started

Max 1000 characters allowed 0/1000

**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.

Study ID	Study Code	Study typology	Status	Study Protocol	Ethics Committee evaluation	Ethics Committee feedback	Study start-up	Study conclusion	Publications and results	Study data summary printing	Covid vaccine study data summary printing
7	test3	Transversal	Started	●		●	●	●		PDF	⚙️
6	test2	Prospective Retrospective	Submitted	●	●					PDF	-
5	test1	Prospective	Updated	●	●					PDF	⚙️

Items per page: 10 | 1 - 3 of 3 | < >

Legend

- new activity
- activity in progress
- completed activity
- activity to verify

Export PDF | Export CSV

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*.

**Study conclusion**

Date of conclusion of the study \*

Enrollment date of the last subject

Number of subjects included in the study \*

Has the study ended early? \*  Yes  No

If yes, indicate the reasons for the early conclusion

Reason for early conclusion

Max 1000 characters allowed 0/1000

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.

Study ID	Study Code	Study typology	Status	Study Protocol	Ethics Committee evaluation	Ethics Committee feedback	Study start-up	Study conclusion	Publications and results	Study data summary printing	Covid vaccine study data summary printing
7	test3	Transversal	Concluded	●	●	●	●	●	●	📄	⚙️
6	test2	Prospective Retrospective	Submitted	●	●					📄	-
5	test1	Prospective	Updated	●	●					📄	⚙️

Items per page: 10 | 1 - 3 of 3 | < > >>

Export PDF | Export CSV

Legend

- new activity
- activity in progress
- completed activity
- activity to verify

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).

### Publications and results data

**Draft**

No Publication Draft

**Add**

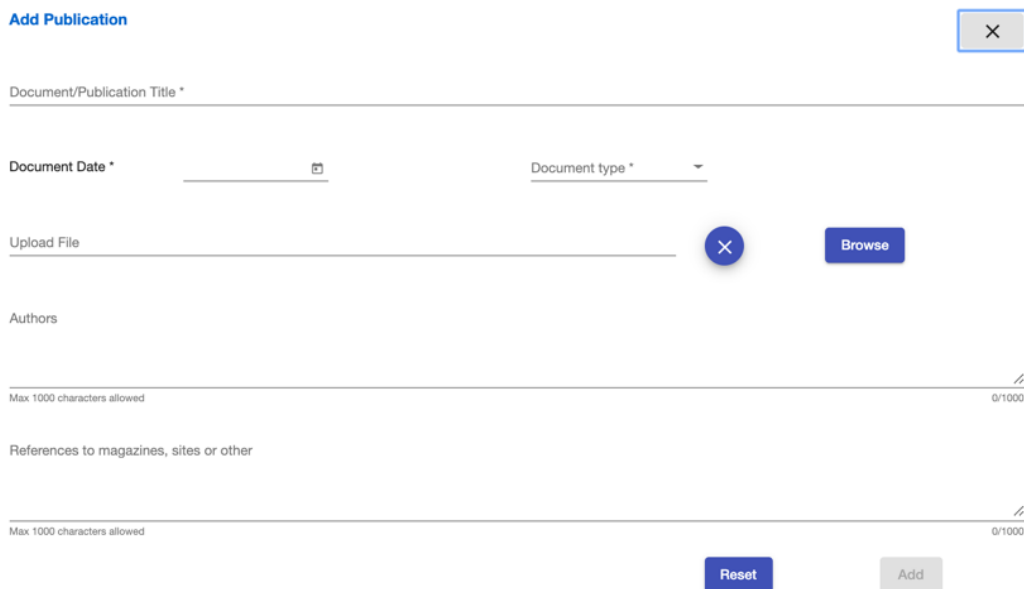
**Inserted**

No Publication Inserted

**Go back**

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*.



**Add Publication** [Close]

Document/Publication Title \*

Document Date \* [Calendar icon] Document type \* [Dropdown arrow]

Upload File [Close] [Browse]

Authors




Max 1000 characters allowed 0/1000

References to magazines, sites or other

Max 1000 characters allowed 0/1000

[Reset] [Add]

**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.


**Publications and results data**

**Draft**

No Publication Draft

[Add]

**Inserted**

Number	Title	Document type	Status	Document date	Actions
1	Document test	Publication	Published	16-12-2019	

[Go back]

**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)*
  - *Participant Center*
  - *Ethics Committee*
- *Research Areas:*

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

**Observational Studies Search**

Identification data and general information ^

---

Study Code Study status Study Scope

---

Date sent to DB from  to

Parole chiave:

Keywords:

**Study typology**

Prospective

Retrospective

Transversal

**Research Area**

Pharmacovigilance

Epidemiology

Immunology

Virology

Other

[Reset Panel](#)

---

Population v


Pharmacological therapy and therapeutic area v

Involved organizations v

**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.

Delete Observational Study

Study ID	Study Code	Study typology	Status	Delegated Study	Delegated User	Study Protocol	Actions
9	test 5	Retrospective	Draft	No			
8	test 4	Prospective	New	No			

Items per page: 5    1 - 2 of 2    |< < > >|

**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.

**Delegated and delegable Observational Studies**

Study ID	Study Code	Study typology	Status	Delegated Study	Delegated person name and surname	Organization	Actions
9	test 5	Retrospective	Draft	No			<a href="#">Delegate/Revoke delegation</a>
8	test 4	Prospective	New	No			<a href="#">Delegate/Revoke delegation</a>
7	test3	Transversal	Concluded	No			<a href="#">Delegate/Revoke delegation</a>
6	test2	Prospective Retrospective	Submitted	No			<a href="#">Delegate/Revoke delegation</a>
5	test1	Prospective	Updated	No			<a href="#">Delegate/Revoke delegation</a>

Items per page: 5 | 1 – 5 of 5 | < > >>

**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.

**Delegated Person data** ✕

Business name \*

Address

Name  Surname

Email  Telephone number

Name	Surname	Email	Telephone Number	Business name	Address	Actions
TEST RSO Applicant	RSO	ibm.sgi.test@gmail.com	0987654321	INNOPHARMA SRL	VIA LAVORATORI AUTOBIANCHI	

**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.

Operations carried out on the study with ID 149

User	Status	Operation Date	Operation	Operation Detail
andrea.applicant	New	12/12/2019	NEW STUDY REGISTRATION	The study has been registered
andrea.applicant	Submitted	12/12/2019	STUDY SUBMITTED	The study has been submitted
COMITATO ETICO LAZIO 1	Evalued	12/12/2019	OPINION/ACKNOWLEDGMENT REGISTERED	An opinio/acknowledgment has been registered for the study
andrea.applicant	Started	12/12/2019	STUDY STARTED	The study has been started
andrea.applicant	Concluded	12/12/2019	STUDY CONCLUDED	The study has been concluded
andrea.applicant	Concluded	15/12/2019	PUBLICATION/RESULT INSERTED	A Publication/Result has been registered for the study

Items per page: 10 1 – 6 of 6 |< < > >|

[Export PDF](#)
[Export CSV](#)

**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:

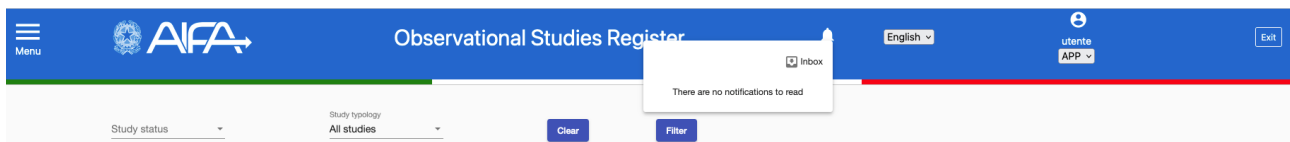
- a) *New study registration*
- b) *Sent to DB*
- c) *Integration required*
- d) *Opinion registered*
- e) *Opinion accepted-rejected*
- f) *Opinion/acknowledgment registered*
- g) *Study start/failure to start*
- h) *Enable study start*
- i) *Study conclusion*
- j) *Publications/results*

## 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.

**Notifications and e-mails preferences**

Select your preferences about notifications and e-mails

CE modification request	<small>Preference</small> <u>Notification and E-mail</u> ▾
CE feedback insertion	<small>Preference</small> <u>Notification and E-mail</u> ▾
Satellite CE feedback response	<small>Preference</small> <u>Notification and E-mail</u> ▾
Study delegation	<small>Preference</small> <u>Notification and E-mail</u> ▾
Delegated study elimination	<small>Preference</small> <u>Notification and E-mail</u> ▾

Cancel
Save

**Figure 52 - Notifications/emails preferences**