



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 of their own 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	Observational Studies Register
ATC	Therapeutic Anatomical Classification
MA	Marketing Authorization of a medicine
DB	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 identification number and guides the user in entering the study information.

At the end of the data entry procedure the user can register the study; the system sends an automatic e-mail/notification to AIFA users and the contacts of the involved Ethics Committee.

- For all the observational studies typologies studies, the 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 Ethics Committee will be able to enter the final opinion;
- For all the observational studies typologies, the Ethics Committee must enter the data relating to the *Opinion*. In case of an unfavourable opinion, the study cannot be initiated.
- 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
- Study conclusion
- Publications and results

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

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

Pending Opinion	Ethics Committees	<i>When no revisions/integrations of the study are required and the opinion/acknowledgement can be entered</i>
Under Evaluation	Ethics Committees	<i>In this status, revisions/integrations of the study may be requested</i>
Unfavourable Opinion	Applicant (Sponsors/CRO) also by delegation	<i>In this state the study is not approved</i>
Favourable Opinion	Applicant (Sponsors/CRO) also by delegation	<i>In this state the study is approved</i>
To be started	Applicant (Sponsors/CRO) also by delegation	<i>In this state, the study can be started</i>
Started/Not started	Applicant (Sponsors/CRO) also by delegation	<i>If the status is started, you can proceed to the conclusion phase</i>
In Conclusion	Applicant (Sponsors/CRO) also by delegation	<i>In this state, it is possible to proceed to the conclusion phase</i>
Concluded	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 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 the following sections: *Observational Studies*, *Administration* and *Help*.

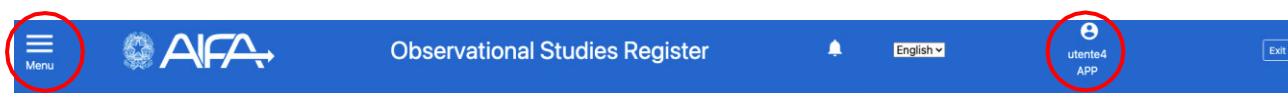


Figure 2 - Header RSO

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*

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

Figure 3 - Applicant Menu

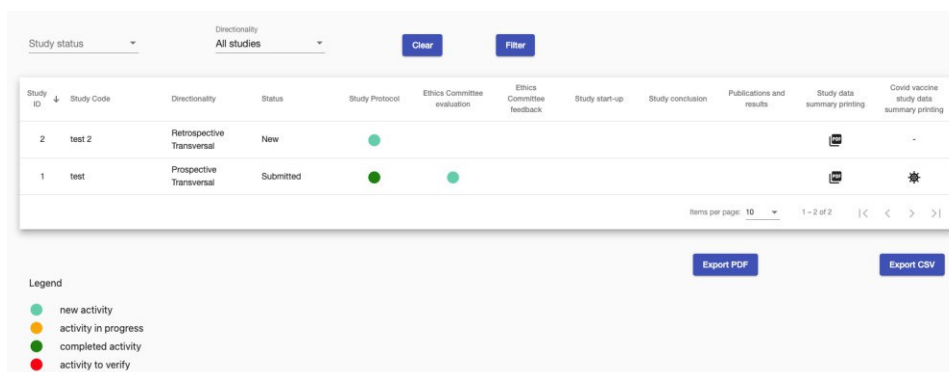
In addition to the Menu, the user's name and profile are shown. The acronym APP refers to the profile of the Applicant user

4. Studies List

In the *Study List* section, the Applicant user will have the possibility to view and operate on all the studies entered by him/her and those entered by other users belonging to the same Organization, with the same access profile to the RSO application.

For each study the user will be able to follow the progress of each study phase.

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



The screenshot shows the 'Studies List' interface. At the top, there are filters for 'Study status' (set to 'All studies') and 'Directionality' (set to 'All studies'), with 'Clear' and 'Filter' buttons. Below the filters is a table with the following columns: 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, and Covid vaccine study data summary printing. The table contains two rows: Study 2 (test 2, Retrospective Transversal, New) and Study 1 (test, Prospective Transversal, Submitted). A legend at the bottom left indicates: new activity (light blue), activity in progress (orange), completed activity (green), and activity to verify (red). At the bottom right, there are 'Export PDF' and 'Export CSV' buttons.



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

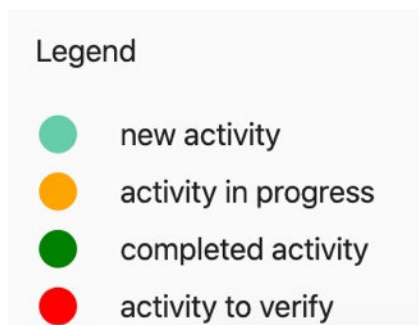
- new activity
- activity in progress
- completed activity
- activity to verify

Export PDF Export CSV

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.

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





The legend shows four colored circles with corresponding labels: a light blue circle for 'new activity', an orange circle for 'activity in progress', a green circle for 'completed activity', and a red circle for 'activity to verify'.

Color	Activity
Light Blue	new activity
Orange	activity in progress
Green	completed activity
Red	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 registration 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. The user 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*, under the Section *Observational Studies*, the Applicant 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, selecting the “*Confirm Registration*” button, the system assigns a unique identification number 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 who 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?

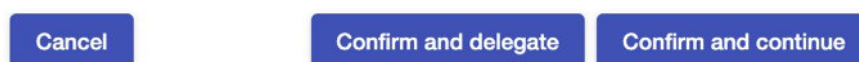


Figure 7 – Study registration confirmation

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 at the top shows the study's identification data, 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 data of the Applicant organization can be searched in the registry by pressing the "Edit" button.

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:

- Open a Ticket selecting the following link: <https://helpdesk.aifa.gov.it/rexpondo/customer.pl>
- 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 X

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	Svizzera	/	6982	
4SC AG	PLANEGG-MARTINSRIED	AM KLOPFERSPITZ	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	

Items per page: 5 1 - 5 of 1354 < > >>

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 Edit

Business name

Address

City Province Zip Code Country

Back
Cancel
Save
Save and proceed

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 *E-mail 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

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 six *tab* (*General, Objective, Protocol, Other Documentation, Therapeutic Area, Population*), 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).

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

Study Descriptive Form

General	Objective	Protocol	Other Documentation	Therapeutic Area	Population			
<div style="margin-bottom: 10px;"> Titolo dello studio ↗ <small>Maximum 2000 characters allowed</small> 0/2000 </div> <div style="margin-bottom: 10px;"> Title of the study ↗ <small>Maximum 2000 characters allowed</small> 0/2000 </div> <div style="margin-bottom: 10px;"> Parole chiave: _____ </div> <div> Keywords: _____ </div>								
<table style="width: 100%;"> <tr> <td style="width: 33%; vertical-align: top;"> Aim * <input type="radio"/> Descriptive <input type="radio"/> Analytic (Etiological) <input type="radio"/> Mixed </td> <td style="width: 33%; vertical-align: top;"> Design * <input type="radio"/> Transversal <input type="radio"/> Cohort <input type="radio"/> Case-Control <input type="radio"/> Other Specify * _____ </td> <td style="width: 33%; vertical-align: top;"> Research Area (just for studies on covid-19 vaccines) <input type="checkbox"/> Pharmacovigilance <input type="checkbox"/> Epidemiology <input type="checkbox"/> Immunology <input type="checkbox"/> Virology <input type="checkbox"/> Other Other * _____ </td> </tr> </table>						Aim * <input type="radio"/> Descriptive <input type="radio"/> Analytic (Etiological) <input type="radio"/> Mixed	Design * <input type="radio"/> Transversal <input type="radio"/> Cohort <input type="radio"/> Case-Control <input type="radio"/> Other Specify * _____	Research Area (just for studies on covid-19 vaccines) <input type="checkbox"/> Pharmacovigilance <input type="checkbox"/> Epidemiology <input type="checkbox"/> Immunology <input type="checkbox"/> Virology <input type="checkbox"/> Other Other * _____
Aim * <input type="radio"/> Descriptive <input type="radio"/> Analytic (Etiological) <input type="radio"/> Mixed	Design * <input type="radio"/> Transversal <input type="radio"/> Cohort <input type="radio"/> Case-Control <input type="radio"/> Other Specify * _____	Research Area (just for studies on covid-19 vaccines) <input type="checkbox"/> Pharmacovigilance <input type="checkbox"/> Epidemiology <input type="checkbox"/> Immunology <input type="checkbox"/> Virology <input type="checkbox"/> Other Other * _____						

Figure 17 – General

After completing the 'General' section, the 'Objective', 'Protocol', "Other Documentation", 'Therapeutic 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;

General	Objective	Protocol	Other Documentation	Therapeutic Area	Population
<div style="margin-bottom: 10px;"> Primary Goal * <input type="checkbox"/> Safety <input type="checkbox"/> Use of the drug <input type="checkbox"/> Appropriateness <input type="checkbox"/> Efficacy in clinical practice (Effectiveness) <input type="checkbox"/> Pharmacoeconomics <input type="checkbox"/> Other (specify) _____ </div> <div style="margin-bottom: 10px;"> Other Goal * _____ </div> <div style="margin-bottom: 10px;"> Obiettivi primari dello studio * _____ ↗ <small>Max 1000 characters allowed</small> 0/1000 </div> <div> Primary objective of the study * _____ ↗ <small>Max 1000 characters allowed</small> 0/1000 </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div> <input type="button" value="Back"/> <input type="button" value="Cancel"/> </div> <div> <input type="button" value="Save"/> <input type="button" value="Save and proceed"/> </div> </div>					

Figure 18 – Objective

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


The information related to the fields *Principles of analysis of collected material and data*, *Interventions and Procedures*, *Inclusion criteria*, *Exclusion criteria*, *Rational study* and *Main outcome measures* should be entered only if the Applicant is registering an observational study on Covid-19 vaccines.

Study Descriptive Form

General	Objective	Protocol	Other Documentation	Therapeutic Area	Population
Study scope * <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div> <input type="radio"/> Cognitive <input type="radio"/> PASS (Post Authorization Safety Study) required by EMA <input type="radio"/> PAES (Post Authorization Efficacy Study) required by EMA <input type="radio"/> PAS (Post Authorization Study) required by FDA <input type="radio"/> Other </div> <div> Other aim * <input style="width: 80%;" type="text"/> </div> </div>					
Protocol (15MB/file max. size allowed)* <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div> Protocol File * </div> <div> Date * 10/29/2025 </div> <div> Protocol Code * </div> <div> Version * </div> <div> <input type="button" value="Attach"/> </div> </div>					
Section just for studies on covid-19 vaccines					
Principles of analysis of the collected material and data <input style="width: 95%;" type="text"/>					
Interventions and procedures <input style="width: 95%;" type="text"/>					
Inclusion criteria <input style="width: 95%;" type="text"/>			Exclusion criteria <input style="width: 95%;" type="text"/>		
Study rational <input style="width: 95%;" type="text"/>					

Figure 19 – Protocol

- **Other Documentation:** The user has the possibility to attach additional supporting documentation, other than the entered Protocol.



User Guide – Observational Studies Register (RSO)

User Guide

Study Descriptive Form

<

General

Objective

Protocol

Other Documentation

Therapeutic Area

Popula >

No documents inserted

Add

Back

Cancel

Save

Save and proceed

Figure 20 – Other Documentation

Clicking on the *Add* button the following screen will be opened:

File Details Other Documentation

×

Type Document

Document (max. size 15MB/file) *

File *

Date *

12/2/2025

Update

Figure 21 - File Details Other Documentation

and, selecting the *Document Type*, the list of documents to be attached will opened:

File Details Other Documentation
✕

Type Document

Cover letter

Protocol synopsis

Declaration of conformity of the protocol submitted to the version approved b...

List of information regarding the location where the study will be carried out, i...

List of participating centers and their supervisors

CVs and Dols of the principal investigators of all centers involved in the study

Update

Figure 22 - Document type selection

At least one document from this list must be attached.
 The form for uploading the file (e.g., Protocol Synopsis) is shown below:

File Details Other Documentation
✕

Type Document
 Protocol synopsis


Documento (dim. max. 15MB/file) *
 File *
 Protocol Synopsis.pdf

Date *
 10/7/2025

Update

Figure 23 - Uploading file form

Once the file has been selected, click *Update*; the form below will be opened where is possible to click *Save* to upload the file and add additional documentation, or click *Save and Continue* to upload the file and proceed to the next step.





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Study Descriptive Form

General
Objective
Protocol
Other Documentation
Therapeutic Area
Popula

File name	File name	Date	Actions
Protocol synopsis	Protocol Synopsis.pdf	07-10-2025	 

Add

Back
Cancel
Save
Save and proceed

Figure 24 - Upload addition other documentation

The same steps must be repeated to attach any other supportive documentation.

- **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:* one or more clinical conditions could be entered by selecting them from the MedDRA taxonomy by clicking on the “Add” button. After entering 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
Other Documentation
Therapeutic Area
Population

Therapeutic Area

Therapeutic Area *

Description *

Condizione Clinica *

Clinical Condition *

MedDRA Classification of the Clinical Condition

No Classification Inserted

☐ Not applicable

Figure 25 – 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
Other Documentation
Therapeutic Area
Population

Gender *

☐ Male
☐ Female

☐ Renal impairment
☐ Hepatic impairment
☐ Immunosuppressed
☐ Pregnant women

Special population

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 26 – 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, it should be included 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 27 – Numerosity and duration

5.7 Pharmacological therapies

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

- Add by ATC
- Add by proprietary medicinal product
- Add medicine not authorized use

Please note: the last functionality is only available for Retrospective studies.

Observational Study

Study ID Study code *
653 studio 27/10/2025

Pharmacological Therapies

Add by ATC

Add by brand name

Add Unauthorized Use Medicine

☐ Not applicable

Comment *

Max 1000 characters allowed

Back

Cancel

Save

Save and proceed

Figure 28 – Pharmacological therapy

- *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 proprietary medicinal product 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	Show specialty	<input type="checkbox"/>
A01	STOMATOLOGICAL PREPARATIONS	2	Show specialty	<input type="checkbox"/>
A01A	STOMATOLOGICAL PREPARATIONS	3	Show specialty	<input type="checkbox"/>
A01AA	Caries prophylactic agents	4	Show specialty	<input type="checkbox"/>
A01AB	Antifungives and antiseptics for local oral treatment	4	Show specialty	<input type="checkbox"/>

Items per page: 5
 1 – 5 of 215
 |< < > >|

Add

Figure 29 – Search by ATC

- *Add by Proprietary medicinal product*

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 specialty ×

ATC Code
A01

ATC Description

AIC Code

AIC Owner

Drug Specialty

Pack

Active Ingredient

[Reset](#) [Search](#)

ATC Code	ATC Description	Drug Specialty	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" DENTIFRICIO 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 30 – Search by proprietary medicinal product

Search criteria for medicine brand name ×

ATC Code
att

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 31 – Search Medicine “Can’t find what you are looking for?”

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

After entering the data for the pharmacological therapy, the Applicant should select 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 32 – Declaration

In the following section all the checkboxes must be selected:

Pharmacological Therapy Details
×

ATC Code
A01AB11

Drug brand name
STRAMINOL

AIC Code
009846041

Pack
30 COMPRESSE 1 MG

Active Ingredients
DODECARBONIO CLORURO,N.D.

Notes

Max 1000 characters allowed

ATC Description
VARI

Declaration of drug use conditions *

☐ 1. The drug(s) is/are prescribed in the indications of use authorized for marketing within Italy *

☐ 2. The prescription of this drug(s) 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. The diagnostic procedures correspond to current practice, without incurring additional burdens for patients following participation in the study and without any additional burden on the National Health Service consequent to its implementation*

Cancel
Save

Figure 33 – Therapy Details

If it is not possible to indicate any pharmacological 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 brand name
Add Unauthorized Use Medicine

☒ Not applicable

Comment *

Max 1000 characters allowed 0/1000

N.B.:
 Given that the RSO AIFA collects data related to observational pharmacological studies 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 34 - Not Applicable

- *Add medicine not authorized use*

This functionality will only be available for retrospective studies and it is related to the use of a medicine different from the one stated in the Summary of Product Characteristics or is related to medicines without marketing authorization used in line with the condition of use as provided by the Annex 2 of the guideline. Clicking on the “Add unauthorised medicine” button the screen below will be opened, where two buttons are available: one for medicines with marketing authorisation and the other for medicines without marketing authorisation.

Add unauthorized use medicine

Add medicine with AIC
Add medicine without AIC

Figure 35 – Add medicine not authorized use

Selecting the button “Add medicine with AIC” the following section will be available where it could be possible to search by *ATC code, ATC description*, etc.

Add unauthorized use medicine
×

ATC Code	ATC Description
AIC Code	AIC Owner
Drug brand name	Pack
Active Ingredient	

Attention: the string must be at least 3 characters long to make the search.

Reset
Search

Figure 36 – Add medicine with AIC

Once the medicine has been selected it is necessary to click on the Declaration of use related to medicines in unauthorized use, as shown in the figure below:

Pharmacological Therapy Details
×

ATC Code A01AB11	ATC Description VARI
Drug brand name STRAMINOL	
AIC Code 009846027	
Pack COLLUTTORIO 4% 20 ML	
Active Ingredients DODECARBONIO CLORURO,N.D.	

Notes

Max 1000 characters allowed 0/1000

Declaration of drug use conditions *

☒ 1. The drug(s) being studied has/have not been prescribed within the conditions authorised for placing it on the market in Italy, for example use as provided for by Law 648/1996, by Ministerial Decree 07/09/2017 and by Law 94/1998 (specify the use)*

Enter usage here

☒ 2. The study is only retrospective and is aimed at collecting data from patients who have taken the drug in accordance with the use previously described *

☒ 3. The informed consent signed by the patient for the use of the drug is prior to the submission of the proposed observational study *

☒ 4. The decision to prescribe the drug to the individual subject was made completely independently from the decision to include the subject in the study *

☒ 5. No diagnostic or evaluation procedures outside of current clinical practice are foreseen for the purposes of the proposed study, as it is a data collection relating to retrospective uses of the drug *

Cancel
Save

Figure 37 – Declaration of use

Selecting the button “Add medicine without AIC” the following section will be available where the user must enter the name of the medicine as free text and then select the items of the Declaration of use related to medicines in unauthorized use as shown in the case of medicines with MA.

Add unauthorized use medicine (INN if available) ×

Enter medicinal description (INN if available)

Add

Figure 38 – Add medicine in not authorized use – not authorized medicine

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* as shown in the figure below:

Add Participant Center ×






Region
Lazio

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	
001123	LAZIO	ROMA	ROMA	VIA MILANO 1	ALTRAISTRUTTURAPERTESTUSC	
120254	LAZIO	ROMA	ROMA	VIA CESARE FERRERO DI CAMBIANO 29 .	ARS MEDICA SPA	
120180	LAZIO	ROMA	ROMA	VIA AURELIA 860 .	AURELIA HOSPITAL	


Items per page: 5 1 – 5 of 179

Can you not find what you are looking for?

Indicate Center not in registry

Figure 39 – Search participating centers

The coordinating Participating Center will be the one associated with the new single Ethics Committee (having code *OCE00**), as shown in the example below, where the Coordinating Center checkbox has been set on “YES” and will not be editable. This Coordinating Participating Center is the dedicated structure created for the census of new Ethics Committees.

 AGENZIA ITALIANA DEL FARMACO	User Guide – Observational Studies Register (RSO)
User Guide	

Participant Center Details
✕

Coordinating center?*
☒ Yes
☐ No

Designed Ethics Committee

COMITATO ETICO LAZIO AREA 1 (OCE000000037)

Doctors/pediatricians total number * 0

Pediatricians details *
 Upload file * ✕
Browse

Discipline ▼

Study coordinator

Qualification ▼

Name _____

Surname _____

Attention: please check the coordinator data

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

Add

Figure 40 – Coordinating clinical site details

The user must fill in the following fields:

- *Total number of responsible doctors/pediatricians*, if different from zero, and in this case, a document detailing the responsible doctors/pediatricians must be attached.
- The *Discipline*
- The details of the *Study Coordinator Responsible for the study*, which is a mandatory field.

Only for analytical purposes, it is required to enter all sites involved in the study as participating centers, which will not be associated with any Ethics Committee. In this case, the screen below will be displayed, where the Coordinating Center checkbox has been set on “No” and cannot be modified.

Participant Center Details

✕

Coordinating center?*

☐ Yes
☒ No

Doctors/pediatricians total number *

0

Pediatricians details *

Upload file * ✕ Browse

Discipline ▼

Study coordinator

Qualification ▼

Name Surname

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

Figure 41 - Participant Center Details

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.

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 42 - Details for ASL Structure

5.9 Impact on SSN (National Health System)

In this section, if the Applicant is registering 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.

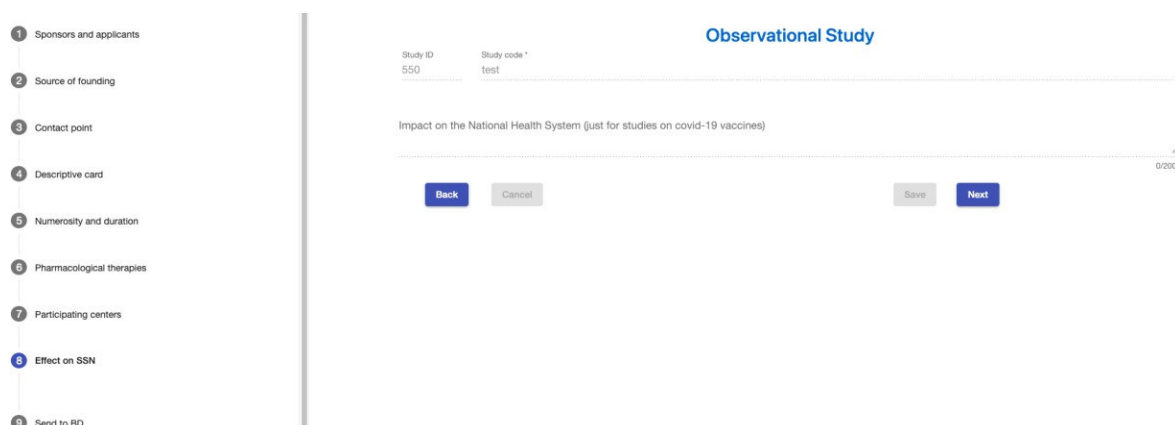


Figure 43 – Effect on SSN

5.10 RSO Submission Form

Before proceeding with the registration of the study (Send to BD) the Applicant must download the PDF containing the study data and attach it in the documentation area (Step 4 “Descriptive form” - Tab “Other Documentation”) described in the previous paragraphs.

5.11 Send to DB


In this section the user will view a summary overview of the different sections, where any error messages are highlighted when any sections/tabs have not been filled in case of absence of mandatory data.

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

Then the user will view a page containing a summary table with all the relevant studies.


Check Study Data

Check result:

 Scarica modulo RSO

There are some errors: please check data before submitting the study.

- ✗ Sponsors and Applicants - There are some errors, please check data.
- ✗ Source of founding - There are some errors, please check data.
- ✗ Contact point - There are some errors, please check data.
- ✗ Descriptive form - There are some errors, please check data.
- ✗ Numerosity and duration - There are some errors, please check data.
- ✗ Pharmacological therapies - There are some errors, please check data.
- ✗ Participating centers - There are some errors, please check data.
- ✗ Effect on SSN - There are some errors, please check data.

 Aggiungi modulo RSO

You are going to submit the study into the database. Once you confirm the operation, the study will be available for the Ethics Committees and AIFA.

Back

Cancel

Send to DB








Figure 44 – Check Study Data

6. Study Revision/integration

For all observational studies type, the *Ethics Committee* may request a revision/integration of the study's registered data after viewing it.

In this case, the Applicant will be able to view the requests of the *Ethics Committee*, through the appropriate icon (see Figure 45– Study Revision) available in the *EC Evaluation* column; afterwards, it will be possible to modify or integrate the study according to the indications specified in the notes entered by the Ethics Committee.

The user will be able to change/integrate the study accessing through a special icon in the *Study Protocol* column highlighted as 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								-
5	test1	Prospective	Revising								

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

Export PDF Export CSV

Legend


















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

Figure 45 - Study Revision

7. Ethics Committee Opinion


Once the *Ethics Committee* has expressed its opinion, the Applicant will be able to click on the relevant icon of completed activity (see Figure 46– 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 46 – Ethics Committee opinion

In this section, the summary data of the opinions expressed by the *Ethics Committee* 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 47 – Opinion data

By clicking on , the user can access the opinion detail form, through it will be possible to view the details of the opinion expressed by the *Ethics Committee*.

Opinion data



Data of the involved Ethics Committee

Participant Center Structure *

STRUTTURA PER COMITATO ETICO LAZIO AREA 1

Ethics Committee denomination COMITATO ETICO LAZIO AREA 1

Discipline Allergology

Qualification	Dr.	Responsible name	Elena	Responsible surname	Graniero
----------------------	-----	-------------------------	-------	----------------------------	----------

Dates of receipt

Request date of receipt * 10/1/2025

Revision/Integration request date of receipt 10/1/2025

Opinion of the involved Ethics Committee

Opinion *

Favourable

Opinion date of insertion * 10/1/2025

Cancel

Figure 48 – Opinion details

8. Study start-up

Clicking the new activity icon (see Figure 49- *Study start-up*) under the column *Study start-up*, the Applicant can enter the data on the study start.

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 49 – Study start-up

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

A study can only be started after it has received the positive opinion by the Ethics Committee. The user can save the Study start data at any time using the “Save” button and cancel the entered data using the “Cancel” button.

Then it will be possible to 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 50 – Study start data





9. Study conclusion

After the study start, the new activity icon (see Figure 51- Study Conclusion) under the *Study conclusion* column will be available, through 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								
6	test2	Prospective Retrospective	Submitted								-
5	test1	Prospective	Updated								

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

Legend

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

Export PDF Export CSV

Figure 51 – 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, it should be indicated whether *the study has ended in advance*, and in this case the related reasons for the early conclusion should be reported.

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 proceed 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

Go back Save Confirmation of data Conclusion

Figure 52 – 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, through the appropriate icon (see Figure 53 - Publication and results).

This phase of the study remains always opened (*activity in progress*). It will be always 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 |< < > >|

Legend

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

Export PDF Export CSV

Figure 53 – Publication and results

To add a new document, the **Add** button, located in the *Draft* section (see Figure 53 - Publication and results data) should be clicked on.

Publications and results data

Draft

No Publication Draft

Add

Inserted

No Publication Inserted

Go back

Figure 54 - Publications and results data

In particular, the Applicant should 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
X

Document/Publication Title *

Document Date *

Document type *

Upload File



X
Browse

Authors

References to magazines, sites or other

Reset
Add

Figure 55 – Add Publication

Once added a document, it will remain *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 modify 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 56 – 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*
 - *Proprietary medicinal product*
 - *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

Study typology

☐ Prospective
☐ Retrospective
☐ Transversal

Parole chiave:

Keywords:

Research Area

☐ Pharmacovigilance
☐ Epidemiology
☐ Immunology
☐ Virology
☐ Other

Reset Panel

Population

Pharmacological therapy and therapeutic area

Involved organizations


Reset

Search

Figure 57 – 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 submitted by all users belonging to the same Organization via the button .

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

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

Furthermore, if the registration of a study has been delegated by the Sponsor to an Applicant, the Delegated 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 58 – Delete Study

13. Study Delegation

The Sponsor is allowed to delegate a study. This allows Sponsor to delegate an *Observational Study*, for example, to a user of a CRO or a national branch. Once the user is delegated, the delegation will automatically extend to the entire Organization they belong to; therefore, the other users of the same Organization will also be automatically enabled to view and edit the study.

The Delegation of Study action can be carried out at any stage of the same.

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

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

Figure 59 – 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 already delegated.

Delegated Person data
×

Business name *
 INNOPHARMA SRL

Address
 VIA LAVORATORI AUTOBIANCHI

Name _____ Surname _____

Email _____ Telephone number _____

Reset Search


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 60 – Delegated Person data

Once the delegation has been made, the Applicant will be always able to revoke it and will always have access to the study data as read-only. The revocation of the delegation can only be carried out by the Applicant; no member of the delegated Organization can revoke the delegation on their own.

Furthermore, the delegated user can delete an assigned study (only under registration), while the delegating user can delete it only after the delegation has been 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

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Figure 61 – Operations history

For each operation, the following information are shown:

- Operation date and time
- Study status
- Carried out activity
- Operation details
- User who carried out that operation

In particular, the historicized actions are following ones:

- New study registration*
- Sent to DB*
- Integration required*
- Opinion registered*
- Study start/failure to start*
- Enable study start*
- Study conclusion*
- Publications/results*

15. Notifications

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

The actions that can result in a notification (or e-mail) sending are the following ones:

- *EC request for modification*
- *EC opinion data entry*
- *Study delegation*
- *Study elimination by the Delegated user*
- *Study start enabled*

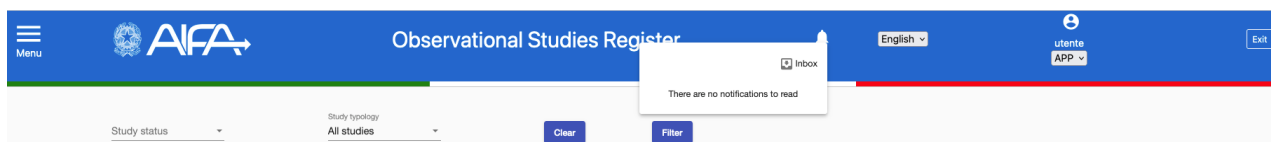


Figure 62 – Applicant Inbox Notifications

16. Notifications and e-mails preferences

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

Notifications and e-mails preferences

Select your preferences about notifications and e-mails

CE modification request	Preference ▼
CE feedback insertion	Preference ▼
Study delegation	Preference ▼
Delegated study elimination	Preference ▼

Figure 63 - Notifications/e-mails preferences