

**S.S. Clinical Trial Center**

Direttore ad interim: Dott.ssa Raffaella Cavi

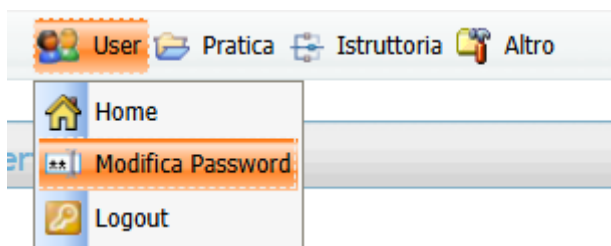
Instructions for submitting a study through the ASST Sette Laghi Clinical Trial Portal

Creation of User Credentials

Access to the ASST Sette Laghi Clinical Trial Portal (PraticheWEB) requires personal login credentials. Users who do not already have login credentials may request them from the Technical and Scientific Secretariat by sending an e-mail to segreteria.comitatoetico@asst-settelaghi.it, specifying their first name, surname, and affiliated institution or organization.

Access the **ASST Sette Laghi Clinical Trial Portal (PraticheWEB)** at: <https://portalesperimentazioneclinica-asstsettelaghi.it/> and sign in using your personal credentials.

To change your password, click **"User"** and then select **"Modifica Password"**. Enter your current password and type your new password twice to confirm the change.



Note: Passwords expire after 60 days. Once expired, users will be prompted to change their password before they can access the system. The following message will be displayed: *"The following error has occurred: Your password has expired. Please change your password and log in again"*

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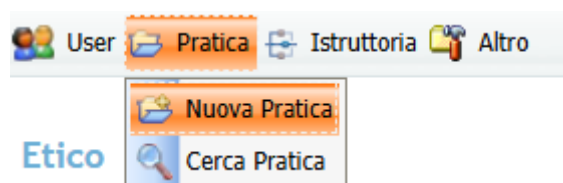
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New study registration

From the homepage, select "**Pratica**" and then click "**Nuova Pratica**" to create a new study record.



The study registration page contains all information and documentation related to the study. Complete each section by entering the required information. Please note that underlined fields are mandatory.

Note: Depending on the type of study, some mandatory fields may not be clearly indicated. If any required information is missing, the system will notify you when you attempt to save the application.

To register the study, click the "**Salva**" button located at the bottom of the page. If any mandatory information is missing, the system will prompt you to complete the required fields. Once all required information has been provided, click "**Salva**" again. Upon registration, the study will be assigned a unique reference number corresponding to the year in which the application was submitted. To add further information or modify existing data, retrieve the study by selecting "**Pratica**" and then "**Cerca Pratica**". Next, click "**Modifica**" in the row corresponding to the relevant study.



Complete the following tabs:

- Study
- Sponsor and/or CRO
- Local Principal Investigator
(do not modify the value already entered in the "Report Frequency (Days)" field)
- Study Type, selecting one of the following options:
 - Clinical Trial with a Medicinal Product
 - Observational Study

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- Medical Device Study
- Genetic Study
- Other Study Type
- General Characteristics
- All other mandatory and available fields required to ensure the study information is entered correctly.

After saving the required information and obtaining the application number, it will be possible to upload the study documentation in the **"Documenti"** section.

The list of required documents, differentiated according to the type of study, is available on the ASST Sette Laghi website at the following link: <https://www.asst-settelaghi.it/template-documenti>

Please ensure that all required documentation is complete before uploading it to the platform.

- Click **"Modifica"** in the upper right corner, then select **"Allega Documento"**;
- Click **"Scegli File"**, locate the document to be uploaded, and then click **"Allega"**.

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**Ospedale di Circolo
Fondazione Macchi**

Regione Lombardia

User Pratica Istruttoria Altro

Allega Documento

Il nome del file da allegare non deve contenere caratteri speciali (/,*;,B, etc.) ma solo da A a Z e numeri (es. scheda11.pdf)

File Nessun file selezionato

Allegati :

Classe Documento:

- Documentazione
- Contratti
- Relazioni
- Delibere
- Verbali
- Sedute
- Safety Report
- Comunicazioni al Promotore
- Documenti di Consegna
- Annotazioni Segreteria Tecnico Scientifica

On the following page, complete all required fields, making sure that the **status** field is always set to " **Da Valutare** ", then click " **Salva** ".

**Ospedale di Circolo
Fondazione Macchi**

Regione Lombardia

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File Nessun file selezionato

Allegati :

Classe Documento:

Indice	Valore	Obbligatorio
Titolo	Non specificato	☒
Ver		☐
Data Ver		☐
		☐
		☐
Stato	Da Valutare	☒

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Please select the appropriate document title from the **document Title** drop-down list, ensuring that it corresponds to the uploaded document. Please also enter the correct document version and date. Repeat this procedure for each document. **Once all documentation has been uploaded, click "Avvia ITER".**

Note: If you are in "**Modifica**" mode, you must switch to "**Visualizza**" mode by clicking "**Visualizza**" in the upper-right corner of the page. The "**Avvia ITER**" button is available only in "**Visualizza**" mode.



Upon completion of the data entry and initiation of the process, the system will automatically send an email requesting completion of the Declaration by the Head of the Operational Unit. Once this step has been completed, a second automated email will be sent requesting completion of the Declaration by the Principal Investigator.

Through these declarations, the Head of the Operational Unit and the Principal Investigator of the study will be required to confirm the documentation and information uploaded to the platform, thereby assuming their respective responsibilities for the information and documentation submitted.

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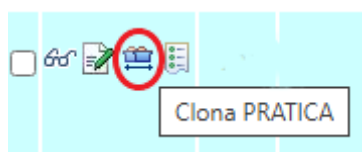
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Multicentre studies conducted within ASST Sette Laghi

For studies involving multiple Operational Units within ASST Sette Laghi, the platform allows users to avoid repeatedly entering the same information for each participating centre by using the "**Clona Pratica**" function.



In the duplicated application, all data specific to the participating centre must be amended, including:

- Healthcare Organisation/Institution;
- Facility;
- Operational Unit;
- Local Principal Investigator;
- Investigator's email address;
- any additional centre-specific information.

Once the changes have been completed, click the **Salva** button.

The system will create a new application, assigning it a sequential number different from that of the original application.

This operation can be repeated for all participating centres involved in the study. Per quanto riguarda la documentazione:

- Documents specific to an individual centre must be uploaded to the relevant application;
- Documents common to all participating centres (e.g. the protocol, Investigator's Brochure, case report form, and other non-centre-specific documentation) may be uploaded only once to the original application and subsequently associated with the other applications.

Associating documents with other applications

To associate documents that have already been uploaded with other applications:

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1. Open the application containing the documentation to be shared.
2. Select the desired documents by ticking the checkbox to the left of each document.
3. Click the **Associa ad altra Pratica** button, located in the header of the checkbox selection column.
4. Use the search form to locate the application relating to the other participating centre.
5. Select the desired application and click **Associa ad altra Pratica** again.

The selected documents will then be made available in the associated applications as well.

Note: Any annotations already entered in the documents' descriptive fields will automatically be associated with the other applications as well.

Cloning an application does not automatically initiate the administrative process.

Therefore, for each application generated using the **Clona Pratica** function, it will be necessary to:

1. Open the application;
2. Click **Avvia ITER**.

Important: Each application relating to a different participating centre must be initiated separately so that it can follow its own assessment and approval process.

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