



ENCEPP E-Register of Studies - Guide

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1. Background

1.1. *The ENCePP Study Concept*

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP) has been created by the European Medicines Agency with a view to strengthening the available expertise and resources in Europe in the area of pharmacoepidemiology and pharmacovigilance. Ultimately, the network's goal is to both facilitate and enhance the conduct of collaborative pharmacoepidemiology and pharmacovigilance studies. A key element of ENCePP is to uphold high standards throughout the research process based on the principles of transparency and scientific independence. To this end, the concept of an 'ENCEPP study' was introduced to identify those studies which are conducted in accordance to the following general principles:

- A maximum level of transparency is provided as regards the use of agreed methodological standards in the study protocol, the development and agreement of the study protocol, and the communication of the results;
- The primary purpose of a study shall be to generate data of potential scientific or public health importance and not to promote the sale of a medical product;
- The design of the research shall not be aimed towards producing a pre-specified result;
- The contractual arrangements between investigators and the study funder should clearly define the research assignment and should address in sufficient detail critical areas of interaction, remuneration, protocol agreement, analysis of results and publication of results;
- Remuneration shall only be granted as specified in the research contract and shall not depend upon a particular study result;
- The results of a study shall always be published, preferably in a peer-reviewed journal, or made available for public scrutiny within an acceptable time frame, regardless of the (positive or negative) results and the statistical significance;
- Relevant information on the research process and results shall be publicly available;

The study must be registered in the publicly accessible register of ENCePP studies prior to its start, thereby making publicly available information on the study including the expected timelines, and updating the register with the results (or references to publications) on study completion.

1.2. *CoRe Requirements*

In practice, all pharmacoepidemiological and pharmacovigilance studies can qualify as "ENCEPP studies" provided that the (primary) **lead investigator belongs to an entity that is included in the ENCePP Inventory of Centres and Networks** (i.e. ENCePP resources database) and that the "CoRe requirements" are met:

1. Code of Conduct

The signed **declaration** (Annex 2 to the Code) and **checklist** (Annex 3 to the Code) have to be provided to the ENCePP Secretariat before the study commences.

2. ENCePP Checklist for Study Protocols

The signed **checklist** for Study Protocols must be provided to the ENCePP Secretariat before the study commences. The study protocol must be uploaded in the E-Register.

The original and final versions of the protocol will be made publicly available after the final study report.

3. E-Register of Studies

The study must be included in the electronic register of studies before it commences. Study findings, regardless of their (positive or negative) results, must subsequently be published in the electronic register.

In essence, investigators that accept to conduct an ENCePP study commit to a maximum level of transparency with regard to relevant information pertaining to their investigation. This includes publication of study findings regardless of their (positive or negative) results and granting access to relevant information of the study protocol.

1.3. ENCePP Study Seal



Provided all the CoRe requirements have been fulfilled and the ENCePP Secretariat has confirmed the receipt of all necessary documents, a study may *a-priori* be considered as an “ENCePP Study”. A letter of confirmation will be dispatched and a corresponding “ENCePP seal” will be displayed in the electronic ENCePP Register of Studies which may also be used in connection with this study. The seal will make immediately recognisable to the general public that the study was conducted in adherence to the ENCePP research principles and methodological standards and through transparency and clarity of roles, will increase trust in the robustness of the research.

However, investigators are reminded of the ongoing obligations the ENCePP study seal places on the conduct of a study, namely to adhere to the entirety of the provisions of the ENCePP Code of Conduct throughout the research process. In particular, researchers are obliged to:

- Regularly update the entry of the study in the register, as milestones are reached or in case of changes to the protocol that may affect the interpretation of the study.
- Update the ENCePP Checklist for Study Protocols and re-submit it via the E-Register of studies in case of changes to the protocol that may affect the interpretation of the study.
- After finalisation of the study report, provide the final version of the protocol through the ENCePP E-Register of studies. Both the original and the final versions of the protocol will be made publicly available on the ENCePP E-Register of studies at that stage.
- Make publicly available a clear summary of the main study results, whether positive or negative, and including results from prematurely terminated studies according to the timetable agreed in the research contract. In addition, an abstract of the study results shall be provided, via the E-Register of studies, for publication within 3 months following the final study report.

Investigators of ENCePP Studies are obliged to inform the ENCePP Secretariat without delay if a study deviates from and/or no longer follows the rules of the Code. In this event the concerned study shall not be entitled to the “ENCePP seal” and thus the title “ENCePP study”, unless its deviation is judged

by the ENCePP Steering Group not to affect the standards expected of an ENCePP Study, including the principles of transparency and independence.

2. E-Register of Studies: How does it work?

The electronic ENCePP register of studies (<http://www.encepp.eu/encepp/studiesDatabase.jsp>) aims to provide a free and publicly accessible resource for the online registration of pharmacoepidemiological and pharmacovigilance studies.

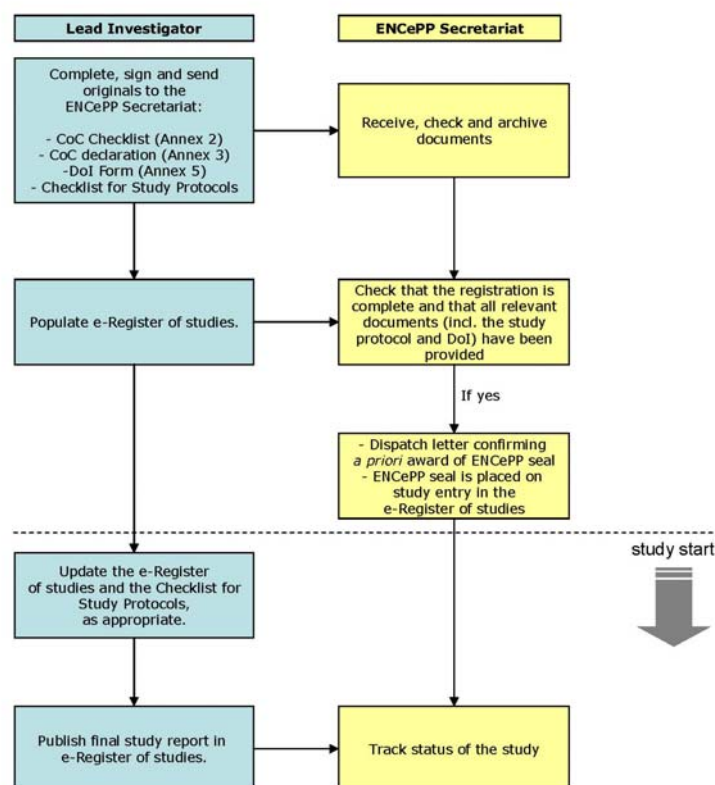
Its purpose is to:

- Increase transparency
- Reduce publication bias
- Promote information exchange
- Facilitate collaborations within the scientific community
- Facilitate optimal use of pharmacoepidemiology and pharmacovigilance expertise in Europe by preventing unnecessary duplication of research.

Registration of studies in the electronic register is **mandatory for “ENCePP studies”**; it is **encouraged for all post-authorisation studies**.

For clinical trials conducted in the EU, registration in the EUDRACT database is a legal obligation. Additional registration of clinical trials in the ENCePP E-Register is only obligatory for “ENCePP studies”.

2.1. How to register an ENCePP Study - Flowchart



2.2. How to register an ENCePP Study – Step by Step Guide

Investigators who wish to register their studies should complete the online “Data Entry Form” available on the ENCePP website (<http://www.encepp.eu/encepp/studiesDatabase.jsp>) and submit the application to the ENCePP Secretariat. This needs to be done **before the study starts**.

2.2.1. Important User Information

DO NOT use the ‘Enter’-key to move in application. Always use the **‘Tab’-key** or your mouse to move from one data field to the next; using the ‘Enter’-key will take you to Screen 1.

Timeout is 4 hours, i.e. if you do not save your data within this timeframe it will be lost.

Use **‘Save & Exit’** often to ensure that no data is lost. To return to the latest saved version of the questionnaire either use the ‘Resume draft’-function of the database, or alternatively create a **favourite browser link** for easy resume access. The link will be displayed when you return to the form after having, at a minimum, completed all the mandatory information on the first page of the data form, and pressed ‘Save & Exit’. The format of this link will be as follows:

http://www.encepp.eu/encepp/studyRegistration.htm?resumeLabel=ENCEPP/SDPP/xxxx&adminEmail=email_access

The **display format** of the pages changes depending on the stage of data entry. During ‘Add a study’-mode the four pages of the data entry form are displayed – and need to be completed – consecutively. The same applies for partially or fully completed questionnaires in ‘resume draft’-mode. Once all sections have been completed and by clicking on ‘Review and Submit’ the display of the pages changes to Tabs which are identical to the public registry. The information may be edited by section prior to submitting the whole entry to the ENCePP Secretariat. The Tabs view is also present in ‘Edit’-mode when reviewing data that has already been submitted.

Only **pdf documents** of 2Mb or less each can be uploaded to the database; only pdfs are supported.

2.2.2. How to add a study

Go to ENCePP Website (www.encepp.eu)

Click on “Add Study”:



or

Click on “E-Register of Studies”;

And then click on “Add Study”:

ENePP European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Home | Sitemap | Links | Contact Us

Home > Studies Database

Electronic Register of Studies

The electronic ENCePP register of studies aims to provide a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies. Its purpose is to:

- Increase transparency
- Reduce publication bias
- Promote information exchange
- Facilitate collaborations within the scientific community.
- Facilitate optimal use of pharmacoepidemiology and pharmacovigilance expertise in Europe by preventing unnecessary duplication of research.

Registration of studies in the electronic register is mandatory only for "ENCePP studies"; it is voluntary for all other studies.

If you want to search for studies registered in the database, please click on the button below:

[Search register of studies](#)

If you would like to register a new study please click on the button below:

[Add Study](#)

If you wish to resume a draft application that you have started earlier (but have not submitted yet) or update a returned application from the Secretariat, please follow the link: [Resume Draft/Returned application](#).

If you already have an entry in the Electronic Register of Studies and would like to update it please click below:

[Edit Study](#)

For assistance please contact us at: encepp_studies@ema.europa.eu

You will be guided to an introduction page.

Click on "Next":

ENePP European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

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Home > Add Study Intro

ENCePP Electronic Register of Studies

This electronic register of studies is open to register all pharmacoepidemiological and pharmacovigilance studies regardless of whether there is an application for the ENCePP study seal or the research centre participating in the ENCePP network.

Registration of studies in this electronic register is mandatory for those studies who wish to apply for the "ENCePP study seal"; it is voluntary for all other studies.

The information entered in this register is available to the general public.

Please press 'next' at the bottom of the page and complete the questionnaire, if:

- You are the principal (lead) investigator conducting a pharmacoepidemiological and/or pharmacovigilance study, and
- You would like to register your study in the present register

[Go Back](#) [Next](#)

Accept "Terms and Conditions" and click on "Next":

Complete online questionnaire (total of 19 questions).


A pdf-version of the questionnaire may be viewed/downloaded by clicking on the words “study questionnaire”:

On completion of questionnaire:

a) If you are **ready to submit the data**, click on “Review and Submit” → this will allow you to review the data entered so far, edit if necessary, and from the last tab you can choose to “Submit” the data to the ENCePP Secretariat for review and approval. Once the entry has been approved, you will receive an email with a password for future updates. Of note, this password is not record-specific, but will provide access to all studies registered by a single investigator.

NOTE: On clicking "Review and Submit" the display of the pages changes to Tabs which are identical to the public registry. The information may be edited by section prior to submitting the whole entry to the ENCePP Secretariat.

b) If you **do not wish to submit the data yet**, and would like to resume the completion of the form later, click on "Save draft & Exit" → your login details for editing your entry at a later date will be displayed on screen (do not forget to note them down!).

19. Other relevant documents 

Conflict(s) of interest of investigator(s)
Document Latest version

Composition of Steering Group and Observers
Document Latest version

Other documents

Description	Document	Latest version
<input type="text"/>	<input type="text"/> <input type="button" value="Browse..."/>	<input type="text"/> <input type="button" value="Browse..."/> <input type="button" value="+"/> <input type="button" value="-"/>

Reminder for investigators applying for the ENCePP Seal: Please make sure you have submitted hard copies of the documents listed below to the ENCePP secretariat so that they can be scanned and uploaded for you.

Submitted

- Signed Code of Conduct Checklist
- Signed Code of Conduct Declaration
- Signed Checklist for Study Protocols

b) a)

2.2.3. How to edit an existing entry

Existing entries may be edited any time following acceptance by the ENCePP Secretariat (e.g. updates as milestones are reached, changes to the protocol that may affect the interpretation of the study, upload of documents, etc.).

Go to ENCePP Website (www.encepp.eu);

Click on "E-Register of Studies";

Click on "Edit Study":

ENePP European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

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Electronic Register of Studies

The electronic ENCePP register of studies aims to provide a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies. Its purpose is to:

- Increase transparency
- Reduce publication bias
- Promote information exchange
- Facilitate collaborations within the scientific community.
- Facilitate optimal use of pharmacoepidemiology and pharmacovigilance expertise in Europe by preventing unnecessary duplication of research.

Registration of studies in the electronic register is mandatory only for "ENCePP studies"; it is voluntary for all other studies.

If you want to search for studies registered in the database, please click on the button below:

Search register of studies

If you would like to register a new study please click on the button below:

Add Study

If you wish to resume a draft application that you have started earlier (but have not submitted yet) or update a returned application from the Secretariat, please follow the link:
[Resume Draft/Returned application.](#)

If you already have an entry in the Electronic Register of Studies and would like to update it please click below:

Edit Study

For assistance please contact us at: encepp_studies@ema.europa.eu

When prompted, enter your username (email of admin contact) and password;

Click on "Next":

ENePP European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Home Sitemap Links Contact Us

Home > Authentication

[* mandatory information]

To edit one of your existing resources, please provide the following information: ?

Username:*
 (Email of administrative contact)

Password:*

[forgotten password?](#)

Next

NB: If you have forgotten your password, click on "forgotten password" to retrieve it. You will be prompted to enter the email address of the administrative contact and the password will be sent to this address.

Your data will be retrieved and may be edited. Once you have completed your update(s), re-submit the data.

2.2.4. How to retrieve a draft application/returned application

Draft application that have been started earlier (but have not been submitted yet) or applications that have been returned by the ENCePP Secretariat for the purpose of requesting additional information, can be retrieved by following these steps:

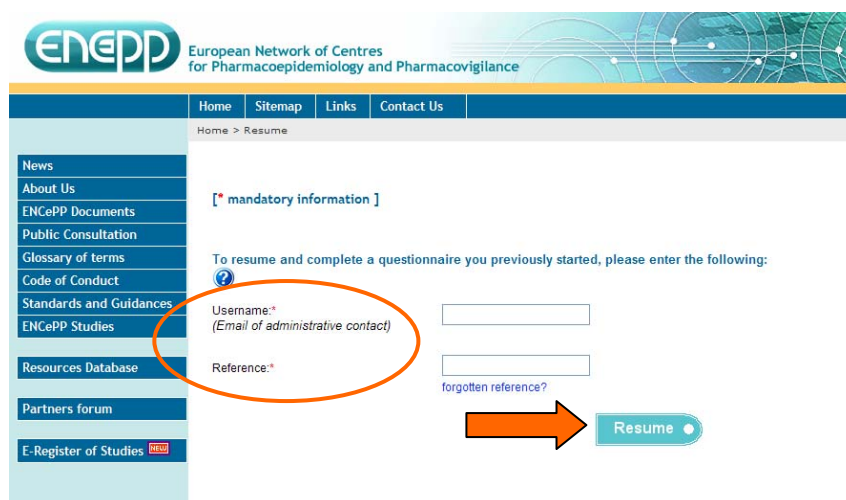
Click on “Resume Draft/Returned application”:



The screenshot shows the ENCePP website's 'Electronic Register of Studies' page. The page title is 'Electronic Register of Studies'. Below the title, there is a description of the register's purpose and a list of goals: 'Increase transparency', 'Reduce publication bias', 'Promote information exchange', 'Facilitate collaborations within the scientific community', and 'Facilitate optimal use of pharmacoepidemiology and pharmacovigilance expertise in Europe by preventing unnecessary duplication of research.' There are three buttons: 'Search register of studies', 'Add Study', and 'Edit Study'. The 'Resume Draft/Returned application' link is circled in orange. The breadcrumb trail is 'Home > Studies Database'.

When prompted, enter your username (e-mail of admin contact) and reference and click on “Resume”:

NB: If you have forgotten your reference, click on “forgotten reference” to retrieve it. You will be prompted to enter the email address of the administrative contact and the password will be sent to this address.



The screenshot shows the 'Resume' page on the ENCePP website. The page title is 'Resume'. Below the title, there is a section for 'mandatory information'. The text says: 'To resume and complete a questionnaire you previously started, please enter the following:'. There are two input fields: 'Username: (Email of administrative contact)' and 'Reference:'. The 'Resume' button is circled in orange. The breadcrumb trail is 'Home > Resume'.

2.2.5. Further Steps / Submission of Documents

As soon as the data has been submitted electronically, the following original signed documents should be sent to the ENCePP Secretariat (c/o EMA, 7 Westferry Circus, London E14 4HB, United Kingdom):

- a) **checklist** of the Code of Conduct (Annex 2)
- b) **declaration** (Code of Conduct Annex 3)
- c) **checklist for study protocols**

Upon receipt of the documents, the ENCePP Secretariat checks for completeness of the submitted data, declarations and checklists.

If the CoRe requirements are met, the ENCePP Secretariat dispatches a letter signed by the Chair of the ENCePP Steering Group, confirming a priori eligibility of the study to be considered as an "ENCEPP study" and places the corresponding ENCePP study seal in the E-Register of studies. In addition, the applicant will receive an email confirming that the study has been accepted, including login details for future updates.

At this stage, the ENCePP Secretariat uploads the signed declaration and checklists to the E-Register.

PDF-versions of the related documentation (signed checklists, signed declaration and any other information relevant to the study) are publicly available in the 'documents' section of the study in the E-Register. This complies with the transparency requirements laid down in the Code of Conduct.

On completion of the online questionnaire, the investigator has the option of making the protocol publicly available already at this stage, or after the final study report.

2.3. Searching the E-Register of studies

The screenshot shows the ENCePP website interface. The header includes the ENCePP logo and the text 'European Network of Centres for Pharmacoepidemiology and Pharmacovigilance'. Below the header is a navigation bar with links for Home, Sitemap, Links, and Contact Us. A breadcrumb trail indicates the current location: Home > Studies Database. The left sidebar contains a menu with various site sections. The main content area is titled 'Electronic Register of Studies' and provides information about the register's purpose and goals. A red circle highlights the 'Search register of studies' button, which is a key feature for finding studies in the database.

Choose from available search criteria:

- Status of Study
- Title of Study
- Acronym
- Study type
- Study requested by a regulator
- Coordinating Study entity
- Research Network
- Study drug
- Medical condition
- ENCePP Seal
- Population age
- Other population
- Scope of the Study

(NB: If no search criteria are chosen, the search will return all entries)

Click on "Search".

The search result will be displayed; ENCePP studies will display the ENCePP seal.

To view individual entries, click on the study title:

Home > Search results

6 Studies found

Status	Official Title	Lead Investigator	Last Updated
Finalised	Cardiac profile of patients using rosiglitazone-containing anti-diabetes medicines: a study using the THIN database	Mr Jim Slattery	11/11/2010
Finalised	Validation of statistical signal detection procedures in eudravigilance post-authorization data: a retrospective evaluation of the potential for earlier signalling.	Dr Yolanda Alvarez	20/10/2010
Finalised	Impact of Body Mass Index and Obesity on Clinical Response to Systemic Treatment for Psoriasis	Dr Luigi Naldi	13/10/2010
Planned	International Active Surveillance study - Folate and Oral Contraceptive Utilization Study	Dr Juergen Dinger	16/11/2010
Planned	Long-term outcomes and adverse events of therapy with inhaled corticosteroids, long-acting beta-2-agonists and anticholinergic drugs in hospitalised patients with Chronic Obstructive Pulmonary Disease (COPD) - a cohort study based on health information systems in three Italian regions.	Dr Nera Agabiti	27/10/2010
Planned	International Active Surveillance Study of Women Taking Dienogest for Endometriosis: Visanne Post-approval Observational Study	Dr Juergen Dinger	21/10/2010

Show search criteria

- Please click [here](#) to know more about ENCePP seal

[Go Back](#)

2.4. Printing an individual study record

Once an individual study has been selected, it is possible to print or save a pdf-version of the record by clicking on "Print" at the bottom of the screen. This print option is available on all four pages of the study record:

Phone number (incl. country code)	390683060374
Alternative phone number	
Fax number (incl. country code)	390683060374
Email address	kirchmayer@asplazio.it



Public Enquiries

Title	Dr
Last name	Agabiti
First name	Nera
Address line 1	Via Santa Costanza 53
Address line 2	
Address line 3	
City	Roma
Postcode	00198
Country	Italy
Phone number (incl. country code)	390683060402
Alternative phone number	
Fax number (incl. country code)	390683060374
Email address	kirchmayer@asplazio.it

[Top](#)

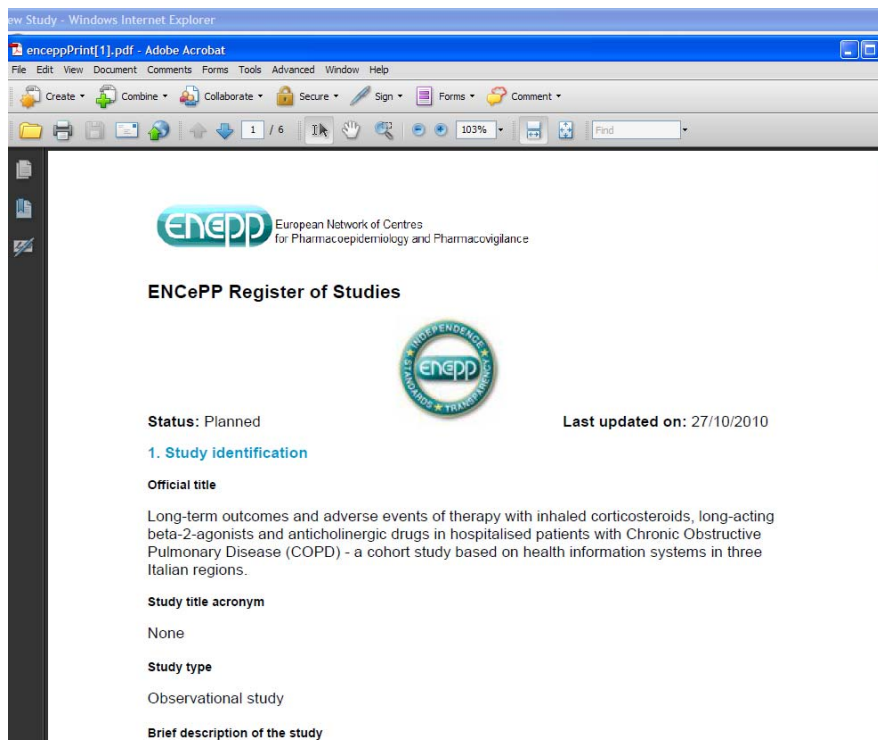
[Go Back](#) [Print](#)

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 EUROPEAN MEDICINES AGENCY 

Version: 3.0.40

This will open a pdf-version of the record which can be printed or saved on a local drive:



ew Study - Windows Internet Explorer

enceppPrint[1].pdf - Adobe Acrobat


File Edit View Document Comments Forms Tools Advanced Window Help

Create Combine Collaborate Secure Sign Forms Comment

1 / 6 103% Find

ENePP European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

ENCePP Register of Studies



Status: Planned **Last updated on:** 27/10/2010

1. Study identification

Official title

Long-term outcomes and adverse events of therapy with inhaled corticosteroids, long-acting beta-2-agonists and anticholinergic drugs in hospitalised patients with Chronic Obstructive Pulmonary Disease (COPD) - a cohort study based on health information systems in three Italian regions.

Study title acronym

None

Study type

Observational study

Brief description of the study

2.5. How to register non-ENCePP studies

The electronic register of studies is open to register all pharmacoepidemiological and pharmacovigilance studies regardless of whether there is an application for the ENCePP study seal or the research centre is part of the ENCePP network.

Investigators who only wish to register their studies (i.e. no request is made for an ENCePP study seal) need to submit a completed data entry form and any other relevant document they wish to make publicly available. There is no obligation to adhere to the ENCePP Code of Conduct or comply with the ENCePP Checklist for Study Protocols. However, investigators are required to regularly update the entry of their studies in the register.

2.6. Study Status – Automatic Reminders

A study may have the status “planned”, “ongoing” or “finalised”; the database foresees five different study timelines, three of which are mandatory:

- **Date when funding contract was signed:** when the planned or the actual date is entered, the status of the study will be “planned”;
- **Start date of data collection:** when the actual date is entered, the status of the study will change from “planned” to “ongoing”;
- **Date of final study report:** when the actual date is entered, the status of the study will change from “ongoing” to “finalised”. For ENCePP studies it is mandatory to upload the final study report in the database when the actual date of the study report is entered.

Unless the relevant “actual dates” have been entered, automatic reminders are sent 30 days after the planned date for the start of data collection, and 30 days after the planned date of the final study report.

3. Documents

All relevant documents are available for download from the ENCePP website.

- ENCePP Code of Conduct
http://www.encepp.eu/code_of_conduct/index.html
- Checklist of the ENCePP Code of Conduct (Annex 2)
http://www.encepp.eu/code_of_conduct/index.html
- Declaration of compliance with the Code of Conduct (Annex 3)
http://www.encepp.eu/code_of_conduct/index.html
- Declaration of Interests for ENCePP Studies (Annex 5)
http://www.encepp.eu/code_of_conduct/documents/ENCePPDoIForm.pdf
- ENCePP Checklist for Study Protocols
http://www.encepp.eu/standards_and_guidances/index.html

A pdf-version of the data entry form may be downloaded from the ENCePP website:

<http://www.encepp.eu/encepp/studyRegistration.htm#>

4. Information and contact

More information can be found on the ENCePP website: www.encepp.eu or by contacting the ENCePP Secretariat at encepp_secretariat@ema.europa.eu or encepp_studies@ema.europa.eu