



14 March 2017
EMA/505161/2015

FAQ – EU PAS Register

Q1	Which studies should be registered in the EU PAS Register?	3
Q2	Who can register a study?.....	3
Q3	When should I register my study?.....	3
Q4	Is it mandatory to provide the primary/lead investigator's email address?.....	3
Q5	What if a primary/lead investigator has not been designated?	3
Q6	Does the EU PAS Register accept XML file uploads?.....	4
Q7	What do the different timelines mean?	4
Q8	Where can I find the date of initial registration of my study?	4
Q9	Which information should I enter in the field 'study drug information'?	4
Q10	Is it required to complete the items marked with "*for ENCePP Seal studies"?	4
Q11	What are the legal obligations relating to transparency and the EU PAS Register?	4
Q12	When is it necessary to upload the study protocol and the study report?.....	5
Q13	What should be the format of the protocol and the report for PASS?.....	6
Q14	What if the size of my protocol or study report is too big to upload?.....	6
Q15	How many versions of the protocol can be uploaded?	6
Q16	I have uploaded the protocol by mistake. Can I delete it?	6
Q17	How do I retrieve a draft entry?	6
Q18	How do I make changes to an existing study record?.....	7
Q19	Is there a milestone update policy?	7
Q20	How do I change the status of my study?.....	7
Q21	Can I make changes to an 'actual date'?	7
Q22	How do I obtain login details for editing my study record?.....	7
Q23	Are my login details record-specific?.....	8
Q24	How do I obtain the unique EU PAS Register number (study reference number) for my study?.....	8
Q25	How do I reference a study?	8
Q26	Is a transfer of ownership of a study record possible?.....	9
Q27	What to do if a study was terminated or cancelled after entry in the EU PAS Register?9	
Q28	My study is a pharmacovigilance activity included in the risk management plan (RMP) of an authorised medicinal product. In which category does my study fall?	9



Additional guidance:

- [EU PAS Register Guide](#)
- [Questions and Answers to support the implementation of the Pharmacovigilance legislation](#)
- [Good Pharmacovigilance Practices \(GVP\) Module VIII](#)

Q1 Which studies should be registered in the EU PAS Register?

The EU PAS Register is a publicly available register of non-interventional post-authorisation studies (PAS). All non-interventional PAS regardless of whether they are initiated, managed or financed by a marketing authorisation holder (MAH), or whether they are conducted by a research centre that is a partner of the ENCePP network or any other research centre, including from outside the European Union, should be registered.

According to the EU legislation, MAHs shall register all non-interventional post-authorisation safety studies (PASS) relating to authorised medicinal products either imposed as an obligation by a competent authority in accordance with Articles 10 or 10a of Regulation (EC) No 726/2004 or with Articles 21a or 22a of Directive 2001/83/EC. They should also register any other PASS conducted voluntarily in accordance with the recommendations of [Module VIII of the Good pharmacovigilance practices](#).

Information on post-authorisation efficacy studies (PAES) that are not clinical trials (i.e. outside the scope of Directive 2001/20/EC) should also be entered in the EU PAS Register to support transparency on post-authorisation efficacy studies (PAES), whether they are initiated, managed or financed by a marketing authorisation holder voluntarily or pursuant to an obligation.

Q2 Who can register a study?

Any designated individual (e.g. staff member of the research centre, sponsor or pharmaceutical company acting as study funder) may register the study with the agreement of the primary/lead investigator. The decision of who enters the study in the EU PAS Register should be with the primary/lead investigator who is ultimately responsible for the provided information. The individual entering the study should provide the full name and contact details of the primary/lead investigator.

Q3 When should I register my study?

Registration of studies can be done at any stage (i.e. from planning of the study to completion of its final report), but it is recommended to register them before the study commences (i.e. start of primary data collection or data extraction for secondary use of data).

Q4 Is it mandatory to provide the primary/lead investigator's email address?

If desired, the primary/lead investigator's name does not need to be linked to their personal email address, but a collective mailbox address or the address of another designated individual can be indicated for further correspondence (e.g. for receipt of acknowledgment emails).

Q5 What if a primary/lead investigator has not been designated?

For studies where no primary/lead investigator has been designated the details of the individual person responsible for the conduct of the study should be provided and included under the section referring to the primary/lead investigator.

Q6 Does the EU PAS Register accept XML file uploads?

The EU PAS Register must be populated via the data entry form and it does not accept XML files for upload.

Q7 What do the different timelines mean?

Date when funding contract was signed:

Date at which the contract between the funder of the study and the organisation in charge of conducting the study (or the primary/lead investigator) has been signed. In case of multiple funding contracts, the date of signature of the first contract relating to the study should be provided.

Start date of data collection ('study start'):

The date from which information on the first study subject is first recorded in the study dataset or - in the case of secondary use of data - the date from which data extraction starts.

End date of data collection:

This is equivalent to the start date of data analysis.

Q8 Where can I find the date of initial registration of my study?

The database will only display the date of the latest update to the study record. It is therefore recommended to save a .pdf file of the study record (which includes the date) when the study is first registered in the EU PAS Register. The .pdf file can be generated via the 'print' function.

Q9 Which information should I enter in the field 'study drug information'?

The drug name(s) as stated in the protocol should be entered. Single-constituent drugs can be searched by substance name (INN). The brand name can also be entered specifying the country and the substance name. A maximum of 10 different study drugs can be entered.

In cases where the substance INN(s) is not known or cannot be found in the drop-down list, a query should be run by ATC code. Further information on ATC codes is available on the WHO website:

http://www.whocc.no/atc_ddd_index/.

Q10 Is it required to complete the items marked with “*for ENCePP Seal studies”?

For ENCePP Seal studies conducted by registered ENCePP Centres there is a requirement to provide certain documentation in the EU PAS Register before the study starts (e.g. ENCePP Code of Conduct declaration & checklist, checklist for study protocols, declaration of interest). These ENCePP Seal specific requirements are not needed for the registration of any other post-authorisation study (PAS) in the EU PAS Register.

Q11 What are the legal obligations relating to transparency and the EU PAS Register?

The pharmacovigilance legislation requires the EMA to publish in a publicly available register ('the EU PAS Register') the **protocols and abstracts of results** of PASS imposed as an **obligation** by a competent authority in accordance with Articles 10 or 10a of Regulation (EC) No 726/2004 or with

Articles 21a or 22a of Directive 2001/83/EC. It also specifies that the final report of such imposed PASS must provide the date of registration in this register.

In order **to support transparency on all non-interventional PASS and to facilitate exchange of pharmacovigilance information between the Agency, regulatory authorities and marketing authorisation holders**, the marketing authorisation holders should also enter in the EU PAS Register all non-interventional PASS conducted voluntarily in the EU or included in the risk management plan agreed in the EU. Further information about the requirements for the registration of PASS is available in the guideline on [Good Pharmacovigilance Practices \(GVP\) module VIII](#), chapter VIII.B.

Q12 When is it necessary to upload the study protocol and the study report?

As outlined in [GVP Module VIII](#), marketing authorisation holders (MAHs) are encouraged to register a PASS (either conducted voluntarily or pursuant an obligation imposed by a regulatory authority) in the EU PAS Register and to make the protocol available before the study commences (please see GVP Module VIII.B). The same applies to substantial amendments to the protocol, progress and final study reports. For a definition of ‘substantial amendments’, see GVP Module VIII.B.2.

Where prior publication of the protocol could threaten the validity of the study or the protection of intellectual rights, a study protocol with redactions made by the MAH may be entered into the register prior to the start of data collection. The complete protocol should then be entered in the register at the end of data collection.

See also overview provided below:

▲ Legal obligation ✓ Recommended in the GVP guideline ★ Optional

Management of study

	PASS with MAH involvement	
	Imposed as an obligation	Conducted voluntarily
Standard format of protocol and study report	▲	✓
Pharmacovigilance Risk Assessment Committee (PRAC) involvement	▲	(if PASS required in RMP)
Registration of study in the EU PAS Register	▲	✓
Study not to promote medicinal product	▲	▲
Restricted payment to healthcare professional	▲	▲
Quality systems	▲	✓
ENCePP methodological standards	✓	✓
ENCePP checklist for study protocol	✓	✓
ENCePP code of conduct	✓	✓
ENCePP study seal	★	★

Reporting of study information

	PASS with MAH involvement	
	Imposed as an obligation	Conducted voluntarily
Protocol and progress reports to be submitted upon request to national competent authority (NCA) of Member State (MS) where study is conducted	▲	▲
Final report to be sent to NCA of MS where the study is conducted, within 12 months of the end of data collection	▲	▲
Data generated in the study to be monitored	▲	▲
Any information that may influence the benefit-risk balance to be reported to NCAs of MSs where the product is authorised	▲	▲
Reporting of suspected adverse reactions in studies with primary data collection	▲	▲
Final manuscript of article to be transmitted to NCAs within 15 days after acceptance by journal editor	✓	✓

Q13 What should be the format of the protocol and the report for PASS?

Regarding the format and content of protocol, abstract and final study report the Implementing Regulation 520/2012 provides in Annex III a clear structure which MAHs have to follow when submitting protocol, abstract and final study report to regulatory authorities for PASS imposed as an obligation. To this end the Agency has published guidance for the submission of PASS protocols on the EMA website:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/10/WC500133174.pdf. Similar guidance is provided for abstracts and final study reports: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2013/01/WC500137939.pdf.

To ensure the same level of transparency, scientific and quality standards for all PASS, MAHs should follow the format and content requirements also when making information about PASS available in the EU PAS Register, however this is a recommendation and not a legal requirement as applicable to PASS conducted pursuant to an obligation.

Q14 What if the size of my protocol or study report is too big to upload?

Only pdf documents of 10Mb or less each can be uploaded to the database. In cases where the size of the document is too big to upload, it is recommended to split the document into sections and upload the individual sections as 'other documents' under Q19. Up to 5 individual sections (of max. 10Mb each) may be uploaded here:

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="-"/>

Q15 How many versions of the protocol can be uploaded?

The database accepts the 'initial' and 'latest' versions of the protocol. There is no limit to the number of latest versions of the study protocol that can be uploaded in the system. The 'initial' document cannot be deleted and no changes are possible once it has been uploaded and submitted. Within Edit mode (Edit a Study) if a "Latest" version has been uploaded, this can be overwritten as often as necessary with a newer version, but only the very latest version will be visible.

Q16 I have uploaded the protocol by mistake. Can I delete it?

Once the 'initial' version of the protocol has been uploaded and the study record submitted for approval, the document can no longer be deleted or overwritten.

Q17 How do I retrieve a draft entry?

Prior to submission, errors in the draft entry may be corrected via the function '[Resume draft/rejected application](http://www.encepp.eu/encepp/completeQuestionnaire.htm)' (<http://www.encepp.eu/encepp/completeQuestionnaire.htm>).

Login requirements: email address provided for the primary/lead investigator and study reference number.

The procedure is described in more detail in the document 'EU PAS Register Guide' (http://www.encepp.eu/encepp_studies/documents/EUPASRegisterGuide.pdf).

Q18 How do I make changes to an existing study record?

Once the entry has been submitted and accepted, changes may be made via the '[Edit](http://www.encepp.eu/encepp/editResource/authenticateUser.htm)' function (<http://www.encepp.eu/encepp/editResource/authenticateUser.htm>).

Login requirements: email address provided for the primary/lead investigator and password provided in the acknowledgement email when the study was first registered.

The procedure is described in more detail in the document 'EU PAS Register Guide' (http://www.encepp.eu/encepp_studies/documents/EUPASRegisterGuide.pdf).

Q19 Is there a milestone update policy?

As stated in [GVP Module VIII](#), it is recommended that data should be kept up to date at all times and changes should be made within 2 weeks following the date of the amended protocol at the latest.

Q20 How do I change the status of my study?

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 Seal 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.

Q21 Can I make changes to an 'actual date'?

Only 'actual dates' in the future can be edited.

Q22 How do I obtain login details for editing my study record?

Once the registration of a study in the EU PAS Register has been submitted and accepted the primary/lead investigator contact will receive an acknowledgement email with login details to further amend the study record (for example providing the actual dates for milestones). These login details remain valid for any future amendments to the study record.

From: EU_PAS_Register@ema.europa.eu[SMTP:EU_PAS_Register@EMA.EUROPA.EU]
Sent:
To:

Subject: Your study registration in the EU PAS Register Reference: EUPASxxxxxx has been accepted

Dear ,

Thank you for submitting your application to register your study with the EU PAS Register. We are pleased to inform you that your application has been accepted and that the information on your study has been entered in the EU PAS Register which is accessible to the public.

You may login with your username and password to update your details at any time.

Your username is: <email address provided for the PLI>

Your password is: <password>

For further information or queries, please do not hesitate to contact us at mailto:EU_PAS_Register@ema.europa.eu

We look forward to working with you.

Kind regards,
EU PAS Register

Q23 Are my login details record-specific?

The login details will provide access to all studies registered under the same username, i.e. email address provided for the primary/lead investigator.

Q24 How do I obtain the unique EU PAS Register number (study reference number) for my study?

The unique EU PAS Register number will be issued on registration of the study (via the 'Add Study' function). The primary/lead investigator will receive an automatic acknowledgment email with the date of the study registration, the study reference number and login details for updating the study record as milestones are reached.

The format of the unique EU PAS Register number is: EUPASXXXXXX, as illustrated below:

From: EU_PAS_Register@ema.europa.eu[SMTP:EU_PAS_Register@EMA.EUROPA.EU]
Sent:
To:

Subject: Your study registration in the EU PAS Register Reference: EUPASxxxxxx has been accepted

Dear ,

Thank you for submitting your application to register your study with the EU PAS Register. We are pleased to inform you that your application has been accepted and that the information on your study has been entered in the EU PAS Register which is accessible to the public.

You may login with your username and password to update your details at any time.

Your username is: <email address provided for the PLI>

Your password is: <password>

For further information or queries, please do not hesitate to contact us at mailto:EU_PAS_Register@ema.europa.eu

We look forward to working with you.

Kind regards,
EU PAS Register

Please note that for studies registered prior to 15 July 2016 the EU PAS Register number prefix 'ENCEPP/SDPP' has been replaced by 'EUPAS' with the sequential number unchanged.

Q25 How do I reference a study?

It is recommended to always reference the study title (or acronym) together with the unique EU PAS Register number (see Q24). In addition, the static world wide web (www) hyperlink to an individual study may be included which will always link to the most recent update of the study record.

Q26 Is a transfer of ownership of a study record possible?

Currently there is no process implemented to transfer ownership of a study record in the EU PAS Register from one coordinating study entity to another, e.g. from one primary lead investigator (PLI) to another PLI or to a marketing authorisation holder (MAH) as study sponsor.

The EU PAS Register login (username and password) provided at the time of study registration is not study record-specific and provides access to all studies registered with the same respective coordinating study entity as applicable. Therefore a transfer of ownership of a study record is only possible by re-registering the study in the EU PAS Register, providing the new coordinating study entity's contact details with the specified email address becoming the new username. This process will generate a new study number (EUPASXXXXXX) and password linked to the new coordinating study entity's contact details for future amendments of the study record.

To avoid duplicate registration, the previous study record will have to be deleted from the EU PAS Register. For this purpose, a written confirmation from the previous coordinating study entity providing relevant details is required prior to the re-registration, i.e. the full study title, name and contact details (email address) of the new PLI (or MAH as study sponsor) who then owns the study record, signed and dated by the previous coordinating study entity.

Both the new and previous coordinating study entity (i.e. PLI or MAH) will be informed once the 'old' study record has been deleted and the transfer is completed. A record of all related correspondence and documentation will be kept on file.

Q27 What to do if a study was terminated or cancelled after entry in the EU PAS Register?

The EU PAS Register referred to in [GVP Module VIII](#) on post-authorisation safety studies (PASS) has been developed under the guiding principle of transparency to the general public about ongoing research relating to medicines used in clinical practice. Transparency requirements for non-interventional PASS aim also to facilitate exchange of pharmacovigilance information between the Agency, Member States and marketing authorisation holders. In addition, the EU PAS Register provides a repository for all pharmacovigilance and pharmacoepidemiological studies, especially those conducted in Europe, regardless of whether they are initiated, managed or financed by a marketing authorisation holder voluntarily or pursuant an obligation, or whether they are conducted by a research centre that is a partner of the ENCePP network or any other research centre.

There is no provision in GVP or in the legislation which determines if or when study records may be deleted from the EU PAS Register. By adding a note in the field 'Brief description of the study' the coordinating study entity may indicate if a study was terminated prematurely or cancelled, including relevant explanatory information. As appropriate the study status should be set to 'finalised' (which requires the provision of a final date for mandatory milestones).

Q28 My study is a pharmacovigilance activity included in the risk management plan (RMP) of an authorised medicinal product. In which category does my study fall?

A post-authorisation study may constitute a pharmacovigilance activity required in the Risk Management Plan (RMP) of an authorised medicinal product. Studies are categorised as follows, according to regulatory procedure.

EU RMP category 1 (imposed as condition of marketing authorisation)

A post-authorisation safety study (PASS) may be imposed as condition of the marketing authorisation because it is key to the benefit-risk profile of the product. In the EU Risk Management Plan (EU RMP) these studies are referred to as category 1 studies in the pharmacovigilance plan of an authorised medicinal product. If the condition is a non-interventional PASS, it will be subject to the supervision set out in Art 107 (m)-(q) of Directive 2001/83/EC and the format and content of such non-interventional PASS as described in Implementing Regulation 526/2012 Annex III (see GVP Module VIII).

EU RMP category 2 (specific obligation of marketing authorisation)

A PASS may be a specific obligation in the context of a conditional marketing authorisation (MA) or a MA under exceptional circumstances. In the EU RMP these studies are referred to as category 2 studies in the pharmacovigilance plan of an authorised medicinal product. If the specific obligation is a non-interventional PASS, it will be subject to the supervision set out in Article 107 (m)-(q) of Directive 2001/83/EC and the format and content of such non-interventional PASS as described in Implementing Regulation 526/2012 Annex III (see GVP Module VIII).

EU RMP category 3 (required)

PASS which do not fall in category 1 or 2 but are required to investigate a safety concern as part of the pharmacovigilance plan of an authorised medicinal product are legally enforceable. In the EU RMP these studies are referred to as category 3 studies (see GVP Module VIII).

Non-EU RMP only

PASS which are included in risk management systems outside the jurisdiction of EU medicines regulation (e.g. Risk Evaluation and Mitigation Strategies (REMS) under US regulation).

Not applicable

Any post-authorisation study (PAS) which is not subject to regulatory supervision and not a RMP pharmacovigilance activity.