



Standard operating procedure

Title: Evaluation procedure – ENCePP database of research resources		
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1. Purpose

The purpose of this SOP is to provide a harmonised approach for members of the ENCePP Secretariat to handle applications received via the ENCePP database of research resources from research centres, networks and data sources wishing to join ENCePP. It is designed to ensure that such applications are handled in an efficient and consistent manner.

This SOP is not applicable to any other Agency databases.

2. Scope

This SOP applies to the ENCePP Secretariat in the Pharmacovigilance and Risk Management Sector of the Patient Health Protection Unit of the European Medicines Agency. The scope relates to the responsibilities of the Secretariat with regard to the practical handling of the applications received and does not cover technical aspects related to the ENCePP database of research resources *per se*.

3. Responsibilities

It is the responsibility of the Head of the Pharmacovigilance and Risk Management Sector to ensure that this procedure is adhered to within the sector. The responsibility for the execution of a particular part of this procedure is identified in section 9. Procedure.

4. Changes since last revision

New SOP.



5. Documents needed for this SOP

ENCePP Database of Research Resources:

<http://www.encepp.eu/encepp/resourcesDatabase.jsp>

ENCePP distribution list:

Cabinets/13. Projects/ENCePP/ENCePP Inventory/*Database of Research Resources/ENCePP email list.xls

Background Notes - ENCePP Database of Research Resources:

Cabinets/13. Projects/ENCePP/Procedures_WIN/Database of Research Resources/Background Notes_database of research resources.doc

List of members of the ENCePP Partner Forum:

Cabinets/13. Projects/ENCePP/IT projects/User Forum /ENCePP Partner Forum.xls

6. Related documents

ENCePP Code of Conduct: http://www.encepp.eu/code_of_conduct/index.html

Mandate and Rules of Procedure of the ENCePP Plenary:

<http://www.encepp.eu/documents/publications/Rules%20of%20Procedure%20and%20Mandate%20of%20the%20ENCePP%20Plenary.pdf>

ENCePP Partner Forum User Manual:

Cabinets/13. Projects/ENCePP/IT projects/User Forum/ENCePP Forum User manual.doc

JForum Admin User Guide:

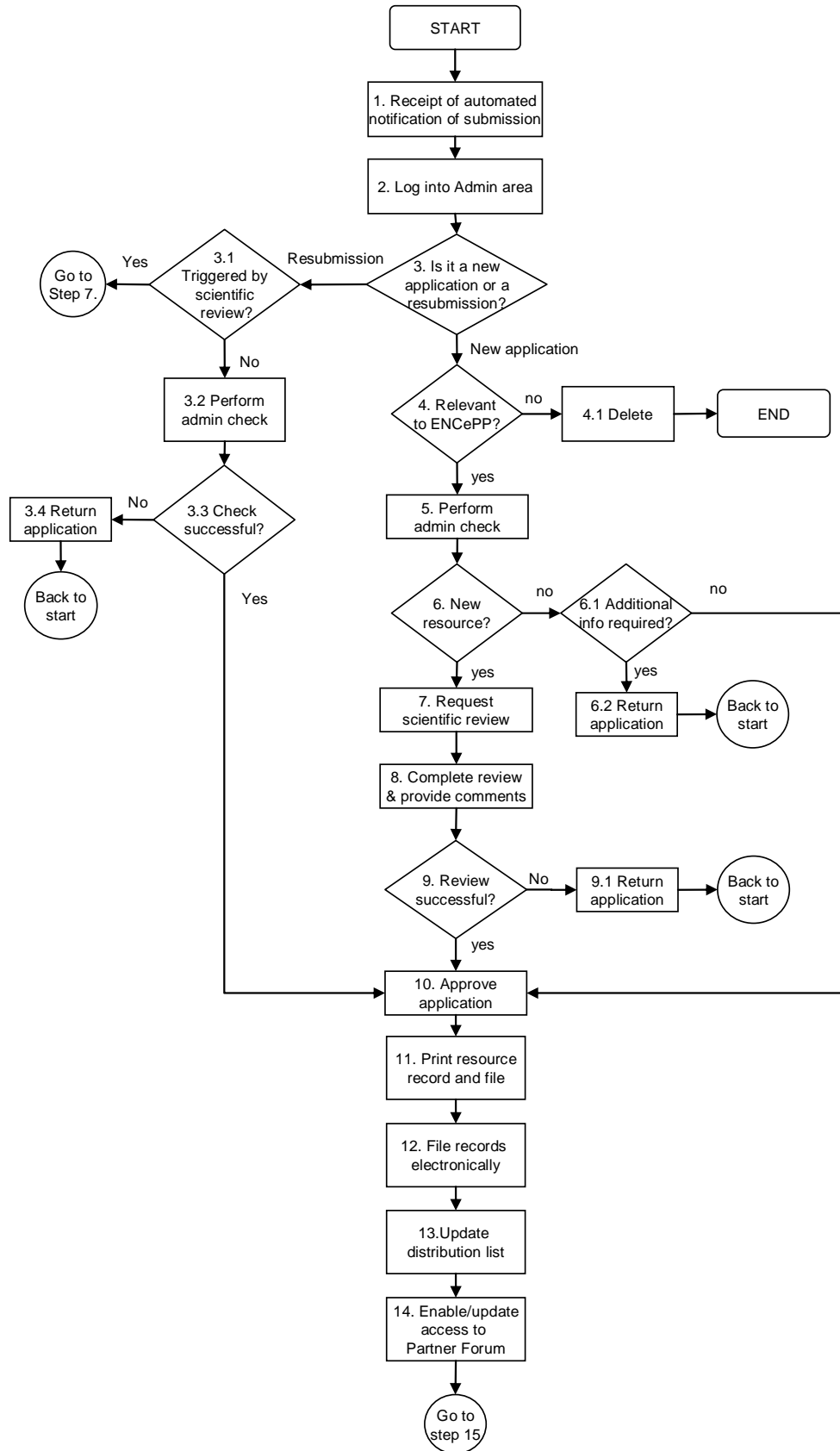
Cabinets/13. Projects/ENCePP/IT projects/User Forum/JForum ADMIN User Guide

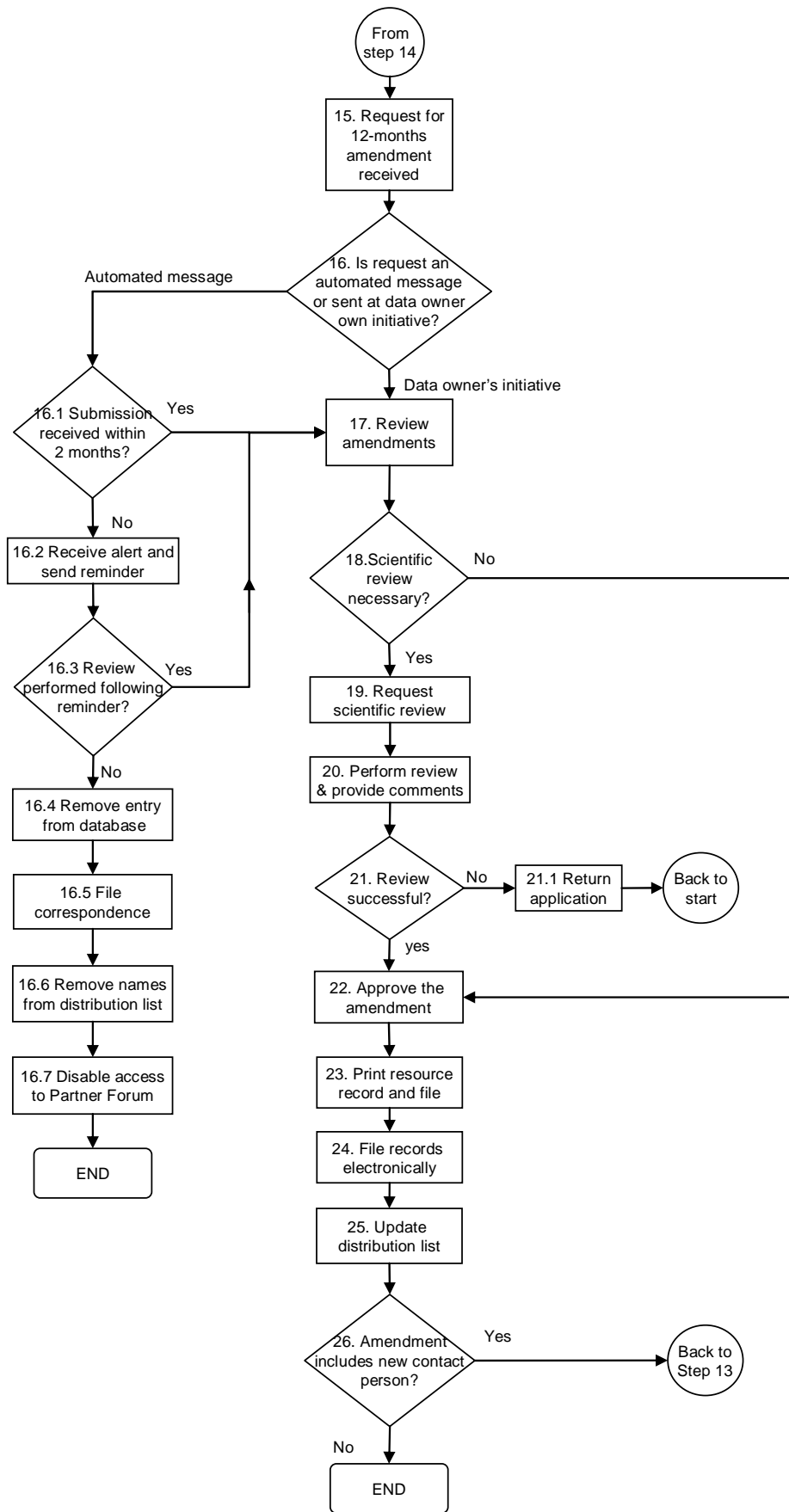
7. Definitions

<i>AST</i>	Assistant in the ENCePP Secretariat
<i>Centre</i>	For-profit or not-for-profit EU research organisation in the field of pharmacoepidemiology and pharmacovigilance
<i>Data source</i>	EU healthcare databases and/or electronic registries in the field of pharmacoepidemiology and pharmacovigilance
<i>DREAM</i>	Document Records Electronic Archive Management System
<i>ENCePP</i>	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
<i>ENCePP Database of Research Resources</i>	Electronic index of available EU research organisations and data sources in the field of pharmacoepidemiology and pharmacovigilance
<i>ENCePP Partner Forum</i>	Electronic discussion forum, accessible on the ENCePP website and via password issued to registered ENCePP partners only
<i>ENCePP Resource</i>	A centre, network or data source included in the ENCePP inventory
<i>ENCePP Secretariat</i>	Administrators and Assistants in the Section for Coordination and Networking, coordinating the work of the different bodies of ENCePP, and supporting the communication and information flow between stakeholders, ENCePP partners and any other interested party

<i>"Known" centres, networks, data sources</i>	Included in the non-electronic ENCePP Inventory before 31/01/2010
<i>Network</i>	National or international collaboration of centres
<i>"New" centres, networks, data sources</i>	Not included in the ENCePP Inventory as of 31/01/2010
<i>Re-submission</i>	Updated application following evaluation of a research resource by the ENCePP Secretariat and/or the Scientific Evaluator which was returned to the data owner with a request for additional information or changes
<i>Resource Record</i>	pdf printout (electronic or hardcopy) of the complete data set, as submitted by the centre, network or data source
<i>SSO</i>	Single sign-on (the same username and password used for MMD, EudraLink and other Eudra-applications)
<i>Scientific Evaluator</i>	ENCEPP Coordinator or member of the team "Business Coordination and Scientific Projects" within the P-PV Sector who performs the scientific review of a new submission to the ENCePP database of research resources

8. Process map(s)/ flow chart(s)





9. Procedure

In principle, evaluations (administrative and scientific) have to be completed within **two weeks** of submission of applications.

Step	Action	Responsibility
1	Receive an automated notification in the ENCePP Secretariat mailbox when a new application is submitted online.	AST
2	Log into the Administration area on the ENCePP website. Click on "Applications awaiting approval".	AST
3	Is it a new application or a re-submission? New application, go to 4. Re-submission, go to 3.1	AST
3.1	<i>If the re-submission was triggered by a scientific review, go to 7.</i> <i>If the re-submission was triggered by the administrative review of the initial submission, go to 3.2</i>	AST
3.2	Perform the administrative check of the application.	AST
3.3	<i>If the administrative check of a re-submission is successful, go to 10.</i> <i>If the administrative check of a re-submission is unsuccessful, go to 3.4</i>	AST
3.4	Click on 'Return' the application. Edit the automated e-mail message to include administrative comments before dispatch. The data is automatically transferred to the section Draft applications in the Administration area (status: 'returned'). <i>Go to START.</i>	AST
4.	<i>If the application is relevant to ENCePP, go to 5.</i> <i>If the application is irrelevant to ENCePP, contains invalid data, or is a duplicate entry, go to 4.1</i>	AST
4.1	Delete the entry by clicking on 'delete'. ➤ Choose the reason for deletion from the list of available options: - invalid (<i>i.e. outdated or nonsensical information</i>) - inappropriate (<i>i.e. not relevant to ENCePP</i>) - duplicate entry (<i>i.e. resource is already entered in the database</i>) ➤ Click on 'delete' again to finish process. An automated notification of deletion will be dispatched to the respective administrative contact. END of Procedure.	AST

Step	Action	Responsibility
5.	Perform an administrative check to ensure that all mandatory information has been completed, any hyperlinks are working and the application does not contain any spelling mistakes.	AST
6.	<i>If the application was submitted by a "new" resource, go to 7. If the application was submitted by a "known" resource, go to 6.1</i>	AST
6.1	<i>Additional information or updates are required? Yes, go to 6.2 No, go to 10.</i>	AST
6.2	Click on 'Return' the application. Edit the automated e-mail message to include administrative comments before dispatch. The data is automatically transferred to the section Draft applications in the Administration area (status: 'returned'). <i>Go to START.</i>	AST
7.	Send email to scientific evaluator requesting review of the application, indicating administrative comments if any.	AST
8.	Complete review (directly in the database, via own SSO login) and send comments by e-mail to the ENCePP Secretariat, giving detailed instructions on what additional information is required.	Scientific Evaluator
9.	<i>If the review was successful go to 10. If the review was unsuccessful and additional scientific information or updates are required, go to 9.1</i>	AST
9.1	Click on 'Return' the application. Edit the automated e-mail message to include administrative and/or scientific comments before dispatch. The data is automatically transferred to the section Draft applications in the Administration area (status: 'returned'). <i>Go to START.</i>	AST
10.	Click on 'Accept' the application. An automated e-mail message is sent to the administrative contact, containing login details for future updates. The data is automatically transferred to the publicly available/searchable database and the section Approved applications in the Administration area.	AST
11.	Print the resource record and file in hardcopy.	AST

Step	Action	Responsibility
12.	File relevant records electronically: <ul style="list-style-type: none"> ➤ File the resource record in the individual resource folder in DREAM (for location see section 10. Records). ➤ File all automated notifications and email correspondence under the individual resource folder in DREAM (for location see section 10. Records). 	AST
13.	Add email addresses of administrative and scientific contact(s) to the ENCePP distribution list in DREAM (for location see section 10. Records).	AST
14.	Enable access to ENCePP Partner Forum: <ul style="list-style-type: none"> ➤ Add administrative and scientific contact(s) to list of Forum members (for location see section 5. Documents needed for this SOP) ➤ Create username and password for administrative and scientific contact(s) in the online Forum. ➤ E-mail login details and user manual to contacts. 	AST
15.	Receive copy of request for amendment.	AST
16.	<i>If the request is an automated message requesting 12-monthly amendment, go to 16.1.</i> <i>If the request is submitted on data owners own initiative, go to 17.</i>	AST
16.1	<i>If the submission was received within 2 months, go to 17.</i> <i>Otherwise, go to 16.2.</i>	AST
16.2	Receive alert two weeks prior to the lapse of the review deadline. Send reminder to the data owner.	AST
16.3	If data owner performs the review following the reminder, go to 17. Otherwise, go to 16.4	AST
16.4	Remove entry from the database: <ul style="list-style-type: none"> ➤ Log into the Administration area on the ENCePP website. Go to the list "Approved applications" and choose the entry to be deleted. Click on 'delete' the entry. ➤ Choose the reason "invalid data" from the list of available options and click on 'delete' to finish the process. <p>The entry is automatically removed from the database.</p> <p>An automated notification of deletion is dispatched to the respective administrative contact. This notification is automatically copied to the ENCePP Secretariat.</p>	AST

Step	Action	Responsibility
16.5	File all relevant automated notifications and email correspondence under the individual resource folder in DREAM (for location see section 10. Records).	AST
16.6	Remove the names of relevant administrative and scientific contact(s) from the ENCePP distribution list in DREAM (for location see section 10. Records).	AST
16.7	Disable access to ENCePP Partner Forum and remove names of relevant administrative and scientific contact(s) from list of Forum members (for location see section 5. Documents needed for this SOP). END of Procedure.	AST
17.	Review the amendments by comparing the submitted data with the existing pdf printout of the resource. Mark any changes.	AST
18.	<i>If amendments were made to the scientific information and further review is necessary, go to 19.</i> <i>If amendments are administrative and no further review is necessary, go to 22.</i>	AST
19.	Send email to scientific evaluator requesting review of the amendments, indicating administrative comments if any.	AST
20.	Complete review (directly in the database, via own SSO login) and send comments by e-mail to the ENCePP Secretariat, giving detailed instructions on what additional information is required.	Scientific Evaluator
21.	<i>If the review was successful go to 22.</i> <i>If the review was unsuccessful and additional information or updates are required go to 21.1</i>	AST
21.1	Click on 'Return' the amendment. Edit the automated e-mail message to include scientific comments before dispatch. The data is automatically transferred to the section Draft applications in the Administration area (status: 'returned'). <i>Go to START.</i>	AST
22.	Click on 'Accept' the amendment. An automated e-mail message is sent to the administrative contact, containing login details for future updates. The data is automatically transferred to the publicly available/searchable database and the section Approved applications in the Administration area.	AST
23.	Print the resource record and file in hardcopy.	AST
24.	File relevant records electronically: ➤ File the resource record in the individual resource folder in	AST

Step	Action	Responsibility
	DREAM (for location see section 10. Records). <ul style="list-style-type: none"> ➤ File all automated notifications and email correspondence under the individual resource folder in DREAM (for location see section 10. Records). 	
25.	As necessary, update email addresses of administrative and scientific contact(s) to the ENCePP distribution list in DREAM (for location see section 10. Records).	AST
26.	<i>If the amendment includes new administrative and/or scientific contact persons, go to 13.</i> <i>If no new contact added, END of Procedure.</i>	AST

10. Records

10.1. Electronic Filing

All notifications that are generated by the system in relation to the evaluation process (i.e. submission of new entry, request for additional information, re-submission of data, confirmation of acceptance of data, rejection of entry) are copied automatically to the ENCePP Secretariat mailbox (*Public Folders* ↪ *Chrono In* ↪ *WORKFLOW* ↪ *ENCePP_Secretariat*). The ENCePP Secretariat archives all individual notifications in date order (naming convention: *yymmdd_subject*) in DREAM under individual headers for each resource.

Every time a resource is approved, and for tracking purposes, the resource record (i.e. pdf-printout) is saved electronically in DREAM. The records are saved under the resource's short name, i.e. *<shortname in ENCePP inventory.pdf>*; amendments are saved as new versions; retention period is 30 years.

All internal e-mail exchanges between the ENCePP Secretariat and scientific reviewers relating to the evaluation of a resource are saved in date order (naming convention: *yymmdd_subject*) in the individual resource folder in DREAM.

Location of correspondence and resource records (pdf printout) relating to the **Inventory of Research Centres:**

Cabinets/13. Projects/ENCePP/ENCePP Inventory/*Database of Research Resources/01_Inventory of Research Centres/*<individual centre name>*

Location of correspondence and resource records (pdf printout) relating to the **Inventory of Networks:**

Cabinets/13. Projects/ENCePP/ENCePP Inventory/*Database of Research Resources/02_Inventory of Networks/*<individual network name>*

Location of correspondence and resource records (pdf printout) relating to the **Registry of Data Sources:**

Cabinets/13. Projects/ENCePP/ENCePP Inventory/*Database of Research Resources/03_Registry of Data Sources/*<individual data source name>*

The **distribution list/email list** of all contacts included in the ENCePP Database of Research Resources is saved at the following location:

Cabinets/13. Projects/ENCEPP/ENCEPP Inventory/*Database of Research Resources/ENCEPP email list.xls

The list of members of the **ENCEPP Partner Forum**, including their usernames, is saved at the following location:

Cabinets/13. Projects/ENCEPP/IT projects/User Forum /ENCEPP Partner Forum.xls

10.2. Hardcopy Filing

Printouts of all resource records (historical and current) are filed in the folder "ENCEPP Database of Research Resources"; the file is located in office 1-729g.