



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Standard operating procedure

Title: Organisation and management of ENCePP plenary meetings		
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Lead author	Approver	Effective date: 18-NOV-10
Name: Eeva Rossi	Name: Peter Arlett	Review date: 18-NOV-13
Signature: ON FILE	Signature: ON FILE	Supersedes: N/A
Date: 15-NOV-10	Date: 15-NOV-10	TrackWise record no.: 2940

### 1. Purpose

The purpose of this SOP is to describe internal procedures and tasks performed by the ENCePP Secretariat in order to provide consistently high standard support to ENCePP Plenary meetings.

### 2. Scope

This SOP applies to the ENCePP Secretariat in the Communication & Networking Section, Pharmacovigilance & Risk Management Sector, Patient Health Protection Unit.

### 3. Responsibilities

It is the responsibility of the PV-RM Head of Sector to ensure that this procedure is adhered to within the ENCePP Secretariat. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of **9. Procedure**.

### 4. Changes since last revision

New SOP.

### 5. Documents needed for this SOP

"External PhV/PEpi events" document in relevant year folder:  
DREAM/Cabinets/13. Projects/ENCEPP/Meetings/External Meetings/YYYY

SOP on Meeting Requests, SOP/T/6001

Agenda template: DREAM/Cabinets/13. Projects\ENCEPP\Procedures\_WIN\Templates

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom

**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416

**E-mail** [info@ema.europa.eu](mailto:info@ema.europa.eu) **Website** [www.ema.europa.eu](http://www.ema.europa.eu)

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List of participants template: DREAM/Cabinets/13. Projects\ENCePP\Procedures\_WIN\Templates

Seating plan template for room 2A: DREAM/Cabinets/13. Projects\ENCePP\Procedures\_WIN\Templates

Web publication transmission slip: Word File\New\Templates\TS – Event

Outlook “News Form”

## 6. Related documents

Mandate, Objectives and Rules of Procedure for the ENCePP Plenary:

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

Rules of Procedure for the ENCePP Plenary (EMA/364259/2009):

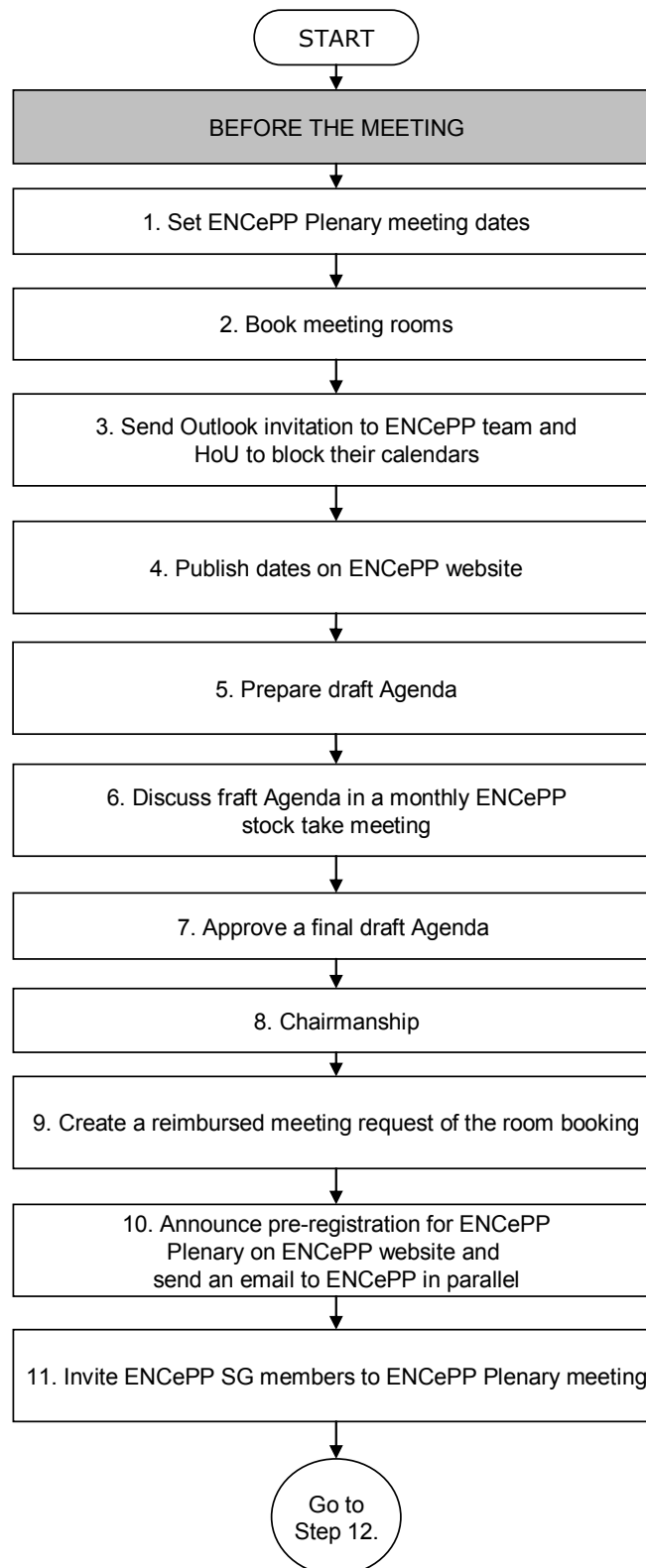
<http://www.encepp.eu/documents/publications/Rules%20of%20Procedure%20and%20Mandate%20of%20the%20ENCePP%20Plenary.pdf>

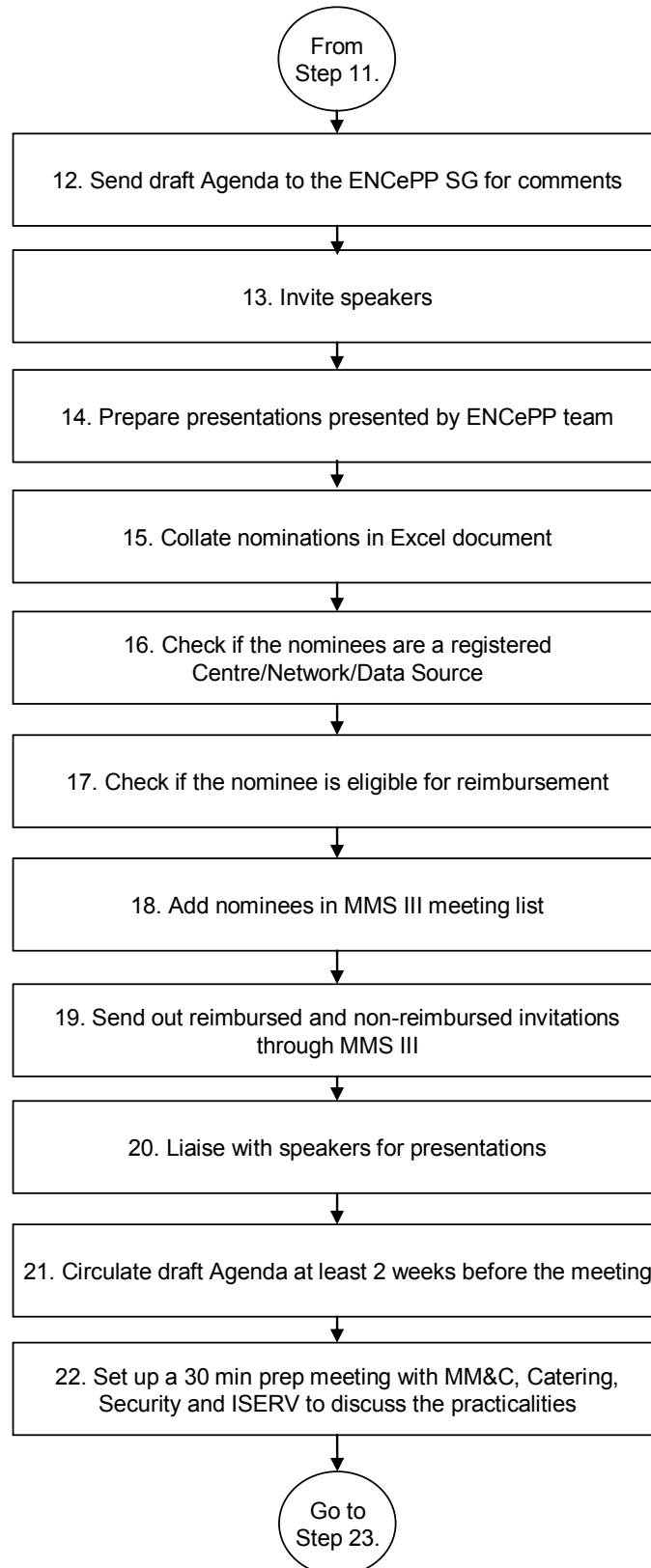
Annual ENCePP Workplan: <http://www.encepp.eu/publications/index.html>

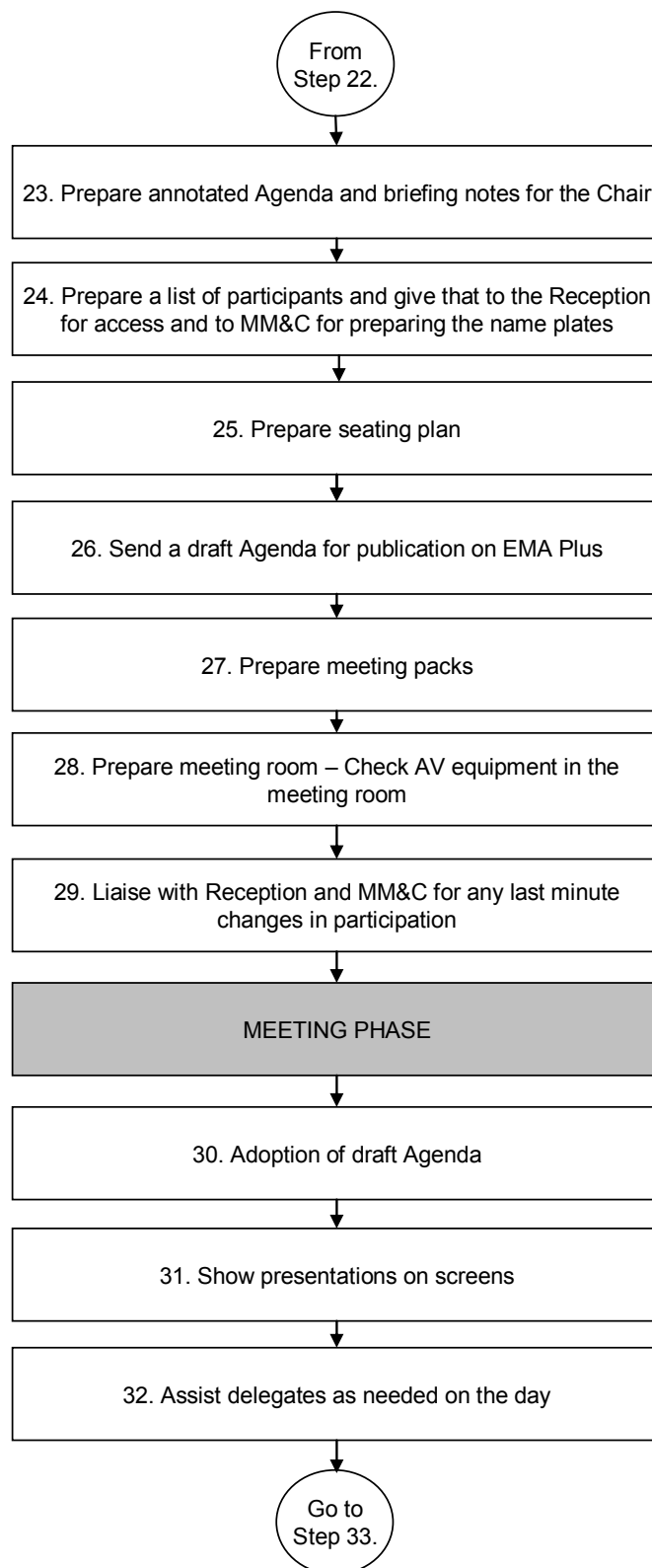
## 7. Definitions

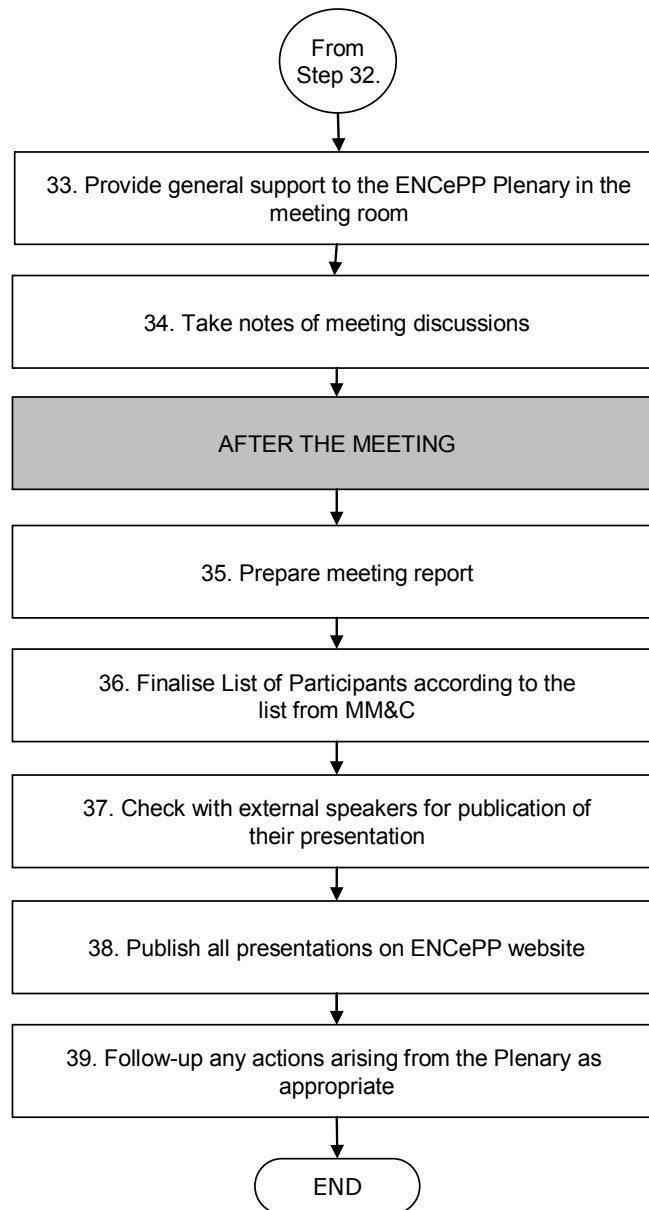
AD:	Scientific Administrator working in the ENCePP Secretariat
AST:	Assistant or Administrative Assistant working in the ENCePP Secretariat
EMA:	European Medicines Agency
ENCePP:	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
ENCePP Secretariat:	Administrators and Assistants in the Section for Co-ordination and Networking, co-ordinating the work of the different bodies of ENCePP, and supporting the communication and information flow between stakeholders, ENCePP partners and any other interested party
ENCePP team:	PV-RM HoS, P-PV-CN SH, ENCePP Secretariat, Sector colleagues providing additional support and advice appointed by HoS
HoS:	Head of Sector
HoU:	Head of Unit
MM&C:	Meeting Management & Conference department
MMS:	Meeting Management System
PEpi:	Pharmacoepidemiology
PhV:	Pharmacovigilance
P-PV-CN SH:	Section Head, Co-ordination and Networking, PV-RM Sector
PV-RM:	Pharmacovigilance and Risk Management Sector
SG:	Steering Group

## 8. Flow chart









## 9. Procedure

Step	Action	Responsibility
<b>BEFORE THE MEETING</b>		
1	Set ENCePP Plenary meeting dates preferably one year in advance. Check the availability of the internal EMA colleagues. Check availability of meeting rooms in MMS II. Check also for possible clash with external PhV/PEpi events taking place (document in relevant year folder: DREAM/Cabinets/13. Projects\ENCEPP\Meetings\External Meetings).	AST
2	Book meeting room 2A in MMS II as soon as the dates have been agreed. Book the room also for the late afternoon of the previous day if available in order to set the room up the day before.	AST
3	Send Outlook invitation to ENCePP team and HoU to block their calendars.	AST
4	Publish dates on ENCePP website	AST
5	Prepare a draft Agenda from issues identified during previous SG meetings and internal ENCePP stock take meetings. Use the ENCePP plenary meeting agenda template.	AST
6	Chair the 1 <sup>st</sup> discussion of a draft Agenda in a monthly internal ENCePP stock take meeting approx. 3 months before the meeting. A decision to be made on the speakers.  Update the draft Agenda following the discussion.	HoS  AST
7	Approve a final draft Agenda as per discussions in the ENCePP stock take meeting.	HoS
8	Check if the Executive Director is available to do the 'opening remarks' and if not, check HoU availability. If HoU is not available to chair the meeting, the next in line is the HoS.	AST
9	Create a reimbursed meeting request of the room booking in MMS II (see SOP on Meeting Requests, SOP/T/6001). Set the number of reimbursed delegates as agreed in the budget.	AST
10	Publish an announcement of pre-registration for ENCePP Plenary on ENCePP website and send an email including the announcement to ENCePP partners in parallel. ENCePP partners contact details are in two Outlook distribution lists kept up to date by AST.	AST
11	Invite ENCePP SG members to ENCePP Plenary meeting. Send out an email to ENCePP SG members informing that the pre-registration is now open and that they will receive a reimbursed invitation to the ENCePP Plenary meeting in due course. Ask them to confirm their attendance. Send out reimbursed invitations to ENCePP SG members using MMS III.	AST

Step	Action	Responsibility
12	Send the draft Agenda to the ENCePP SG for comments and give a deadline for comments.	AST
13	Invite speakers by email as agreed in the internal ENCePP stock take meeting. Explain what we expect the presentation to cover, how long the time slot is and attach the draft Agenda for their information.	AD
14	Ensure that presentations to be given by ENCePP team are prepared. Refer to draft Agenda.	AD
15	Collate nominations in Excel document saved under 'attendance' folder for relevant meeting in EDMS. Save the nomination email under 'nominees' sub folder. DREAM/Cabinets/13. <i>Projects\ENCePP\Meetings\Plenary Meetings</i>	AST
16	Check if the organisation of the nominee is registered in the ENCePP Database of Research Resources. If it is not, send an email to explain that they need to join ENCePP to receive an invitation to the Plenary. Give relevant weblinks for an easy access.	AST
17	Check if the nominee is eligible for reimbursement. Refer to 'III b. Rules of Participation' in 'Mandate, Objectives and Rules of Procedure for the ENCePP Plenary' (EMEA/364259/2009).	AST
18	Add nominees in MMS III meeting list. Update this list in MMS III on a continuous basis as nominations are received.	AST
19	Send out reimbursed and non-reimbursed invitations through MMS III according to the 'Mandate, Objectives and Rules of Procedure for the ENCePP Plenary' (EMEA/364259/2009)	AST
20	Liaise with speakers for presentations. Ask for a presentation preferably 2 days before the meeting. Save presentations under 'Presentations' folder in relevant meeting folder in EDMS.	AST
21	Circulate the draft Agenda to ENCePP partners at least 2 weeks before the meeting by email.	AST
22	Set up a 30 min prep meeting with MM&C, Catering, Security and ISERV to discuss the practicalities of the meeting (e.g. coffee breaks, red badges, registration table etc.).	AST
23	Prepare an annotated Agenda for the ENCePP team and briefing notes for the Chair. Add any relevant comments/notes that the Chair needs to know or announce to the Plenary.	AST
24	Prepare a list of participants and give to Reception (for access reasons and preparation of visitor badges) and to MM&C (for preparation of name plates).	AST
25	Prepare a seating plan for the meeting room. Speakers should be at the front in inner row. The remaining delegates are placed in alphabetical order by country. Observers will be on a separate row.	AST



Step	Action	Responsibility
	Use a seating plan template.	
26	Send short announcement text and draft Agenda to the 'News editors' mailbox the day before the meeting at the latest for publication on EMA Plus internal web page on the day of the meeting.	AST
27	Prepare meeting packs. The meeting pack includes a draft Agenda, List of Participants and any documents that are considered necessary to facilitate the discussion. Give relevant documents to reprographics for copying by day before the meeting. All presentations will be displayed in the room and published on ENCePP website after the meeting. Generally, no paper copies of presentations will be prepared for delegates.	AST
28	Prepare meeting room, if possible the afternoon before the ENCePP Plenary meeting. Liaise with MM&C regarding placing of name plates. Place one meeting pack with each name plate. Check that the AV equipment in the meeting room is working.	AST
29	Liaise with Reception and MM&C for any last minute changes in participation to ensure that all delegates are listed in MMS III and are given access to the building.	AST
<b>DURING THE MEETING</b>		
30	Ensure draft Agenda is adopted.	HoS
31	Show presentations on screens. Assist by showing and operating presentations on screens.	AST
32	Assist delegates as needed on the day.	AST
33	Provide general support to the ENCePP Plenary in the meeting room as required.	AD
34	Take notes of meeting discussions to facilitate Meeting Report preparation.	AD
<b>AFTER THE MEETING</b>		
35	Prepare Meeting Report. Send the report to ENCePP team for internal comments/agreement.	AD
36	Finalise List of Participants according to the attendance list received from MM&C after the meeting.	AST
37	Check with external speakers for publication of their presentation. Send an email to each external speaker asking for approval to publish their presentation on the ENCePP website.	AST
38	Publish Meeting Report, List of Participants and presentations on ENCePP website. Use a TS Event transmission slip in File\New\Templates\TS – Event. Fill in the requested information, put a hard copy of each document to be published in the sign off	AST

Step	Action	Responsibility
	folder and circulate for sign-off.	
39	Ensure that any actions arising from the Plenary are followed up as appropriate.	AD

## 10. Records

Meeting related documents (Agenda, List of Participants, Presentations, Meeting report) are saved electronically in a relevant sub folder of the meeting folder, per year and meeting date:

DREAM/Cabinets/13. Projects\ENCePP\Meetings\Plenary Meetings

ENCePP Plenary meeting invitations are filed in Outlook under:

Public folders / All Public folders / Chrono out / Chrono MMS Invitation

Meeting related email correspondence is located in Outlook under:

Public folders / All Public folders / Chrono in / Workflow / ENCePP Secretariat