



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Organisation of EMA Human Scientific Committees' Working Party meetings with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP)		
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1. Purpose

The purpose of this SOP is to ensure planning, preparation and effective support, of the PCWP and HCPWP meetings (including training sessions, joint meetings and any other ad-hoc PCWP/HCPWP related meetings and workshops).

2. Scope

This SOP applies to the Patients and Healthcare Professionals Department (S-PH) in the Stakeholders and Communication Division.

3. Responsibilities

It is the responsibility of the Head of Department to ensure that this procedure is adhered to. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section **9. Procedure**.

4. Changes since last revision

The SOP has been updated to bring procedural aspects up-to-date; reflect the new organisational structure at the Agency; to include the HCPWP and to improve general language.

Revision of the following took place:



1. title of SOP changed to 'Organisation of EMA Human Scientific Committees' Working Party meetings with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP)'
2. section 5 Documents needed for this SOP:
 - 2.1. update of templates for agendas, tables of actions, minutes, lists of participants, cover pages, request form for eligibility of special daily allowance and the accompanying guidance document
 - 2.2. removal of templates for the declaration of interests and confidentiality undertaking and the nomination form for European experts as these are available through the expert database
 - 2.3. removal of the CV template as this is now done electronically
 - 2.4. removal of the electronic visitor request form as delegates are invited through MMS
 - 2.5. inclusion of new template 'email to speakers requesting presentations'.
3. section 6 Related documents and webpages:
 - 3.1. removal of MMS user manual as superseded by electronic link on delegate page in MMSe
 - 3.2. inclusion of HCPWP Mandate and rules of procedure
4. section 7 Definitions:
 - 4.1. inclusion of definitions for eCV, eDOI, HCPWP, Hdiv, Hdep, MB, S-PH
 - 4.2. removal of definitions for CV, DOI, HoU, SH, P-MI, P-MI-PIN
5. section 9 Procedure:
 - 5.1. changes to entire section to reflect procedural changes, new organisational structure and inclusion of HCPWP
6. section 10 Records:
 - 6.1. update of DREAM locations

5. Documents needed for this SOP

- Templates for agendas – named 'Template_Agenda HCPWP'; 'Template_Agenda PCWP'; and 'Template_Agenda joint PCWP-HCPWP'
- Templates for Lists of Participants (LoPs) – named 'Template_LoP HCPWP'; 'Template_LoP PCWP'; and 'Template_LoP joint PCWP-HCPWP'
- Templates for minutes – named 'Template_Minutes HCPWP'; 'Template_Minutes PCWP'; and 'Template_Minutes joint PCWP-HCPWP'
- Templates for tables of actions – named 'Template_ToA HCPWP'; 'Template_ToA PCWP'; and 'Template_ToA joint PCWP-HCPWP'
- Template email to speakers requesting presentations
- Request form for eligibility of special daily allowance and accompanying guidance document

All the above templates are available in DREAM under: Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CxMP - PCWP/1. Governance/10. Templates; and under:

Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CxMP - HCPWP/1. Governance/10. Templates

- Photocopy request form - available from reprographics
- Transmission slip for publication of general web content – available in Word-file-new-My templates-more-transmission slips-TS-general content
- Transmission slip for publication of event on web - available in Word-file-new-My templates-more-transmission slips-TS-event
- News form – available in Outlook-New items-more items-choose form-news form - follow instructions on the intranet for submitting a news item
- Broadcast/Recording Request Form – available from the Communication Service
- Event Request Form (needed for training sessions) – available from the Meeting and Conference Management Department

6. Related documents and webpages

- ECD user guide for ECD managers – available from IT service helpdesk
- DREAM user manual – available from IT service helpdesk
- European Medicines Agency policy on the handling of conflicts of interests of scientific committee members and experts (EMA/513078/2010) – available on the external website under About us/How we work/Conflicts of interest/Policy for scientific experts/Policy 44: Handling of conflicts of interest of scientific committee members and experts:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097905.pdf
- Delegate welcome page: <https://mmse.ema.europa.eu/mmse/welcome.do>
- Mandate, objectives and rules of procedure for the European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) (EMA/369907/2010) – available on the external website under: Committees/Working parties and other groups/CHMP/ Patients' and Consumers' Working Party/Mandate, objectives and rules of procedure:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/02/WC500073497.pdf
- Mandate, objectives and rules of procedure for the European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) (EMA/36437/2013) – available on the external website under: Committees/Working parties and other groups/CHMP/ Healthcare Professionals' Working Party/Mandate, objectives and rules of procedure:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/07/WC500145741.pdf

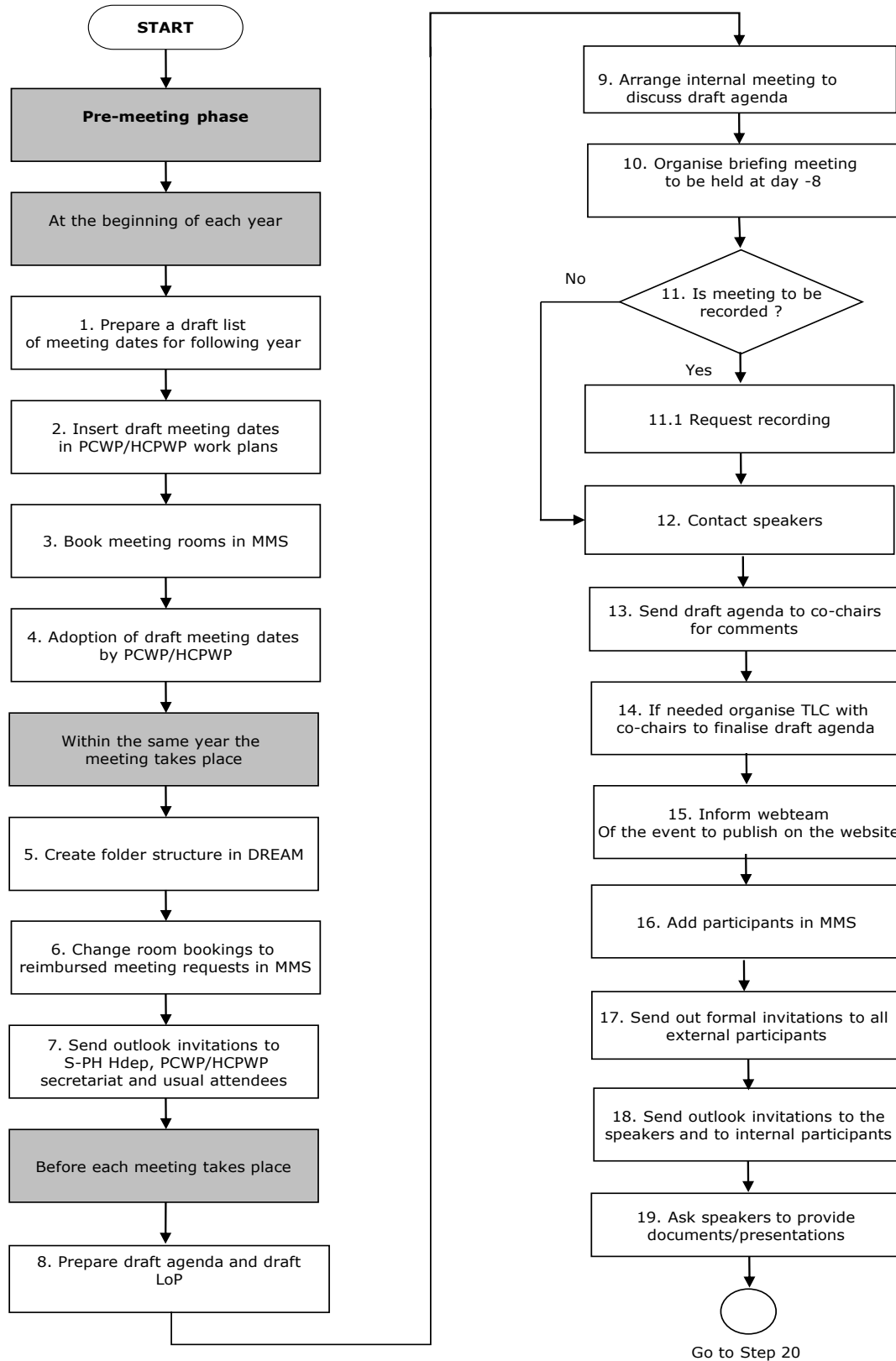
7. Definitions

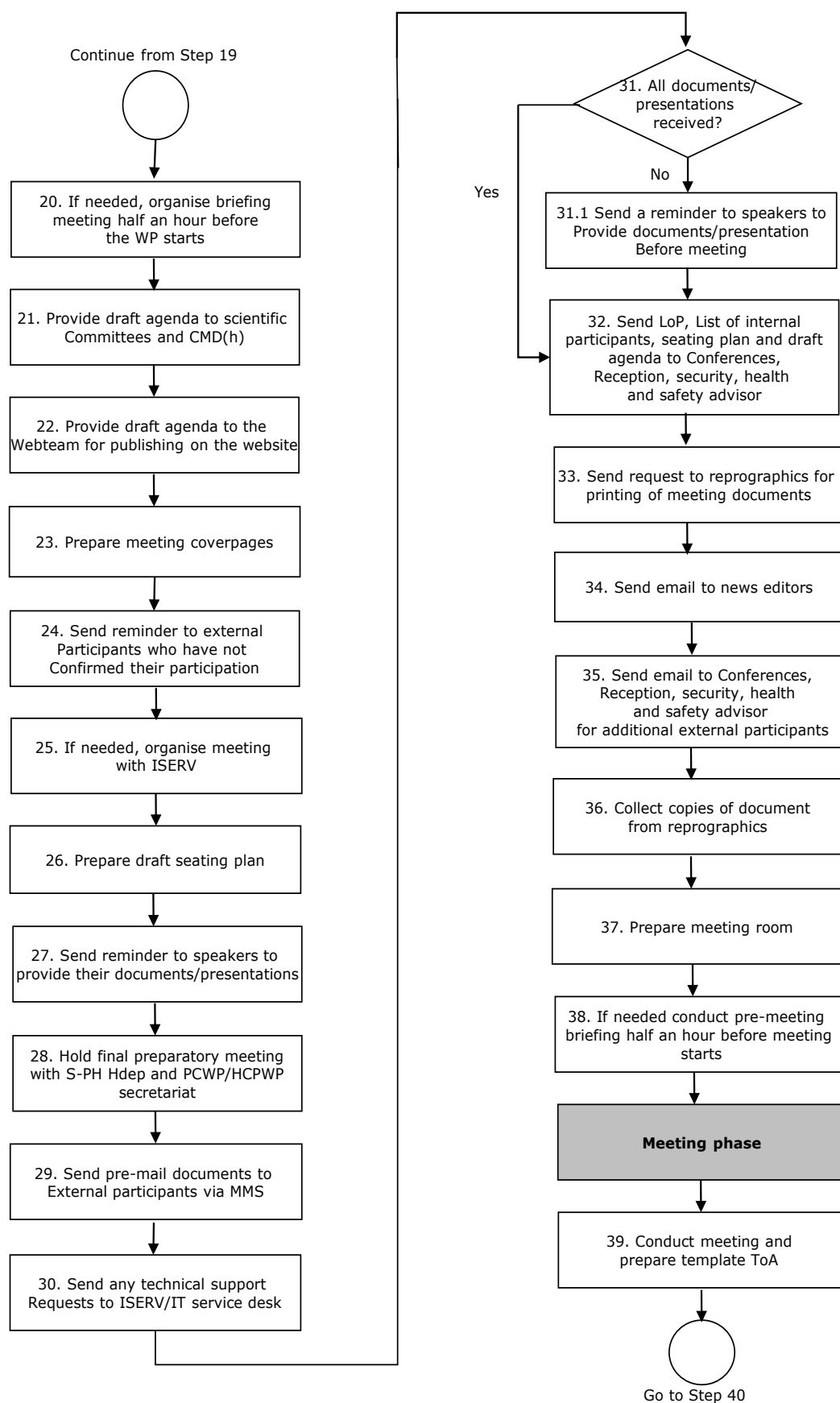
In this procedure the following abbreviations are used:

AD	Administrator (in S-PH)
AST	Assistant (in S-PH)
CMD(h)	Coordination Group for Mutual Recognition and Decentralised Procedures–Human

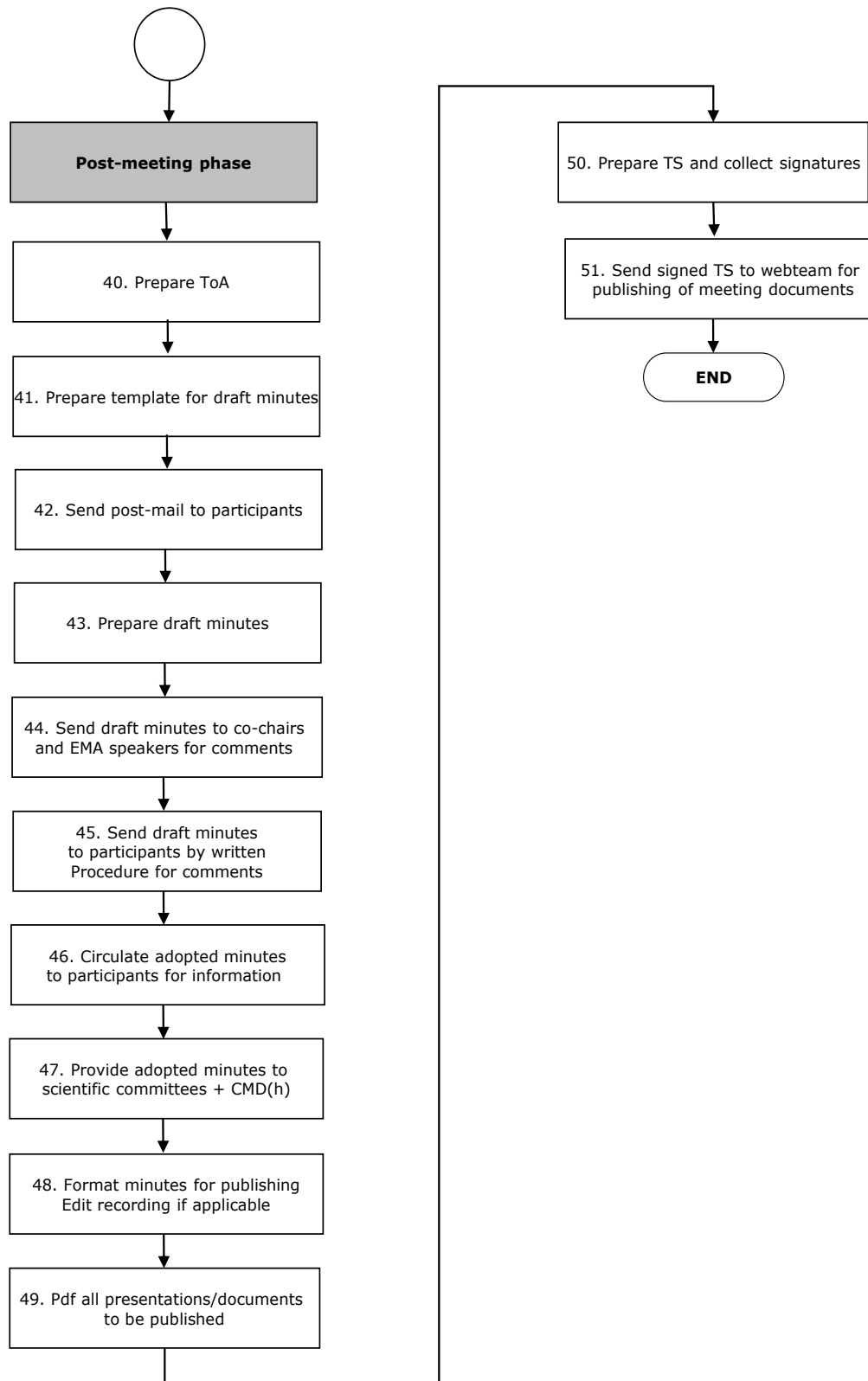
DDA	Double daily allowance
eDoI	Electronic public declaration of interests and confidentiality undertaking of European Medicines Agency (EMA) management board members, scientific committee members and experts
DREAM	Document Records Electronic Archive Management
ECD	Eudra Common Directory
eCV	Electronic Curriculum Vitae
HCPWP	EMA Scientific Committees' Working Party with Healthcare Professionals' Organisations
Hdep	Head of Department (of Patients and Healthcare Professionals Department (S-PH))
Hdiv	Head of Division (of Stakeholders and Communication Division (S))
LoP	List of participants
MB	EMA Management Board
MMS	Meeting Management System
PCWP	EMA Scientific Committees' Working Party with Patients' and Consumers' Organisations
S-PH	Patients and Healthcare Professionals Department
ToA	Table of actions
TS	Transmission slip
WP	Working party

8. Process maps/flow charts





Continue from Step 39.



9. Procedure

Step	Action	Responsibility
Pre-meeting phase		
At the beginning of each year		
1	Prepare a draft list of meeting dates for the following 2 years for approval by the PCWP/HCPWP co-chairs and secretariat. Ensure dates do not clash with scientific committee meetings; MB meetings (if possible arrange WP meetings 1 week before MB meetings, especially in June); DIA meetings; and any other relevant meetings or EMA/UK bank holidays. Ensure room availability.	AST/AD
2	Once agreed, insert draft meeting dates in PCWP/HCPWP Work Plans.	AST
3	Book meeting rooms for following 2 years using MMS (refer to MMS user manual for instructions). Remember to book the meeting room for the afternoon of the day before the meeting for room preparation. Note: Room bookings for meetings taking place in the following year(s) can be booked with an allocated budget but can only be transformed into meeting requests the same year the meeting is taking place (according to MMS).	AST
4	Include the draft list of meeting dates on the next PCWP and HCPWP meeting agenda for adoption by the members. If any dates are amended/cancelled, update/release the room booking accordingly.	AST
Within the same year the meeting takes place		
5	Create the folder structure in DREAM for each meeting date containing the following subfolders entitled: Agenda and LoP Documents and Presentations Minutes and Post-meeting actions Pre-mail Pre-meeting actions and correspondence The PCWP and HCPWP folders are located in DREAM under: Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CxMP – PCWP/2. Meeting Organisation/<year>/<date>, and under Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/ CxMP – HCPWP/2. Meeting Organisation/<year>/<date>. For joint meetings ensure links in each folder.	AST
6	Change room bookings in MMS into reimbursed meeting requests within the first quarter of the year (refer to MMS user manual for instructions).	AST
7	Send internal Outlook invitations blocking the meeting day(s) in the calendars of S-PH Hdep, PCWP/HCPWP secretariat and usual attendees.	AST

Step	Action	Responsibility
Before each meeting takes place (day 0 is the meeting day)		
8	By day –45 Prepare draft agenda (including list of potential speakers). Prepare draft LoP. Save draft agenda and LoP in the relevant meeting folder in DREAM (see step 5 for location).	AD/AST
9	By day –44 Arrange and have meeting with S-PH Hdep and PCWP/HCPWP secretariat for discussion of draft agenda.	AD/AST
10	Send Outlook invitation to S-PH-Hdep and PCWP/HCPWP secretariat for briefing meeting to be held at day -8 (see step 28).	AST
11	Is WP meeting to be recorded? Yes: got to step 11.1 No: go to step 12.	AST
11.1	Request recording from Communication Department.	AD/AST
12	By day –43 Contact speakers to confirm availability or arrange alternatives.	AD
13	By day –40 Send draft agenda to external co-chair(s) for comments within 5 days.	AD/AST
14	By day -35 If needed, organise a teleconference with the S-PH Hdep, the PCWP/HCPWP secretariat and the co-chair(s) to finalise the draft agenda.	AD/AST
15	By day –34 Inform the Webteam of the meeting date(s) to be published on the external website under the section 'News & events' (use TS for events). Agenda to be published later, see step 22.	AST
16	By day -33 Add participants to the meeting in MMS (refer to MMS user manual for instructions). Note: new participants will have to be entered into ECD first.	AST
17	By day –30 Send out formal invitations to all external participants (including both reimbursed and non-reimbursed participants as per budget allocated) using MMS. Then send the draft agenda through MMS to the external participants. Monitor accepted/declined invitations and update MMS and LoP as necessary.	AST
18	By day –29 Send outlook invitations to the speakers and any other EMA participants for specific topics identifying the time slot.	AST
19	Ask all speakers to provide documents/presentations by day -14 (see template 'email to speakers requesting presentations'). Save documents/presentations in respective meeting folder.	AD/AST
20	If needed, send outlook invitations/email to the S-PH Hdep, the PCWP/HCPWP administrators and the external co-chair(s) to meet half an hour before WP meeting starts (see step 38).	AST
21	By day –15	AST

Step	Action	Responsibility
	Provide scientific committee secretariats (except PRAC as they do not table documents which are for information) and CMD(h) secretariats with draft agenda(s) prior to their respective meetings, for information. To be tabled via MMD for those secretariats using it, otherwise email a link.	
22	Provide the Webteam with the draft agenda for publishing under the 'News & events' section on the external website (use TS for events).	AST
23	Prepare meeting cover pages, list of internal nameplates and list of newcomers and save them in the relevant DREAM folder.	AST
24	By day -14 Send reminder to external participants who have not yet confirmed their attendance. Check if available budget. If yes send email for additional observers.	AST
25	If needed, organise meeting with ISERV to discuss meeting needs concerning catering, poster stands, health and safety, reception etc. ¹	ISERV/AST
26	Prepare a draft seating plan according to the LoP.	AST
27	By day -10 Send reminder to speakers who have not yet sent their documents/ presentations.	AST
28	By day -8 Hold final preparatory meeting with S-PH Hdep and PCWP/HCPWP secretariat with print-outs of all meeting documents (update meeting documents after meeting, if necessary). Review which documents can be sent in the pre-mail.	AST/AD
29	By day -7 Send pre-mail documents via MMS to the meeting participants including: 1. draft agenda; 2. draft list of participants; 3. documents/presentations as agreed during final preparatory meeting (except for workshops). 4. Application form and accompanying guidance document for DDA (not in case of training sessions, or workshops unless speakers). Zip all documents together and save in the meeting folder in DREAM.	AST/AD
30	By day -5 Send any technical support requests to ISERV/IT service desk (e.g. computer and audio-visual support, requesting laptops etc).	AST
31	By day -4 All documents/presentations received? No: go to step 31.1 Yes: go to step 32.	AST

¹ For workshops ISERV arrange this briefing meeting, for usual PCWP/HCPWP meetings the S-PH assistant arranges a briefing meeting if necessary.

Step	Action	Responsibility
31.1	Contact speaker directly by email, with a reminder to send documents/presentations before the day of the meeting.	AD/AST
32	By day –2 Send list of participants, list of internal nameplates, seating plan and draft agenda to Meeting and Conference Organisation colleagues, reception, security, and health and safety colleagues. Include details of any mobility/visually impaired etc delegates.	AST
33	Send request to reprographics for printing of meeting documents using a photocopy request form. For training sessions, check if any documents need to be printed (e.g. Agency Work Plan, Training Manual) for tabling at the meeting and include if necessary.	AST
34	Send email to the news editors for the publishing of a message on the agency news section of the intranet on the day the meeting is taking place. Message to contain the following: 1. title and time(s) of the meeting(s) and meeting room(s); 2. short text describing the meeting(s); 3. draft agenda(s) to be linked.	AST
35	By day –1 Send email to Meeting and Conference Organisation colleagues, reception, security and health and safety colleagues informing of any additional participants who confirmed attendance or apologies after the 48 hour cut-off point.	AST
36	Collect copies of documents from reprographics for circulation at the meeting and give a pack to the PCWP/HCPWP secretariat and internal co-chair. Also give the internal co-chair the list of newcomers and any apologies and the seating plan.	AST
37	Prepare meeting room. Ensure wireless connection code slips are already in the room, otherwise collect from IT.	AST
38	Day 0 If needed, conduct pre-meeting briefing with relevant Working Party secretariat and all co-chairs half an hour before start of meeting.	AD
Meeting phase		
39	Conduct meeting.	AD
	Prepare template for ToA and save in the relevant folder in DREAM.	AST
Post-meeting phase		
40	By day +1 Prepare table of actions. Obtain agreement from EMA chair and send to all participants.	AD
41	By day +2 Prepare template for draft minutes and include participants and save in the relevant folder in DREAM.	AST
42	By day +5 Send post-mail pack to all participants via MMS. ZIP all documents together and save in the relevant folder in DREAM.	AST

Step	Action	Responsibility
43	Prepare draft minutes.	AD
44	By day +14 Send draft minutes to all co-chairs and EMA speakers for comments within 5 days. Check with speakers/document owners that their presentations/documents can be published.	AD
45	By day +20 Send draft minutes by written procedure for comments to external participants and speakers, informing that if no comments are received, the document will be considered adopted (7 days later).	AST
46	By day +27 Remove the word "Draft" from the title of the minutes. Circulate adopted minutes for information to participants via MMS.	AST
47	Provide adopted minutes to scientific committees (except PRAC as they do not table documents which are for information) and CMD(h), to be circulated for information. Document to be tabled via DREAM or a link sent, as appropriate (refer to DREAM user manual for instructions).	AST
48	By day +28 Format minutes for publishing. Edit recording if applicable.	AST AD
49	PDF all presentations (removing any notes) and documents to be published. Save on the G Drive under External Information Draft/Sign off/S-Division/S-PH.	AST
50	Prepare TS and print outs of all meeting documents to be published and circulate in a sign-off folder for signature by S-PH Hdep and PCWP/HCPWP administrators. If the meeting was recorded insert the link for the Webteam to publish.	AST
51	By day +30 Send signed TS to the webteam for publishing the meeting documents on the EMA external website on the relevant PCWP/HCPWP webpage(s). The links to include in the TS are one or more of the following, depending on the meeting: Committees/Working parties and other groups/Patients' and Consumers' Working Party/meetings/<year>: http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000318.jsp&mid=WC0b01ac0580289efe Committees/Working parties and other groups/Healthcare Professionals' Working Party/meetings/<year>: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000580.jsp&mid=WC0b01ac05806a7aa4 Partners & Networks/Patients and consumers/Training & support/In-house training sessions: http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000575.jsp&mid=WC0b01ac058077ce81#In-house training sessions	AST

Step	Action	Responsibility
	Once the meeting documents are published, send an email to the external participants including a link to the relevant webpage informing them of publication.	

10. Records

All PCWP and HCPWP meeting related documents (including pre/post-meeting mailings) are stored electronically in the following folders in DREAM:

Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CxMP - PCWP/2. Meeting Organisation /<year>/<date>

Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CxMP - HCPWP/2. Meeting Organisation /<year>/<date>

Cabinets/09. Relationship management and communication/09.1 Stakeholder liaison/06 Joint interaction PCOs & HCPs/Workshops & conferences /<year>/<date>