



Work instructions

Title: Organisation of scientific advice and protocol assistance pre-submission meetings		
Applies to: H-HM-SA		
Status: PUBLIC		Document no.: WIN/H/3035
Lead Author	Approver	Effective Date: 24-JUN-13
Name: Maria Rivero-Gonzalez	Name: Spiros Vamvakas	Review Date: 24-JUN-16
Signature: On file	Signature: On file	Supersedes: WIN/H/3035 (01-JUL-08)
Date: 20-JUN-13	Date: 20-JUN-13	TrackWise record no.: 3339

1. Changes since last revision

- Streamlining of process reducing the amount of emails sent to applicant
- Coordinators participation is no longer required
- Post-meeting timelines not created
- Extension of deadlines for receipt of packages
- Shortening of deadline for sending List of Comments

2. Records

All documents are saved electronically only by product name and year in DREAM under:

- Cabinets/01. Evaluation of Medicine/SA/H/2-New & Ongoing Requests/201X/[SAWP date]/
'with pre-sub'

All emails pertaining to the scheduling of the meeting are saved under subfolder '08 Pre-submission'. These include invitations, confirmations, list of participants, teleconference arrangements and the list of comments. A subfolder is also created to store the draft package to be used at the pre-submission meeting and includes the presentation.

No paper copies of these documents are archived.

3. Related documents

WIN/H/3039: Validation of scientific advice/protocol assistance request



4. Documents related to these WIN

All templates listed below are located at X:\Templates\Others\H – Scientific advice

- Template 1: Tentative applicant invitation to pre-submission meeting
Template 2: Email to applicant about logistics relating to meeting
Template 3: EMA invitation to pre-submission meeting
Template 4: List of comments following pre-submission meeting

5. Definitions

- DREAM: Document records electronic archive management
EudraLink: System for secure transmission of e-mails and file attachments
HoS: Head of Sector
H-HM-OD: Orphan Medicines Section
H-HM-PDM: Paediatric Medicines Section
H-HM-SA: Scientific Advice Section
H-QM: Quality of Medicines Sector
H-SE: Safety and Efficacy Sector
LoI: Letter of intent
P-R-RA: Regulatory Affairs Section
P-CI: Compliance and Inspection Sector
PA: Protocol assistance
PTL/M: Product team leader/member
SH: Section Head
SAA: Scientific advice administrator
Sec: Secretary

6. Instructions

Step	Action	Responsibility
Organisation of pre-submission meeting		
1	Within 10 working days after the deadline for receiving LoIs: <ul style="list-style-type: none">• identify relevant EMA meeting participants from the following (consult with SAA if necessary):<ul style="list-style-type: none">– Core members: H-HM-SA, H-HM-SSP.– Optional: H-QM SH, P-R-RA SH, H-HM-PDM SH, P-CI HoS secretary for identification of participant(s).	Sec

Step	Action	Responsibility
	<ul style="list-style-type: none"> Identify suitable meeting date taking into account participants' availability, scheduled monthly scientific meetings, meeting rooms availability and applicant's request for specific dates. Ensure SAA in charge of the procedure is available on chosen date. If not, ask SAA to find suitable cover amongst the SA SAA. Book meeting room. 	
2	<p>Send invitation to applicant (Template 1).</p> <p>Send email (Template 2) about meeting logistics and request for background information (electronic only) to reach EMA at least 5 working days prior to the meeting or as per agreed date.</p>	Sec
3	Send invitation to EMA participants via Outlook including a link to the relevant DREAM folder where the documents will be saved by a specified date (Template 3). Request participants to review documentation prior to the meeting.	Sec
4	On receipt of the reply from the applicant, provide paper copy of main parts of the documentation to SA/PA Project Manager.	Sec
5	Agree on additional SAA participation if necessary (2 EMA participants minimum per meeting).	SAA
6	Make sure that relevant participants are joining the meeting (e.g. quality experts if quality questions are being asked).	SAA
7	Submit visitor requests for applicant's participants.	Sec
	Pre-submission meeting	
8	Make necessary technical arrangements for displaying applicant's presentation slides during meeting (computer/wireless mouse).	Sec
9	<p>Set up meeting room and applicant's presentation slides on computer.</p> <p>Accompany applicant to meeting room.</p>	Sec
10	Hold internal discussion prior to meeting with the applicant (max. 15 minutes).	SAA
11	Discuss the questions and structure of the package (see WIN/H/3039 for detailed information on what should be in the package).	SAA
12	Draft the list of comments (Template 4) and circulate it to the other EMA meeting participants for comments.	SAA
13	Finalise the list of comments.	SAA
14	Send list of comments to applicant within 2 working days after meeting.	Sec