



Standard operating procedure

Title: Arrangements for handling of conflicts of interests for EMA scientific meetings		
Status: PUBLIC		Document no.: SOP/EMA/0126
Lead author	Approver	Effective date: 08-OCT-12
Name: Sheila Kennedy	Name: Guido Rasi	Review date: 08-OCT-15
Signature: PUBLIC	Signature: PUBLIC	Supersedes: N/A
Date: 19-SEP-12	Date: 05-OCT-12	TrackWise record no.: 3716

1. Purpose

To describe the procedure for handling of conflicts of interests at the level of the European Medicines Agency's scientific meetings, i.e. the risk minimisation measures and documented evidence in relation to conflicts of interests for meeting participants (members, alternates and other experts) before, during and after the meeting.

2. Scope

This SOP applies to administrators, assistants and secretaries in the secretariats of the Scientific Committees, Working Parties, Drafting Groups, Working Groups, Scientific Advisory Groups, Ad Hoc Expert Groups and other groups of the European Medicines Agency.

This SOP is applicable to meeting participants falling within the scope of the 'European Medicines Agency policy on the handling of conflicts of interests of Scientific Committee members and experts' attending a Scientific Committee, Working Party, Drafting Group, Working Group, Scientific Advisory Group, Ad Hoc Expert Group or other group meeting at the Agency, i.e. face-to-face meeting, virtual meeting e.g. via Vitero or Adobe connect, participation in the meeting via teleconference or participating in a written (consultation) procedure of that body.

The SOP does not apply to:

- NCA staff and experts participating in the work at national level for services provided to the Agency as covered by the Memorandum of Understanding between the Agency and the NCAs (e.g. meetings in the context of assessment falling under the role of the Rapporteur (pre-submission meeting, (co-)rapporteurs meetings with companies, peer review meetings, FDA teleconference, etc.). However, if NCA staff or experts attend a Scientific Committee, Working Party, Drafting



Group, Working Group, Scientific Advisory Group or Ad Hoc Expert Group meeting at the Agency, the SOP becomes applicable;

- members, alternates and experts attending a training, conference or workshop (e.g. public discussion during guidance development) held at the Agency including participants not pertaining to NCAs (e.g. industry);
- observers from non EU countries attending a Scientific Committee, Working Party, Drafting Group, Working Group, Scientific Advisory Group or Ad Hoc Expert Group meeting at the Agency.

3. Responsibilities

It is the responsibility of each Head of Unit, Head of Sector and Section Head to ensure that this procedure is adhered to within his/her own Unit, Sector and Section. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

New SOP

5. Documents needed for this SOP

- Electronic Declaration of Interest and Confidentiality Undertaking form (template located in the Expert database)
- Evaluation of Conflicts of Interests form (template located in Excel\File\New\On my computer\Experts and in X:\Templates\Filenew\Experts)
- Meeting Agenda or specific meeting document
- SOP/EMA/0040 – Evaluation of conflicts of interests of experts for involvement in EMA activities

6. Related documents

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, in particular Art. 63.2 (http://ec.europa.eu/health/files/eudralex/vol-1/reg_2004_726_cons/reg_2004_726_cons_en.pdf)
- EMEA Code of Conduct (EMEA/6470/03/2368) (Intranet: Integrated management system\Quality Manual\Policies; Internet: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000178.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028c78# - Home>About Us\Committees\Handling conflicts of interest)
- European Medicines Agency policy on the handling of conflicts of interests of Scientific Committee members and experts (Policy/0044) (Intranet: Integrated management system\Quality Manual\Policies; Internet: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000178.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028c78# - Home>About Us\Committees\Handling conflicts of interest)
- Overview of the allowable interests for the EMA scientific activities (EMA/358101/2010) (Internet: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000178.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028c78#)

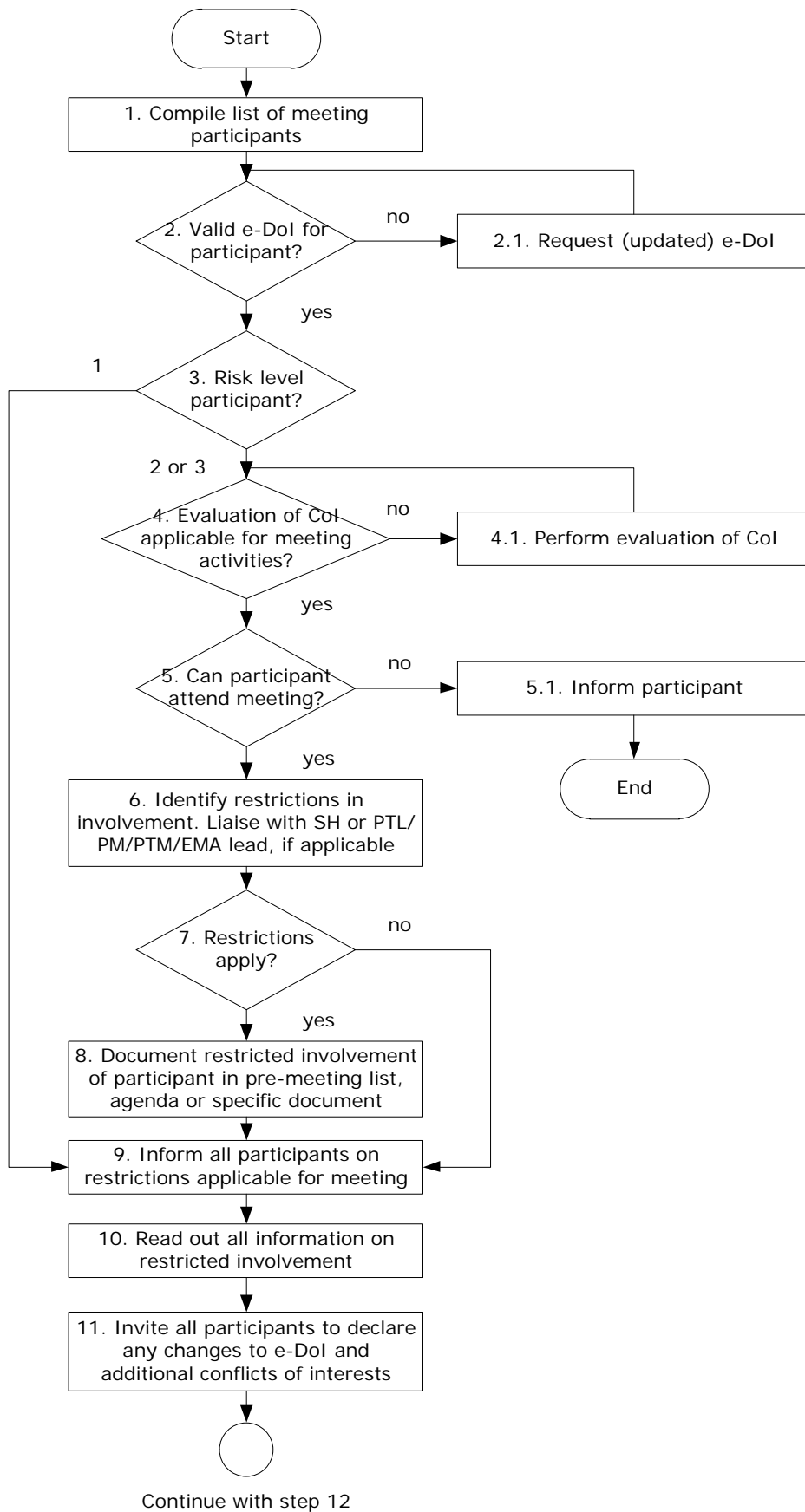
[g_000178.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028c78#](#) - Home\About Us\Committees\Handling conflicts of interest)

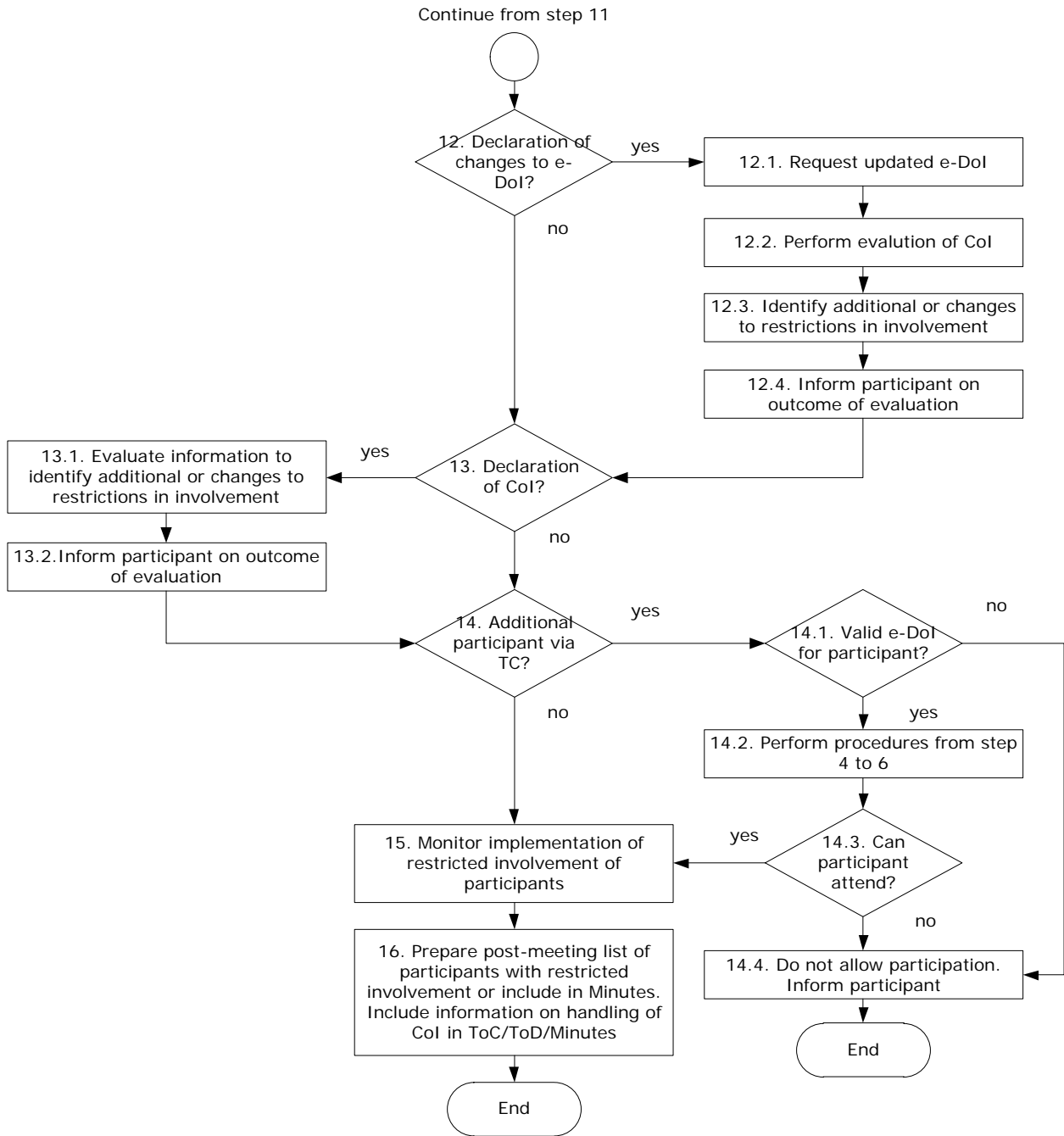
- Procedural guidance on inclusion of declared interests in European Medicines Agency's electronic declaration of interests form (EMA/123723/2012)

7. Definitions

CoI:	Conflicts of interests
DREAM:	Document Records and Electronic Archive Management system
e-DoI:	Electronic declaration of interests and confidentiality undertaking form
EMA:	European Medicines Agency
HoS:	Head of Sector
HoU:	Head of Unit
MMD:	Managing Meeting Documents system
PM:	Product manager
PTL:	Product team leader
PTM:	Product team member
Secr AD:	Administrator in the meeting secretariat
Secr AST:	Assistant/secretary in the meeting secretariat
SH:	Section Head
TC:	Teleconference
ToC:	Table of conclusions
ToD:	Table of decisions

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





9. Procedure

Step	Action	Responsibility
Pre-meeting		
1	Compile a list of participants to the meeting, attending in person or via teleconference.	Secr AST
2	Verify for each meeting participant if a valid e-DoI exists and a risk level has been assigned (green status and risk level in the Experts database). If yes, go to step 3. If no, go to step 2.1.	Secr AST
2.1	Request the meeting participant to submit an (updated) e-DoI. Return to step 2.	Secr AST
3	For meeting participants with risk level 1, continue with step 9. For meeting participants with risk level 2 or 3, go to step 4.	Secr AST
4	Verify for each participant with risk level 2 or 3, if an evaluation of the conflicts of interests on the current e-DoI for the meeting activities exists and if the outcome of this evaluation is still applicable (in particular with regard to the time frames for restrictions for declared interests, e.g. interest > 0 and ≤ 2 years versus > 2 years). If yes, go to step 5. If no, go to step 4.1. <i>Note: An overview of the status of the e-DoI and evaluation of conflicts of interests form for participants attending a meeting regularly can be maintained by the meeting secretariat.</i>	Secr AST
4.1	Perform the evaluation of conflicts of interests for the meeting participant for involvement in the meeting activities in accordance with SOP/EMA/0040. Return to step 4.	Secr AD
5	Determine if the participant can attend the meeting. If yes (with or without restrictions), go to step 6. If no (no involvement), go to step 5.1.	Secr AD
5.1	Inform the participant by e-mail that he/she is not allowed to attend the meeting. Save the communication to the participant in DREAM. End of procedure. <i>Note: Template 3 from SOP/EMA/0040 could be used for this</i>	Secr AD

Step	Action	Responsibility
	<i>purpose.</i>	
6	<p>Identify restricted involvement of the meeting participant for items (medicinal products, guidelines, etc) on the draft agenda of the meeting based on the outcome of his/her evaluation of conflicts of interests.</p> <p><i>Note: An (rolling) overview of established conflicts of interests for participants attending a meeting regularly can be maintained by the meeting secretariat.</i></p> <p>If applicable, liaise with Section Heads or PTLs/PMs/PTMs/EMA leads responsible for a particular product/procedure/guideline/topic with regard to potential conflicts of interests for items on the meeting agenda.</p>	Secr AD
7	<p>If no restrictions apply to the meeting participant, continue with step 9.</p> <p>If restrictions apply to the meeting participant, go to step 8.</p>	Secr AD
8	<p>Document the restricted involvement of the participant for the meeting in a pre-meeting list of participants, the draft agenda or another specific meeting document. Give details on the restrictions applicable.</p> <p>Save the pre-meeting list, draft agenda or other specific meeting document in the meeting folder in DREAM.</p>	Secr AD
9	<p>Inform all participants on the restrictions applicable for the meeting by sending the pre-meeting list, agenda or other specific meeting document by e-mail or Eudralink or by making the document available in MMD.</p> <p>Put the PTLs/PMs/PTMs/EMA lead for the concerned product/procedure/guideline/topic in cc of the e-mail/Eudralink, in particular in case of restrictions in voting or as necessary.</p> <p>Save the e-mail/Eudralink message in the meeting folder in DREAM.</p>	Secr AST
During the meeting		
10	<p>At the start of the meeting, prior to any discussion of the agenda items, read out all information on restricted involvement of all identified participants or refer to the pre-meeting list as sent prior to the meeting and highlight the modifications made after the sending of the document.</p>	Secr AD
11	<p>Immediately following the announcement from step 10, invite all participants present to declare any changes to their current e-DoI, any additional conflicts of interests on items on the agenda or any changes, omissions or errors to already declared interests and/or</p>	Secr AD

Step	Action	Responsibility
	identified conflicts of interests.	
12	Does a meeting participant declare changes to his/her current e-DoI at the start or during the meeting? If no, go to step 13. If yes, go to step 12.1.	Secr AD
12.1	Prior to any further participation of the expert in the meeting, request the meeting participant to submit an updated e-DoI as soon as possible. <i>Note: In order not to interrupt his/her support to the meeting, the Secr AD can delegate under his/her responsibility the actions described in steps 12.1 to 12.4 to a colleague.</i>	Secr AD
12.2	Perform the evaluation of conflicts of interests for the meeting participant based on the updated e-DoI in accordance with SOP/EMA/0040.	Secr AD
12.3	Identify additional or changes to restrictions in involvement of the meeting participant for items on the meeting agenda based on the outcome of the evaluation of conflicts of interests.	Secr AD
12.4	Prior to the involvement in the meeting, inform the meeting participant on the outcome of the evaluation of conflicts of interests and on the impact of his/her participation or (restricted) involvement in the meeting. Save the communication to the participant in DREAM.	Secr AD
13	Are conflicts of interests on items on the meeting agenda declared by a meeting participant at the start or during the meeting? If no, go to step 14. If yes, go to step 13.1.	Secr AD
13.1	Prior to any further participation of the expert in the meeting, evaluate the information provided by the meeting participant against the items on the meeting agenda to identify potential additional changes to restrictions in involvement of the participant for items on the agenda. <i>Note: In order not to interrupt his/her support to the meeting, the Secr AD can delegate under his/her responsibility the actions described in steps 13.1 to 13.2 to a colleague.</i>	Secr AD
13.2	Prior to involvement in the meeting, inform the meeting participant on the outcome of the evaluation and on the impact of his/her participation or (restricted) involvement in the meeting. Save the communication to the participant in DREAM.	Secr AD

Step	Action	Responsibility
14	<p>Is an additional participant attending the meeting either in person or via teleconference which was not foreseen prior to the start of the meeting?</p> <p>If no, go to step 15.</p> <p>If yes, go to step 14.1</p>	Secr AD
14.1	<p>Prior to participation of the expert in the meeting, verify for the additional participant if a valid e-DoI exists and a risk level has been assigned (green status and risk level in the Experts database).</p> <p>If yes, go to step 14.2.</p> <p>If no, go to step 14.4.</p> <p><i>Note: In order not to interrupt his/her support to the meeting, the Secr AD can delegate under his/her responsibility the actions described in steps 14.1 to 14.4 to a colleague.</i></p>	Secr AD
14.2	Perform the procedure described in step 4 to 6 of this SOP.	Secr AD
14.3	<p>Can the additional participant attend the meeting?</p> <p>If yes, go to step 15.</p> <p>If no, go to step 14.4.</p>	Secr AD
14.4	<p>Do not allow the participant to attend the meeting.</p> <p>Inform the participant accordingly.</p> <p>Save the communication to the participant in DREAM.</p> <p>End of procedure.</p>	Secr AD
15	<p>Monitor the implementation of restricted involvement of participants (e.g. in terms of not participating in the discussions, not participating in the deliberations and voting).</p> <p>In case of non-compliance with the restrictions, immediately inform the Chairperson and the concerned participant.</p> <p><i>Note: Participants with restricted involvement are not required to leave the meeting room. Any participant who would like to leave the meeting room is allowed to do so.</i></p> <p>Remind the Chairperson in case restrictions apply to voting.</p> <p><i>Note: In case restrictions for voting apply to a member, the alternate is allowed to vote which is subsequently recorded in the ToC, ToD and/or Minutes.</i></p>	Secr AD
Post-meeting		
16	Prepare a post-meeting list of participants with restricted involvement for the meeting (as annex to the meeting Minutes) or	Secr AD

Step	Action	Responsibility
	<p>include the information in the meeting Minutes. Give details on the restrictions applicable for each participant (attending in person or via teleconference).</p>	
	<p>Include in the ToC, ToD, Minutes and/or annex to the meeting Minutes the following information:</p> <ul style="list-style-type: none"> • Statement that information on the restricted involvement of participants has been provided/read out by the meeting secretariat at the start of the meeting, including clarifications or additional information as required. • Statement that the meeting participants were invited to declare any changes to their current e-DoI and any conflicts of interests on the items on the agenda. • Statement that discussions, deliberations and voting have taken place in full respect of the restricted involvement of participants as announced by the meeting secretariat at the start of meeting. • Outcome of the evaluation of conflicts of interests and any changes to restrictions in involvement in the meeting for participants who declared changes to their current e-DoI and/or conflicts of interests on items on the meeting agenda at the start or during the meeting. • Information on replacement of a member by the alternate for voting in case restrictions for voting on a topic applied to the member. 	
	<p>Save the ToC, ToD and/or Minutes as well as the post-meeting list of participants in the meeting folder in DREAM.</p>	

10. Records

The meeting ToC, ToD and Minutes including the post-meeting list of participants with information on restricted involvement for the meeting are filed in the master file of the concerned meeting in paper or saved electronically in DREAM as per current practice (retention time: as specified for the concerned meeting in accordance with the business classification scheme).

Correspondence on conflicts of interests for meetings is saved in the meeting folder or the individual expert's folder in DREAM.