

5 May 2025
EMA/49128/2025
Stakeholders and Communication Division

Draft agenda – Training session for patients, consumers and healthcare professionals involved in medicines-related activities at EMA

Wednesday 2 July 2025, 09:30CEST – 16:15CEST (registration at 09:00CEST)
EMA meeting room 2A, breakout rooms 0C/0D/0E

Chair: Juan Garcia Burgos

Time	Agenda item	Speaker	Room
09:00	Registration and reimbursement arrangements		2A
09:30	Welcome and health and safety information, description of the day's objectives	Juan Garcia Burgos	
1. Scientific advice			
09:40	1.1. Presentation: Scientific advice and protocol assistance at EMA Learning outcomes: gain an understanding of what scientific advice is and its place in the regulatory pathway; understand where patients/consumers and healthcare professionals can contribute to the process	TBC	2A
10:0	Division into 4 breakout groups and introduction of trainers		2A
10:15	1.2. Breakout sessions on scientific advice Interactive discussion with EMA Scientific Officer and review of training document based on real documents used in scientific advice	EMA Scientific Officers	2A 0C 0D 0E
11:25	<i>Coffee break (15 minutes)</i>		
11:40	Short feedback and introduction to the next topic	Kaisa Immonen	

Time	Agenda item	Speaker	Room
2. Document reviews			
11:50	2.1. Presentation: Overview of document reviews Learning outcomes: Understanding the aim and scope of EMA documents and the purpose of the review; understand the structures of the documents; feel confident about reviewing documents	EMA Medical Writer	2A
12:15	<i>Lunch break (1 hour)</i>		
13:15	Division into 4 breakout groups and introduction of trainers		2A
13:25	2.2. Breakout sessions on document reviews Interactive session with EMA medical writers and review of training documents based on real EMA documents intended for patients/consumers and/or healthcare professionals	EMA medical writers	2A/ 0C 0D 0E
14:45	<i>Coffee break (15 minutes)</i>		
15:00	Short feedback and introduction to the next topic	Kaisa Immonen	
3. Involvement as patient or HCP expert in EMA activities			
15:10	3.1. How can you get involved in EMA activities? Learning objectives: gain an overview of opportunities for involvement, remuneration of experts, registration and submission of declaration of interests; Understand how EMA's policy on competing interests applies to patients/consumers and healthcare professionals	Maria Mavris / Kaisa Immonen	2A
15:30	Q&A	All	
Concluding session			
15:45	Feedback and quiz	Kaisa Immonen / Maria Mavris	
16:00	Conclusions	Juan Garcia Burgos	
16:15	<i>End of meeting and departures</i>		