17, 18, 20 October 2022
EMA/630927/2022
Stakeholders and Communication Division

Draft Agenda – Training sessions for patients, consumers and healthcare professionals involved in medicine regulatory activities

17 October 09:00 – 12:00 CEST – Virtual meeting
18 October 14:00 – 16:00 CEST – Virtual meeting
20 October 09:00 – 11:00 CEST – Virtual meeting

DAY 1: 17 October, 09:00hrs to 12:00hrs CEST

Chair: Juan Garcia-Burgos (EMA)

Time	Agenda item	Speaker
08:45	Connection to virtual room and technical checks	
1. Introduction		
09:00	Welcome and objectives of training sessions	Juan Garcia Burgos
09:15	1.1 Overview of regulatory pathway of a medicine	Maria Mavris
09:45	1.2 Introduction to breakout session and facilitators	Giulia Gabrielli
2. Breakout session		
09:55	2.1 **Scientific Advice:** Learning outcomes: gain an understanding of the relevant areas where patients and healthcare professionals can contribute, such as meaningful clinical trial endpoints, feasibility of trial design, etc.	Colleagues from Scientific Advice team
11:45	Feedback and conclusions	

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

DAY 2: 18 October, 14:00hrs to 16:00hrs CEST

Chair: Juan Garcia-Burgos (EMA)

Time	Agenda item	Speaker
13:45	Connection to virtual room and technical checks	
1. Introduction		
14:00	1.3 Introduction to breakout session and facilitators	Maria Mavris
2. Breakout session		
14:10	2.1 Document review – choice of medicine overview, safety communication or DHPC Learning outcomes: • Appreciate the aim and scope of the documents • Understand the structure of the documents • Feel confident about reviewing the documents	Colleagues from Medical writers' team
15:45	Feedback and conclusions	

DAY 3: 20 October, 09:00hrs to 11:00hrs CEST

Chair: Juan Garcia-Burgos (EMA)

Time	Agenda item	Speaker
08:45	Connection to virtual room and technical checks	
1. Introduction		
09:00	Welcome and objectives of training session	
09:05	1.1 Introduction to Health Technology Assessment (HTA) • General principles and differences between marketing authorisation and HTA • EUnetHTA 21 and EU HTA Regulation: Relevance of HTA and opportunities for expert involvement • Collaboration between HTAs and EMA under the HTA Regulation • Joint HTA Production: Joint Scientific Consultations (JSC) and Joint Clinical Assessment (JCA)	Colleagues from EUnetHTA 21: Anne Willemsen (ZIN) Maggie Galbraith (HAS) Daniel Ritter (G-BA) Stephanie Said (G-BA)
09:20	1.2 Introduction to breakout session and facilitators 2 breakout rooms: 1. Patients (and consumers) 2. Healthcare professionals	Colleagues from EUnetHTA21

Time	Agenda item	Speaker
2. Health Technology Assessment session		
09:30	2.1 **Expert involvement in JSC and JCA** Learning outcomes: • Gain an overview of the processes and opportunities for expert involvement • Get to know the purpose and scope of the documents and meetings for JSC and JCA • Understand what is expected from the expert • Understand the handling of confidentiality and conflict of interest by EUnetHTA 21	Colleagues from EUnetHTA21
10:45	Feedback and conclusions	