

24 November 2021 EMA/516784/2021 Stakeholders and Communication Division

Agenda - Annual PCWP/HCPWP meeting with all eligible organisations

24 November 2019, 13:20hrs to 16:30hrs

Co-Chairs: Juan Garcia Burgos (EMA), Kaisa Immonen (PCWP), Ulrich Jäger (HCPWP)

Time	Торіс	Speaker	
13:15	Joining and technical checks		
13:20	Welcome and introduction / Health and safety information	Co-Chairs	
1. Update on ongoing initiatives			
13:30	1.1 European collaboration between regulators and Health Technology Assessment (HTA) bodies	Michael Berntgen (EMA) Bruno Sepodes (CHMP)	
13:55	Q&A		
14:05	1.2 ICH E8 Guideline on general considerations for clinical studies	Fergus Sweeney (EMA) Spiros Vamvakas (EMA)	
14:25	1.3 Implementation of the clinical trials regulation	Pieter Vankeerberghen (EMA)	
14:40	Q&A		
14:50	1.4 Medicine repurposing pilot project	Cesar Hernandez Garcia (HMA)/ Christelle Bouygues (EMA)	
15:05	Q&A		
15:15	Coffee break		

 Temporary visiting address
 Spark building
 Orlyplein 24
 1043 DP Amsterdam
 The Netherlands

 For deliveries
 refer to www.ema.europa.eu/how-to-find-us

 Send us a question via www.ema.europa.eu/contacts
 Telephone +31(0)88 781 6000
 An agency of the European Union



 \odot European Medicines Agency, 2021. Reproduction is authorised provided the source is acknowledged.

Time	Торіс	Speaker	
2. Capturing challenges and priorities for 2021 and beyond			
15:25	2.1 Civil society members in EMA scientific committees: an overview	Maria Mavris (EMA)	
15:35	Q&A		
15:45	2.2 Future challenges and key priorities for patient and healthcare professionals' organisations	Co-Chairs	
15:55	Discussion		
3. AOB			
16:25	Wrap up and conclusion	Co-Chairs	
16:30	End of meeting		