



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 September 2021
EMA/364259/2021
Stakeholders and Communication Division

Agenda – PCWP/HCPWP joint meeting

21 & 22 September 2021, Virtual meeting

DAY 1: 21 September, 12:45hrs to 16:30hrs CET

Co-chairs: Juan Garcia-Burgos (EMA), Kaisa Immonen (PCWP), Ulrich Jaeger (HCPWP).

Time	Topics	Speaker
12:45	Joining and technical checks	
1. Introduction		
13:00	1.1 Opening remarks	Kaisa Immonen (PCWP) Ulrich Jaeger (HCPWP) Juan Garcia-Burgos (EMA)
2. COVID-19 update		
13:10	2.1 Update on vaccines and therapeutics	Marco Cavaleri (EMA)
13:30	2.2 Safety surveillance	Georgy Genov (EMA)
13:40	2.3 Results from user testing information materials on COVID-19 vaccines	Claudio Costantino (University of Palermo); Rosa Gonzalez-Quevedo (EMA)
13:50	Q&A	All
3. Impact of pharmacovigilance activities on healthcare and patient safety		
14:10	3.1 Enhancing engagement between PRAC and stakeholders	Priya Bahri (EMA) / Raymond Anderson/ Cathalijne van Doorne (PRAC)
14:25	Q&A	All

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



Time	Topics	Speaker
14:35	3.2 Update on new guidance on risk minimisation measures (GVP modules XVI RMM)	Nuria Semis-Costa/ Thomas Goedecke (EMA)
14:45	Q&A	All
14:50	3.3 Direct Healthcare Professional Communications: reflection on publication and dissemination of DHPCs	Tiago Villanueva (UEMO)/ Jan De Belie (PGEU)/ Morgane De Verdier (EMA)
15:20	Q&A	All
15:30	<i>Break</i>	
4. Clinical Trials		
15:40	4.1 Clinical Trial Regulation and Clinical Trials Information System (CTIS) - what changes in 2022	Fergus Sweeney (EMA)
15:55	4.2 CTIS: functionalities and support for clinical trial sponsors, availability of clinical trial data to the public	Fia Westerholm (EMA)
16:10	Q&A	All
16:25	Wrap up	Co-Chairs
16:30	<i>End of meeting</i>	

DAY 2: 22 September 2021, 09:15hrs to 12:45hrs CET

Co-chairs: Juan Garcia-Burgos (EMA), Kaisa Immonen (PCWP), Ulrich Jaeger (HCPWP).

Time	Topics	Speaker
09:15	Joining and technical checks	
09:30	Welcome	Kaisa Immonen (PCWP) Ulrich Jaeger (HCPWP) Juan Garcia-Burgos (EMA)
5. Update on Big Data		
09:40	5.1 Big Data Steering Group updated workplan and Clinical Trials Raw data project	Peter Arlett/ Francois Domergue/ Eftychia-Eirini Psarelli (EMA)
09:55	Q&A	All
10:10	5.2 Outcome of public consultation on the registry-based studies guideline	Virginie Hivert (EMA Cross-Committee Registries Task Force member)/ Xavier Kurz (EMA)
10:25	Q&A	All
10:35	<i>Break</i>	
6. Looking ahead into 2022		
10:45	6.1 PCWP/HCPWP workplan 2019-2022 and EMAN Strategy to 2025: topic prioritisation for 2022 6.2 Meetings for 2022 and related aspects 6.3 New mandate 2022-2025 and co-chair elections 6.4 Launch of annual re-assessment of eligibility	Nathalie Bere/ Ivana Silva (EMA)
11:15	Discussion	All
7. Update on EMA's Extended mandate		
11:45	7.1 Progress update 7.2 Plans for communication and stakeholder engagement	Hilde Boone (EMA) Melanie Carr (EMA)
12:00	Q&A	All
12:30	AOB	All
12:40	Wrap up	Co-chairs
12:45	<i>End of meeting</i>	