



01 March 2022  
EMA/15726/2022  
Stakeholders and Communication Division

## Agenda – PCWP/HCPWP joint meeting

2 - 3 March 2022, Virtual meeting

### DAY 1: 2 March, 12:45hrs to 16:45hrs CET

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

Time	Topics	Speaker
12:45	Joining and technical checks	
<b>1. Introduction</b>		
13:00	1.1 Opening remarks	Kaisa Immonen (PCWP) Ulrich Jaeger (HCPWP) Juan Garcia-Burgos (EMA)
<b>2. COVID-19 update</b>		
13:10	2.1 Update on vaccines and therapeutics	Marco Cavaleri (EMA)
13:25	2.2 Safety surveillance on vaccines and therapeutics	Priya Bahri (EMA)
13:40	Q&A	All
<b>3. Update on EMA projects and initiatives</b>		
14:00	3.1 Accelerating clinical trials in the EU (ACT-EU)	IJsbrand Den Rooijen, Fergus Sweeney, Frank Petavy (EMA)
14:20	Q&A	All
14:30	3.2 Big Data Steering Group (BDSG)	Jesper Kaejr (BDSG co-chair)
14:40	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](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



Time	Topics	Speaker
14:50	3.3 Data Analysis and Real World Interrogation Network (DARWIN-EU)	Andrej Segec (EMA)
15:00	Q&A	All
15:10	<i>Break</i>	
15:20	3.4 Electronic product information (ePI)	Elizabeth Scanlan (EMA)
15:35	Q&A	All
15:45	3.5 Nitrosamines impurities	Maria Filancia (EMA)
16:00	Q&A	All
<b>4. EMA Extended mandate</b>		
16:10	4.1 Engagement and Communication Plan	Inga Abed (EMA)
16:15	4.2 Preparation for multi-stakeholder workshop	Ivana Silva (EMA)
16:20	Q&A	All
16:30	<b>Wrap up</b>	Co-Chairs
16:45	<i>End of meeting</i>	

## DAY 2: 3 March 2021, 09:00hrs to 13:00hrs CET

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

Time	Topics	Speaker
09:00	Joining and technical checks	
09:15	Welcome	Kaisa Immonen (PCWP) Ulrich Jaeger (HCPWP) Juan Garcia-Burgos (EMA)
<b>5. Advanced Therapies (ATMPs)</b>		
09:20	5.1 Awareness raising on the development and evaluation of ATMPs	Ana Hidalgo, Patrick Celis (EMA)
09:50	Q&A	All
<b>6. Members' voice</b>		
10:15	6.1 European Federation for Primary Care <i>"Convey Family Medicine principles in Health care and in Pharmaceutical care"</i>	Pieter van den Hombergh (EFPC)
	6.2 European Hematology Association <i>"Recommendations for reducing bureaucracy in Clinical Trials"</i>	Natacha Bolaños (EHA)
	6.3 European Heart Network <i>"EU Medical Device Regulation implementation and availability of cardiac devices"</i>	Christine Dhen, Marilena Vrana (EHN)
	6.4 European Federation of Allergy and Airways Diseases <i>"Improving lung health through the future European Health Data Space"</i>	Isabel Proaño Gómez, Erna Botjes (EFA)
	6.5 International Patient Organisation for Primary Immunodeficiencies <i>"Status of Primary Immunodeficiency Healthcare"</i>	Jose Drabwell, Leire Solis (IPOPI)
11.45	Break	
<b>7. Looking ahead into 2022</b>		
12.00	7.1 Call for new mandate 2022-2025	Ivana Silva (EMA)
	7.2 PCWP/HCPWP workplan and EMAN Strategy to 2025: topic prioritisation	Nathalie Bere (EMA)
	7.3 Highlights of PCWP/HCPWP 2019-2022 mandate	Maria Mavris (EMA)

<b>Time</b>	<b>Topics</b>	<b>Speaker</b>
12:50	<b>Wrap up</b>	Co-chairs
13:00	<i>End of meeting</i>	