



03 May 2022
EMA/72089/2022
Stakeholders and Communication Division

Draft Agenda – PCWP/HCPWP joint meeting

1 - 2 June 2022, Virtual meeting

DAY 1: 1 June, 12:45hrs to 16:30hrs CET

Chair: Juan Garcia-Burgos (EMA)

Time	Topics	Speaker
12:45	Joining and technical checks	
1. Introduction		
13:00	1.1 Opening remarks	Melanie Carr (EMA) Juan Garcia-Burgos (EMA)
2. Tour de Table		
13:15	2.1 Mandate 2022-2025: members' introduction	All
14:20	Break	
3. Clinical trials		
14:30	3.1 Discussion on issues related with Good Clinical Practice as part of the ongoing review of the ICH E6(R3)	Co-moderation: Milton Bonelli (EMA) Francois Houyez (EURORDIS) Piotr Szymański (ESC) Panellists: Bärbel Witte (BfArm) Martin Landray (ESC) Gunilla Andrew-Nielsen (CTCG) Ditte Zerlang Christensen (CTCG) Monique AL (CTCG) Greet Musch (CTCG) Camelia Mihaescu (EMA)
16:20	Wrap up	Juan Garcia Burgos
16:30	<i>End of meeting</i>	

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DAY 2: 2 June, 09:00hrs to 13:00hrs CET

Chair: Juan Garcia-Burgos (EMA)

Time	Topics	Speaker
09:00	Joining and technical checks	
09:15	Welcome	Juan Garcia-Burgos (EMA)
4. COVID-19 update		
09:20	4.1 Update on vaccines and therapeutics	Marco Cavaleri (EMA)
09:50	4.2 Safety surveillance on vaccines and therapeutics	Priya Bahri (EMA)
10:05	4.3 Opening our Procedures at EMA to Non-EU authorities (OPEN) pilot	Martin Harvey (EMA) Victoria Palmi Reig (EMA)
10:20	Q&A	All
5. Big Data		
10:35	5.1 General update	Peter Arlett (EMA)
10:50	5.2 Pilot on raw data analysis	Eftychia-Eirini Psarelli (EMA)
11:05	5.3 DARWIN EU®	Andrej Segec (EMA) Aldo Maggioni (ESC) Elizabeth Vroom (UPPMD)
11:25	Q&A	
11:40	<i>Break</i>	
6. EMA communications and information on medicines for patients and healthcare professionals		
11:50	6.1 Use of EMA communications	Elisabeth Fleck (EMA)
12:05	Q&A	
7. Looking ahead 2022-2025		
12:20	7.1 Feedback from streamlining eligibility self-certification	Nathalie Bere (EMA)
12:30	7.2 Adoption of PCWP/HCPWP work plan 2022-2025	Maria Mavris (EMA)
12:40	7.3 Call for Co-chairs	Ivana Silva (EMA)
12:50	AOB	
12:55	Wrap up	
13:00	<i>End of meeting</i>	