



17 March 2020
EMA/126621/2020
Stakeholders and Communication Division

Agenda – ICH E6(R3) Good Clinical Practice workshop with PCWP and HCPWP

3 June 2020, 09:30hrs to 13:30hrs – virtual meeting

Co-chairs: Juan Garcia Burgos (EMA), Fergus Sweeney (EMA)

Time	ICH Guideline renovation	Speaker
09.30	Welcome and introduction	Juan Garcia Burgos (EMA) Fergus Sweeney (EMA)
1. Setting the scene		
09:40	Opening remarks	Kaisa Immonen (PCWP) Ulrich Jaeger (HCPWP)
09:50	1.1 Introduction to the ICH guideline development process	Milton Bonelli (EMA) Lenita Lindstrom (EC) Edit Szepessy (EC)
10:10	1.2 Introduction to ICH E6(R3) and stakeholders' engagement	Lisbeth Bregnhøj (DKMA)
10:25	1.3 Clinical Trials Transformation Initiative (CTTI) survey results	Pamela Tenaerts (CTTI)
2. ICH E6(R3) GCP Expert Working Group perspectives		
10:40	2.1 ICH E6(R3) GCP EWG	Lisbeth Bregnhøj (DKMA) Gabriele Schwarz (BfArM) Rebecca Stanbrook (EFPIA) Susanne Nørskov (EFPIA)

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Time	ICH Guideline renovation	Speaker
11:00	Break	
3. Patients, consumers, healthcare professionals and clinical researchers Perspectives		
11:10	3.1 PCWP perspectives	Marco Greco (EPF) François Houyez (EURORDIS)
11:40	3.2 HCPWP perspectives ECRIN EORTC	Martin Dreyling (EHA) Martin Landray (ESC) Jacques Demotes-Mainard (ECRIN) Denis Lacombe (EORTC)
4. Discussion		
12:20	Q&A	All
5. Next steps		
13:20	Next steps and closing remarks	Juan Garcia Burgos (EMA) Fergus Sweeney (EMA)
13:30	End of workshop	