Draft agenda

Day 1 – 5 October 2021

13:45	**Connection to virtual room and technical checks**	
14:00	**Welcome & Introduction**	**Sini Eskola (EFPIA) & Jan Geissler (Patvocates)**
14:10	**Session 1 – Setting the scene & Sharing experience – CTA approval**	**Anja Schiel (EMA SAWP, NoMA)**
5’	• Introduction	Anja Schiel (EMA SAWP, NoMA)
15’	• CTFG experience of CCTs	Elke Stahl (CTFG, BfArM)
15’	• US pilot feedback - FDA’s experience so far	Dionne Price (FDA)
15’	• CTTI, European initiatives, IMI EU Pearl	Solange Corriol-Rohou (AstraZeneca, EFPIA)
15:00	**Session 2 - Stakeholders’ priorities & expectations**	**Claas Röhl (NF Patients United)**
10’	• Patients	Dominique Hamerlijnck (EUPATI)
10’	• Regulators - EU & beyond	Anthony Humphreys (EMA)
10’	• Ethics Committees	Martin Brunner (Ethics Committee, AT)
10’	• HTA bodies	Niklas Hedberg (TLV SE, EUnetHTA)
10’	• Sponsors: Industry, Academia & non-profit organisations	Lucia D’Apote (Amgen, EFPIA)
10’	• Investigators	Birgit Geoerger (Gustave Roussy Institute, FR)
25’	• Panel discussion	
16:25	**Coffee break**	
16:45	**Breakout sessions**	
	• Design of Master Protocols	Chairs: Christine Fletcher (GSK, EFPIA) & Lada Leyens (Roche, EFPIA)
	• Regulatory processes and system	Chairs: Anja Schiel (EMA SAWP, NoMA) & Lucia D’Apote (Amgen, EFPIA)
	• Patient involvement	Chairs: Claas Röhl (NF Patients United, AT) & Solange Corriol-Rohou (AZ, EFPIA)
18:45	**Concluding remarks**	**Christine Fletcher (GSK, EFPIA), Mireille Muller (Novartis, EFPIA) & Anja Schiel (EMA SAWP, NoMA)**
19:00	**End of Day 1**	

Day 2 – 6 October 2021

13:45	**Connection to virtual room and technical checks**	
14:00	**Introduction to Day 2**	**Sini Eskola (EFPIA) & Peter Arlett (EMA)**
14:10	**Session 1 – Feedback from Day 1 Breakout sessions**	**Breakout sessions Chairs**
14:40	**Session 2 – Breakout sessions**	
	• Trials incorporating historical controls or with adaptative features	Chairs: Christine Fletcher (GSK, EFPIA) & Frank Bretz (Novartis, EFPIA)
	• CCT implementation/operational aspects	Chairs: Olga Kholmanskikh (CTFG, FAMHP) & Josse R. Thomas (Ethics Committee, BE)
	• Education & Training	Chairs: Begonya Nafria Escalera (eYPAGnet, ES) & Mireille Muller (Novartis, EFPIA)
16:40	**Coffee break**	
16:50	**Feedback from Day 2 Breakout sessions**	**Breakout sessions Chairs**
17:20	**Panel session to discuss main outputs & propose next steps/action plan**	**Moderators: Anja Schiel (EMA SAWP, NoMA) & Nick Sykes (Pfizer, EFPIA)**
	• EU Commission	Kristof Bonnarens (EC DG SANTE)
	• FDA	Dionne Price (FDA)
	• CTFG	Elke Stahl (CTFG Co-Chair, BfArM)
	• Ethics Committees	Josse R. Thomas (Ethics Committee, BE)
	• Patient representatives	Rita Magenheim (GENTURIS)
	• HTA bodies	Niklas Hedberg (SE TUV, EunetHTA)
	• Industry	Christine Fletcher (GSK, EFPIA)
	• NGO	Stephane Lejeune (EORTC)
18:20	**Concluding remarks**	**Christine Fletcher (GSK, EFPIA), Mireille Muller (Novartis, EFPIA) & Anja Schiel (EMA SAWP, NoMA)**
18:30	**End of Day 2**	

List of speakers

Alexandru Costescu	European Commission
Anja Schiel	Chair EMA SAWP, NoMA, Norway
Ann Marie Janson Lang	CTFG Co-Chair, MPA Sweden
Antony Humphreys	Head Regulatory Science Strategy Task Force, EMA
Begonya Nafria Escalera	eYPAGnet, Spain
Birgit Geoerger	Gustave Roussy Institute– France
Cecile Spiertz	EU-PEARL consortium - Janssen
Christine Fletcher	GSK -EFPIA
Claas Röhl	NF Patients United, Austria
Dieter Haering	Novartis
Dimitrios Athanasiou	EURORDIS Board Member in World Duchenne Organization, European Patients Forum
Dionne Price	Director, Division of Biometrics IV, CDER, FDA
Dominique Hamerlijnck	EUPATI
Elke Stahl	CTFG Co-Chair – BfArM; Germany
Frank Bretz	Novartis - EFPIA
Hans Joachim Helms	Roche
Heinz Schmidli	Novartis
Jacoline Bouvy	Technical Director, NICE Scientific Advice
Jan Geissler	Patvocates
Josse R. Thomas	BAREC, Belgium
Juliana Sholter	Amgen
Kristof Bonnarens	European Commission, DG SANTE
Lada Leyens	Roche - EFPIA
Laurence O'Dwyer	Chair EU-IN - HMA, HPRA
Lucia D'Apote	Amgen - EFPIA
Marius Thomas	Novartis
Martin Brunner	Ethics Committee, AT
Matthew Sydes	Professor of Clinical Trials and Methodology, MRC Clinical Trials Unit, UCL
May Mo	Amgen
Mireille Muller	Novartis - EFPIA
Nathalie Seigneuret	IMI
Nick Sykes	Pfizer-EFPIA
Niklas Hedberg	SE TUV, EUnetHTA
Olga Kholmanskikh	CTFG – FAMHP, Belgium
Peter Arlett	Head of Data Analytics and Methods Task Force, EMA
Rita Magenheim	ePAG- GENTURIS
Ruchi Upmanyu	Roche
Sandra Petraglia	CTFG, AIFA Italy
Sharon Love	UCL
Sini Eskola	EFPIA secretariat
Solange Corriol-Rohou	AstraZeneca - EFPIA
Stephane Lejeune	EORTC
Stéphanie Kromar	EORTC