ANNEXES

Annex A Conference programme

Annex B List of registered attendees

Annex C Further conference-related documents

Annex A Conference programme

Presenters and topics

SESSION	PRESENTER	TOPIC
Session 1	Thomas Lönngren, EMEA	Opening statement, objectives, and background Scope of legislation Definitions Clinical-trial authorisation and IMP dossier: ▪ To ethics committee ▪ To competent authority IMP-related issues (definitions, labelling, GMP, etc.) Ethics committee structures and processes Competent authority processes Roles of ECs and NCAs Trials conducted in third countries, including developing countries
Session 2	**Session chair:** Rui Santos Ivo - European Commission DG Enterprise **Session co-chairs:** Stefan Bielak – ESF/Olgahospital Stuttgart, Germany Birgitta Pettersson – MPA, Sweden **Speakers:** Commercial sponsors Alan Morrison - EuropaBio/Amgen, UK Non-commercial sponsors Monique Podoor – EORTC, Belgium NCA Hartmut Krafft – PEI, Germany Ethics committees Michael Fuchs – EUREC/University of Bonn Trials in developing countries Fernand Sauer – Honorary Director General of the European Commission	
Session 3	**Session co-chairs:** Helena Beaumont – INFARMED, Portugal Detlef Niese –EuropaBio/Novartis Pharma, Switzerland **Speakers:** Commercial sponsors Gaby Danan – EFPIA/Sanofi-Aventis, France Non-commercial sponsors Stefan Bielak – ESF/ Olgahospital Stuttgart, Germany NCA Brian Davis – MHRA, UK Pierre Henri Bertoye – AFSSAPS, France Ethics committees Dominique Sprumont –EUREC/University of Neuchâtel	Dossier maintenance, including substantial amendments Safety information, collection, reporting and review of safety information: ▪ Expedited reports ▪ Annual safety reports Databases: ▪ EudraCT ▪ EudraVigilance Inspection (GCP, GMP)

Session 4	**Session co-chairs**: Christine-Lise Julou – EFPIA, Belgium Tamás Paál – OGYI, Hungary **Panel members**: Including the morning session chairs and co-chairs: Large-scale clinical trials Rory Collins – CTSU Oxford, UK Investigators Silvio Garattini, 'Mario Negri' Institute for Pharmacological Research, Italy Jacques Demotes, ECRIN/ESF, France Commercial sponsors John Poland – ACRO/Covance, UK Dagmar Chase – EUCROF/Clinrex, Germany Patients Nikos Dedes - Patients and Consumers Working Party Non-commercial sponsors Patrick Schöffski – EORTC, Belgium Commercial sponsors Alan Morrison – EuropaBio/Amgen, UK Mats Ericson – EFPIA /Wyeth Research, France Ethics committees Ritva Halila – EUREC/NCA Finland NCA Chantal Belorgey – AFSSAPS, France	Potential solutions and recommendations for the future, including views from patients, health professionals and investigators: ▪ Implementation within the current framework ▪ Implementation requiring changes to guidelines ▪ Solutions requiring changes to the legislation
Session 5	**Session chair:** Georgette Lalis – European Commission, DG Enterprise **Session co-chair:** Kent Woods – MHRA, UK Panel members: One senior speaker each from: Commercial sponsors Andrea Rappagliosi –EuropaBio/Merck Serono International, Switzerland Susan Forda – EFPIA/Lilly Industries, UK Patients Nikos Dedes – Patients and Consumers Working Party	Final stakeholders' views with general discussion and conclusions

	Non-commercial sponsors Jacques Demotes – ECRIN/ESF/EMRC, France	
	Ethics committees Francois Chapuis – EUREC/Hospices Civils de Lyon Octavi Quintana-Trías – European Commission, DG Research	
	NCA Kent Woods – MHRA UK	
Session 6	Georgette Lalis – European Commission, DG Enterprise	Perspectives for the future

Annex B List of registered attendees

Session chairs and co-chairs

Title	Surname	Name	Organisation		Country
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Prof Dr	Bielack	Stefan	European Science Foundation (ESF)	Olgahospital Stuttgart	Germany
Dr	Julou	Christine-Lise	European Federation of Pharmaceutical Industry Association (EFPIA)	European Federation of Pharmaceutical Industry Association (EFPIA)	Belgium
Mme	Lalis	Georgette	European Commission, DG Enterprise	European Commission, DG Enterprise	
Dr	Niese	Detlef	European Association of Bioindustries (EuropaBio)	Novartis Pharma AG	Switzerland
Prof	Paál	Tamás	National competent authority	National Institute of Pharmacy	Hungary
Dr	Pettersson	Birgitta	Clinical Trials Facilitation Group (CTFG)	Medicinal Products Agency	Sweden
Mr	Santos Ivo	Rui	European Commission, DG Research	European Commission, DG Enterprise	
Prof	Woods	Kent	National competent authority	Medicines and Healthcare Products Regulatory Agency (MHRA)	UK

Speakers and panellists

Title	Surname	Name	Organisation		Country
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Mrs	Chase	Dagmar	European CRO Federation (EUCROF)	Clinrex GmhH	Germany
Prof	Collins	Rory	Clinical Trial Service Unit Oxford	University of Oxford	UK
Dr	Danan	Gaby	European Federation of Pharmaceutical Industry Association (EFPIA)	Sanofi-Aventis	France
Dr	Davis	Brian	Clinical Trials Facilitation Group (CTFG)	Medicines and Healthcare Products Regulatory Agency (MHRA)	UK
Mr	Dedes	Nikos	Patients and Consumers Working Party	European AIDS Treatment Group	Belgium
Prof	Demotes	Jacques	European Clinical Research Infrastructure Network/European Science Foundation/European Medical Research Council (ECRIN/ESF/EMRC)	Inserm	France
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Dr	Forda	Susan	European Federation of Pharmaceutical Industry Association (EFPIA)	Eli Lilly and Company Ltd	UK

Title	Surname	Name	Organisation		Country
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Dr	Krafft	Hartmut	National competent authority	Paul-Ehrlich Institute	Germany
Mr	Morrison	Alan	European Association of Bioindustries (EuropaBio)	Amgen	UK
Dr	Podoor	Monique	European Organization for Research and Treatment of Cancer (EORTC)	European Organization for Research and Treatment of Cancer (EORTC)	Belgium
Dr	Poland	John	Association of Clinical Research Organizations (ACRO)	Covance	UK
Dr	Quintana-Trías	Octavi	European Commission, DG Research	European Commission, DG Research	
Dr	Rappagliosi	Andrea	European Association of Bioindustries (EuropaBio)	Merck Serono International SA	Switzerland
Mr	Sauer	Fernard		Honorary Director of the European Commission	
Prof	Schöffski	Patrick	European Organization for Research and Treatment of Cancer (EORTC)	European Organization for Research and Treatment of Cancer (EORTC)	Belgium
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Ms	Altavilla	Annagrazia	Task Force in Europe for Drug Development for the Young (TEDDYNoe)	Espace Ethique Méditerranéen (EEM)	France
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Title	Surname	Name	Organisation		Country
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Title	Surname	Name	Organisation		Country
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