



London, 30 July 2007
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Conference programme

European Commission-EMEA Conference on the Operation of the Clinical Trials Directive (Directive 2001/20/EC) and Perspectives for the Future.

Date

3 October 2007.

Location

European Medicines Agency, Canary Wharf, London, UK.

Scope and objective of the meeting

The scope of the conference is the European Union clinical trials legislation and its implementation in the context of clinical trials of medicinal products.

The objective is to provide an overview of the experience to date with the operation of Directive 2001/20/EC and their implementing texts, and to describe its impact, problems encountered and offer recommendations for the future.

At its meeting of 5 December 2006, the Pharmaceutical Committee endorsed a report on the activities of the 'Ad hoc group for the development of implementing guidelines for directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use'.

This report confirms that experience with implementation of the legislation varies between the Member States, and that it is not yet possible to fully assess the impact of some of the guidance prepared. Nevertheless, it appears clear that, unfortunately, some of the obstacles as regards the administrative burden and differences in implementation have not yet been overcome.

The purpose of the conference should be a stocktaking, involving the Member States and all major stakeholders, with a view to evaluating whether further work on the implementation will provide opportunities to resolve existing problems and whether a revision of the Directive is necessary.

Session topics

- What aspects of Directive 2001/20/EC and its implementing rules work well?
- What does not work well?
- What can be remedied within the present legal framework?
- What should a new legal framework look like?

Participants

Attendance at the meeting will be by invitation only, due to limitations of space. The meeting organisers are working to ensure the participation of a wide range of stakeholders' associations, including commercial and non-commercial sponsors and CROs, investigators, patients' representatives, ethics committees and national competent authorities.

The detailed programme is provided on the following pages:

SESSION	PRESENTER	TOPIC
Session 1	Thomas Lönngren, EMEA	Opening statement, objectives, and background
Session 2	<p>Session Chair: Rui Santos Ivo - European Commission DG Enterprise</p> <p>Session Co-Chairs: Stefan Bielak – ESF/Olgahospital Stuttgart, Germany Birgitta Pettersson – MPA, Sweden</p> <p>Speakers: Commercial Sponsors Alan Morrison - EuropaBio/Amgen, UK</p> <p>Non-Commercial sponsors Monique Podoor – EORTC, Belgium</p> <p>NCA Hartmut Krafft – PEI, Germany</p> <p>Ethics Committee Michael Fuchs – EUREC/University of Bonn</p> <p>Trials in developing countries Fernand Sauer – Honorary Director General of the European Commission</p>	<p>Scope of legislation</p> <p>Definitions</p> <p>Clinical Trial Authorisation and IMP Dossier</p> <ul style="list-style-type: none"> • To Ethics committee • To Competent Authority <p>IMP related issues (definitions, labelling, GMP etc)</p> <p>Ethics committee structures and processes</p> <p>Competent authority processes</p> <p>Roles of ECs and NCAs</p> <p>Trials conducted in third countries, including developing countries</p>
Coffee		
Session 3	<p>Session Co-Chairs: Detlef Niese –EuropaBio/Novartis Pharma, Switzerland Helena Beaumont – INFARMED, Portugal</p> <p>Speakers: Commercial Sponsor Gaby Danan – EFPIA/Sanofi-Aventis, France</p> <p>Non-Commercial sponsors Stefan Bielak – ESF/ Olgahospital Stuttgart, Germany</p> <p>NCA Brian Davis – MHRA, UK Pierre Henri Bertoye – AFSSAPS, France</p> <p>Ethics Committee Dominique Sprumont –EUREC/University of Neuchâtel</p>	<p>Dossier maintenance including substantial amendments</p> <p>Safety information, collection, reporting and review of safety information</p> <ul style="list-style-type: none"> • Expedited reports • Annual safety reports <p>Databases:</p> <ul style="list-style-type: none"> • EudraCT • EudraVigilance <p>Inspection (GCP, GMP)</p>
Lunch		Buffet Lunch

Session 4	<p>Session Co-Chairs: Tamás Paál – OGYI, Hungary Christine-Lise Julou – EFPIA, Belgium</p> <p>Panel members : Commercial Sponsors - Alan Morrison –EuropaBio/Amgen, UK - John Poland – ACRO/Covance, UK - Mats Ericson - EFPIA /Wyeth Research, France</p> <p>Non-Commercial sponsors - Carole Moquin-Patthey – ESF, France - Patrick Schöffski –EORTC, Belgium</p> <p>Investigators – Silvio Garattini, 'Mario Negri' Institute for Pharmacological Research, Italy - Jacques Demottes, ECRIN, France</p> <p>Ethics Committees Eugenijus Gefenas - EUREC/Lithuanian Bioethics Committee</p> <p>NCA Chantal Belorgey – AFSSAPS, France</p> <p>Patients Nikos Dedes - Patients and Consumers Working Party</p>	<p>Potential solutions and recommendations for the future, including views from patients, health professionals and investigators:</p> <ul style="list-style-type: none"> - implementation within the current framework - implementation requiring changes to guidelines - solutions requiring changes to the legislation
Coffee		
Session 5	<p>Session Chair: Georgette Lalis - European Commission, DG Enterprise</p> <p>Session Co-Chair: Kent Woods – MHRA, UK</p> <p>Panel members: One senior speaker each from:</p> <p>Commercial sponsor Andrea Rappagliosi –EuropaBio/Merck Serono International, Switzerland Susan Forda – EFPIA/Lilly Industries Ltd, UK</p> <p>Non-commercial sponsor Carole Moquin-Patthey - ESF, France Jacques Demottes – ECRIN, France</p> <p>Ethics Committees Francois Chapuis –EUREC/Hospices Civils de Lyon</p> <p>Octavi Quintana-Trías – European Commission, DG Research</p>	<p>Final stakeholders views with General discussion and conclusions</p>

	NCA Kent Woods–MHRA UK	
Session 6	Georgette Lalis – European Commission DG Enterprise	Perspectives for the Future