

Final Multidisciplinary Workshop

Designing the Future Conditions for Clinical Research in Europe

Diamant Centre, Brussels, Belgium

17 March 2010

organised by the

European Forum for Good Clinical Practice



'where science & ethics meet'

On behalf of the

'Road Map Initiative for Clinical Research in Europe'



Workshop Rationale

All stakeholders in the clinical research process agree that the planning and performance of clinical trials is unnecessarily complex in Europe as a result of the introduction of the new legislation in 2004 without a measurable improvement of clinical trial participant safety and quality of the data. And many clinical researchers complain that important trials are not performed due to the complexity and related costs of clinical trial organisation in the current environment. Research on the impact of the regulatory requirements like the ICREL Project has provided reliable data on the current situation and encouraged the need for developing solutions. The "Roadmap Initiative for Clinical Research in Europe" has identified the bottlenecks and performed 5 workshops (Single CTA, Co-Sponsorship, Risk-based Approach, Ethical Review, and Safety Reporting) to discuss options for solutions with all different stakeholders involved in the process. The results of these workshops were or are in the process of being reported. Highly interesting, innovative proposals were made – partly broadly agreed and partly controversially discussed. The aim of the Roadmap Initiative is to further debate these proposals and to prepare a list of items for the European Commission to radically improve the situation for clinical research in Europe. This may need new legislation, change of the current legislation and/or adaptation of the current guidelines for implementation in the Member States.

In this Final Workshop the proposals made in the Workshops will be summarized and discussed by all stakeholders involved, further optimized and prioritized with the aim to design a proposal to the Commission for an overall new regulatory environment for clinical trials in Europe that attracts and encourages clinical research in Europe to the benefit of the patients.

Programme Committee

Jane Apperley	Imperial College London, United Kingdom
Xavier Carné	Hospital Clinic 1 Provincial de Barcelona, Spain
Jacques Demotes	European Clinical Research Infrastructures Network (ECRIN), INSERM, EFGCP, France
Christiane Druml	Ethics Committee of the Vienna Medical University, Austria
Ingrid Klingmann	Pharmaplex, ICREL, EFGCP, Belgium
Christine Kubiak	European Clinical Research Infrastructures Network (ECRIN), INSERM, EFGCP, France
Stéphane Lejeune	European Organisation for Research and Treatment of Cancer (EORTC), Belgium

Faculty

Christiane Abouzeid	BioIndustry Association (BIA), United Kingdom
Jane Apperley	Imperial College London, United Kingdom
Chantal Bélorgey	Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), Clinical Trials Facilitation Group (CTFG), France
Xavier Carné	Hospital Clinic 1 Provincial de Barcelona, Spain
Kim Champion	CLINT, United Kingdom
Jacques Demotes	European Clinical Research Infrastructures Network (ECRIN), INSERM, EFGCP, France
Nathalie Dubois	European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Christiane Druml	Ethics Committee of the Vienna Medical University, Austria

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Jan Geissler	European Cancer Patient Coalition, Germany
David Haerry	European AIDS Treatment Group (EATG), Switzerland
Clara Heering	Quintiles, Belgium
Angelika Joos	Merck Sharp & Dohme, Belgium
Ingrid Klingmann	Pharmaplex, ICREL, EFGCP, Belgium
Françoise Meunier	European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Dietger Niederwieser	European Group for Blood and Marrow Transplantation (EBMT), Germany
Chris Parkinson	GlaxoSmithKline (GSK), United Kingdom
Martyn Ward	Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Workshop Language

The language of the Workshop will be English.

Workshop Venue

Diamant Centre Brussels – Einstein Room

Boulevard A. Reyerslaan 80 - 1030 Brussels, Belgium

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Registration & Information

E-mail conferences@efgcp.be or visit www.efgcp.be

Agenda

- 08:00 Registration and Welcome Coffee
- 08:45 **Welcome and Introduction**
Ingrid Klingmann, Pharmaplex, ICREL, European Forum for Good Clinical Practice (EFGCP), Belgium
Jacques Demotes, European Clinical Research Infrastructures Network (ECRIN), INSERM, EFGCP, France
- Session 1: Conclusions from the Single CTA and Co-Sponsorship Workshops**
- Chairpersons:** *Françoise Meunier, European Organisation for Research and Treatment of Cancer (EORTC), Belgium*
Christine Abouzeid, BioIndustry Association (BIA), United Kingdom
- 08:55 **Single CTA Workshop** – Presentation & Discussion
Clara Heering, Quintiles, Belgium
- 09:35 **Co-Sponsorship Workshop** – Presentation & Discussion
Jane Apperley, Imperial College London, United Kingdom
- 10:15 Break
- Session 2: Conclusions from the Risk-Based Approach and Ethical Review Workshops**
- Chairpersons:** *Chantal Belorgey, Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), Clinical Trials Facilitation Group (CTFG), France*
Christiane Druml, Ethics Committee of the Vienna Medical University, Austria
- 10:35 **Risk-Based Approach Workshop** – Presentation & Discussion
Jacques Demotes, European Clinical Research Infrastructures Network (ECRIN), INSERM, France
- 11:55 **Ethical Review Workshop** – Presentation & Discussion
Xavier Carné, Hospital Clinic 1 Provincial de Barcelona, Spain
- 12:45 Lunch
- Session 3: Conclusions from the Pharmacovigilance and EPPOSI Workshops**
- Chairpersons:** *Angelika Joos, Merck Sharp & Dohme, Belgium*
Kim Champion, CLINT, United Kingdom
- 13:45 **Pharmacovigilance Workshop** – Presentation & Discussion
Nathalie Dubois, European Organisation for Research and Treatment of Cancer (EORTC), Belgium
- 14:25 **EPPOSI Workshop on Clinical Trials in Europe** – Presentation & Discussion
David Haerry, European AIDS Treatment Group (EATG), Switzerland
- 15:05 Break
- Session 4: Recommendations for the Future Conditions for Clinical Research in Europe**
- 15.25 **Panel & Open Forum Discussion:**
'Can we agree on the key elements of a future legislative environment for clinical research in Europe? – Recommendations for the European Commission'
- Chairpersons:** *Jacques Demotes, European Clinical Research Infrastructures Network (ECRIN), INSERM, EFGCP, France*
Chris Parkinson, GlaxoSmithKline (GSK), United Kingdom
- Introduction: the Proposal of the Roadmap Initiative for Clinical Research in Europe**
Ingrid Klingmann, Pharmaplex, ICREL, EFGCP, Belgium
- Panelists** *Dietger Niederwieser, European Group for Blood and Marrow Transplantation (EBMT), Germany*
Martyn Ward, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom
Jan Geissler, European Cancer Patient Coalition, Germany
- 17:20 **Conclusions and next steps** - *Ingrid Klingmann, Pharmaplex, ICREL, EFGCP, Belgium*
- 17:30 **End of Workshop**