

EFGCP Annual Conference 2017

Meeting the Ethical Standards under the Clinical Trials Regulation:

*the Burning Questions (and Answers)
for Researchers, Sponsors and Patients*



21 & 22 February 2017

Diamant Conference Centre
Brussels, Belgium

Organised by



where science and ethics meet

conferences@efgcp.eu - www.efgcp.eu

Conference Rationale

The Clinical Trial Regulation is now less than 2 years away and if we are to grasp this opportunity to improve research and regulation for patient benefit it is imperative we look together (public, patients, researchers and regulators) at both the procedural requirements of and ethical changes required.

As one of the most important, longstanding, European fora for debate around clinical research, bringing all interested parties together, the European Forum for Good Clinical Practice has taken an active role in the approaching the new CTR ([EFGCP Multi-Stakeholder Workshop & Discussion on How to Ensure Optimal Ethical Review within the New Clinical Trials Regulation?](#) 13th April, MCE Conference Centre, Belgium). The 2017 Annual Conference will discuss procedural arrangements already underway and address the ethical challenges that the CTR present, providing opportunity for debate, access to expertise and examples of how these challenges can be met. Workshops with people who can support and help you to solve your problems will be organised.

Programme Committee

Hugh Davies	Health Research Authority (HRA), United Kingdom
Sini Eskola	European Federation of Pharmaceutical Industries and Associations, Belgium
Kim Champion	University College London (UCL), EFGCP, United Kingdom
Nicky Dodsworth	Premier Research, EFGCP, United Kingdom
Belen Granell Villen	Association of the British Pharmaceutical Industry (ABPI), United Kingdom
Kaisa Immonen Charalambous	European Patients' Forum (EPF), Belgium
Eric Klasen	Medtronic, EFGCP, Switzerland
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Marianne Maman	Novartis Pharma, Switzerland
Heather Sampson	University of Toronto, Office of Research Michael Garron Hospital, Canada
Mary Lynne Van Poelgeest	World Federation of Incontinent Patients, EFGCP, the Netherlands
Florian von Raison	Novartis Pharma, Switzerland
Frank Wells	EFGCP, United Kingdom

Faculty

Kerstin Breithaupt-Grögler	kbr, Clinical Pharmacology Services, Germany
Xavier Carné	Hospital Clinic de Barcelona, Spain
Anna Chioti	Luxembourg Institute of Health (LIH), Luxembourg
Giulio Maria Corbelli	European AIDS Treatment Group (EATG), Italy
Marek Czarkowski	Centre for Bioethics of Supreme Medical Council, Poland
Bill Davidson	Health Research Authority (HRA), United Kingdom
Hugh Davies	Health Research Authority (HRA), United Kingdom
Lode Dewulf	UCB, Belgium
Nicky Dodsworth	Premier Research, EFGCP, United Kingdom
Sini Eskola	European Federation of Pharmaceutical Industries and Associations, Belgium
Susan Forda	Lilly, EFPIA Scientific Regulatory and Manufacturing Policy Committee European, United Kingdom
Jozef Glasa	Slovak Medical University/Institute of Medical Ethics & Bioethics, EFGCP, Slovakia
Dianne Gove	Alzheimer Europe, Luxembourg
Marco Greco	European Patients' Forum, Italy
Andrea Heckenberg	Medical University of Vienna, Austria
Eric Klasen	Medtronic, EFGCP, Switzerland

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21st & 22nd February 2017 – Diamant Conference Centre, Brussels, Belgium – Preliminary Programme

Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Greg Koski	Alliance for Clinical Research Excellence and Safety (ACRES), Massachusetts General Hospital, Harvard Medical School, USA
Dirk Lanzerath	EUREC, Germany
Sylvia Lobo	Pfizer, United Kingdom
Marianne Maman	Novartis Pharma, Switzerland
Anastassia Negrouk	European Organisation for Research & Treatment of Cancer (EORTC), Belgium
Martin O’Kane	Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom
Tom Quinn	Kingston and St George’s Joint Faculty, United Kingdom
Heather Sampson	University of Toronto, Office of Research Michael Garron Hospital, Canada
Thomas Schindler	BoehringerIngelheim, Germany
Ernst Singer	Medical University of Vienna, Austria
Cees Smit	Voor Zeldzame en Genetische Aandoeningen (VSOP), Patients Network for Medical Research and Health (EGAN), The Netherlands
Paul Strickland	Strickland Quality Assurance, EFGCP, United Kingdom
Mary Lynne Van Poelgeest	World Federation of Incontinent Patients, EFGCP, the Netherlands
Frank Wells	EFGCP, United Kingdom
Beat Widler	Widler&Schieman, Alliance for Clinical Research Excellence and Safety (ACRES), Switzerland

Conference Language

The language of the Conference will be English.

Registration & Information

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

Conference Venue

DIAMANT Conference & Business Centre
 80 Bd. A. Reyers
 BE-1030 Brussels
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 Website: www.diamant.be

Support the conference with corporate or institutional sponsoring

EFGCP has decided to open sponsoring opportunities - both corporate with companies and institutional with universities, NGOs and associations - to support this key discussion. Every organisation is invited to contribute to the success of this event while interacting directly with all major stakeholders involved in clinical research, sharing your opinions with peers and renowned experts, and being among the first to learn about the latest development on the topic! Ask for detailed information at info@efgcp.eu.

Programme

Tuesday 21st February 2017

08:15 *Registration and Welcome Coffee*
09:00 *Welcome*
 Ingrid Klingmann, Pharmaplex, EFGCP, Belgium

PLENARY SESSION 1

WHAT OPPORTUNITIES DOES THE CTR GIVE US TO IMPROVE RESEARCH AND HEALTH?

Chairpersons: *Sini Eskola, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium & Mary Lynne Van Poelgeest, World Federation of Incontinent Patients (WFIP), EFGCP, The Netherlands*

09:05 *What is different about the CTR? What are its opportunities?*
 Anna Chioti, Luxembourg Institute of Health (LIH), Luxembourg
09:25 *How can we use CTR to make research and healthcare better?*
 Marco Greco, European Patients' Forum, Italy
09:45 *Current proposals for collaboration between Competent Authorities and RECs*
 Martin O'Kane, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom
10:05 *Questions & Discussion*
11:00 *Coffee Break*

PLENARY SESSION 2

NEW ETHICAL ISSUES RAISED IN THE CLINICAL TRIAL REGULATION

Chairpersons: *Eric Klasen, Medtronic, EFGCP, Switzerland & Cees Smit, Voor Zeldzame en Genetische Aandoeningen (VSOP), Patients Network for Medical Research and Health (EGAN), The Netherlands*

11:30 *Involving lay representation as required by the Regulation: what is their role and how should this be discharged in RECs*
 Giulio Maria Corbelli, European AIDS Treatment Group (EATG), Italy
11:50 *What opportunity does the CTR offer for Research involving pregnant women?*
 Lode Dewulf, UCB, Belgium
12:10 *Emergency research: the continuing challenge and how can we develop a harmonized approach across Europe?*
 Tom Quinn, Kingston and St George's Joint Faculty, United Kingdom
12:30 *Questions & Discussion*
13:00 *Lunch*

BREAK-OUT SESSION - WORKSHOPS1-2-3

- 14:00 Workshop 1: **How should RECs work across EU to harmonise review under the CTR?**
Chair: *Dirk Lanzerath, EUREC, Germany*
Rapporteur: *(invited)*
- Workshop 2: **Low intervention studies**
Chair: *Andrea Heckenberg, Medical University of Vienna, Austria*
Rapporteur: *Xavier Carné, Hospital Clinic de Barcelona, Spain*
- Workshop 3: **Ethical Aspects of Risk-Based Monitoring under the new CTR**
Chair: *Nicky Dodsworth, Premier Research, EFGCP, United Kingdom*
Rapporteur: *Sylvia Lobo, Pfizer, United Kingdom*
- 15:30 *Coffee Break*
- 16:00 **Feedback from Workshops 1-2-3**
Chair: *Frank Wells, EFGCP, United Kingdom*

PLENARY SESSION 3 **THE JOSEPH HOET LECTURE ON ETHICS IN CLINICAL RESEARCH**

Chairperson: *Ingrid Klingmann, Pharmaplex, EFGCP, Belgium*

- 16:30 **Ethical Performance under the Clinical Trial Regulation**
Ernst Singer, Medical University of Vienna, Austria

- 17:00 EFGCP Annual General Meeting (for EFGCP Members)
- 18:30 EFGCP Annual Conference Social Event

Wednesday, 22nd February 2017

- 08:30 *Welcome Coffee*

PLENARY SESSION 4 **CONSIDERATIONS ON TRANSPARENCY,** **CONSENT AND THE CTR**

Chairperson & moderator: *Heather Sampson, University of Toronto, Office of Research Michael Garron Hospital, Canada*

- 09:00 **Transparency: how it will affect research involving drugs and devices**
Bill Davidson, Health Research Authority (HRA), United Kingdom
- 09:20 **Questions & Discussion**

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21st & 22nd February 2017 – Diamant Conference Centre, Brussels, Belgium – Preliminary Programme

- 09:30 **Oxford Debate on: The Clinical Trial Regulation will add little to help medicines research, promote patient rights or improve our health; it will be a barrier rather than a solution.**
 For the motion: *Greg Koski, Alliance for Clinical Research Excellence and Safety (ACRES), Massachusetts General Hospital, Harvard Medical School, USA*
 Against the motion: *Hugh Davies, Health Research Authority (HRA), United Kingdom*
- 10:20 Summary
- 10:30 Coffee Break

BREAK-OUT SESSION - WORKSHOPS4-5-6

- 11:00 Workshop 4: **What does CTR mean for the constitution and proper working of RECs?**
Chair: *Jozef Glasa, Slovak Medical University/Institute of Medical Ethics & Bioethics, EFGCP, Slovakia*
Rapporteur: *Marek Czarkowski, Centre for Bioethics of Supreme Medical Council, Poland*
- Workshop 5: **Writing lay summaries for drugs and devices research**
Chair: *Kerstin Breithaupt-Grögler, -kbr- Clinical Pharmacology Services, Germany*
Rapporteur: *Thomas Schindler, BoehringerIngelheim, Germany*
- Workshop 6: **CTR and the vulnerable**
Chair: *Dianne Gove, Alzheimer Europe, Luxembourg*
Rapporteur: *Marianne Maman, Novartis Pharma, Switzerland*
- 12:30 Lunch
- 13:30 **Feedback from Workshops 4-5-6**
Chair: *Paul Strickland, Strickland Quality Assurance, EFGCP, United Kingdom*

PLENARY SESSION 5
DESIGNING THE FUTURE OF THE CLINICAL TRIAL

Chairpersons: *Beat Widler, Widler&Schieman, Alliance for Clinical Research Excellence and Safety (ACRES), Switzerland & Co-Chair invited*

- 14:00 **CTR and radical new concepts in treatments: is the CTR help or hindrance? Changing models of research and the CTR: how do we “futureproof” regulations and provide flexibility so we don’t hinder innovative treatment drug developments**
Anastassia Negrouk, European Organisation for Research & Treatment of Cancer (EORTC), Belgium
- 14.20 **CTR and adaptive study design: flexibility should be the key**
Susan Forda, Lilly, EFPIA Scientific Regulatory and Manufacturing Policy Committee European, United Kingdom
- 14:40 **Europe, the CTR and research across the globe: fit for purpose?**
Greg Koski, Alliance for Clinical Research Excellence and Safety (ACRES), Massachusetts General Hospital, Harvard Medical School, USA
- 15:00 Questions & Discussion
- 15:30 Summary & Conclusions from the Conference: **Using the CTR to make us better.**
- 15:40 End of the Conference