

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 patients, 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

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

Faculty

| | |
|----------------------------|---|
| Kerstin Breithaupt-Grögler | kbr, Clinical Pharmacology Services, Germany |
| Xavier Carné | Hospital Clinic de Barcelona, Spain |
| Giulio Maria Corbelli | European AIDS Treatment Group (EATG), Italy |
| 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 |
| Dianne Gove | Alzheimer Europe, Luxembourg |
| 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 |
| Andrea Heckenberg | Medical University of Vienna, Austria |
| Eric Klasen | Medtronic, EFGCP, Switzerland |
| Ingrid Klingmann | Pharmaplex, EFGCP, Belgium |
| Greg Koski | Alliance for Clinical Research Excellence and Safety (ACRES), Massachusetts General Hospital, Harvard Medical School, USA |

Meeting the Ethical Standards under the Clinical Trials Regulation

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|--------------------------|---|
| Dirk Lanzerath | EUREC, Germany |
| Sylvia Lobo | Pfizer, United Kingdom |
| Marianne Maman | Novartis Pharma, Switzerland |
| 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 Toronto East General Hospital, Canada |
| Thomas Schindler | Boehringer Ingelheim, Germany |
| Ernst Singer | Medical University of Vienna, Austria |
| Paul Strickland | Strickland Quality Assurance, EFGCP, United Kingdom |
| Mary Lynne Van Poelgeest | World Federation of Incontinent Patients, EFGCP, the Netherlands |
| Beat Widler | Widler & Schiemann, 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
Tel: +32 2 706 88 00
Fax: +32 2 706 88 11
E-mail: info@diamant.be
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?*
Speaker invited
- 09:25 *How can we use CTR to make research and healthcare better?*
Speaker invited
- 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 & Co-Chair invited*

- 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 - WORKSHOPS 1-2-3

- 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:** *Monitoring and the 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: (invited)

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 Toronto East General 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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- 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 - WORKSHOPS 4-5-6

- 11:00 **Workshop 4: What does CTR mean for the constitution and proper working of RECs?**
Chair: *(Invited)*
Rapporteur: *Jozef Glasa, Slovak Medical University/Institute of Medical Ethics & Bioethics, EFGCP, Slovakia*
- Workshop 5: Writing lay summaries for drugs and devices research**
Chair: *Kerstin Breithaupt-Grögler, -kbr- Clinical Pharmacology Services, Germany*
Rapporteur: *Thomas Schindler, Boehringer Ingelheim, 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**
Speaker invited
- 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