Introduction

A revision of the Clinical Trials Regulation has been adopted by European legislation makers. This revised framework will bring significant advances compared to today’s situation. However, the original objectives of this legislation should be remembered: these were to enhance efficiency of the overall clinical trials authorization process and, in turn, to boost the EU’s competitiveness as a place to conduct research and make for more efficient patients access to new innovative treatments.

Especially the procedure for assessment and approval of multinational clinical trial authorisation applications will change: in future, each Member State will have to generate one single opinion and the competent authority of the “reporting Member State” will coordinate the assessment process until a common decision is reached. Ethics committees are supposed to be an essential part of this assessment process but it is left to the Member State to decide how this will be achieved.

Today, we are at a critical stage in the process where the new rules have to be integrated into the national systems in each Member State. When establishing procedures at national level, it is now essential that Ethics Committees find ways to ensure both a reliable independent ethical review delivered within the defined time frame as well as the relevant level of collaboration during the process with the national competent authority. This will require a re-thinking of ethical review processes and Ethics Committee infrastructure in most Member States. Early discussion with Ethics Committee members and competent authorities from other countries and with concerned stakeholders could help to define the optimal solutions and support the development of a streamlined and a more harmonised system for the European Union.

This workshop aims to facilitate an exchange of opinions on opportunities and threats of the new CTA assessment requirements for the ethical review. It will also be an opportunity for early feedback from some Member States on potential concepts and options for the successful collaboration between ethics committees and competent authorities. Learnings from real life experience over the past decade will be used to identify the most critical aspects for different stakeholders: ethic committees, competent authorities, patients, investigators, commercial and non-commercial sponsors. Specific national hurdles that need to be overcome in the Member States will be identified to enable Europe to emerge as an attractive place for conducting Clinical Research.

This will not only benefit commercial and non-commercial sponsors, but specifically patients who are eagerly waiting to participate in Clinical Trials and benefit from new treatment options.

Programme Committee

Ingrid Klingmann | Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium
Sabine Atzor | F. Hoffmann-La Roche, Switzerland
Angelika Joos | Merck Sharp & Dohme, Belgium
Anastassia Negrouk | European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Fabien Peuvrelle | Celgene, European Forum for Good Clinical Practice (EFGCP), Switzerland

Faculty

Monique Al | Central Committee on Research Involving Human Subjects (CCMO), The Netherlands
Cristina Avendaño Solá | Hospital Universitario Puerta de Hierro, Spain
Marek Czarkowski | Polish Chamber of Physicians and Dentists, Poland
Jozef Glasa | Slovak Medical University/Institute of Medical Ethics & Bioethics, European Forum for Good Clinical Practice (EFGCP), Slovakia
Angelika Joos | Merck Sharp & Dohme, Belgium
Ingrid Klingmann | Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium
Flaminia Macchia | European Organisation for Rare Diseases (EURORDIS), France
Mihaela Matei | European Clinical Research Infrastructures Network (ECRIN), France
Geneviève Michaux          Hunton & Williams, Belgium
Anastassia Negrouk        European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Gérard Nguyen             Rett Syndrome Europe, France
Fabien Peuvrelle          Celgene, European Forum for Good Clinical Practice (EFGCP), Switzerland
Kurt Racké                Ethics Committee of the University of Bonn, Germany
Robert Rubens             University Hospital Ghent, Belgium
Cees Smit                 European Genetic Alliances Network (EGAN) / Vereniging Samenwerkende Ouder- en Patiëntenorganisaties (VSOP), European Forum for Good Clinical Practice (EFGCP), The Netherlands
Antonio Spagnolo          Università Cattolica del Sacro Cuore, Italy

Workshop Venue

Square Congress Centre
Rue Ravenstein 2
1000 Brussels - Belgium
Tel.: + 32 (0)2 515 1300 – Fax.: +32 (0)2 515 1320
E-mail: info@square-brussels.com
Website: http://www.square-brussels.com

Workshop Language

The language of the workshop will be English.

Registration & Information

OPEN EVENT - E-mail conferences@efgcp.eu or visit www.efgcp.eu
Agenda

Thursday 11th September

09:00  Registration & Welcome Coffee
09:50  Welcome, General Introduction & Aim of the Day
   Ingrid Klingmann, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium

SESSION 1: OPPORTUNITIES AND THREATS FOR ETHICAL REVIEW

Chairperson: Speaker invited

10:00  Keynote: Why Do We Need Optimal Ethical Review in the Regulation?
   Cees Smit, European Genetic Alliances Network (EGAN) / Vereniging Samenwerkende Ouderen Patiëntenorganisaties (VSOP), European Forum for Good Clinical Practice (EFGCP), The Netherlands

10:15  Presentation of the requirements around Ethical Review in the New Assessment Procedure
   Geneviève Michaux, Hunton & Williams, Belgium

11:00  Discussion: Identification of the Opportunities and Challenges for Ethical Review in Real Life for the Different Stakeholders
   Chair: Jozef Glasa, Slovak Medical University/Institute of Medical Ethics & Bioethics, European Forum for Good Clinical Practice (EFGCP), Slovakia & Flaminia Macchia, European Organisation for Rare Diseases (EURORDIS), France
   Panelists: Anastassia Negrouk, European Organisation for Research and Treatment of Cancer (EORTC), Belgium, Gérard Nguyen, Rett Syndrome Europe, France, Fabien Peuvrelle, Celgene, European Forum for Good Clinical Practice (EFGCP), Switzerland, Robert Rubens, University Hospital Ghent, Belgium

12:30  Lunch Break

SESSION 2: WHAT WILL MAKE THE REGULATION A SUCCESS ON NATIONAL LEVEL?

13:30  The Future Approach to Ethical Review of Clinical Trials
   What Should We Do Differently on National Level?
   A Panel Discussion with Statements from France, Italy, UK, Germany, Poland, Netherlands, Belgium, Slovakia, Spain
   Chair: Angelika Joos, Merck Sharp & Dohme, Belgium
   Panelists: Monique Al, Central Committee on Research Involving Human Subjects (CCMO), The Netherlands, Cristina Avendaño Solá, Hospital Universitario Puerta de Hierro, Spain, Marek Czarkowski, Polish Chamber of Physicians and Dentists, Poland, Jozef Glasa, Slovak Medical University/Institute of Medical Ethics & Bioethics, European Forum for Good Clinical Practice (EFGCP), Belgium
Practice (EFGCP), Slovakia, Mihaela Matei, European Clinical Research Infrastructures Network (ECRIN), France, Kurt Racké, Ethics Commitee State Rheinland-Pfalz, Germany, Antonio Spagnolo, Università Cattolica del Sacro Cuore, Italy

15:00  Coffee Break
15:30  Pros and Cons of the Different Approaches for Ethical Review - Open Discussion Around the Different Proposals
   Chair: Ingrid Klingmann, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium
   Panelists: Session Speakers and Chairs, Representatives from Industry, Academia, Patient, CA, EC invited
16:55  Conclusions & Next Steps
17:00  End of Workshop