

Workshop on  
**The Benefits of a Simplified and Coherent Clinical Trials Framework in Europe**

**1 December 2011 – 13:30-16:00**  
**European Parliament, room JAN 6Q1**

**Focus:**

*"A simplified and coherent framework for clinical trials in the European Union is vital. This will benefit patients by improving the development of and access to innovative medicines while contributing to the goals of the EU 2020 strategy"*

**The registration desk will be open from 12.30 to 14.00 in the Altiero Spinelli entrance in front of Place du Luxembourg**

**Programme:**

**13:00-13:30: Tea/Coffee Break in front of meeting room JAN 6Q1**

**13:30-13:55:**

**Welcome note: Prof. Philippe Juvin, MD PhD, MEP (EPP, France)**

**Introduction: Dr. Detlef Niese, Head of Global Development External Affairs, Novartis Pharma AG, and Vice-Chair for Science, EuropaBio Healthcare Council**

**Keynote speech: Nessa Childers, MEP (S&D, Ireland)**

**Revision of the Clinical Trials Directive: State of Play and Next steps:**

*Patricia Brunko, Head of Unit D3 – Pharmaceuticals, DG SANCO, European Commission*

**13:55 – 14:45. Views from the different stakeholders in the clinical eco-system**

**Moderated by Prof. Philippe Juvin, MD PhD, MEP**

- **Patients' Perspective: A Viewpoint from Patients Living with Rare Diseases**  
*Flaminia Macchia, EU Public Affairs Director, EURORDIS*  
**Presentation, followed by Q&A**
- **Industry's Perspective:**  
*Dr. Christiane Abouzeid, Head of Regulatory Affairs, BioIndustry Association (BIA), and Topic Leader, EuropaBio Clinical Trials Topic Group*  
**Presentation, followed by Q&A**
- **Academia's Perspective:**  
*Prof. Hubert E. Blum, President, Federation of European Academies of Medicine (FEAM) and Dean of Medicine, University of Freiburg*  
**Presentation, followed by Q&A**

**By invitation only**

**To register:** Please contact Pauline Bastidon, Healthcare Biotechnology Manager at EuropaBio:  
[p.bastidon@europabio.org](mailto:p.bastidon@europabio.org)

▪ **Experience with the harmonisation of multinational clinical trials and CTD revision:**

**Member States' perspective:**

*Dr. Hartmut Krafft*, Co-Chair, EU Heads of Medicines Agencies' Clinical Trials Facilitation Group, Coordinator of the Voluntary Harmonisation Procedures and Head of the Clinical Trials Section, Paul-Ehrlich Institute, Germany

**Presentation, followed by Q&A**

▪ **Health professionals/Ethics Committees' Perspective:**

*Prof. Olivier Chassany*, Chairman of a French Ethics Committee, Paris, and Medical Head of the Department of Clinical Research and Development, AP-HP (Assistance Publique – Hôpitaux de Paris)

**Presentation, followed by Q&A**

**14:45. – 15:45. Panel discussion**

**Moderated by Prof. Philippe Juvin, MD PhD, MEP**

**With:**

**Prof. Olivier Chassany**, Chairman of a French Ethics Committee, Paris and Medical Head of the Department of Clinical Research and Development, AP-HP (Assistance Publique – Hôpitaux de Paris)

**Kaisa Immonen-Charalambous**, Senior Policy Adviser, European Patient's Forum (EPF)

**Prof. Dermot Kelleher**, Vice-President elect of FEAM and Head of School of Medicine and Vice Provost for Medical Affairs, Trinity College Dublin

**Dr. Hartmut Krafft**, Co-Chair, EU Heads of Medicines Agencies' Clinical Trials Facilitation Group, Coordinator of the Voluntary Harmonisation Procedures and Head of the Clinical Trials Section, Paul-Ehrlich Institute, Germany

**Flaminia Macchia**, EU Public Affairs Director, EURORDIS

**Charmian Wells**, Vice-President of Regulatory Affairs, Circassia Limited, and member of the EuropaBio Clinical Trials Topic Group

**Members of the audience will have the opportunity to ask questions to panel members and take part in the discussion.**

**15:45-16:00: Conclusions:**

**Wrap up and MEP's perspective: Dr. Antonyia Parvanova, MD, MEP (ALDE, Bulgaria)**

**« Take home messages », by Prof. Philippe Juvin, MD PhD, MEP**

**By invitation only**

**To register:** Please contact Pauline Bastidon, Healthcare Biotechnology Manager at EuropaBio:  
[p.bastidon@europabio.org](mailto:p.bastidon@europabio.org)