The European Association for Bioindustries

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

- **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