



**Ophthalmic Pan-European Clinical Trials and the  
Impact of EU Directive (2001/20/EC)**

A one-day meeting organised by the European Vision Institute, to be held at the Royal Society of Medicine, London, 18<sup>th</sup> April 2005.

**Organising Committee:**

Professor Adam Sillito, London  
Professor José Sahel, Paris  
Dr Helen Jones, London

**Advisory Group:**

Professor José Cunha-Vaz, Professor José Sahel, Professor Adam Sillito,  
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**Programme**

**Speakers and topics**

***Session 1 - Differing Perspectives on the Impact of the EU Clinical Trials Directive***

*Academic Perspective on the Impact of the Clinical Trials Directive*

Professor José Sahel, INSERM / Paris VI University, Paris

*Industrial Perspective on the Impact of the Clinical Trials Directive*

Dr Ian Braithwaite, Clinical Development Director, AstraZeneca UK

*Bringing Clinicians to the Clinical Trials Culture – the importance of Phenotyping*

Professor Eberhardt Zrenner, Tuebingen Germany

*Patient User Group Perspective on the Impact of the Clinical Trials Directive*

Mr Michael Griffith, Chief Executive, Fighting Blindness, Ireland

***Session 2 - Pharmacovigilance and Drug Safety Across EU Member states***

*Pharmacovigilance and Drug Safety Across EU Member states*

BfArM (Federal Institute for Drugs and Medical Devices), Germany (to be confirmed)

*Implementation of Eudract and the Eudravigilance Databases*

Dr Panos Tsintis, Head of Sector - Pharmacovigilance and Post-Authorisation Safety and Efficacy of Medicines, EMEA (to be confirmed)

***Session 3 - Management and Responsibilities, including sponsorship: Impact on Pan-European non-commercial trials***

*Management and Sponsorship*

Dr Eric Postaire, Director, Clinical Research Department, INSERM, France

*Practical Guidance – MRC/DH Clinical Trials Toolkit*

Dr Sarah Dickson, Research Governance Co-ordinator, MRC, UK

*Clinical Research Organisation Perspective*

Sue Lydeard, Research & Development Manager, Moorfields Eye Hospital NHS Foundation Trust, London UK

*The Impact of the EU Directive on Ethical Review in Europe*

Mr Francis Crawley, Secretary General & Ethics Officer, European Forum for Good Clinical Practice (EFGCP)

***Session 4 - Impact of the Clinical Trials Directive on Funding for Pan-European non-commercial trials***

*EC Funding Possibilities*

Directorate General for Research, European Commission, speaker to be confirmed

*Department of Health View*

Marc Taylor, Head of Research Policy and Governance, Department of Health

*European Clinical Research Infrastructures Network (ECRIN)*

Professor Jacques Demotes, Co-ordinator of ECRIN, INSERM / CHU de Bordeaux

***Panel Discussion***

***Summing Up address:*** Professor José Cunha-Vaz, Portugal

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