Multidisciplinary Workshop

Innovative Approaches to Clinical Trial Co-Sponsorship in the EU

Hammersmith Conference Centre

Hammersmith Hospital

Du Cane Road, London

Monday 21 September 2009

09.30 – 17.30

organised by

Excellence in Science EBMT European Group for Blood and Marrow Transplantation

CLINT: facilitating international prospective clinical trials in stem cell transplantation

On behalf of the

"Road Map Initiative on Clinical Research in Europe"

European Clinical Research ECRIN Infrastructures Network

EF GCP

EORTC European Organisation for Research and Treatment of Cancer

ICREL Impact on Clinical Research of European Legislation

ELN European LeukemiaNet

Workshop Rationale

Directive 2001/20/EC, the "Clinical Trial Directive" requires there to be a single "sponsor" (an individual, company, institution or organization which takes legal responsibility for the initiation, management and/or financing of a clinical trial). In multinational clinical trials the demands this places on the sponsor are particularly onerous considering the widely varying implementation of the directive. Many organizations are unwilling or unable to take on this role, particularly academic institutions where there are legal limitations and the risks and associated costs of fulfilling the responsibilities are too high. As a result the number of academic investigator-led trials on a multinational level has declined since the introduction of the directive. Mechanisms need to be found that enable sponsors to formally/legally share responsibility for the management and financing of clinical trials, such as delegation of certain responsibilities in co-sponsorship. This workshop will explore the experience of sponsorship of multinational clinical trials from the perspective of the investigator, the academic institution and the pharmaceutical industry, as well as considering the legal and insurance aspects involved. It will also examine proposals for more research-friendly sponsorship possibilities, as evidenced by the UK approach and the experience in Germany between National Lead Organizations. The workshop will look at the development of a Collaboration Agreement as the backbone for defining roles and responsibilities. In the afternoon, break out sessions will focus discussions on how to improve collaboration in clinical trials in the commercial sector, the public sector and in public-private projects with a view to coming up with recommendations for better conditions for co-sponsorship in future legislation.

Programme Committee

Jane Apperley	CLINT Project, Imperial College London, United Kingdom
Kim Champion	European Group for Blood and Marrow Transplantation (EBMT), UK
David Coles	CLINT Project, University of Lancashire, UK
Jacques Demotes	European Clinical Research Infrastructures Network (ECRIN), INSERM, EFGCP, France
Nicola Gökbuget	European LeukemiaNet, Germany
Fiona Mc Donald	CLINT Project, EBMT, Spain
Ingrid Klingmann	ICREL, EFGCP, Pharmaplex, Belgium
Christine Kubiak	ECRIN, INSERM, EFGCP, France
Stéphane Lejeune	European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Dietger Niederwieser	EBMT, University of Leipzig, Germany
Mohamad Mohty	EBMT, University of Nantes, France
Anastassia Negrouk	European Organisation for Research and Treatment of Cancer (EORTC), Belgium

Workshop Language

The language of the Workshop will be English.

Agenda

09:30 Welcome and Introduction
Jane Apperley, CLINT Project, Imperial College London, United Kingdom
Jacques Demotes, ECRIN, INSERM, EFGCP, France

Session 1

Experience in Multinational Clinical Trial Management within Current Legislation

Chairperson: *Jacques Demotes, ECRIN, INSERM, EFGCP, Paris, France*

09:40 Example 1 – Investigator Perspective
Selim Corbacioglu, University of Ulm, Germany (to be confirmed)

10:00 Example 2 – Lawyer + Insurance Perspective
Anne Larcheveque, University Hospital of Nantes, France

10:20 Example 3 – Academic Institution Perspective
Anastassia Negrouk, EORTC, Brussels, Belgium

10:40 Example 4 – Pharmaceutical Sponsor Perspective
To be confirmed by IK

11:00 Panel and Open Forum Discussion:
'Efficient Risk Identification in Clinical Trials Involving Multiple Organisations'

Chairpersons: *To be confirmed*

11:40 Coffee Break

Session 2

Proposals for More Research-Friendly Sponsorship Conditions

Chairperson: *Jane Apperley, CLINT project, Imperial College, UK*

12:00 Example 1 - the UK approach
Julia Brown, Clinical Trials Research Unit, Leeds, UK

12:20 Example 2 – Co-Sponsorship of National Lead Organisations
Jürgen Grebe, Head of ZKS Münster, KKS Network, Germany

12:40 The Collaboration Agreement as Backbone for Distribution of Roles and Responsibilities
Richard Tiner, London, UK (To be confirmed by IK)

13:00 Panel and Open Forum Discussion:
'Which Conditions for Co-Sponsorship Were Most Suitable for the EU?'

Chairpersons: *To be confirmed*

13:40 Lunch

Break-Out Sessions

How Can Collaboration in Clinical Trials be Improved?

14:30 Break-Out Group 1: Optimized Conditions for Co-Sponsorship in the Commercial Sector of Pharma Companies, Biotech Companies, SMEs
Chair: *Representative of EFPIA or Europabio (To be confirmed by IK)*
Rapporteur: *To be confirmed*

Break-Out Group 2: Optimized Conditions for Co-Sponsorship in the Public Sector of Universities, Private Research Institutions, Foundations, Public Funding Institutions
Chair: *Stephen O'Brien, Royal Victoria Infirmary, Newcastle, UK*
Rapporteur: *Didier Blaise, Institut Paoli Calmettes, Marseille, France*

Break-Out Group 3: Optimized Conditions for Co-Sponsorship in Public-Private Projects
Chair: *Richard Peters, Genzyme, Cambridge, USA*
Rapporteur: *To be confirmed*

15:30 Coffee Break

Session 3

Recommendations for Co-Sponsorship Solutions in the EU

15:45 Reports from the Break-Out Groups

16:30 Panel and Open Forum Discussion:
'Recommendations for Better Conditions for Co-Sponsorship in Future Legislation'

Chairpersons: *Ingrid Klingmann, EFGCP, Brussels*
Pam Bacon, AMGEN Europe, Zug, Switzerland

17:20 Conclusions and next steps

17:30 End of Workshop