EFGCP Multidisciplinary Workshop

A Single CTA in Multinational Clinical Trials - Dream or Option?

Diamant Centre, Brussels, Belgium

7 July 2009

organised by the

European Forum for Good Clinical Practice

'where science & ethics meet'

On behalf of the

'Road Map Initiative for Clinical Research in Europe'

Workshop Rationale

Directive 2001/20/EC, the "Clinical Trial Directive" introduced the concept of a Clinical Trial Authorisation (CTA) by a competent authority and a favourable opinion from a lead or central research ethics committee as a pre-requisite for the performance of a clinical trial. In multi-national clinical trials this authorisation process has to be followed in each country where the clinical trial is supposed to be performed. The content of the CTA application dossier is defined by each Member State in a different way. Each competent authority reviews the same protocol and often the outcome is a different set of requests for changes which require substantial amendments and another review cycle. As a result the trial preparation period for multi-national trials has significantly increased so that the effect of the harmonised fixed review periods for a protocol by the EU national competent authorities is vanished. The ethical review process follows the same principles but is even more complex as the national differences in dossier requirements and review content are even larger. As an increasing percentage of trials are nowadays organised in a multi-national structure, the clinical trial authorisation process has become a very complex process which requires detailed knowledge of the national requirements and a substantial amount of administrative resources in the sponsor organisations. Especially non-commercial and SME sponsors struggle with these difficulties.

Sponsors, competent authorities, ethics committees and patient organisations are currently exploring within their communities how the CTA process could become more efficient without increasing the risks for the trial participants. A single CTA for multi-national clinical trials would obviously reduce the complexity of the process and the resources required but it would have to satisfy the very different needs of the stakeholders. And a clear definition of the respective roles for the competent authority (e.g. assessment of the IMPD at the EU level) and for the ethics committees (e.g. protection of participants at the national level) would be necessary.

This Workshop will give the opportunity for commercial and non-commercial sponsors, competent authorities, ethics committees and patients to exchange their experiences, ideas, interests and expectations and to identify common ground for a proposal for a more efficient CTA process to be laid out in revised clinical trials legislation.

Programme Committee

Yves Geysels	Novartis, EFGCP, Belgium
Willy de Greef	EuropaBio, Belgium
Yves Juillet	Les Entreprises du Médicament (LEEM), France
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Anastassia Negrouk	European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Cor Oosterwijk	European Genetic Alliances' Network (EGAN), The Netherlands
Richard Tiner	Association of the British Pharmaceutical Industry (ABPI), United Kingdom
Frank Wells	Cambridgeshire 4 Research Ethics Committee, EFGCP, United Kingdom

Faculty

Christiane Abouzeid	BioIndustry Association (BIA), United Kingdom
Jane Apperley	Imperial College London, United Kingdom
Chantal Bélorgey	Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), Clinical Trials Facilitation Group (CTFG), France
Xavier Carné	Hospital Clinic 1 Provincial de Barcelona, Spain

Jacques Demotes	European Clinical Research Infrastructures Network (ECRIN), INSERM, EFGCP, France
Mats Ericson	Amgen, United Kingdom
Stefan Führing	DG Entreprise, European Commission
Jan Geissler	European Cancer Patient Coalition, Germany
Angelika Joos	Merck Sharp & Dohme (MSD), Belgium
Ingrid Klingmann	Pharmaplex, ICREL, EFGCP, Belgium
Hartmut Krafft	Paul-Ehrlich-Institut (PEI), Clinical Trials Facilitation Group (CTFG), Germany
Mihail Kritikos	DG Research, European Commission
Ruth Ladenstein	St. Anna Children's Cancer Research Institute, Vienna, Austria
Françoise Meunier	European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Anastassia Negrouk	European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Detlef Niese	Novartis, Switzerland
Cor Oosterwijk	European Genetic Alliances' Network (EGAN), The Netherlands
Chris Parkinson	GlaxoSmithKline (GSK), United Kingdom
Yannick Plétan	Pfizer, France
Rui Santos-Ivo	APIFARMA, Portugal
Jiri Simek	University of South Bohemia, Czech Republic
Matthew Sydes	Medical Research Council, United Kingdom
Jean-Pierre Tassignon	Crossover CRI, EFGCP, Belgium
Alan Tyndall	University of Basel, Switzerland
Martyn Ward	Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom
Frank Wells	Cambridgeshire 4 Research Ethics Committee, EFGCP, United Kingdom

Workshop Language

The language of the Workshop will be English.

Workshop venue

Diamant Centre Brussels – Einstein Room
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Registration & Information

E-mail conferences@efgcp.be or visit www.efgcp.be

Agenda

08:45 Welcome and Introduction
Ingrid Klingmann, Pharmaplex, ICREL, EFGCP, Belgium
Jacques Demotes, European Clinical Research Infrastructures Network (ECRIN), INSERM, EFGCP, France

Session 1

The Current Status of Clinical Trial Authorisation

Chairpersons: *Jacques Demotes, European Clinical Research Infrastructures Network (ECRIN), INSERM, EFGCP, France*
Detlef Niese, Novartis, Switzerland

08:55 Current status of clinical trial authorisation in the EU – the viewpoint of the competent authority
Martyn Ward, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

09:15 Current status of clinical trial authorisation in the EU – the viewpoint of the commercial sponsor
Angelika Joos, Merck Sharp & Dohme (MSD), Belgium

09:35 Current status of clinical trial authorisation in the EU – the viewpoint of the academic sponsor
Alan Tyndall, University of Basel, Switzerland

09:55 Interaction with competent authorities in a pan-European investigator-driven trial: the EURAMOS experience
Matthew Sydes, Medical Research Council, UK

10:15 Panel and Open Forum Discussion:
'Can we agree on a common priority list of deficiencies in the current CTA system?'
Chairpersons: *Xavier Carné, Hospital Clinic 1 Provincial de Barcelona, Spain*
Christiane Abouzeid, BioIndustry Association (BIA), UK

Panelists: Chairs and Speakers of Session 1

10:55 Coffee break

Session 2

Proposals for a More Efficient CTA Procedure

Chairpersons: *Chris Parkinson, GlaxoSmithKline (GSK), United Kingdom*
Anastassia Negrouk, Regulatory Affairs and Intergroup Unit, European Organisation for Research and Treatment of Cancer (EORTC), Belgium

11:15 CTFG Proposal: 'The Voluntary Harmonization Procedure'
Hartmut Krafft, Paul Ehrlich Institute (PEI), Clinical Trials Facilitation Group (CTFG), Germany

11:30 Proposal of the "Road Map Initiative to Clinical Research in Europe": A suitable approach for clinical trials legislation
Jane Apperley, Imperial College London, United Kingdom

11:45	EFPIA proposal *Mats Ericson, Amgen, United Kingdom*
12:00	A more efficient CTA procedure - How can the Commission contribute? *Stefan Führing, DG Entreprise, European Commission*
12:15	Panel and Open Forum Discussion: 'Which process would be most suitable for the EU?'
Chairpersons:	*Chantal Bélorgey, Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), Clinical Trials Facilitation Group (CTFG), France* *Rui Santos Ivo, APIFARMA, Portugal*
Panelists:	Chairs and Speakers of Session 2 and *Ruth Ladenstein, St. Anna Children's Cancer Research Institute, Vienna, Austria*
13:15	Lunch

Session 3

How would a single CTA affect Research Ethics Committee Procedures?

Chairpersons:	*Mihail Kritikos, DG Research, European Commission* *Jean-Pierre Tassignon, Crossover CRI, EFGCP, Belgium*
14:00	A common submission dossier and review procedures – how far could European research ethics committee procedures be harmonised in the interest of patient protection? – The viewpoint of an ethics committee member *Jiri Simek, University of South Bohemia, Czech Republic*
14:20	Impact areas for a more harmonized approach to ethical review in Europe on academic research and patients' faster access to new treatments *Anastassia Negrouk, Regulatory Affairs and Intergroup Unit, European Organisation for Research and Treatment of Cancer (EORTC), Belgium*
14:40	Could reliable protection of participants be achieved by a single CTA and a central research ethics committee opinion with local REC support? – The viewpoint of a patient *Jan Geissler, European Cancer Patient Coalition, Germany*
15:00	Panel and Open Forum Discussion: 'What would a single CTA and more coordinated REC procedures mean for both patient protection and faster clinical drug development?'
Chairpersons:	*Frank Wells, Cambridgeshire 4 Research Ethics Committee, EFGCP, United Kingdom* *Yannick Plétan, Pfizer, France*
Panelists:	Chairs and Speakers of Session 3 and *Cor Oosterwijk, European Genetic Alliances' Network (EGAN), The Netherlands*
16:00	Conclusions and next steps *Ingrid Klingmann, Pharmaplex, ICREL, EFGCP, Belgium*
16:15	End of Workshop