EFGCP Workshop on

Striving for Professionalism in IITs

26 & 27 February 2014 – Courtyard Hotel, Brussels, Belgium

Organised by

European Forum for Good Clinical Practice

In Collaboration with

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Introduction

The value and importance of investigator-initiated trials (IITs) are broadly accepted in healthcare. Treatment optimization, exploration of new indications, head-to-head comparison of new medicines, investigation of long-term treatment outcomes and/or efficiency of treatments are important tasks of the medical community. Like for pharma company-initiated trials the overall responsibility for the trials lies also in IITs with the ‘Sponsor’. But in contrast to privately sponsored studies the infrastructure to fulfill these sponsor obligations is not always available in an academic environment. The complex legal, regulatory, financial and organisational requirements are not reliably known in the investigator-, hospital- and university- community interested and engaged in doing clinical research. In addition, the legal conditions for academic sponsorship vary from country to country which makes the organisation of multinational trials even more difficult.

This workshop aims at bringing together investigators, academic organisations, hospital and university administration representatives, regulators, ethics committee members, lawyers, pharmaceutical companies, SMEs and patient representatives from different countries to learn about different approaches to sponsorship and public-private partnerships in conducting clinical trials in different countries. Focus will be on different sponsor tasks and business models, contracting and training. As a result of these multi-stakeholder discussions it is intended to support professionalism in IITs through working out recommendations for facilitating and harmonizing the framework and organisation for investigator-initiated clinical research.

Programme Committee

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Monique Podoor  Pharmakon, Luxembourg
Gilles Vassal  Gustave Roussy, France
Eddy Trippas  UCB Pharma, Belgium
Marc Uritch  Swiss Tropical and Public Health Institute, Switzerland
Gerald van Roey  European Centre for Clinical Research Training (ECCRT), EFGCP, Belgium
Verena Voelter  Celgene, Belgium

Workshop Venue

Courtyard By Marriott Hotel
Avenue des Olympiades 6
1140 Brussels - Belgium
Tel.: + 32 (0)2 337 08 08 – Fax.: +32 (0)2 337 08 00
Website: http://www.marriott.com/hotels/fact-sheet/travel/brucy-courtyard-brussels/

Workshop Language

The language of the workshop will be English.

Registration & Information

OPEN EVENT - E-mail conferences@efgcp.eu or visit www.efgcp.eu
EFGCP Workshop on Striving for Professionalism in IITs
26 & 27 February 2014, Courtyard Hotel, Brussels, Belgium - Final Programme

Agenda

Wednesday 26th February

09:30  Registration & Welcome Coffee
10:15  Welcome, General Introduction & Aim of the Day
       *Ingrid Klingmann*, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium

SESSION 1: THE SPONSOR IN IITs

Chairpersons: *Anne Kranich*, GSO Amsterdam, The Netherlands & *Vincent Diebolt*, F-CRIN, INSERM, France

10:30  Overview of the Sponsor’s obligations
       *Ran Frenkel*, Investigator Initiated Sponsored Research Association (IISRA) & Clinipace Worldwide, Switzerland

11:00  Who can be an Academic Sponsor? – Responsibilities & National Legal Differences
       *Christine Kubiak*, European Clinical Research Infrastructures Network (ECRIN), France;
       *Christine Mathieu*, UZ Leuven, Belgium & *Anne Kranich*, GSO Amsterdam, The Netherlands

11:45  Discussion
12:30  Lunch Break

SESSION 2: PRACTICAL IMPLEMENTATION OF THE SPONSOR’S ROLE

How does it work? What works well? What are the difficulties?

Chairpersons: *Carsten Bokemeyer*, Universitätsklinikum Hamburg-Eppendorf, Germany & *Gerald van Roey*,
               European Centre for Clinical Research Training (ECCRT), EFGCP, Belgium

13:30  View from a Large Research Organisation
       *Denis Lacombe*, European Organisation for Research and Treatment of Cancer (EORTC), Belgium

14:00  View from a Hospital
       *Gilles Vassal*, Gustave Roussy, France

14:30  View from an Investigator
       *Alan Burnett*, Cardiff University School of Medicine, United Kingdom

15:00  Discussion
15:30  Coffee Break
SESSION 3: HOW DO ACADEMIC SPONSORS ENSURE THE QUALIFICATION OF INVESTIGATORS AND THEIR STAFF?

Chairpersons: Jean-Paul Deslypere, Aesculap CRO, Singapore & Katelijne De Nys, UZ Leuven, Belgium

16:00 How does this work in Switzerland? Marc Urich, Swiss Tropical and Public Health Institute, Switzerland

16:30 The PharmaTrain CLIC Initiative Ingrid Klingmann, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium

17:00 Discussion

17:30 End of Day 1

Thursday 27\textsuperscript{th} February

08:30 Welcome Coffee

SESSION 4: HOW TO MANAGE IIT SPONSORSHIP IN PUBLIC-PRIVATE PARTNERSHIPS?

Chairpersons: Eddy Trippas, UCB Pharma, Belgium & Gilles Vassal, Gustave Roussy, France

09:00 Different Collaboration Models Ann Marinus, European Organisation for Research and Treatment of Cancer (EORTC), Belgium

09:30 IIT and Co-Sponsoring Geneviève Michaux, Hunton & Williams, Belgium

10:00 The Industry Prospective Verena Voelter, Celgene, Belgium

10:30 Discussion

11:00 Coffee Break

SESSION 5: SPONSORSHIP IN PUBLICLY-FUNDED CLINICAL TRIALS

Chairpersons: Insa Bruns, Central Office of the KKS-Network, Germany & Jacques Demotes, European Clinical Research Infrastructures Network (ECRIN-ERIC), France

11:30 Overview from the European Commission – DG Research Mark Goldammer, DG Research, European Commission

12:00 Options in National Public Funding: The UK Jane Kinghorn, Translational Research Office, University College London, United Kingdom

12:30 Options in National Public Funding: France Dominique Deplanque, Clinical Investigation Center (CIC), University Hospital of Lille, France

13:00 Lunch
SESSION 6: HOW TO FACILITATE CONTRACTING IN IITs?

Chairpersons:  Ingrid Klingmann, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium & Christine de Balincourt, European Organisation for Research and Treatment of Cancer (EORTC), Belgium

14:00  The UK National Contract Model  
Darla Champigny, University College London (UCL) Joint Research Office, United Kingdom

14:30  Negotiating a clinical trial master agreement  
Monique Podoor, Pharmakon, Luxembourg

15:00  Large Research Organisations: The ECRIN Approach  
Jacques Demotes, European Clinical Research Infrastructures Network (ECRIN-ERIC), France

15:30  Discussion

16:00  Conclusions & Next Steps  
Ingrid Klingmann, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium

16:15  End of the Workshop