EFGCP Multi-Stakeholder Workshop on
Indemnity Schemes for Clinical Trials: A Societal Obligation?

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EORTC Headquarters, Brussels, Belgium

Organised by

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Rationale/ Background:
Indemnity coverage of subjects enrolled in clinical trials is a vital ethical pre-requisite and an important element in Good Clinical Practice (GCP). Ensuring fast and easily accessible coverage of healthcare costs for healthy volunteers and patients enrolled in clinical trials with drugs who experience any kind of damage – independent of a potential causal relationship with the study medication - is a formal sponsor obligation. However, especially in academically sponsored studies the current level of insurance fees to be paid to insurance companies becomes prohibitive to independent academic drug research. The requirement in the Directive that, “provision has been made for the insurance or indemnity to cover the liability of the investigator and sponsor,” has been interpreted differently in different member states, meaning that separate insurance is needed and different models of covering exist from country to country. Insuring international trials is not only very costly, it is also bureaucratic and complex. In addition, this patchwork of regulation results in the ethically dubious position that patients taking part in the same trial in different countries, have different levels of insurance protection. In their Draft Regulation on Clinical Trials the European Commission is proposing that the national health care systems cover the liability for patients in – at least – the publicly sponsored clinical trials. This suggestion is opposed by different Member States and stakeholder groups for a variety of reasons. As the period for consensus finding is coming to an end it appears important to bring representatives from different stakeholder groups together to evaluate the pro’s and con’s of existing national practices and conditions in Europe, to achieve a better understanding of the needs and expectations of the different stakeholders and to work out pragmatic recommendations that could satisfy stakeholder needs while preserving European attractiveness for biomedical research.

Programme Committee

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Philip Lange Møller  Danish Health and Medicines Authority (DKMA), Denmark

Greet Musch  Federal Agency for Medicines and Health Products, Belgium

Anastassia Negrouk  European Organisation for Research and Treatment of Cancer (EORTC), Belgium

Burkhardt D. Swik  German Pharmapool, Germany

**Workshop Venue**

EORTC Headquarters - Tagnon Meeting room (2nd floor)  
Avenue Mounier 83/11 - 1200 Brussels  
Tel: +32 2 774 16 11 - Email: eortc@eortc.be - Website: www.eortc.org

**Workshop Language**

The language of the workshop will be English.
Agenda

09:45  Registration & Welcome Coffee
10:15  Welcome, Report from the EORTC Insurance Workshop in 2010
       Françoise Meunier, European Organisation for Research and Treatment of Cancer (EORTC), Belgium
General Introduction & Aim of the Day:
       Ingrid Klingmann, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium

SESSION 1: Overview Over Current Insurance / Indemnity Coverage Systems in Europe

Chair:  Philip Lange Møller, Danish Health and Medicines Authority (DKMA), Denmark
10:20  Key Note: The need for a harmonised, Affordable Insurance/Indemnity Coverage System in Europe in the Interest of Patients and Research
       Ruth Ladenstein, St. Anna Kinderkrebsforschung e.V., Austria
10:45  Insurance/Indemnity Coverage System and Experiences with this System in Germany
       Speaker: Insa Bruns, Central Office of the KKS-Network, Germany
11:00  Insurance/Indemnity Coverage System and Experiences with this System in Denmark
       Speaker: Peter Jakobsen, Patient Insurance Association, Denmark
11:15  Coffee Break
11:30  Insurance/Indemnity Coverage System and Experiences with this System in Sweden
       Speaker: Philip Lange Møller, Danish Health and Medicines Authority (DKMA), Denmark
11:45  Insurance/Indemnity Coverage System and Experiences with this System in Spain
       Speaker: Cristina Avendaño Solá, Hospital Universitario Puerta de Hierro, Spain
12:00  Roundtable Discussion: Can we agree on a preferred system? Should there be different solutions for studies under academic and industry sponsorship?
       Chairs: Anastassia Negrouk, European Organisation for Research and Treatment of Cancer (EORTC), Belgium & Anne Kranich, GSO, Germany
12:45  Lunch Break

SESSION 2: Approaches to Risk Definition and Cost Calculations

Chair:  Greet Musch, Federal Agency for Medicines and Health Products, Belgium
13:30  What are the true risks in different types of clinical trials with different populations and in different indications that require financial coverage?
       Speaker: Katelijne de Nys, UZ Leuven, Belgium
       Discussion
14:00   Ethics Committees’ liability concerns in industry-sponsored clinical trials  
        Speaker: Karin Meissner, F. Hoffmann-La Roche, Switzerland  
        Discussion

14:30   An insurer's view: What are the principle conditions of the business model for 
        insurance/indemnity coverage and how is the risk assessed?  
        Speaker: Burkhardt D. Swik, German Pharmapool, Germany  
        Discussion

15:00   Coffee Break

SESSION 3: Conclusions and Recommendations from the Workshop

Chairs: Ingrid Klingmann, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium  
        & Ruth Ladenstein, St. Anna Kinderkrebsforschung e.V., Austria

15:15   Introduction: The European Commission’s Suggestion in the Draft Clinical Trial  
        Regulation and Proposals from the European Parliament and the Council of Europe  
        Speaker: Anastassia Negrouk, European Organisation for Research and Treatment of Cancer  
        (EORTC), Belgium

15:35   Roundtable Discussion: Recommendations, Work Plan, Summary and Closure

16:45   End of Meeting