

# Multidisciplinary Workshop

## Risk Based Approach in Clinical Trials

18<sup>th</sup> January 2010  
Barcelona, Spain

*Organised by ECRIN*



*on behalf of the “Roadmap Initiative for Clinical Research in Europe”*



AISBL International Non-Profit Association under Belgian law IVZW



## Workshop Rationale

The 2001/20/EC Directive on clinical trials requires similar provisions for all types of clinical trials on medicinal products. This feature, however, appears poorly adapted to the diversity of clinical research, and results under some circumstances in unnecessary burden for investigators and sponsors, especially in post-marketing studies. In its recital 11, the 2005/28/EC Directive on good clinical practice intended to define specific modalities for non-commercial trials. A draft guidance document was released for public consultation, but was not adopted, as it appeared more relevant to define regulatory requirements based on the risk associated with the study, rather than on its commercial or non-commercial objective.

This results in a need for in-depth a discussion on the risk-based approach to clinical trial regulation. Some pilot initiatives were already developed – among other various risk-based approach to monitoring strategies, a risk based approach to national legislation (but excluding clinical trials on medicinal products), or an expedited review process for ethics committees. And of course risk assessment is central for insurance of clinical trials. However there is a need for a more comprehensive approach to compare the underpinning definition of risk (hazard to participants? hazard to data quality? hazard to public health?), the number of risk categories and their definition, and the solutions proposed for implementation of risk-based regulation in each individual processes. Among other, this raises the question of who will be in charge of validating the risk level for a given protocol.

This workshop will give the opportunity to present the expectations of investigators and sponsors as regards of risk based approach, to discuss how the risk categories could be defined, and which process should be affected by this risk-based regulation. It will explore how risk-based adaptation of current requirements can be implemented in the various clinical trials processes (e.g.; ethical and regulatory submissions, monitoring, safety, insurance, labelling, documentation...). A roundtable discussion will allow all the relevant stakeholders to discuss the acceptability and the feasibility of the solutions proposed.

The ultimate goal is to produce ground for recommendations, acceptable for all stakeholders, which will be discussed and released during the final Stakeholder Conference in Brussels on 17th March 2010. The recommendations will be submitted to the European Commission requesting initiation of the necessary legal steps to create an efficient risk based approach while preserving participants' protection and data quality.

## **Programme Committee**

Xavier Carné, Hospital Clinic I Provincial Barcelona, ECRIN, Spain

Christine De Balincourt, European Organisation for Research and Treatment of Cancer (EORTC), Belgium

Jacques Demotes INSERM, ECRIN, France

Ingrid Klingmann EFGCP, Pharmaplex, Belgium

Christine Kubiak, INSERM, ECRIN France

Stéphane Lejeune European Organisation for Research and Treatment of Cancer (EORTC), Belgium

Nuria Sanz, Hospital Clinic I Provincial Barcelona, ECRIN, Spain

Lea Stankovski, INSERM, ECRIN, France

## **Workshop Language**

The language of the Workshop will be English. No translation will be provided.

## **Venue**

Room "Farreras Valentí"

Hospital Clinic Barcelona

C/Villarroel nº 170.

08036 Barcelona, Spain

## DRAFT Programme

<b>8h45</b>	Welcome and Introduction Objectives – Risk-based approach, risk categories, risk adapted requirements. <i>Jacques Demotes, INSERM, ECRIN, France</i>
	<b>Session I: Why is there a need for a risk-based approach, how to define risk and risk categories, and which processes should be affected</b>
9h00	Academic Sponsor experience. <i>François Lemaire, Assistance Publique-Hôpitaux de Paris, France</i>
9h25	Pharma Industry Sponsor experience. <i>Beat Widler, F. Hoffmann-La Roche AG, Switzerland</i>
	<b>Session II: Implementation of risk-based adaptation in various processes</b>
9h50	Expedited ethical review. <i>Michael Wolzt, Vienna Medical School, Austria</i>
10h15	Competent authorities perspective (Submission – Assessment of the risk- Labelling). <i>Chantal Bélorgey, AFSSAPS, France</i>
<b>10h40</b>	<b>Coffee break</b>
11h00	Monitoring. <i>Valérie Journot, INSERM, France</i>
11h25	Pharmacovigilance. <i>Mariantonia Serrano Castro, AEMPS, Spain</i>
11h50	Insurance. <i>Burkhard Swik, Munich RE, Germany</i>
12h15	Inspection. <i>Fergus Sweeney, EMEA, United-Kingdom</i>
<b>12h40</b>	<b>Lunch</b>
<b>13h30</b>	<b>Session III: Panel Discussion with Stakeholders</b> <i>Chairperson: Jane Apperley, Imperial College London, EBMT, UK</i> <b>Previous speakers with Patients associations, CRO, EORTC</b> <b>What is the acceptability and feasibility of the proposed solutions?</b>
<b>15h00</b>	<b>Coffee break</b>
<b>15h15</b>	<b>Session IV: Open Forum Discussion</b> <i>Chairpersons: Christiane Druml, Medical University of Vienna, Austria</i> <i>Ingrid Klingmann, EFGCP, Belgium</i> <b>What would be the best appropriate solutions?</b>
<b>17h15</b>	<b>Next steps.</b>
<b>17h30</b>	<b>End of the workshop</b>