

# How to Achieve a Successful New Trial Legislation?

An EFGCP Multi-Stakeholder Workshop on  
Consensus and Strategy Development

Husa President Park Hotel, Brussels, Belgium  
4 July 2011

Organised by



European Forum for Good Clinical Practice

In Collaboration with



[www.efgcp.eu](http://www.efgcp.eu) - [conferences@efgcp.eu](mailto:conferences@efgcp.eu)

## Introduction

The European clinical trials legislation will be revised. The complaints from all stakeholders and the objective ICREL data about over-boarding and unnecessary bureaucracy with resulting increases in study delays and costs as well as evidence of a decreasing number of clinical trials in Europe without a demonstrable improvement of patient safety raised the political pressure to consider a revision of the Clinical Trials Directive 2001/20/EC.

Experience of the stakeholders in the last 7 years as well as several problem identification and solution finding initiatives have helped to design options for true improvement in a revised clinical trial legislation.

The European Commission has released a Reflection Paper for consultation that proposes a selection of these identified options.

Broad consensus about the need for most of the improvement topics as well as some consensus about the most preferred options has already been achieved between academia and pharmaceutical industry sponsors as well as patients. However, less agreement on these options is expressed by national competent authorities and ethics committees.

To further build consensus about preferred options and to develop strategies on how to enhance consensus building amongst all stakeholders in all EU Member States and the European Parliament to enable rapid new legislation for clinical trials, EFGCP would like to invite you to participate in this 1-day workshop.

## Programme Committee

Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Angelika Joos	Merck Sharp & Dohme, Belgium
Fabien Peuvrelle	Celgene, Switzerland
Jan Geissler	Patvocates, EFGCP, Belgium
Jacques Demotes	European Clinical Research Infrastructures Network (ECRIN), INSERM, France
Stéphane Lejeune	European Organisation for Research and Treatment of Cancer (EORTC), Belgium

## Confirmed Faculty

Xavier Carné	Hospital Clínic de Barcelona, Spain
Jacques Demotes	European Clinical Research Infrastructures Network (ECRIN), INSERM, France
Elmar Doppelfeld	Permanent Working Party of German Research Ethics Committees, Germany
Christiane Druml	Ethics Committee of the Vienna Medical University, Austria
Stefan Führung	DG SANCO, European Commission
Jan Geissler	Patvocates, EFGCP, Belgium
David Haerry	European AIDS Treatment Group (EATG), Switzerland
Clara Heering	Quintiles, Belgium
Angelika Joos	Merck Sharp & Dohme, Belgium
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Petra Knupfer	Landesärztekammer Baden-Württemberg, EFGCP, Germany
Ruth Ladenstein	St. Anna Children's Hospital, SIOPE, Austria
Kevin Loth	Celgene, Belgium
Françoise Meunier	European Organisation for Research and Treatment of Cancer (EORTC), Belgium

**EFGCP Workshop on How to Achieve a Successful New Trial Legislation  
Husa President Park Hotel, Brussels, Belgium – 4 July 2011  
Preliminary Programme**

Anastassia Negrouk	European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Detlef Niese	Novartis, Switzerland
Fabien Peuvrelle	Celgene, Switzerland
Dominique Sprumont	University of Neuchâtel & TRREE Project, Switzerland
Burkhard Swik	Münchener Rückversicherung, Germany
Martyn Ward	Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

### Workshop Language

The language of the Workshop will be English.

### Workshop Venue

#### HUSA PRESIDENT PARK HOTEL

Boulevard du Roi Albert II, 44

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### Registration & Information

E-mail [conferences@efgcp.eu](mailto:conferences@efgcp.eu) or visit [www.efgcp.eu](http://www.efgcp.eu)

# Agenda

08:30 Registration and Welcome Coffee

## SESSION 1

**Chair:** *(invited)*

09:00 Key issues for the new clinical trials legislation in the EU

- Centralisation versus decentralisation
- National parity versus optimal expertise
- Patient safety and quality of data
- Respect of cultural and ethical differences

**Speaker:** *Stefan Führung, DG SANCO, European Commission*

09:20 The legislation development process in the EU institutions

- Overview of the role of the 3 institutions
- What happens after the Commission proposal is issued?
- Various scenario and alternative option opened to in the concept paper

**Speaker:** *Kevin Loth, Celgene, Belgium*

09:45 Introduction to Break-out Group topics

Topics to be discussed in the following Break-out Groups with the intention to identify the level of consensus, areas of disagreement between the stakeholders, and to formulate the topic-related elements of an EFGCP Position Paper on key elements of the desired new clinical trials legislation that can be used in further debates on consensus building between all stakeholders in all Member States.

Introduction to Break-out Group 1: **New clinical trial approval system**  
*Angelika Joos, Merck Sharp & Dohme, Belgium*

Introduction to Break-out Group 2: **Risk-based approach to clinical trial legislation**  
*Jacques Demotes, European Clinical Research Infrastructures Network (ECRIN), INSERM, France*

Introduction to Break-out Group 3: **Peculiarities in patient populations and trial designs**  
*Detlef Niese, Novartis, Switzerland*

10:30 Coffee break

11:00

## BREAK-OUT SESSIONS

### Break-out Group 1: Increasing the benefits for patients and European clinical research through an optimised study approval process

**Chair:** *Angelika Joos, Merck Sharp & Dohme, Belgium*

- Pro's and Con's of the current CTA system, VHP and the proposed CAP system
- Needs and options for a new ethical review system
- Pro's and Con's of a common submission dossier for competent authorities – and ethics committees (?)

**Confirmed Discussants:**

- *Stefan Führung, DG SANCO, European Commission*
- *Petra Knupfer, Landesärztekammer Baden-Württemberg, EFGCP, Germany*
- *Clara Heering, Quintiles, Belgium*
- *Anastassia Negrouk, European Organisation for Research and Treatment of Cancer (EORTC), Belgium*
- *David Haerry, European AIDS Treatment Group (EATG), Switzerland*
- *and the audience*

**Rapporteur:** *(invited)*

### Break-out Group 2: Applying a risk-based approach to clinical trial documentation, supervision and patient liability insurance

**Chair:** *Jacques Demotes, European Clinical Research Infrastructures Network (ECRIN), INSERM, France*

- Pro's and Con's of OECD proposal
- Pro's and Con's of the Roadmap Initiative for Clinical Research Proposal
- Other options
- Patient insurance coverage by national public health systems – a realistic possibility?

**Confirmed Discussants:**

- *Martyn Ward, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom*
- *Françoise Meunier, European Organisation for Research and Treatment of Cancer (EORTC), Belgium*
- *Xavier Carné, Hospital Clínic de Barcelona, Spain*
- *Christiane Druml, Ethics Committee of the Vienna Medical University, Austria*
- *Ruth Ladenstein, St. Anna Children's Hospital, SIOPE, Austria*
- *Jan Geissler, Patvocates, EFGCP, Germany*
- *Burkhard Swik, Münchner Rückversicherung, Germany*
- *and the audience*

**Rapporteur:** *(invited)*

**Break-out Group 3: Peculiarities in trial participants and trial design**

**Chair:** *Detlef Niese, Novartis, Switzerland*

- Options for clinical trials in emergency situations
- Options to promote paediatric trials
- Aspects on clinical trials in third countries to be covered in European clinical trial legislation

**Confirmed Discussants:**

- *Dominique Sprumont, University of Neuchâtel & TRREE Project, Switzerland*
- *Elmar Doppelfeld, Permanent Working Party of German Research Ethics Committees, Germany*
- *and the audience*

**Rapporteur:** *(invited)*

12:30	<i>Lunch</i>
13:30	<b>Reports from the Rapporteurs and Open Forum Discussion:</b> Agreement seeking on Break-out Groups' proposed elements of an EFGCP Position Paper on the key elements of the desired future clinical trials legislation  <b>Chair:</b> <i>Fabien Peuvrelle, Celgene, Belgium</i>
15:00	<i>Coffee break</i>
	<b>SESSION 2</b>
15:20	<b>How to facilitate and streamline the debates in EU Member States and European Parliament to achieve fast consensus?</b>  <b>Chair:</b> <i>Ingrid Klingmann, Pharmaplex, EFGCP, Belgium</i>  <u>Introduction 1:</u> The nuts and bolts in EU decision-making <i>Speaker invited</i>  <u>Introduction 2:</u> Effective communication on EU and Member State level to facilitate consensus building <i>Speaker invited</i>  <b>Open Forum Discussion: A plan for efficient European consensus building towards rapid revision of the clinical trials legislation</b>
16:50	Conclusions and next steps
17:00	End of Workshop